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- Intrarater and Inter-rater Reliability of
- 2 Active Cervical Range of Motion in Patients
- **With Nonspecific Neck Pain Measured**
- 4 With Technological and Common Use
- **Devices: A Systematic Review With**

6 Meta-regression

Abstract

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Objectives: The purpose of this systematic review was to compare intrarater and inter-rater reliability of active cervical range of motion (ACROM) measures obtained with technological devices to those assessed with low-cost devices in patients with nonspecific neck pain. As a secondary outcome, we investigated if ACROM reliability is influenced by the plane of the assessed movement.

Methods: Medline, Scopus, Embase, the Cochrane Library, CINHAL, PEDro, and gray literature were searched until August 2016. Inclusion criteria were reliability design, population of adults with nonspecific neck pain, examiners of any level of experience, measures repeated at least twice, and statistical indexes on reliability. A device was considered inexpensive if it cost less than €500. The risk of bias of included studies was assessed by Quality Appraisal of Reliability Studies.

Results: The search yielded 35 151 records. Nine studies met all eligibility criteria. Their Quality Appraisal of Reliability Studies mean score was 3.7 of 11. No significant effect of the type of device (inexpensive vs expensive) on intraclass correlation coefficient (ICC) was identified for intrarater (ICC = 0.93 vs 0.91; P > .99) and inter-rater reliability (ICC = 0.80 vs 0.87; P > .99). The plane of movement did not affect inter-rater reliability (P = .11). Significant influences were identified with intrarater reliability (P = .0001) of inexpensive devices, where intrarater reliability decreased (P = .01) in side bending, compared with flexion-extension.

Conclusions: The use of expensive devices to measure ACROM in adults with nonspecific neck pain does not seem to improve the reliability of the assessment. Side bending had a lower level of intrarater reliability. (J Manipulative Physiol Ther 2017;xx:1-12)

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© 2017 by National University of Health Sciences. https://doi.org/10.1016/j.jmpt.2017.07.002 Introduction

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Neck pain (ie, pain in the neck with or without pain 39 referred into 1 or both upper limbs that lasts at least 1 day) is 40 a common complaint in the global population.¹ It was 41 estimated that about the 5% of population at any time 42 suffers from neck pain.¹ Objective evaluation of active 43 range of motion, for neck pain as much as for other 44 condition, is a cornerstone of clinical assessment,^{2,3} just 45 like history taking, visual inspection, and passive motion 46 examination.⁴ 47

Changes in active cervical range of motion (ACROM) 48 are considered adequate indicators for treatment effect³ and 49

Key Indexing Terms: Neck Pain; Range of Motion, Articular; Validation Study as Topic; Cost Control

prognosis for nonspecific neck pain³ but not useful for 50 diagnosing the condition. However, results from previous 51 systematic reviews on reliability of ACROM measurement 52 53 indicate conflicting conclusions because of potential selection biases. In former studies, an asymptomatic sample 54 was sometimes used to test ACROM, and reviews pooled 55 data from this population with a symptomatic one.^{3,5-7} 56 Moreover, data were pooled from patients with multiple 57 58 diagnoses, mixing results of measures in specific neck pain (ie, neck pain originating from systemic conditions like 59 rheumatic diseases or identified causes like radiculopathy) 60 with nonspecific ones.^{3,5-7} In the end, previous reviews did 61 not perform an adequate assessment of methodological 62 quality of identified studies: In some cases there was a 63 complete lack of assessment^{5,6}; in others the assessment 64 was performed by tools that were not validated.^{2,7} To avoid 65 such biases, it was decided to create this systematic review 66 with stricter criteria in the selection procedure. 67

Neck pain is highly disabling and demands direct and 68 69 indirect costs (eg, public or private health costs, insurance refunds, working days lost). Some studies have estimated 70 that a patient with nonspecific back and neck pain will 71 spend about \$5500 per year,^{8,9} with a trend of increasing 72 costs,^{8,9} mainly because of medical specialty costs, 73 possibly related to innovative contents and collaborative 74 markets with producers of supplies.¹⁰ 75

To contain costs for spine pain management, it is 76 important to evaluate if devices are reliable and 77 cost-worthy. Therefore, the purpose of this systematic 78 79 review was to compare intrarater and inter-rater reliability of ACROM measures from technological devices to those 80 assessed with low-cost devices in patients with nonspecific 81 neck pain. As a secondary outcome, we investigated if 82 ACROM reliability is influenced by the plane of the 83 assessed movement. 84

85 METHODS

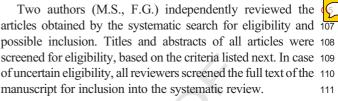
86 Search Strategy

This systematic review was written in accordance with 87 the PRISMA (Preferred Reporting Items for Systematic 88 Reviews and Meta-Analyses) statement for reporting 89 systematic reviews and meta-analyses of studies, ¹⁰ without 90 91 registering a protocol review. A systematic search was performed in 6 electronic databases (Medline, Scopus, 92 Embase, the Cochrane Library, CINHAL, and PEDro) from 93 each databases' inception until August 2016; in addition, a 94 gray literature search was performed on articular mobility 95 96 textbooks, with no limits about year of publication.

A search strategy was built using keywords combined
with Boolean operators. Relevant hand-searched articles,
found in textbooks, were also included to obtain as
complete information as possible. The search strategies
are reported in Appendix 1.

A hand search of the reference lists of the articles screened 102 for inclusion was also performed to locate any publications 103 not identified through the electronic database searches. 104

Eligibility Criteria



Inclusion Criteria. Studies were included only if intrarater 112 or inter-rater reliability design was adopted. Publications in 113 any language as full-text articles and peer review were 114 included. Studies based on participants with nonspecific 115 neck pain¹¹ were included for the review. Examiners with 116 various levels of experience and education were included 117 for review, and no restrictions were made based on their 118 demographics. Studies were included if the measurement of 119 ACROM was performed at least twice (by the same rater or 120 different raters). The studies were included if they provided 121 statistics about reliability of measurements such as 122 intraclass correlation (ICC), standard error of measurement, 123 and limits of agreement. 124

Exclusion Criteria. Types of studies excluded were letters, 125 editorials, comments, case studies, protocols, guidelines, 126 conference proceedings, review articles, and those whose 127 full text was not available. Also excluded were studies with 128 asymptomatic participants or with mixed populations 129 (healthy and symptomatic) where data were pooled together 130 without any distinction and those involving participants 131 with other pathologic conditions different from nonspecific 132 neck pain. Students were not included as raters. Studies 133 where the measurement of ACROM was performed only 134 once by a single rater or was not performed were not 135 included. Studies were excluded if they did not provide 136 statistics about reliability of measurements. 137

Quality Assessment

The Quality Appraisal of Reliability Studies (QAREL) 139 checklist evaluated the risk of bias.¹² It has been reported to 140 have acceptable levels of content validity (good) and 141 inter-rater reliability ($\kappa > 0.60$).¹³ It has been used in 142 systematic reviews aimed at reliability of clinical tests in 143 rehabilitation.¹⁴⁻¹⁶ In this systematic review, a QAREL 144 checklist was adopted to assess methodological quality both 145 across studies and within studies. 146

A QAREL is composed of 11 items and assesses the 147 external validity, internal validity, and statistical methods of 148 reliability studies. Based on guidelines provided, each item 149 is equally weighted and scored as *Yes*, *No*, *Unclear*, or *Not* 150 *Applicable*. Former systematic reviews of inter-rater and 151 intrarater reliability based on QAREL scores have used 152

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50%,¹⁶⁻¹⁸ 60%,^{15,17,19} and 70%¹⁷ cutoff points to define 153 high-quality evidence. Because operational definitions of 154 study quality can affect the overall levels of evidence¹⁰ and 155 no consensus on a single cutoff point for defining study 156 quality exists, we interpreted QAREL scores using the 157 mean proposed value of 60%. Studies were therefore 158 defined as high quality if 60% of applicable QAREL 159 checklist items were scored as Yes. 160

As recommended to improve reliability, criteria by 161 which judgments were made for each item of QAREL were 162 defined before the methodological assessment was done.¹³ 163 Two independent researchers (G.R., A.R.) evaluated 164 independently the quality of reliability studies and dis-165 agreement was resolved by discussion or use of a third 166 reviewer (M.T.). The agreement between the 2 reviewers 167 for rating studies based on quality scales was calculated by 168 к coefficient. 169

170 Data Extraction

Two independent reviewers (M.S., A.B.) extracted data, including authors' names, year of publication, mean age of patient enrolment, type of instrument used, movement of ACROM measured, ICC, standard error of the mean, and limits of agreement. Discrepancies in interpretation were resolved by discussion seeking consensus and use of a third reviewer (M.T.) if needed. Data are shown in Tables 1 and 2

178 Data Analysis and Synthesis

Continuous variables are given as means and standard 179 deviation (SD) and categorical variables as number of 180 participants. The total flexion and extension measure (if not 181 available) was obtained by taking the mean of flexion and 182 extension values in each study. The total rotation and 183 side-bending measure (if not available) was obtained by 184 taking the mean of left and right values for rotation and side 185 bending in each study. To investigate the associations of the 186 ICC with age, ACROM, and tool type, a univariate, and 187 188 later a multivariate, analysis was performed by using the linear mixed effects model. In addition, the linear mixed 189 effects model, corrected for age effect, was again used to 190 study which direction of movement was more reproducible 191 between inexpensive tools. Studies were considered as a 192 193 random effect in all mixed effects models.

After fitting each model, residual analyses were 194 performed to check for adequacy of the mixed model 195 assumptions. In particular, the Shapiro-Wilk test and the 196 quantile-quintile plot of the standardized residuals were 197 used to check for normality assumptions of the error terms. 198 The standardized residual vs predicted mean values plot 199 was used to check for the assumption of constant variance. 200 The plot of the fitted values obtained from the model of 201 interest against the observed values was used to assess the 202 linearity of the model. 203

The likelihood ratio test was used as a test of statistical 204 significance. Differences with a P value < .05 were selected 205 as significant in all the comparisons. Data were acquired 206 and analyzed in R Version 3.2.3 software.²⁰ 207

Devices used to measure active cervical range of motion 208 were divided into expensive and inexpensive tools. This 209 division was made to evaluate if complex and technological 210 devices are cost-worthy because of their superior reliability. 211 A former study was found that arbitrarily established a 212 cutoff to determine whether a device was considered 213 affordable or not at maximum €1000.² However, in this 214 study a device was considered inexpensive if it cost a 215 maximum of €500, so that it could be bought by 216 self-employed physical therapists without great economic 217 effort, and not only by research laboratories. 218

Search Results

Searching the databases yielded 35 151 citation postings. 221 Research strategies on each database are detailed in 222 Appendix 1. Two reviewers independently reviewed the 223 titles and abstracts, and 35 114 articles were eliminated. 224 There was no agreement on the selection of 60 studies. 225 Disagreements were resolved by a consensus-based discus- 226 sion,²¹ with a strong level of agreement (percentage of 227 greement = 99.3%)²¹ and high inter-reviewer reliability (κ 228 coefficient $k_w = 0.96$; 95% CI: 0.95-0.97). A total of 37 229 articles were regarded as possibly relevant and were 230 retrieved as full articles. Nine studies met all eligibility 231 criteria. Excluded studies and motivation of exclusion are 232 shown in Appendix 2. There was no disagreement in the 233 procedures of application of eligibility criteria and data 234 extraction. The selection process is shown in Figure 1. 235

Characteristics of the Studies

Two of the selected studies investigated both inter-rater 237 and intrarater reliability.^{22,23} The others assessed only 1 238 value.²⁴⁻²⁹ 239

The number of participants with neck pain ranged from 19^{27} 240 to 56 per study, and the sum of them was 288. The mean age of 241 the participants had a minimum value of 33.6 years $(SD = 10.3)^{26}$ 242 and a maximum value of 59 years $(SD = 5.6)^{29}$ 243

Six studies used inexpensive devices to measure ACROM: 244 universal inclinometer, ²³ standard dual-arm goniometer, ^{23,28} 245 gravity inclinometer, ^{27,28,30} and cervical range of motion 246 device. ^{26,29} Only 3 studies used expensive devices: the Cybex 247 Electronic Digital Inclinometer 320 (EDI-320), ²² the Ortho- 248 pedic Systems Incorporated (OSI) Computerized Anatometry 249 6000 Spine Motion Analyzer (SMA), ²⁴ and the Flock-of-Birds 250 system. ²⁵ Only 6 studies reported the mean Neck Disability 251 Index value^{22,23,27-30}; only 3 of them reported the mean 252 duration of symptoms, ^{22,23,28} so no subgroup analysis could be 253 performed to identify differences between patients with 254

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t1.2 Table I. Intrarater Reliability

	Study	Participants	Examiners	Instrument	Туре	Position	Direction	ICC	SEM	LoA	_
1	Dunleavy et al ²⁹ (2013)	n = 36	n = 5 examiners	CROM	IE	Sit erect posture	Flexion	0.93	3.5		_
		Diagnosis = chronic neck pain	(not specified)	device			Extension	0.96	2.7		t
		Age = 59 (SD 5.6)	Experience = not declared				Left side bending	0.88	2.8		t
		M/F = not declared	Training = yes (15 h)				Right side bending	0.92	2.1		t
		$NDI = 12.6 \pm 6$					Left rotation	0.96	2.8		t
							Right rotation	0.94	2.8		1
	26										
	Fletcher and Bandy ²⁶ (2008)	n = 22	n = 1	CROM device	IE	Sit erect posture	Flexion	0.88 (0.73-0.95)	4.1		
		Diagnosis = neck pain	(physical therapist)				Extension	0.92 (0.80-0.97)	3.0		
		$Age = 33.6 (SD \ 10.3)$	Experience ≥ 10 y				Left side bending	0.89 (0.76-0.95)	3.9		
		M/F = 7/15	Training = not declared				Right side bending	0.93 (0.83-0.97)	2.5		
		NDI = not applicable					Left rotation	0.96 (0.91-0.98)	2.9		
		(also n = 25 asymptomatic participants, not included in meta-regression)					Right rotation	0.92 (0.81-0.97)	3.3		t
	Hoving et al^{22} (2005)	n = 32		EDI-320 inclinometer	Е	C ¹	Total	D		-2.5 ± 11.1	
	Hoving et al (2005)		n = 2 physical therapists	EDI-320 inclinometer	E	Sit erect posture		Rater a: 0.96 (0.93-0.98)		-2.5 ± 11.1	
		Diagnosis = neck pain	Experience = not declared				flexion-extension	· · · · ·		10.111	
		Age = 45 (SD 9.2)	Training = yes					Rater b:		1.0 ± 11.1	
		M/F = 12/20 NDI = 15.2 ± 8.3	(once a wk for 3 mo, plus a trial on 5 healthy					0.97 (0.93-0.98)			
		$NDI = 15.2 \pm 8.5$	plus a trial on 5 healthy participants				Total side	Rater a:		-0.1 ± 10.4	
			* *					0.93 (0.86-0.97)		-0.1 ± 10.4	
			before this study)				bending	0.93 (0.86-0.97) Rater b:		-0.6 ± 9.8	
								0.93 (0.86-0.96)		-0.0 ± 9.8	
								0.95 (0.80-0.90)			t
						Supine	Total rotation	Rater a:		-5.9 ± 13.5	
						Supine	Total Iotation	0.96 (0.91 - 0.98)		-5.9 ± 15.5	
								Rater b:		-2.7 ± 14.4	
								0.96 (0.92-0.98)		-2.7 ± 14.4	
								0.50 (0.52 0.50)			
	Petersen et al24 (2000)	n = 20	n = 1 examiner	OSI SMA instrument	Е	Sit erect posture	Flexion	0.68	3.92		
		Diagnosis = neck pain	(not specified)				Extension	0.87	2.66		
		Age = 40.2 (SD 8.7)	Experience ≥ 14 y				Left side bending	0.96	1.85		
		M/F = 7/13	Training = yes (4 h)				Right side bending	0.92	2.35		
		NDI = not applicable					Left rotation	0.88	2.86		
		(also $n = 30$ asymptomatic					Right rotation	0.94	1.90		
		participants, not included in									
		meta-regression)									
	Schneider et al23 (2013)	n = 56	n = 2 physical therapists	Universal inclinometer	IE	Sit erect posture	Flexion	0.94 (0.90-0.96)	2.6	-11.9 to 9.9	
		Diagnosis = chronic	Experience = 12-16 y				Extension	0.95 (0.91-0.97)	2.9	-11.3 to 9.4	
		neck pain	Training = yes $(1 h)$				Left side bending	0.93 (0.88-0.96)	2.4	-11.7 to 10.0	
		Age = 46 (range 21-64)					Right side bending	0.91 (0.85-0.95)	2.6	-9.8 to 7.4	
		M/F = 19/37									
		NDI = 19 (range 8-18)		Standard dual-armed	IE	Sit erect posture	Left rotation	0.97 (0.95-0.98)	2.5	-12.1 to 10.4	
				goniometer			Right rotation	0.95 (0.92-0.97)	3.2	-12.1 to 10.4	

Study: first author and year of publication; participants: number (n), diagnosis, mean age (with SD or range); examiners: number (n), work experience, training in using the instrument to assess active range of t1.38 motion; instrument: name of instrument to assess active range of motion; position: position of the patient; direction: direction of measured active movement.

CROM, cervical range of motion; E, expensive instrument to assess active range of motion; EDI, Electronic Digital Inclinometer; ICC, intraclass correlation coefficient, with SD in parentheses, if provided; IE, inexpensive instrument to assess active range of motion; LoA, limits of agreement; M/F, male/female; NDI, Neck Disability Index; OSI SMA, Orthopedic Systems Incorporated Spine Motion Analyzer; SD, t1.39 standard deviation; SEM, standard error of the mean.

Rondoni et al Reliability of Cervical ROM Devices

(0.83-0.96)	
(0.56-0.88)	
(0.58-0.88)	

t2.2 Table 2. Inter-rater Reliability

t2.3	Study	Participants	Examiners	Instrument	Туре	Position	Direction	ICC	SEM	LoA	
t2.4	Assink et al ²⁵ (2005)	n = 30	n = 2 examiners (not specified)	Flock-of-Birds system	Е	Sit erect posture	Total flexion-extension	0.91 (0.83-0.96)		-12.4 to 9.6	
		Diagnosis: neck pain	Experience = not declared			-	Total side bending	0.76 (0.56-0.88)		-17.8 to 17.4	t2.5
		Age = 51.1 ± 9.5	Training = yes (20 h)				Total rotation	0.77 (0.58-0.88)		-18.6 to 21.8	t2.6
		M/F = 13/17	3 , (()								
		NDI = not applicable									
		(also $n = 30$ asymptomatic participants,									
		not included in meta-regression)									
t2.7		not mended in med regression)									
t2.8	Cleland et al ²⁸ (2006)	n = 22	n = 4 physical therapists	Gravity inclinometer	IE	Sit erect posture	Flexion	0.75 (0.50-0.89)	6.8	0.76 ± 16.6	
12.0	Ciciand et al (2000)	Diagnosis = neck pain	Experience = $3-23 \text{ y} (12.3 \pm 10)$	Glavity memometer	IL.	Sh creet posture	Extension	0.74 (0.48-0.88)	4.7	1.6 ± 11.7	t2.9
		Age = 41.0 ± 12.9	Training = yes (manual,				Left side bending	0.66 (0.33-0.84)	3.6	-0.5 ± 9.5	t2.10
		M/F = 4/18	videos then 1-h training session)				Right side bending	0.69 (0.40-0.86)	7	-0.3 ± 9.3 2.2 ± 18.3	t2.10
		M/F = 4/18 NDI = 30.9 ± 10.5	videos then 1-n training session)				Right side bending	0.09 (0.40-0.80)	/	2.2 ± 18.3	t2.11
		$NDI = 30.9 \pm 10.5$			IF.	C ¹	T 0 4 4	0.50 (0.55, 0.00)	~	1 () 12 5	12.12
				Standard dual-armed	IE	Sit erect posture	Left rotation	0.78 (0.55-0.90)	5	1.6 ± 13.5	10.40
10.44				goniometer			Right rotation	0.77 (0.52-0.90)	5.5	-0.3 ± 15.9	t2.13
t2.14					_						
t2.15	Hoving et al ²² (2005)	n = 32	n = 2 physical therapists	EDI-320 inclinometer	E	Sit erect posture	Total flexion-extension	0.95 (0.90-0.98)		3.3 ± 17.0	
		Diagnosis = neck pain	Experience = not declared				Total side bending	0.89 (0.77-0.94)		0.5 ± 17.0	t2.16
		Age = 45 (SD 9.2)	Training = yes (once a wk for 3 mo,			Supine	Total rotation	0.95 (0.90-0.98)		-1.3 ± 24.6	t2.17
		M/F = 12/20	plus a trial on 5 healthy participants								
		$NDI = 15.2 \pm 8.3$	before this study)								
t2.18	20										
t2.19	Piva et al ³⁰ (2006)	n = 30	n = 2 examiners (trained in manual therapy,	Gravity inclinometer	IE	Sit erect posture	Flexion	0.86 (0.73-0.93)	5.6		
		Diagnosis = neck pain	not further specified)				Extension	0.78 (0.59-0.89)	5.8		t2.20
		Age = 41.0 ± 12.0	Experience = $2-10 \text{ y}$				Left side bending	0.85 (0.70-0-92)	4.2		t2.21
		M/F = 12/18	Training = not declared				Right side bending	0.87 (0.75 -0.94)	3.7		t2.22
		$NDI = 24.3 \pm 14.8$									t2.23
						Supine	Left rotation	0.91 (0.82-0.96)	4.1		
							Right rotation	0.86 (0.74-0.93)	4.8		t2.24
t2.25											
t2.26	Shahidi et al ²⁷ (2012)	n = 19	n = 2 physical therapist	Gravity inclinometer	IE	Sit erect posture	Flexion	0.69 (0.36-0.87)			
		Diagnosis = chronic neck pain	Experience = $2-23$ y				Extension	0.78 (0.50-0.91)			t2.27
		$Age = 34.9 \pm 9.9$	Training = yes (3 1-h sessions)				Left side bending	0.68 (0.34-0.87);			t2.28
		M/F = 10/9					Right side bending	0.47 (0.06-0.75)			t2.29
		$NDI = 14.4 \pm 7.3$									t2.30
		(also n = 20 asymptomatic participants,				Supine	Left rotation	0.70 (0.37-0.87)			
		not included in meta-regression)					Right rotation	0.51 (0.09-0.78)			t2.31
t2.32		Č ,					5				
t2.33	Schneider et al ²³ (2013)	n = 56	n = 2 physical therapists	Universal inclinometer	IE	Sit erect posture	Flexion	0.93 (0.86-0.96)	3.4	-10.9 to 6.9	
		Diagnosis = chronic neck pain	Experience = $12-16 \text{ y}$				Extension	0.95 (0.91-0.97)	3.1	-9.4 to 8.7	t2.34
		Age = 46 (range 21-64)	Training = yes $(1 h)$				Left side bending	0.90 (0.68-0.96)	3.2	-10.4 to 4.8	t2.35
		M/F = 19/37	······································				Right side bending	0.90 (0.83-0.94)	3.3	-10.4 to 7.5	t2.36
		NDI = 19 (range 8-18)									t2.37
		·····		Standard dual-armed	IE	Sit erect posture	Left rotation	0.95 (0.71-0.98)	3.4	-4.2 to 11.1	
				goniometer		ereet postare	Right rotation	0.95 (0.91-0.97)	3.3	-7.7 to 10.6	t2.38
				Semoneter			ragin rounion	5.55 (0.51 0.57)	5.5	/./ 10 10.0	12.00

Study: first author and year of publication; participants: number (n), diagnosis, mean age (with SD or range); examiners: number (n), work experience, training in using the instrument to assess active range of t2.39 motion; instrument: name of instrument to assess active range of motion; position: position of the patient; direction: direction of measured active movement.

E, expensive instrument to assess active range of motion; EDI, Electronic Digital Inclinometer; ICC, intraclass correlation coefficient, with SD in parentheses, if provided; IE, inexpensive instrument to assess t2.40 active range of motion; LoA, limits of agreement; M/F, male/female; NDI, Neck Disability Index; SD, standard deviation; SEM, standard error of the mean.

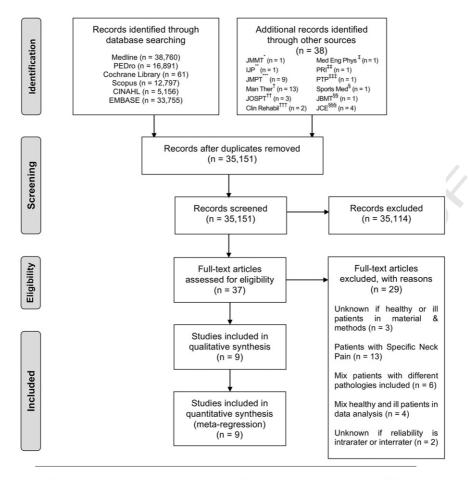
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Reliability of Cervical ROM Devices

Journal of Manipulative and Physiological Therapeutics Month 2017



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^{*}JMMT = Journal of Manual & Manipulative Therapy; ^{**}IJP = Italian Journal of Physiotherapy; ^{***}JMPT = Journal of Manipulative and Physiological Therapeutics; [†]Man Ther = Manual Therapy; ^{***}JOSPT = Journal of Orthopaedic & Sports Physical Therapy; ^{***}TClin Rehabil = Clinical Rehabilitation; ^{*}Med Eng Phys = Medical Engineering & Physics; ^{***}PRI = Physiotherapy research international; ^{****}PTP = Physiotherapy Theory and Practice; [§]Sports Med = Sports Medicine; ^{§§}JBMT Journal of Bodywork & Movements Therapies; ^{§®**}JCE = Journal of Clinical Epidemiology.

Fig 1. Flow diagram of the phases of the selection of studies according to PRISMA.

different disability and between patients with acute, subacute,or chronic neck pain.

All the data are reported in Tables 1 and 2.

294 Quality Appraisal

Methodological quality of included studies was assessed with the QAREL tool. Across studies, the mean score reached by studies was 3.7 of 11, with a maximum score of 7 of 11^{23} and a minimum score of 2 of 11.²⁴ A complete overview of methodological quality across studies is provided in Table 3.

Regarding risk of bias within studies, internal validity was compromised because populations and raters were largely not sufficiently described or not representative. Only 1 study provided a representative population,²⁹ and only 1 reported representative raters.²⁸ All 9 studies instead applied and interpreted appropriately the test.²⁷ External validity was also

lacking, because blinding and practical organization of the 32 test were not clearly reported in most cases. Only a couple of 335 studies stated that raters were blinded to clinical information 336 on patients, ^{23,27} with only 1 specifically declared blinding to 337 the reference standard for the target disorder, ²³ and only 1 did 338 not provide additional cues that were not part of the test. 339 However, blinding of results from 1 rater to other raters, when 340 appropriate, was mainly ensured—6 of 8 studies were scored 341 Yes.^{22,23,25,27,28,30} Raters were also blinded to their own 342 findings in most cases, when appropriate, with 3 of 5 studies 343 reporting that.^{22,23,26} None reported if the examination order 344 was varied, and only 2 studies ensured an appropriate time 345 interval between 2 measurements.^{23,27} Obviously, every 346 study adopted an appropriate statistical measurement of 347 agreement because this item of the QAREL checklist was an 348 inclusion criterion of studies in the present review. A 349 graphical representation of risk of bias within studies is 350 provided in Figure 2. 351

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13.3	Study		External Validity	~			Inte	Internal Validity				Statistical Analysis	
t3.4	(******	Item 1: Representative Sample	Item 1: Item 2: Representative Representative Item 10: Sample Raters Appropri	Item 10: Appropriate Test	Item 3: Blinding Item 4: (Other Raters) Blinding	ltem 5: Item 4: Blinding Blinding (Own Findings) (Reference/Disease)	Item 5: Blinding (Reference/Disease)	Item 6: Item 7: Item 8: Blinding Blinding Examination (Clinical Information) (Additional Cues) Order Varied	Item 7: Blinding (Additional Cues)	Item 8: Examination Order Varied	Item 9: Appropriate Time Interval	I 0	Percentage of Yes (%)
t3.5	Assink et al ²⁵ (2005)	Z	n	X	Y	N/A	z	D	D	D	z	Y	30
t3.6	Cleland et al ²⁸ (2006)	U	Y	Y	Y	N/A	Z	N	Z	n	z	Y	01
t3.7	Dunleavy et al ²⁹ (2013)	Υ	D	Y	D	U	Ŋ	U	U	D	D	Y	27
t3.8	Fletcher and Bandy ²⁶ (2008)	D	D	Υ	D	Υ	U	U	U	D	Z	Y	22
t3.9	Hoving et al^{22} (2005)	n	U	Υ	Y	Υ	U	U	n	n	Z	Y	27
t3.10	Petersen et al^{24} (2000)	D	U	Υ	N/A	U	U	U	U	n	Z	Y	20
t3.11	Piva et al ³⁰ (2006)	Ŋ	U	Y	Y	N/A	U	U	U	U	N	Y	30
t3.12	Schneider et al ²³ (2013)	n	U	Υ	Υ	Υ	Υ	Υ	n	n	Υ	Y	63
t3.13	Shahidi et al ²⁷ (2012)	D	U	Υ	Y	N/A	Z	Υ	Υ	n	Υ	Y	60
t3.14 t3.15	 t3.14 Study: first author and year of publication. t3.15 N. no: N/A. not applicable; U. unknown: Y. ves. 	ear of publica e: U. unknow	tion. m: Y. ves.			0							
	•• / / /		•										

Table 3. Ouality Appraisal

t3.2

There was no agreement on the scoring of 7 of 110 items **380** valued (10 studies, 11 items each). Disagreements were 389 resolved by a consensus-based discussion, with a high level 390 of agreement (percentage of agreement = 93.6%) and good 391 inter-reviewer reliability (κ coefficient k_w = 0.83; 95% CI: 392 0.71-0.95). 393

Meta-regression

Regarding the effect of the tool type on ICC (Tables 4 and 5), 395 no significant tool type effect, corrected for age and motion, 396 on ICC was observed for inter-rater and intrarater 397 reliability (Table 4, P = .99, and Table 5, P = .99, 398 respectively). 399

No significant motion effect on ICC values, corrected for 400 age, was estimated for inter-rater reliability (Table 6; P = .11). 401

Significant motion effect on ICC values, corrected for age, 402 was estimated for intrarater reliability (Table 7; P = .0001). In 403 particular, comparing ICC mean in the side-bending motion 404 group with that in the flexion and extension group, 405 approximately a -0.02 significant decrease (P < .0001) was 406 noted.

Regarding diagnostic residual analysis (Appendix 3), the 408 quantile-quintile plots indicated that the circles crossed or 409 were very close to the diagonal line, and there was no 410 significant evidence of rejecting the null hypothesis of 411 normality using the Shapiro-Wilk tests (P > .05) for all 412 residual models. The plots of standardized residuals against 413 fitted values indicated no trend, and was randomly scattered 414 around 0, with positive and negative values equally likely at 415 any point. The plots of the fitted values against the observed 416 values indicated that the points were quite close, both to the 417 diagonal line and to the regression line of the observed vs 418 fitted values. According to these results, no violations of the 419 mixed model assumptions were identified.

Main Findings

421 422

The main purpose of this systematic review was to 423 determine whether technological devices, used to measure 424 active cervical range of motion in adults suffering from 425 nonspecific neck pain, are cost-worthy because of their 426 superior reliability. Meta-regression analysis performed on 427 pooled data indicated that no difference exists in intrarater 428 and inter-rater reliability between expensive and inexpen- 429 sive devices. 430

As some recent studies have suggested, ^{31,32} cost 431 reduction without loss of efficacy in spinal disorder 432 management is a rising concern in clinical practice and in 433 related research. Choosing a measurement instrument that 434 conciliates cost and effectiveness has become particularly 435 relevant because the expenditure determined by the spinal 436 pathologic conditions is growing and new technologies 437 provide appealing, but expensive, tools for clinical practice. 438

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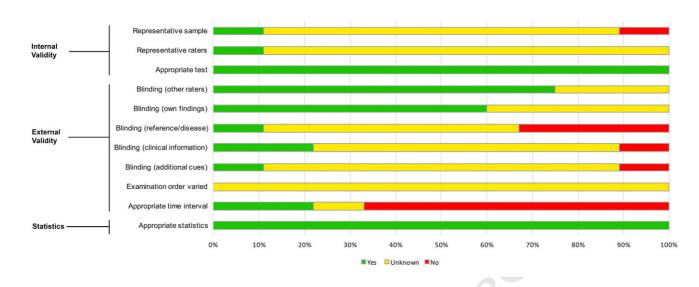


Fig 2. The figure shows the level of biases within included studies for each Quality Appraisal of Reliability Studies item; the green bar represents the percentage of studies scored "yes" for that item, the yellow bar represents the percentage of studies scored "unknown" for that item, and the red bar represents the percentage of studies scored "no" for that item. When items were not applicable, they were not included because they don't contribute to percentage calculation.

		ICC Descriptive Statistics	Mixed Effects Mod	el
t4.3	Characteristics	Mean (SD)	β (95% CI)	Р
t4.5	(Intercept)		0.25 (-0.55 to 1.05)	
t4.6				
t4.7	Tool Type			.99
t4.8	Expensive	0.87 (0.09)	0	
t4.9	Inexpensive	0.80 (0.12)	0.03 (-0.15 to 0.21)	
t4.10	*			
t4.11	Direction			.06
t4.12	Flexion & extension	0.82 (0.09)	0	
t4.13	Rotation	0.86 (0.11)	0.04 (-0.02 to 0.11)	
t4.14	Side bending	0.77 (0.13)	-0.04 (-0.10 to 0.01)	
t4.15	-		. ,	
t4.16	Age	$\rho = 0.58$	0.01 (-0.01 to 0.03)	.43

t4.2 Table 4. Output of the Mixed Effect Model for Interrater Reliability Regarding Tool Types

Characteristics = variable considered; mean (SD) = ICC mean in the characteristic levels with the standard deviation for categorical variable and ICC mean with standard deviation for continuous variable; β (95% CI) = β regression coefficient with 95% CI estimated using mixed effects model; *P* value = the

t4.17 likelihood ratio P value adjusted for multiple comparisons by the Bonferroni correction method.

t4.18 CI, confidence interval; ICC, intraclass correlation coefficient; SD, standard deviation.

439 Common-use and inexpensive measurement instruments
440 that were analyzed for their reliability in the articles included
441 in our review were standard dual-armed goniometer,
442 universal or gravity inclinometer, and CROM device,
443 which cost between €30 and €500.

The expensive instruments analyzed in the papers selected 444 for the present review were EDI-320, OSI SMA, and 445 Flock-of-Birds. The EDI-320 is an electronic, fully portable 446 digital inclinometer.^{2,22} OSI SMA consists in a lightweight 447 aluminum linkage with 6 potentiometers that measures regional 448 spinal motion concurrently on the 3 planes of movement by 449 transforming a voltage change in a measure of ACROM 450 degrees.²⁴ Flock-of-Birds is an electromagnetic tracking 451

system, consisting in a standard range transmitter and 3 receivers: **470** 1 receiver is used to assess natural posture of the participant, and 483 the other 2 are used to measure movements as they are 484 positioned on the forehead and on the sternum.²⁵ 485

All these expensive devices, as also ascertained by a 486 previous study,² were estimated to cost ≥ 6500 . A complete 487 overview of their modes of operation and prices could not 488 be performed because those instruments are out of 489 production or have been superseded by new technologies, 490 as declared by producers. The potentially short life of 491 technology-based devices is a relevant feature that should 492 be considered when investing resources for managing 493 spinal disorders. Inclinometers and handheld goniometers 494

Rondoni et al

Reliability of Cervical ROM Devices

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		ICC Descriptive Statistics	Mixed Effects Model	
t5.3	Characteristics	Mean (SD)	β (95% CI)	Р
t5.5	(Intercept)		0.84 (0.71-0.96)	
t5.6				
t5.7	Tool Type			.99
t5.8	Expensive	0.91 (0.07)	0	
t5.9	Inexpensive	0.93 (0.02)	0.01 (-0.04 to 0.06)	
t5.10				
t5.11	Direction			.56
t5.12	Flexion & extension	0.91 (0.07)	0	
t5.13	Rotation	0.95 (0.02)	0.03 (-0.01 to 0.07)	
t5.14	Side bending	0.92 (0.01)	0.01 (-0.02 to 0.04)	
t5.15				
t5.16	Age	$\rho = 0.29$	0.00 (-0.01 to 0.01)	.79

Table 5. Output of the Mixed Effects Model for Intrarater Reliability Regarding Tool Types t5.2

Characteristics = variable considered; mean (SD) = ICC mean in the characteristic levels with the standard deviation for categorical variable and ICC mean with standard deviation for continuous variable; β (95% CI) = β regression coefficient with 95% CI estimated using mixed effects model; P value = the t5.17 likelihood ratio P value adjusted for multiple comparisons by the Bonferroni correction method.

t5.18 CI, confidence interval; ICC, intraclass correlation coefficient; SD, standard deviation.

t6.2 Table 6. Output of the Mixed Effect Model for Interrater Reliability Regarding Directions

		ICC Descriptive Statistics	Mixed Effects Mo	odel
t6.3	Characteristics	Mean (SD)	β (95% CI)	Р
t6.5	(Intercept)		-0.06 (-0.60 to 0.49)	
t6.6				
t6.7	Direction			.11
t6.8	Flexion & extension	0.81 (0.09)	0	
t6.9	Rotation	0.85 (0.12)	0.04 (-0.03 to 0.10)	
t6.10	Side bending	0.75 (0.14)	-0.06 (-0.12 to 0.01)	
t6.11				
t6.12	Age	0.80 (0.12)	0.02 (0.01-0.03)	.04

Characteristics = variable considered; mean (SD) = ICC mean in the characteristic levels with the standard deviation for categorical variable and ICC mean with standard deviation for continuous variable; β (95% CI) = β regression coefficient with 95% CI estimated using mixed effects model; P value = the t6.13 likelihood ratio P value adjusted for multiple comparisons by the Bonferroni correction method.

t6.14 CI, confidence interval; ICC, intraclass correlation coefficient; SD, standard deviation.

Table 7. Output of the Mixed Effects Model for Intrarater Reliability Regarding Directions t7.2

		ICC Descriptive Statistics	Mixed Effects Mo	del
t7.3	Characteristics	Mean (SD)	β (95% CI)	Р
t7.5 t7.6	(Intercept))	0.89 (0.85-0.94)	
t7.7	Direction			<.0001
t7.8	Flexion & extension	0.93 (0.02)	0	
t7.9	Rotation	0.95 (0.01)	0.02 (-0.01 to 0.03)	
t7.10 t7.11	Side bending	0.91 (0.01)	-0.02 (-0.03 to -0.01)	
t7.12	Age	0.91 (0.02)	0.00 (-0.01 to 0.01)	.18

Characteristics = variable considered; mean (SD) = ICC mean in the characteristic levels with the standard deviation for categorical variable and ICC mean with standard deviation for continuous variable; β (95% CI) = β regression coefficient with 95% CI estimated using mixed effects model; P value = the likelihood ratio P value adjusted for multiple comparisons by the Bonferroni correction method.

t7.13

t7.14 CI, confidence interval; ICC, intraclass correlation coefficient; SD, standard deviation.

are still widespread and constitute common components of 495 the tool box of every practitioner. 496

Only a couple of previous reviews have been published 497 on this topic^{2,7}; they both suggested that the CROM device 498

and single inclinometer have been proven to be reliable,^{2,7} 500 and they are more worth using than other devices because 526 of their affordable costs³ and more solid literature 527 about them.⁸ 528

Unfortunately, their results cannot be directly compared 529 with ours. Both previous reviews summarized data from 530 studies on healthy participants, on mixed population 531 (healthy participants and patients), and on different 532 pathologic conditions (including rheumatic diseases, whip-533 lash, and radicular pathologic conditions), so no firm 534 conclusions can be drawn about reliability in adults with 535 nonspecific neck pain. Moreover, we have conducted a 536 meta-regression analysis on the pooled data that we 537 extracted from the selected papers, whereas in the studies 538 by de Koning et al² and Williams et al⁷ results were 539 presented only as a summary of findings with quality 540 assessment. The intention of Williams et al was to perform a 541 542 meta-analysis, but, as they declared, that was impossible because of the heterogeneity of studies.⁷ 543

As a secondary outcome, a multivariate analysis was conducted using a linear mixed effects model, corrected for age, to assess which direction of movement was more reproducible between inexpensive tools.

548 Inter-rater reliability is not affected by the age or the direction of the movement measured because no statistical 549 difference in ICC values was identified (P = .11). The same 550 does not apply to intrarater reliability, which is not affected 551 by age, but is by direction of the movement (P = .0001). In 552 553 particular, the same rater is more likely to obtain the same measure (P = .01) when measuring movements on the 554 sagittal plane (ie, flexion and extension), instead of on the 555 frontal plane (ie, side bending). This lack of intrarater 556 reliability in the frontal plane has, however, a small impact 557 558 on physical therapists' everyday practice. Among cervical movements, side bending is the least tested as pure 559 movement, being physiologically coupled with rotation— 560 that is, more quantitatively represented-and has only a 561 limited involvement in daily functional tasks.³³⁻³⁵ More-562 over, a recent good-quality review with meta-analysis 563 indicated that side bending was also poorly affected by neck 564 complaints, both acute and chronic.³⁶ Clinicians might be 565 aware that visual estimation of cervical range of motion is 566 not sufficiently reliable, even if they trained in it, as has 567 been reported by previous studies.^{2,37-39} 568

569 Methodological Consideration

Among the included studies, only 2 were of high 570 quality,^{23,27} and they both analyzed inexpensive tools 571 (universal²³ and gravity inclinometer²⁷ and standard 572 dual-armed goniometer²³). They both analyzed inter-rater reliability,^{23,27} but only 1 also included an intrarater reliability 573 574 measure.²³ The quality of the other selected studies ranged 575 from 20% to 40% of positive answers to the applicable 576 QAREL items. Even if each of these studies adopted adequate 577 statistics and selection of tests, reporting of blinding, samples, 578 and raters was unclear or incorrect. Hence, because of their 579 high risk of bias, strong conclusions cannot be drawn from the 580 present review, especially about technological devices. 581

Limitations

A selection bias could have occurred when studies with 583 mixed healthy and unhealthy population were excluded. In 584 these cases, although data of unhealthy participants were 585 requested directly to the authors, we were unable to collect 586 them. Furthermore, studies were included if they investi- 587 gated intrarater or inter-rater reliability in measuring 588 ACROM as the primary outcome. Studies with this 589 investigation as a secondary outcome may have been 590 missed, and for this reason, a selection bias could have 591 occurred. Reviewer bias is also a possible limitation of this 592 review because reviewers were not blinded to the authors. 593

No other systematic review was found in the literature 594 about reliability of active cervical range of motion, 595 including only patients with nonspecific neck pain. 596 Extensive research was conducted to identify all the former 597 studies on this topic, without restrictions of language and 598 date. Further information was also requested from authors 599 when necessary. Even so, because the protocol registration 600 of these studies was not compulsory, publication bias 601 cannot be excluded. 602

Finally, a reporting bias could have occurred because the 603 review was not registered on PROSPERO (an international 604 prospective register of systematic reviews). 605

Conclusions

Intrarater and inter-rater reliability of ACROM measures 607 recorded by expensive or inexpensive devices was not 608 significantly different. However, our results indicate that a 609 reliable and cost-effective measurement seems possible by 610 means of inexpensive devices in common clinical practice. 611 Nevertheless, the methodological quality of the available 612 studies is quite poor; thus, new studies of better quality 613 would empower the strength of our conclusions about 614 reliability of active cervical range of motion measures. 615

FUNDING SOURCES AND CONFLICTS OF INTEREST 616

No funding sources or conflicts of interest were reported 617 for this study. 618

Contributorship Information

Concept development (provided idea for the research): 620 G.R., A.R., M.T. 621

Design (planned the methods to generate the results): 622 G.R., A.R., M.T. 623

Supervision (provided oversight, responsible for orga- 624 nization and implementation, writing of the manuscript): 625 G.R., A.R., M.T. 626

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Data collection/processing (responsible for experiments, patient management, organization, or reporting data): M.S., G., A.B.

Analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results): F.G., D.R.

Literature search (performed the literature search): M.S.,F.G., A.B.

Writing (responsible for writing a substantive part of the manuscript): G.R., A.R., F.G., M.S., F.C.

636 Critical review (revised manuscript for intellectual 637 content, this does not relate to spelling and grammar 638 checking): M.T., G.R., D.R.

Practical Applications

- Measurement of active cervical range of motion during common clinical practice can be effectively performed with low-cost devices.
- Use of expensive devices should be reserved to specific clinical or research conditions.
- Assessment of active cervical side bending is less reliable.

669 APPENDIX A. SUPPLEMENTARY DATA

653 Supplementary data to this article can be found online at 654 https://doi.org/10.1016/j.jmpt.2017.07.002.

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