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Criterion validity of manual assessment of spinal stiffness

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2 Abstract

3 Assessment of spinal stiffness is widely used by manual therapy practitioners as a part of clinical 4 5 diagnosis and treatment selection. Although studies have commonly found poor reliability of such procedures, conflicting evidence suggests that assessment of spinal stiffness may help predict response 6 7 to specific treatments. The current study evaluated the criterion validity of manual assessments of spinal stiffness by comparing them to indentation measurements in patients with low back pain (LBP). As part 8 9 of a standard examination, an experienced clinician assessed passive accessory spinal stiffness of the L3 vertebrae using posterior to anterior (PA) force on the spinous process of L3 in 50 subjects (54% female, 10 mean (SD) age = 33.0(12.8) years, BMI = 27.0(6.0) kg/m2) with LBP. A criterion measure of spinal 11 stiffness was performed using mechanized indentation by a blinded second examiner. Results indicated 12 that manual assessments were uncorrelated to criterion measures of stiffness (spearman rho = 0.06, p = 13 0.67). Similarly, sensitivity and specificity estimates of judgments of hypomobility were low (0.20-0.45) 14 15 and likelihood ratios were generally not statistically significant. Sensitivity and specificity of judgments 16 of hypermobility were not calculated due to limited prevalence. Additional analysis found that BMI explained 32% of the variance in the criterion measure of stiffness, yet failed to improve the relationship 17 between assessments. Additional studies should investigate whether manual assessment of stiffness 18 relates to other clinical and biomechanical constructs, such as symptom reproduction, angular rotation, 19 20 quality of motion, or end feel.

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3 Introduction

Manual assessments of spinal stiffness have long been a cornerstone of the clinical examination 4 for manual practitioners when assessing patients with spinal pain. Such assessments contribute to 5 formulating a clinical diagnosis and often form the basis for treatment technique selection (Maitland 6 7 1986; Greenman 1996; Henderson 2012). For example, traditional manual therapy models use manual assessments of spinal stiffness to determine where to apply manual therapy, which technique to apply, as 8 9 well as the direction and grade of application. A recent survey found that the great majority (98%) of 10 manual physical therapists use manual assessments of spinal motion during their exam and base treatment decisions at least partially on their findings (Abbott et al. 2007). Additionally, emerging 11 evidenced-based models of back pain management, such as the Treatment Based Classification System 12 (Fritz et al. 2007; Hebert et al. 2011), use assessments of spinal stiffness to classify patients with low 13 14 back pain (LBP) into clinically relevant subgroups.

Reliability of an examination procedure that is used for treatment decision-making is considered 15 a prerequisite for its validity (Streiner and Norman 2003; Portney and Watkins 2008). The reliability of 16 manual assessments of spinal stiffness has been extensively studied and systematically reviewed 17 (Seffinger et al. 2004; van Trijffel et al. 2005; Stochkendahl et al. 2006; Schneider et al. 2008) 18 Although estimates of reliability of manual assessment vary widely, with some studies reporting good 19 20 reliability and others reports reliability no better than chance, systematic reviews report substantial 21 qualitative deficits with the majority of these studies (Seffinger et al. 2004; van Trijffel et al. 2005; Stochkendahl et al. 2006). The latest systematic review focusing solely on inter-examiner reliability 22

studies of intervertebral motion assessment of the lumbar and cervical spine (van Trijffel et al. 2005)
found that only four out of 19 included studies were performed in patients with neck and back pain and
that only three of the 19 studies included examiners that were blinded to each other's assessments.
Although inconclusive due to these qualitative shortcomings, common findings of poor reliability,
especially by higher quality studies (van Trijffel et al. 2005; Schneider et al. 2008) have led many
researchers and clinicians to question the continued use of manual assessments of spinal stiffness as a
part of the clinical examination (Wainner 2003; Seffinger et al. 2004; Landel et al. 2008).

Establishing validity for an examination procedure depends upon the procedure's intended use. 30 Despite having poor reliability, some evidence suggests that manual assessment of spinal stiffness may 31 have some predictive validity in determining which patients with back pain are likely to respond best to 32 different treatments. Specifically the presence of stiffness among patients with LBP is predictive of 33 34 clinical success after spinal manipulation (Flynn et al. 2002; Childs et al. 2004). Additionally patients 35 with LBP judged as hypermobile have been found to do better with lumbar stabilization exercise program (Fritz et al. 2005b). These findings were the result of manual posterior to anterior assessments 36 of spinal stiffness defined in the studies as at least one level (L1-L5) being rated as "hypomobile" or 37 "hypermobile" on a 3-point scale (hypomobile, normal, hypermobile). Such findings suggest that 38 manual assessments of spinal stiffness may be sufficiently valid to be useful components of the clinical 39 examination (Wainner 2003). 40

Other studies that have investigated the validity of manual assessments of spinal stiffness have found less encouraging results. Several studies reported that choosing a manual therapy technique based on assessments of spinal stiffness results in no better outcomes than random selection (Chiradejnant et al. 2003a; Haas et al. 2003; Kanlayanaphotporn et al. 2009). Moreover, as a part of a population-based study, Leboeuf-Yde et al. (Leboeuf-Yde et al. 2002) found that manual assessments of spinal stiffness

were not helpful in differentiating people with and without LBP. Although a "gold standard" measure
of spinal stiffness is not well established, several studies have compared manual assessments of spinal
motion to spinal motion assessed by imaging. Both Fritz (Fritz et al. 2005a) and Abbott (Abbott et al.
2005) found moderate agreement between manual assessments of spinal motion and motion during
flexion and extension radiographs while Landel (Landel et al. 2008) found poor agreement between
ratings of spinal motion between concurrent manual and MRI assessments.

A common limitation of the aforementioned criterion validity studies is that their criterions all 52 measured only the amount of spinal motion, whereas clinicians assess both motion and resistance to 53 motion, or spinal stiffness (Abbott et al. 2007; van Trijffel et al. 2009). Spinal indentation is a technique 54 to quantify spinal stiffness using both force and linear displacement data. Previous studies comparing 55 mechanized and manual assessments of spinal stiffness have only been performed in asymptomatic 56 57 subjects and have generally found poor agreement unless examiners are specifically trained to match their assessments to the indentation results (Maher et al. 1998; Chiradejnant et al. 2003b). Therefore the 58 primary purpose of this study was to evaluate the criterion validity of manual assessments of spinal 59 stiffness by comparing such judgments to indentation measurements of spinal stiffness in patients with 60 LBP. Additionally we explored the hypothesis that anthropometric characteristics of the patient (age, 61 sex, and body mass index [BMI]) affect judgements made during manual assessments of spinal stiffness. 62

63 Materials and Methods

64 Participants

Volunteers with LBP were recruited from local physical therapy clinics and a university campus
 as a part of a larger study investigating the effects of spinal manipulation (Fritz et al. 2011). Participant
 inclusion and exclusion criteria are listed in Table 1 and were used to ensure a clinically relevant sample

without contraindications to spinal manipulation. All participants reviewed and signed consent forms
approved by the Institutional Review Board of the University and the rights of the participants were
protected.

71 <u>Procedures</u>

After providing informed consent, participants completed several self-report measures and underwent a standard history and physical examination. The Numeric Pain Rating Scale (NPRS) was used to rate subjective back and leg pain intensity on a scale of 0 (no pain) to 10 (worst imaginable pain) (Childs et al. 2005). The modified Oswestry Disability Questionnaire (ODI) was used to quantify LBPrelated disability (Fritz and Irrgang 2001). The standardized physical examination was similar to a typical clinical examination for LBP and included all of the tests and measures associated with the Treatment Based Classification System (Fritz et al. 2007; Hebert et al. 2011).

79 Index test

A licenced clinician with 8 years of clinical experience and who was blinded to the results of the 80 indentation assessment performed the manual assessment of spinal stiffness. The spinous processes of 81 L1-L5 were palpated on each prone participant. Each spinous process was marked to ensure consistent 82 83 placement between manual assessment and the spinal indentation procedures. The examiner placed the region of the pisiform bone of his dominant hand on the posterior-most portion of the spinous process 84 and then placed his non-dominant hand on top of the dominant hand for support. The participant was 85 asked to relax as the examiner exerted a slow posterior to anterior (PA) force with both hands until he 86 felt he reached the end of available spinal motion. The examiner then released approximately one half 87 of his force and repeated several repetitions of the PA motion to assess the passive accessory spinal 88 89 stiffness (see Figure 1). The stiffness of the each vertebral segment (L1-L5) was recorded as

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"hypomobile", "normal", or "hypermobile" based on based upon the clinician's perception of the
amount of force used and the resultant segmental displacement. The presence or absence of pain was
also recorded during the stiffness assessment of each level.

93 Criterion Standard

After the index test, spinal stiffness was quantified by an examiner blinded to the results of the manual stiffness assessment using a mechanized indentation device with established reliability (Stanton and Kawchuk 2009; Wong et al. 2013) and accuracy (Kawchuk et al. 2006). The indentation device consisted of a saddle tip attached to the terminal end of a linear stepping motor (Dual Motion Motor, HSI, Waterbury, CT) supported vertically by a rigid metal frame (Figure 2). Prior to undergoing indentation, participants were oriented to the machine and procedure including demonstration on a calibration device.

101 The transducer probe was positioned posterior to the L3 spinous process of each prone participant and slowly lowered until contacting the spinous process. L3 was chosen for the level of 102 indentation on all participants as it is generally the segment that is most perpendicular with the 103 indentation transducer. Initial pressure of the transducer was set at a comfortable level below 5 N which 104 105 allowed normal respiration, but restricted participants from taking a full deep inhalation. The participant 106 was then instructed to take a normal breath in and out and hold the breath at the end of exhalation. Towards the end of exhalation, the examiner started the indentation procedure at the preload of 5 N and 107 108 progressed to a maximum load of 60 N before being automatically withdrawn. 60N was selected based 109 on extensive pilot testing and was found to be an appropriate maximal load that adequately challenged the spine while remaining tolerable in our symptomatic sample. Linear indenter displacement was 110 111 quantified by a rotary encoder and signals from the load cell (Measurement Specialties, Hampton, VA)

112	and transformer were collected by customized LABview software (National Instruments, Austin, TX) at
113	a collection rate of 200 Hz. Each indentation lasted approximately 5 second and was performed 3 times
114	on each participant. If participants inhaled before the end of measurement, the repetition was repeated.
115	Force and linear displacement data were used to calculate spinal stiffness. Global Stiffness (GS)
116	was the primary outcome and was calculated as the slope of the force/displacement curve between 5 and
117	60 N. Terminal Stiffness (TS) was additionally calculated as the instantaneous stiffness (N/mm) that
118	occurred at the maximal indentation load. GS and TS measures were each averaged across the 3
119	indentation repetitions to reduce variability (Wong et al. 2013).
120	Data Analyses
121	All data were entered into and analyzed by IBM SPSS 21 (Chicago, IL). Descriptive statistics
122	were performed on sociodemographic and health characteristics of the sample. The statistical
123	significance and strength of relationship between manual assessments of spinal stiffness and indentation
124	measures of spinal stiffness of L3 (GS and TS) were assessed using Spearman's rho correlation analysis.
125	Measurements were then dichotomized in order to calculate diagnostic utility estimates. Manual
126	spinal stiffness outcomes were categorized into those judged by the clinician assessor to be
127	"hypomobile" vs. "normal or hypermobile". Indentation measures (GS and TS) were dichotomized
128	using two different distribution-based cut-offs of "stiffness", greater than vs. less than the sample mean
129	and greater than vs. less than one standard deviation above the sample mean. Point estimates and 95%
130	confidence intervals of sensitivity, specificity, and positive and negative likelihood ratios for each
131	different criterion cut-off were calculated using an excel-based calculator downloaded from the
132	Physiotherapy Evidence Database (www.pedro.org.au). Similar analyses could have been done for
133	hypermobility by comparing those judged by the clinician assessor to be "hypermobile" vs. "normal or

hypomobile". These analyses were not performed, however, as only 5 out of 50 participants werejudged to be "hypermoble".

Lastly, we used stepwise hierarchical linear regression models to explore the hypothesis that anthropometric characteristics of the patient affect judgements made during manual assessments of spinal stiffness. The criterion measures of stiffness (GS and TS) served as the dependent variables. Age, sex, and BMI were entered into the model in the first step in a forward stepwise fashion. A significance value less than 0.05 was required for a variable to enter the model and greater than 0.10 to remove a variable from the model. Manual assessment of spinal stiffness was then force-entered into the second step.

143 **Results**

Fifty-one participants with LBP were recruited. Stiffness data were not captured on one postpartum participant due to the indenter exceeding its maximal displacement before reaching the terminal
load of 60 N. Demographic and clinical characteristics for the remaining 50 participants are presented in
Table 2.

Descriptive statistics for stiffness values alone and their correlation with manual judgements are presented in Table 3. Spearman's rho correlation coefficients were not statistically significant. Since the results for GS and TS were essentially the same for the other analyses, results are only presented for GS. As can be seen in Figure 3, participants who were judged to have "normal" intervertebral motion by manual assessments demonstrated the highest stiffness values.

Based on 2x2 contingency tables (Table 5), sensitivity, specificity, and positive and
negative likelihood ratios of "hypomobility" are displayed in Table 6 using two cut-offs of stiffness

(GS). Regardless of the cut-off, sensitivity and specificity estimates were low (0.20-0.45) and likelihood ratios were generally not statistically different from 1, indicating a judgement of "hypomobile" does not significantly change the post-test likelihood of a participant being "stiff".

158	Of the anthropometric variables entered into the stepwise hierarchical linear regression, only
159	BMI was retained after step one (Table 4) indicating that BMI was predictive of GS (β = -0.566, p <
160	0.001). Specifically BMI explained 32% of the variance associated with GS measures. After
161	accounting for the relationship of BMI and GS, judgement of intervertebral stiffness made during
162	manual assessment was not predictive of GS ($\beta = 0.006$, p = 0.96).

As an additional control measure to ensure that pain with manual assessment was not confounding other analyses, we examined the point-biserial correlation between "pain with L3 assessment" (painful vs. non-painful) and GS. Pain did not significantly correlate with GS ($r_{pb} = -0.17$, p = 0.22) suggesting that pain did not confound the relationship between manual assessment and indentation measures of stiffness.

168 **Discussion**

Clinicians who utilize manual therapy interventions frequently include judgments of spinal 169 stiffness in their examination of patients with LBP (Abbott et al. 2007), presuming that increased 170 stiffness indicates the need for a specific treatment (e.g. spinal manipulation). Re-assessment of spinal 171 stiffness following treatment is then often used as a marker of having delivered a successful treatment if 172 173 stiffness is perceived to have decreased (Tuttle 2009). The evolving paradigm of evidence-based 174 practice dictates that clinicians focus on examination procedures that are both reliable and valid. 175 Although manual assessments of spinal motion have most commonly been found to be unreliable 176 (Seffinger et al. 2004; Stochkendahl et al. 2006; Schneider et al. 2008; van Trijffel et al. 2009) several

studies suggest that such judgements are helpful with predicting benefit with specified treatments (Fritz
et al. 2005b). To further explore the validity and diagnostic utility of manual assessments of spinal
stiffness we compared such judgments to indentation measurements of spinal stiffness. Our results
indicate that judgements of spinal hypomobility made during manual assessment are unrelated to, and
are not helpful in identifying, alterations of spinal stiffness.

182 One possible explanation for our results is that manual assessments of spinal stiffness are inherently unreliable and inaccurate. Previous studies have shown that manual assessments show a great 183 deal of variability in the magnitude and direction of applied force (Latimer et al. 1998; Caling and Lee 184 2001). This could explain the common research finding that such manual assessments are unreliable 185 186 (Seffinger et al. 2004; Stochkendahl et al. 2006; Schneider et al. 2008; van Trijffel et al. 2009) and would support the notion that reliability is a prerequisite of validity. If manual assessments of spinal 187 stiffness are simply unreliable and invalid, their continued use during clinical examination is difficult to 188 justify. This conclusion has been reached by several other authors after reviewing the reliability 189 literature (Troyanovich et al. 1998; Seffinger et al. 2004) and is consistent with studies that find a lack of 190 association between assessments of spinal motion and clinical outcomes (Chiradejnant et al. 2003a; 191 192 Haas et al. 2003; Kanlayanaphotporn et al. 2009).

Another possible explanation for our findings is that judgements based on manual assessments may be evaluating a different construct than spinal stiffness or may be evaluating multiple or combined constructs. In a recent survey of 466 U.S. and New Zealand manual physical therapists, Abbott et al. (2007) found that respondents reported assessing multiple constructs when performing manual assessments of spinal stiffness. "Pain response" was the construct reported most commonly as the most important, followed by "quality of resistance" (i.e. stiffness) and "quantity of translation" of the vertebrae. Many participants however, also reportedly evaluated "quality of end-feel" and "quality of

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motion path" during manual spinal assessments. Other studies comparing manual assessments of spinal
motion to criterion measures assessed both angular spinal rotation and linear spinal displacement
(Abbott et al. 2005; Fritz et al. 2005a). Because our criterion measure (indentation) measures only
linear spinal stiffness, it could be that manual providers are detecting aspects of motion not included by
the criterion test used in this study and/or making judgements on the relationship between constructs
such as pain and stiffness.

206 It is also possible that manual providers consciously or unconsciously account for a patient's anthropometric characteristics (age, sex, and BMI) when manually assessing spinal stiffness, which may 207 208 distort the relationship between manual assessments and indentation measures of spinal stiffness. It was 209 anecdotally apparent during indentation measurements that larger individuals with more adipose tissue 210 were measured as substantially "less stiff". Therefore, we explored the hypothesis that age, sex, and BMI may affect the relationship between manual assessment of spinal stiffness and indentation 211 measures of spinal stiffness. We found that BMI, but not age or sex, was related to indentation 212 measures of spinal stiffness. Moreover, we found that manual judgements of spinal stiffness did not 213 relate to indentation measures after accounting for the relationship between BMI and indentation 214 215 measures.

Perhaps the most salient limitation of the current study is that only one aspect of manual assessment of the spine was evaluated. The examiner simply rated passive accessory vertebral motion as "hypomobile", "normal", or "hypomobile" and did not attempt to qualify different components of spinal motion such as quality of motion, resistance to motion, or end feel. Although this is the same methodology of assessing spinal motion used in studies that have found predictive validity in determining which patients with back pain are likely to respond best to different treatments (Flynn et al. 2002; Childs et al. 2004; Fritz et al. 2005b), it is possible that having providers specifically focus on the

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force-displacement curve on which the mechanized spinal stiffness assessments are based would have 223 224 resulted in better agreement between manual assessments and indentation measures. Additionally, since judgements of hypermobility were relatively infrequent (5 out of 50 participants) we limited our 225 sensitivity, specificity, and likelihood ratio analyses to hypomobility rather than performing them on 226 both hypomobility and hypermobility. Although this limits us from making quantitative conclusions 227 228 about diagnostic utility of judgements of hypermobility, the graph of assessments of each participant (Figure 3), suggest that manual judgements of spinal stiffness are poor discriminators of criterion 229 230 stiffness, regardless of the category breakdown.

Another limitation of the current study is that, regardless of the specific location of the subject's 231 232 back pain, spinal stiffness was always measured at the L3 vertebrae. Although we are unaware of such 233 evidence, it is possible that the assessments of spinal stiffness would better relate to criterion stiffness measures if measured at the most focal areas of pain. Finally, the application parameters of both the 234 manual assessment and the indentation assessment were developed to optimize each separately rather 235 than be standardized together. To maximize generalizability, the examiner performed the manual 236 assessment in an identical fashion that he had previously used in his 8 years of clinical practice. 237 238 Similarly, the parameters of the indentation measures were selected to most accurately measure the 239 force-displacement curve at a tolerable level of force in participants with LBP. There may have been 240 small differences in several parameters between the manual assessment and indentation measures including the amount of load, rate of loading, and padding between the 2 tables that may have adversely 241 affected their relationship. While some of these parameters may have adversely affected the agreement 242 243 between the index and criterion tests, the differences would likely be systematic and would not affect the 244 ordinal relationship (correlation) between the two measures and would also be more representative of 245 clinical practice.

246	Future research should further investigate the clinical utility of manual assessment of spinal
247	stiffness. If additional studies verify the predictive validity of manual assessments, future research
248	should investigate whether manual assessment of spinal stiffness relates to other constructs of spinal
249	motion such as quality of motion or end feel and explore alternative methods of objectively quantifying
250	these different constructs.
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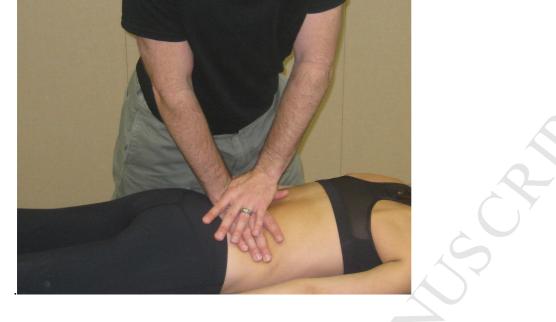
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1 FIGURE 1. Posterior to anterior mobilization used as index test of manual assessment of spinal stiffness



- 2
- 3
- 4 **FIGURE 2.** Mechanized indentation device used as the criterion standard measure of spinal stiffness



6 **TABLE 1.** Study inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Back pain located between the 12 th rib and buttocks, that in the opinion of the screening examiner, was originating from the lumbar region	Neurogenic pain defined by either a positive ipsilateral or contralateral straight leg raise (reproduction of symptoms at $\leq 45^{\circ}$) or reflex, sensation, or strength deficits in a pattern consistent with nerve root compression
Between the age of 18 and 60 years	Osteoporosis
	Prior surgery to the lumbosacral spine
Modified Oswestry Disability score at least 20%	Medical 'red flags' of a potentially serious condition including cauda equina syndrome, major or rapidly progressing neurological deficit, fracture, cancer, infection, or systemic disease
Ability to lie prone and supine for a minimum of 20 minutes	Prior spinal manipulation to the lumbosacral spine or trunk muscle stabilization exercises performed in the previous 4 weeks

TABLE 2. Demographic and Clinical Characteristics (n=50). 10

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Characteristic	
Age	33.0 (12.8) years
Sex	52.0% female
BMI	27.0 (6.0) kg/m2
Numeric Pain Rating*	4.9 (1.6)
Oswestry Disability Score	32.2 (12.0) %
Prior History of LBP	88.0% yes
Duration of Symptoms	184 (41, 758) ^{\dagger} days
Distribution of Symptoms	26.0% with leg pain

Numbers represent mean (standard deviation) unless otherwise indicated 12

*Reports the average of the worst, best and current scores for pain over the last 24 hours 13

† Median (interquartile range). 14

- BMI: Body Mass Index, LBP: low back pain 15
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TABLE 3. Descriptive statistics of spinal stiffness values stratified by manual judgement of spinal stiffness

Manual PA Judgement	Global Stiffness	Terminal Stiffness	
	Mean (SD)	Mean (SD)	
Hypomobile (n = 24)	5.19 (1.28)	4.06 (1.58)	
Normal $(n = 21)$	6.18 (1.84)	4.89 (2.04)	
Hypermobile $(n = 5)$	4.63 (1.12)	3.49 (1.15)	
Spearman's Rho Correlation (p- value)	0.06 (0.67)	0.07 (0.63)	

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FIGURE 3. Global Stiffness (GS) measures of each individual categorized by judged intervertebral stiffness. Interpolation line represents mean of each category.

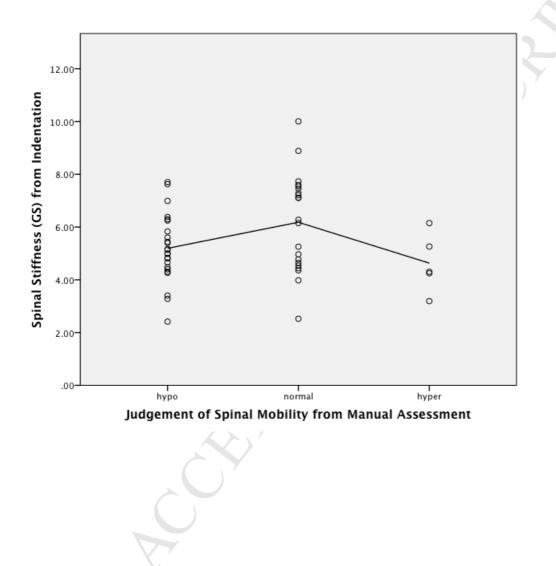


TABLE 4. Hierarchical linear regression analysis predicting criterion measure of spinal

stiffness (GS)

Variables	Standardized β coefficient	Significance of β coefficient	Adjusted R2 Change
Body Mass Index (kg/m2)	-0.566	< 0.001	0.321
Manual Assessment of Spinal Stiffness	0.006	0.958	< 0.001

TABLE 5. 2x2 contingency tables for the two reference standards used to evaluate the manual assessment of stiffness.

	Spinal Indentation			
	> Mean stiffness	\leq Mean stiffness	Total	
Manual assessment				
Rated hypomoble	8	16	24	
Rated normal or hypermobile	13	13	26	
Total	21	29	50	

	Spinal In	dentation	
	>+1SD stiffness	\leq +1SD stiffness	Total
Manual assessment			
Rated hypomoble	2	22	24
Rated normal or hypermobile	8	18	26
Total	10	40	50
			\mathbf{i}

TABLE 6. Diagnostic accuracy of manual assessment of spinal stiffness to detect spinal stiffness (GS)

Criterion	Sensitivity (95%	Specificity (95%	LR + (95% CI)	LR- (95% CI)
Standard	CI)	CI)		
> Mean stiffness	0.38 (0.21, 0.59)	0.45 (0.28, 0.62)	0.69 (0.37,	1.38 (0.82,
			1.31)	2.33)
>+1SD stiffness	0.20 (0.06, 0.51)	0.45 (0.31, 0.60)	0.36 (0.10,	1.78 (1.12,
	Q	7	1.30)	2.82)

GS: Global stiffness