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Intra and Inter-Tester Reliability for Lumbar Flexion and Extension Using the Dualer Digital Inclinometer

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Intra- and Inter-tester Reliability for Lumbar Flexion and Extension Using the Dualer™
Digital Inclinometer

By

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Jennifer Johnson,
Tracy Stommes,
and Kimberly Weeda
Bachelor of Science in Physical Therapy
University of North Dakota, 2001

A Scholarly Project

Submitted to the Graduate Faculty of the

Department of Physical Therapy

School of Medicine

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in partial fulfillment of the requirements

for the degree of

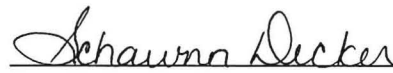
Master of Physical Therapy

Grand Forks, North Dakota

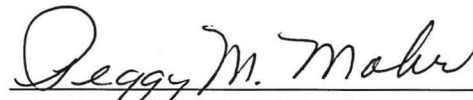
May
2002



This Scholarly Project, submitted by Amber Flatland, Jennifer Johnson, Tracy Stommes, and Kimberly Weeda in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.



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PERMISSION

Title Intra- and Inter-tester Reliability for Lumbar Flexion and
 Extension Using the Dualer™ Digital Inclinometer

Department Physical Therapy

Degree Master of Physical Therapy

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Date 12/5/01

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ABSTRACT

Purpose: The purpose of this study was to determine the intra- and inter-tester reliability of the Dualer™ Digital Inclinator when measuring lumbar flexion and extension. Past studies examining reliability of inclinometers have reported variable results. Few studies in the literature have sought to determine the reliability of the Dualer™ Digital Inclinator for measuring lumbar flexion and extension.

Methods: The subjects who participated in this study were university students between 20 and 41 years of age without a significant history of back pain (n=22). Two testers measured each subject's lumbar flexion and extension, hip flexion and extension, and straight leg raise during each of two measuring sessions.

Results: Intraclass correlation coefficients (ICC) as an indication of intra-tester reliability for lumbar flexion, extension and total motion for tester one were .59, .73, and .76 respectively. ICC values for lumbar flexion, extension and total motion for tester two were .67, .74, and .70, respectively. Inter-tester reliability was not established because of insufficient intra-tester reliability.

Discussion: Many factors may have contributed to the lack of high intra-tester reliability. The subject, tester, and sensitivity of the instrument or procedure may have caused errors. In order to use the Dualer™ with the currently recommended procedure clinically, the clinician must be aware of the limitations and seek to minimize the sources of error.

CHAPTER I

INTRODUCTION

Low back pain is the cause of impairment in many individuals. The average lifetime prevalence of low back pain is 59%, with an annual prevalence of 41%.¹ Frymoyer and Cats-Baril² estimated the direct cost of back pain to be \$24.3 billion within the United States in 1990. They then estimated the total direct and indirect costs of low back disorders to be between \$75 and \$100 billion.

In today's environment of managed care there is a great demand for ease of measurement of both function and treatment outcomes. The American Medical Association (AMA) includes an assessment of lumbar range of motion (ROM) as one of two methods for evaluating spine impairment.³ The other, preferred method is the Diagnosis-Related Estimate, which defines the percentage of whole-person impairment by categories. The AMA recommends the inclinometer technique for measuring lumbar ROM, using either a digital inclinometer or a standard inclinometer.

Problem Statement: Studies, which have been performed to establish inter-and intra-tester reliability for lumbar ROM using an inclinometer technique, have reported conflicting results. There are few studies in literature that have sought to determine reliability of the Dualer™ Inclinometer for quantifying lumbar ROM.

Purpose: The purpose of this study is to establish intra- and inter-tester reliability for the Dualer™ Digital Inclinometer for measuring lumbar flexion and

extension using a method developed from the AMA protocol³ and the Dualer™ Instruction Manual⁴ in healthy individuals between the ages of 20 and 60 years.

Significance: This study is important to the profession of physical therapy since physical therapists are often called upon to perform assessments of lumbar spine ROM in individuals with low back pain to help determine impairments. Before making this assessment, therapists need to make the decision of which inclinometric instrument to use. Some inclinometric instruments are relatively inexpensive, while others cost hundreds of dollars. Upon completion of this study we plan to compare our results to those of previous studies to determine whether the Dualer™ Digital Inclinometer has satisfactory intra- and inter-rater reliability, and compare these values with the intra- and inter-rater reliability values found in other studies. This comparison will allow clinicians to make an informed decision as to which instruments are best suited for clinical purposes.

Research Question #1: Does the Dualer™ Digital Inclinometer have intra-tester reliability in lumbar flexion, extension, and total lumbar motion?

Research Questions #2: Does the Dualer™ Digital Inclinometer have inter-tester reliability in lumbar flexion, extension, and total lumbar motion?

Research Question #3: How do the values obtained for intra- and inter-tester reliability compare with those of other studies examining reliability of the Dualer™ Digital Inclinometer for lumbar ROM?

Research Question #4: How do the values obtained for intra- and inter-tester reliability for flexion and extension compare with the values obtained by other

researchers using different inclinometers?

Null Hypothesis: The Dualer™ Digital Inclinometer has good to excellent intra- and inter-tester reliability for lumbar flexion, extension, and total lumbar motion.

Alternate Hypothesis: The Dualer™ Digital Inclinometer does not have good to excellent intra- and inter-tester reliability for lumbar flexion, extension, and total lumbar motion.

CHAPTER II

LITERATURE REVIEW

Many researchers have performed studies and evaluated tools determining inter- and intra-rater reliability of taking lumbar range of motion (LROM) measurements. Lumbar flexion, extension, and total LROM can be assessed using variations of inclinometer techniques. Several important factors in research design distinguish the investigations that have been performed. The factors include but are not limited to: type/brand of inclinometer, style of landmark placement, procedures used to collect ROM measurements, use of pelvic restraint, and characteristics of subjects. The current study's approach reflects the use of the Dualer™ Digital Inclinometer as recommended by the instructional manual.⁴ We used AMA guidelines for procedures used to collect final LROM measurements without the use of a pelvic restraint.³

The AMA states in the *Guides to the Evaluation of Permanent Impairment* that “an inclinometer is the preferred device for obtaining accurate, reproducible measurements in a simple, practical, and inexpensive way.”³ The AMA guidelines emphasize the importance of limiting the sources of error when taking lumbar range of motion (LROM) measurements. When conducting these procedures, the importance of subject effort as a source of error should be considered. Similarity in measurements found during consecutive trials is one way to gauge if an individual is giving consistent effort. AMA quantifies this similarity as follows: each measurement must be within a

five degree difference from the mean during three consecutive trials if the mean is less than 50 degrees; if the mean is greater than 50 degrees each measurement in the consecutive trials should be at least 10% of the mean. Three consecutive trials need to be obtained within a total of six trials. If unable to achieve three consecutive measures within the specified ranges, the test is considered invalid. Five degrees was used as the maximum difference allowed when determining which measurements to include in the statistical analysis of the current data. AMA also identifies other sources of error in using an inclinometer in measuring lumbar ROM. These sources are associated with the administrator's ease of use of the instrument, stabilization of the instrument and instructions given to subject, and ability to accurately find landmarks.

Studies that specify the use of a digital or electronic inclinometer show variable reliability ranging from not reliable to very reliable.⁵⁻⁸ Nitschke et al⁵ used a dual inclinometer as recommended by the AMA to measure 34 subjects with chronic low back or leg pain of at least six months. This study found poor intra-rater and inter-rater reliability with the Pearson r correlation coefficient in all measurements taken including lumbar flexion and extension. This study suggested and used statistics that measured systematic as well as random differences between two raters and these results showed poor reliability also. A study by Chiarello and Savidge⁷ compared the inter-rater reliabilities of the Cybex EDI-320 (a digital inclinometer) and a fluid goniometer in 12 normal subjects and six patients with low back pain. The researchers described an Intraclass Correlation Coefficient (ICC) of .80 to 1.00 as highly reliable, .60 to .79 as moderately reliable, and below .60 as questionably reliable. For inter-rater reliability, the fluid goniometer had an ICC of .57 for flexion in normals and .82 for flexion in patients.

The ICC for extension in normals was .67 and .86 for patients. The EDI had a flexion ICC of .74 for normals and .64 for patients. The ICC for extension with the EDI was .65 for normal subjects and .83 for patients. The researchers concluded that there was no statistically significant difference between the fluid goniometer and the EDI for measuring spinal flexion and extension.

The double inclinometer technique findings demonstrate discrepancies in intra-rater reliability and inter-rater reliability varying from poor to good.^{5,8-11} Williams et al¹¹ examined reliability of the standard double inclinometer as compared to the modified-modified Schober method of measuring lumbar flexion and extension in 15 subjects with chronic low back pain. The modified-modified Schober method uses a tape measure held over specific landmarks on the spine during LROM. This study found the intratester and intertester reliability of lumbar flexion and extension needs improvement compared to the reliable measurements found in the modified-modified Schober method. Ng et al⁹ reported good intra-tester reliability for lumbar flexion and extension (flexion $r = .87$, extension $r = .92$, total flexion and extension $r = .92$) on 35 healthy male subjects using a double inclinometer technique in conjunction with a pelvic restraint device to stabilize the pelvis. No analysis of intertester reliability was performed in this study.

Most studies used palpation to locate bony landmarks.⁶⁻¹² The landmarks are usually found with the subject in prone or standing with a neutral spine.^{9,10,12} Also, there were differences in who found the landmarks, Ng et al⁹ used a single tester for the study who performed all procedures including palpation in prone. Stude et al⁶ utilized a person that was not an examiner to find the landmarks, not mentioning position of the subject. Rondinelli et al¹⁰ had two examiners who each found the landmarks on the individual

they examined. Sauer et al¹² used radiologic determination of landmarks to place the inclinometer and did a comparative study with the more traditional palpation method. The objective was to determine if LROM measurements taken with inclinometers placed on bony landmarks found by using manual palpation was correlated to those measurements taken using radiography to find the bony landmarks. They examined the inter-rater correlation for a group of 48 subjects using a standard inclinometer and both placement techniques. They found high correlation for total lumbar ROM ($r=.94$; $p<.001$) and lumbar flexion ($r=.88$; $p<.001$), with extension barely correlating ($r=.42$, $p>.05$). A description of the method of finding landmarks varies extensively in the literature.

Variation of methods used for collection of final LROM measurements was evident in the aforementioned studies. Some researchers did not employ AMA procedures regarding number of trials completed in a specific direction of motion or which measurements were used for final results or did not address these issues in their study.^{6,7,9,11,12}

Nitschke et al⁵ and Rondinelli et al¹⁰ stated that they used the standard procedures recommended by AMA to select how many trials the subjects were instructed to perform and which measurements to record. Rondinelli et al¹⁰ compared the intra- and inter-rater reliability of a single inclinometer, double inclinometer and back ROM inclinometer method of measuring lumbar flexion. The intra-rater ICC for the single inclinometer ranged from .85-.86, the double inclinometer ranged from .70-.81, and the back ROM inclinometer ranged from .81-.90. The inter-rater reliability for the single inclinometer had an ICC of .76, with ICCs of .69 and .77 for double inclinometers and back ROM

inclinometers, respectively. The researchers concluded that the three methods for measuring lumbar flexion had considerable variability and low inter-rater reliabilities. They also concluded that intra-rater reliability was high for the back ROM and single inclinometer methods, but moderate for the double inclinometer.

Overall, the research shows that there are considerable inconsistencies in intra-tester and inter-tester reliability findings attributable to the many issues involved in measuring LROM with an inclinometer.

CHAPTER III

METHODOLOGY

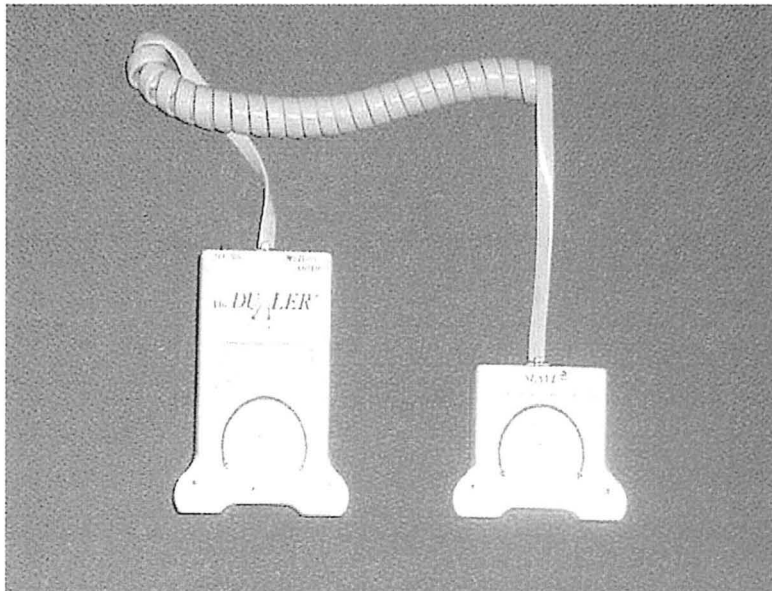
This study was reviewed and approved by the University of North Dakota Institutional Review Board prior to the initiation of the study. A copy of the human Subjects Review form appears in Appendix A. During recruitment all individuals were informed that their participation was strictly voluntary. Components of the study were explained to those wishing to participate. All participants were given and signed a written statement of informed consent (Appendix B).

Subjects: The study population consisted of a random sample of 22 college-age students, 15 females and 7 males, ranging in age from 20 to 41 (mean 22.9 ± 4.4). Individuals were recruited from Physical Therapy and other classes at the University of North Dakota on a volunteer basis. Inclusion or exclusion was based on a short medical questionnaire (Appendix C). Subjects were excluded if they had a history of back or abdominal surgery in the past year, back pain lasting longer than one week in the past year, undergone treatment of back pain by a health professional in the past year, inadequate balance to comply with the testing procedure, were currently pregnant, or felt that an exacerbation of a pre-existing condition may occur. The individuals studied or the testers could discontinue participation at any time, until final measurements were taken. Individuals were required to attend two testing session set two days apart. Two testers were selected to complete the testing. Each tester read protocol booklets, viewed an

instructional video, and performed several practice tests. Each tester measured the individuals once during each testing session. Prior to beginning the testing session, each tester was randomly assigned a card. The tester who began the testing procedure was randomly selected by having the subject choose a card previously assigned to a tester.

Instrumentation: The Dualer™ digital inclinometer was the instrument of study. The Dualer™ has a "master" and a "slave" component, connected by a coiled telephone-type cord. See Figure 1.

Figure 1. Dualer™ Digital Inclinometer. "Master" unit on right, "slave" unit on left.



*Dimensions of the Dualer™ are as follows: "Master" 3.6 inches in height, 2.1 inches in length and 0.7 inches in width with a weight of 7 ounces. The "slave" is 2.1 inches in height and 2.1 inches in length, and 0.7 inches in width with a weight of 4 ounces. The Dualer™ is able to subtract the measured angle of the "slave" from the measured angle of the "master" from a neutral position, to give the rater a digital read out of the specific ROM measured on the "master". The Dualer™ is manufactured by Jtech Medical Industries 357 West 910 South Heber City, UT 84032.

Procedure: Individuals were asked to remove their shoes and stand on a hard floor to eliminate the effects of different shoe heights and add safety to the testing

environment. The individuals were asked to keep their feet shoulder width apart and knees straight during the warm-up and testing procedure. Participants were provided a warm-up, which consisted of three, slow non-ballistic movements into greatest amount of flexion and immediately followed by three movements into greatest amount of extension. Individuals were required to expose their low backs. Marks were placed on the bony landmarks of T₁₂ and S₂ using sticker-type dots, or in the case of an allergy to adhesives, a wax pencil. Using a standard script the participant was instructed on the motions to be tested (lumbar flexion, lumbar extension, hip flexion, hip extension, and SLR). The dialogue took place before each testing session. At the conclusion of measurement by the first tester, a second tester measured the same aforementioned motions on the same participant.

To measure lumbar flexion the Dualer™ “master” was placed over T₁₂ and the “slave” placed over S₂. The individual was asked to stand up tall to achieve “neutral” spine, and the Dualer™ was zeroed. See Figure 2. The individual was then instructed to bend forward as far as they could. See Figure 3. Once motion appeared to be at maximum, the individual was asked if that was as far as they could go. The individuals replied “yes” or “no”. If the reply was “yes,” a measurement was taken and they returned to their starting position. If the reply was “no,” the individual was instructed to bend as far as they could, followed by being asked if that was as far as they were able to go. When the individual responded “yes” then a measurement was taken. This measuring procedure was repeated at least three, but no more than six times as per the AMA guidelines³ and recorded on the data sheet (Appendix D). Lumbar extension was measured immediately after lumbar flexion, without removing or re-zeroing the Dualer™

as per instructional manual.⁴ The individual was asked to bend backward as far as they could. See Figure 4. Using the same script as previously mentioned, the individual indicated when the greatest amount of extension was achieved. Three to six trials of lumbar extension were performed and recorded on the data sheet.

Figure 2. Dualer™ Placement on Lumbar Spine.

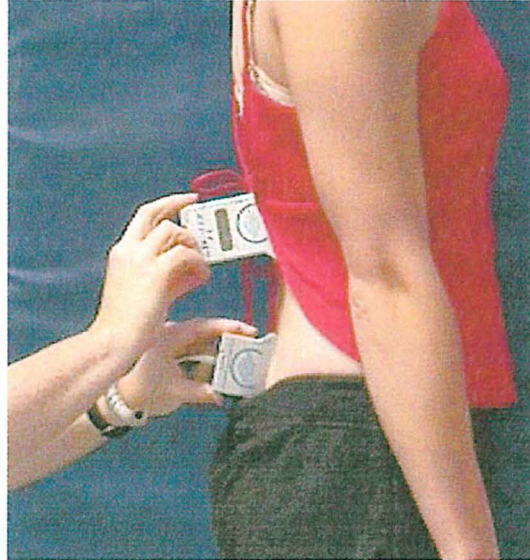


Figure 3. Lumbar Flexion.

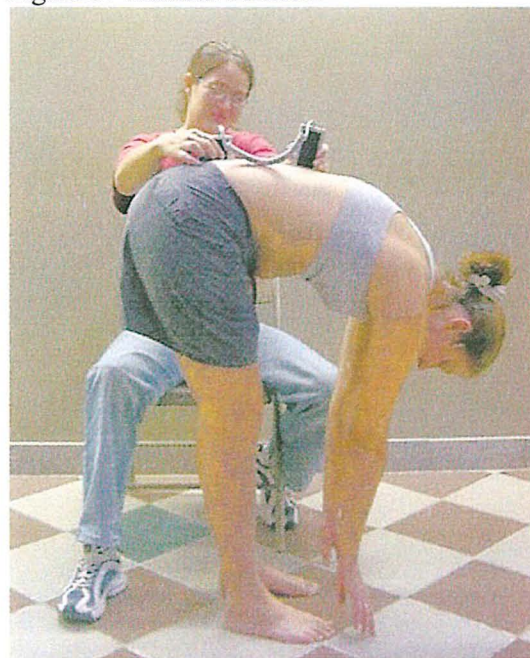
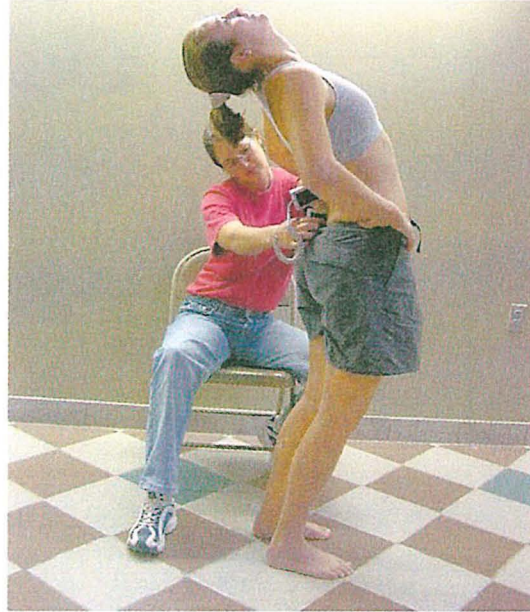


Figure 4. Lumbar Extension.



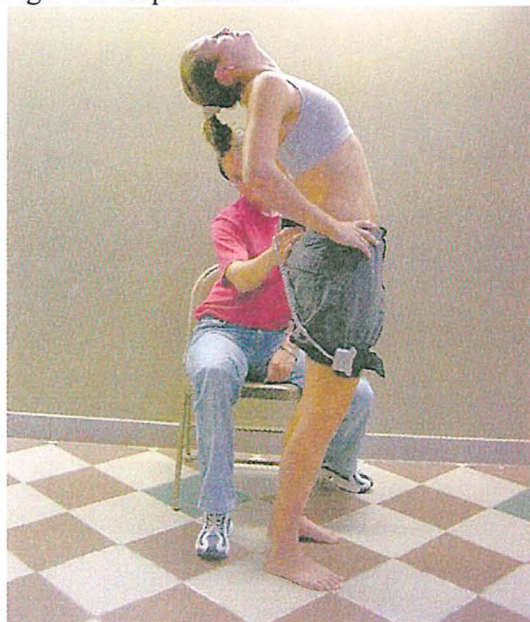
Hip motions were measured by strapping the "slave" to the upper thigh and placing the "master" over S₂. The Dualer™ was zeroed again in neutral spine. Hip flexion was measured first, and the individual was asked to bend forward as far as they could. See Figure 5. Once motion appeared to be at maximum, the individual was asked if that was as far as they could go. The individuals replied "yes" or "no". If the reply was "yes," a measurement was taken and they returned to their starting position. If the reply was "no," the individual was instructed to bend as far as they could, followed by being asked if that was as far as they were able to go. When the response from the individual was "yes" then a measurement was taken. This measurement procedure was repeated at least three, but no more than six times and recorded on the data sheet. Hip extension was measured immediately after hip flexion, without removing or re-zeroing the Dualer™ as per protocol booklet. The individual was asked to bend backward as far as they could.

See Figure 6. Using the same statements as above, the individual indicated when the greatest amount of extension was achieved. Three to six trials of lumbar extension were performed and recorded on the data sheet.

Figure 5. Hip Flexion.



Figure 6. Hip Extension.



A passive straight leg raise (SLR) was measured using only the "master" portion and the metal straight edge. See Figure 7. The participant was in a supine position on a plinth (table) as per the instruction manual.⁴ The tester measured the SLR by placing the Dualer™ on the lower leg and raising it until the opposite leg started to lift from the table. See Figure 8. The SLR was measured once on each lower extremity, and recorded on the data sheet (Appendix D). Once the first tester completed testing, the second tester performed the procedure without having knowledge of prior test results. Individuals were not given a second warm-up at the initiation of testing with the second tester. For the purposes of this study, the testing performed by the first tester was considered warm-up for the second tester. The second tester initiated the second testing procedure within two to five minutes of completion by the first tester.

Figure 7. "Master" on Straight Edge for Measurement of SLR.

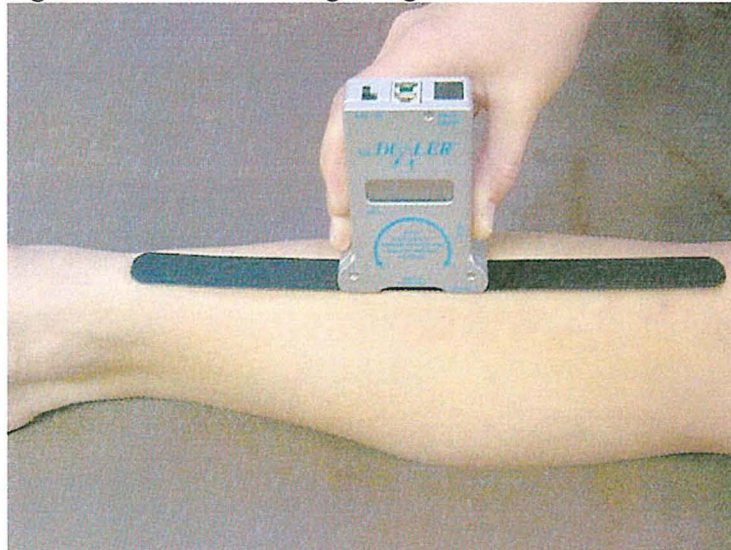


Figure 8. Measurement of SLR.



Lumbar flexion, lumbar extension, hip flexion, and hip extension were measured until three consecutive measurements were within five degrees of each other, for a maximum of six measurements. If six trials failed to show three consecutive measurements, the test was stopped and considered invalid. To determine a valid test, the smallest hip flexion and hip extension measurements were added together. If the sum was greater than 65 degrees for females and greater than 55 degrees for males, the test was considered valid. If the sum was less than 65 or 55 degrees for females and males, respectively, a SLR test was used to determine validity. Of the two SLR measurements, the tightest SLR was subtracted from the sum of smallest hip flexion and hip extension. A test would be considered valid when the calculation was 15 or less degrees as per the AMA disability rating protocol.³ Dual inclinometer techniques adopted from Mayer et al¹³ and the instructional manual that accompanied the Dualer™ were used to develop the testing procedure.

CHAPTER IV

RESULTS

Statistical Analysis: The statistical analysis was performed using The Statistical Power for the Social Sciences (SPSS 10.0™) program. The Intraclass Correlation Coefficient (ICC) and Pearson Correlation Coefficient were used to evaluate intra-tester reliability. The use of the ICC for statistical analysis in reliability studies has been advocated because "it measures agreement rather than dissociation" and "it is useful when more than two sets of data are used as in repeated measures."¹⁴ An alpha level of .05 was established.

An ICC of .90 or above has been recommended for clinical measurements to ensure reliability.¹⁵ An ICC above .75 is classified as good reliability, and an ICC below .75 is classified as poor to moderate reliability.

In the current study ICC values for lumbar flexion, lumbar extension and the total lumbar motion for the two test sessions were compared. Only the values of the 21 subjects who had valid tests were used in the statistical analysis. Means and standard deviations for each movement were also calculated. Lumbar extension had higher reliability than flexion with an ICC of .73 for tester one and .74 for tester two, compared with an ICC of .59 for tester one and an ICC of .67 for tester two for lumbar flexion. Total lumbar motion had an ICC value of .76 for tester one and .70 for tester two. See Table 1.

Table 1. Intra-tester Reliability for Lumbar Flexion, Extension and Total Lumbar Motion. (N=21)

| | | Tester One | Tester Two |
|---------------------|-----------|------------|------------|
| Total Lumbar Motion | Mean | 87.12 | 83.76 |
| | SD | 12.66 | 10.95 |
| | ICC | .76 | .70 |
| | Pearson r | .77 | .70 |
| Lumbar Flexion | Mean | 56.79 | 53.26 |
| | SD | 8.04 | 8.49 |
| | ICC | .59 | .67 |
| | Pearson r | .59 | .67 |
| Lumbar Extension | Mean | 30.33 | 30.50 |
| | SD | 9.57 | 11.16 |
| | ICC | .73 | .74 |
| | Pearson r | .73 | .75 |

Prior to beginning the current study, a pilot study was performed to familiarize the testers with the testing procedure. Eleven of the twelve subjects in the pilot study had valid measurements. See Table 2.

Table 2. Pilot Study: Intra-tester Reliability for Lumbar Flexion, Extension and Total Lumbar Motion. (N=11)

| | | Tester One Time 1-2* | Tester One Time 2-3** | Tester Two Time 1-2* | Tester Two Time 2-3** |
|---------------------|-----------|-------------------------|--------------------------|-------------------------|--------------------------|
| Total Lumbar Motion | Mean | 82.73 | 84.91 | 89.27 | 86.82 |
| | SD | 13.42 | 10.65 | 13.61 | 13.75 |
| | ICC | .52 | .67 | .85 | .79 |
| | Pearson r | .53 | .73 | .86 | .79 |
| Lumbar Flexion | Mean | 56.32 | 57.95 | 56.32 | 57.05 |
| | SD | 6.40 | 4.19 | 6.27 | 5.95 |
| | ICC | .27 | .02 | .54 | .60 |
| | Pearson r | .31 | .02 | .54 | .61 |
| Lumbar Extension | Mean | 26.41 | 26.95 | 33.18 | 30.00 |
| | SD | 10.71 | 11.07 | 11.85 | 11.03 |
| | ICC | .55 | .85 | .88 | .68 |
| | Pearson r | .54 | .86 | .88 | .68 |

*Time 1-2: Compares testing sessions one and two

** Time 2-3: Compares testing sessions two and three

CHAPTER V

DISCUSSION

The use of an inclinometer is important in the practice setting in that it allows for quantitative analysis of an individual's level of impairment and course of improvement during therapy. The Dualer™ Digital Inclinometer is relatively quick and easy to use in the therapy setting, which makes it ideal for clinical use. Before an inclinometer, such as the Dualer™, can be used in the clinical setting it must be shown that it has both intra- and inter-tester reliability.

The first research question asks, "Does the Dualer™ Digital Inclinometer have intra-tester reliability in lumbar flexion, extension, and total lumbar motion?" Intra-tester reliability for the measurement of lumbar flexion, extension, and total lumbar motion with the Dualer™ was found to range from poor to good in healthy subjects ages 20-41. None of the motions measured had intra-tester reliability high enough for clinical purposes, which correlates to our alternate hypothesis.

The second research question asks, "Does the Dualer™ Digital Inclinometer have inter-tester reliability in lumbar flexion, extension, and total lumbar motion?" Statistical analysis of inter-tester reliability was not performed, because intra-tester reliability could not be sufficiently established. Intra-tester reliability for each individual rater must be established prior to examining inter-tester reliability.¹⁵

The third research question states, "How do the values obtained for inter- and intra-tester reliability compare with those of other studies examining reliability of the Dualer™ Digital Inclinator for lumbar ROM?" Nitschke et al⁵ examined the reliability of the Dualer™ in measuring lumbar ROM. They obtained ICC values of .90 for flexion and .70 for extension compared to the current study's ICCs of .75 to .72 for flexion and .55 to .63 for extension. The current study did not run statistical analyses of inter-tester reliability due to the ICC values less than .75 calculated for intra-tester reliability.¹⁵

The fourth research question was, "How do the values obtained for inter- and intra-tester reliability for flexion and extension compare with the values obtained by other researchers using different inclinometers?" Other studies that examined intra-tester reliability with varying methods and instruments calculated ICCs from .16-.92 for flexion and extension.^{6,8-10}

Limitations: There are several factors that may have limited the outcomes of this study. These limitations include: 1) subject variability, 2) awkward positions of tester and subject during testing procedure, 3) variations in Dualer™ position over soft tissue, 4) extreme sensitivity of the Dualer™, 5) complexity of the lumbar spine, 6) level of familiarity of tester with the Dualer™, 7) limitations of palpation in finding bony landmarks, and 8) questionable reliability of the AMA method of measuring lumbar spine ROM.

One possible cause of the lack of intra-tester reliability was subject variability. Differences in muscle flexibility, amount of effort given, and activity level prior to testing all may have altered the values of the measurements between testing sessions. The warm-up performed prior to testing was done in an attempt to control the effects of

muscles warming up and lengthening during the testing procedure, thus altering results between testers and/or testing times. The warm-up was also intended to lessen risk of injury during the testing procedure by preparing the muscles for a maximal effort.

Nitschke et al⁵ attempted to prevent any differences in the subjects' conditions from interfering with intra-tester reliability. They accomplished this by testing the subjects in the same hour on the same day. Even with this control the intra-tester reliability was still poor. The subjects in the current study were tested two days apart. Subjects were not given any restriction as to physical activity performed prior to each testing session. Individual reports were given at testing sessions of varying amounts of physical activity prior to each testing session. Some subjects also reported hamstring soreness at the second testing session, which may have resulted in varied performance between sessions.

Extension was an especially challenging and uncomfortable position for both the subject and the tester. Due to the position of the tester, it was often difficult to maintain an ideal alignment of both portions of the Dualer™ during testing. See Figure 9. The difficulty of simultaneously handling the slave and master portions of the Dualer™ was also noted by Nitschke et al⁵ in their study. Also, the subject may not have been able to maintain the position for an extended period resulting in inaccurate readings. While it can be difficult to maintain balance at extreme ranges of both flexion and extension, extension seems to be particularly difficult position.¹⁶

Figure 9. Tester Position During Measurement of Extension.



Another limitation is the positioning of the Dualer™ over the soft tissue covering the spine. Varying pressures applied while holding the device over the landmarks can create marked variability in the values of the measurements whether in neutral standing, flexion, or extension. The testers made a conscious effort to maintain an even pressure on the Dualer™ during the testing procedure. Also, the Dualer™ is designed to sit over a spinous process, however soft tissue may still have interfered with an accurate reading.

The Dualer™ is a highly sensitive instrument. If subjects do not hold still or if they "bounce" at the end of their range, the reading of the Dualer™ changes rapidly to accommodate for these changes in position. It can be extremely difficult for the tester to get a single, accurate reading. This may have contributed to the unsatisfactory intra-tester reliability.

Lumbar motion occurs across several complex joints. This makes it complicated

to isolate the motion in the lumbar spine. Past studies have discussed the fact that increased difficulty of measuring the spine occurs due to coupled motion of the joints.^{16,17} This coupling of motion results in both rotation and translation at each segment during lumbar movements. Weitz¹⁸ also implied that complexity of measuring the lumbar spine is increased due to movements across each segmental level. One recommendation is that reliability of the Dualer™ be established on a uni-planar joint, such as the knee or elbow, prior to initiating testing on a multifaceted joint such as the lumbar spine. The lack of reliability is likely not due to the instrument itself, but to the fact that the lumbar spine is such an intricate region in which to try to isolate ROM.

Another factor that may have contributed to the unsatisfactory reliability results may have been the amount of tester familiarity with the inclinometer itself. Further practice and learning could result in improved reliability outcomes when using ROM devices. Chiarello et al⁷ stated in their study that by using the Fluid Goniometer frequently and having more practice with the instrument, the reliability rating seemed to improve. This finding could have implications for the use of Dualer™ Digital Inclinometer, also. Testers in the current study read the Dualer™ manual and watched an instructional video on measuring lumbar flexion and extension prior to testing of subjects. A pilot study was also performed prior to initiating the current study to give the testers more experience in measuring lumbar flexion and extension with the Dualer™. Each tester performed over 30 trial measurements on varying subjects in order to familiarize the testers with the Dualer™ and the testing procedure.

Chiarello et al⁷ stated that palpation is a highly important component when measuring ROM because differences in inclinometer placement may alter the

measurement that is recorded. The study found that a two-degree difference, which was statistically significant, was found between trained and non-trained therapists in palpation. However, for clinical purposes a two-degree difference is probably not significant. This difference in inclinometer placement may have played a role in results of the current study. With two testers independently finding the landmarks, there could have been biases and differences in techniques, which may have caused variability resulting in decreased reliability.

The body type of the subject may also affect the identification of landmarks. Mayer et al¹³ stated that identifying landmarks were increasingly difficult to palpate in endomorphic body types. None of the subjects in the current study were considered endomorphic, and it is felt that landmark identification was not impeded by soft tissue.

Nitschke et al⁵ questioned the reliability of the AMA method of measuring lumbar ROM. They concluded that the AMA method did not elicit consistent, uniform and reproducible measurements of LROM, and as a result, felt that it should not be the method used to determine whole-body impairment and compensation. Ng et al⁹ incorporated the use of a pelvic restraint device into their method of measuring LROM with an inclinometer. They felt that the pelvic restraint limited pelvic motion and allowed for more reliable assessments of the motions. Decker (unpublished material, 1993) states that poor tester observational skills may allow the subject to flex knees during testing, resulting in inaccurate measurements. The AMA method includes subject instruction to keep their knees straight. However, due to the awkward position of the tester during measurements, unobserved knee flexion may occur during testing.

Conclusion: Overall, the Dualer™ Digital Inclinometer and the method for using it are quick and relatively uncomplicated. There continues to be a need for more studies that establish both intra- and inter-tester reliability for ROM of the lumbar spine, as well as studies that seek to refine current techniques for testing LROM to improve on ease of testing and reliability. The double inclinometer appears to have potential, but as Merritt et al¹⁹ concluded, it requires much time, preparation, and calculations to perfect the method.

APPENDIX A

____ EXPEDITED REVIEW REQUESTED UNDER ITEM ____ (NUMBER[S]) OF HHS REGULATIONS
____ EXEMPT REVIEW REQUESTED UNDER ITEM ____ (NUMBER[S]) OF HHS REGULATIONS

**UNIVERSITY OF NORTH DAKOTA HUMAN SUBJECTS REVIEW FORM
FOR NEW PROJECTS OR PROCEDURAL REVISIONS TO APPROVED
PROJECTS INVOLVING HUMAN SUBJECTS**

Please include ALL information and check ALL blanks that apply.

PRINCIPAL INVESTIGATOR: Schawnn Decker, Kimberly Weeda,
Amber Flatland, Tracy Stommes, Jennifer Johnson TELEPHONE: 777-6389 DATE: 3/1/01

ADDRESS TO WHICH NOTICE OF APPROVAL SHOULD BE SENT: Physical Therapy Department

SCHOOL/COLLEGE: Medicine DEPARTMENT: Physical Therapy PROJECT DATES: 3/18/01 - 12/7/01
(E.g., A&S, Medicine, EHD, etc.)
(Month/Day/Year)

PROJECT TITLE: Intra and Interester Reliability for Lumbar Flexion and Extension Using the Dualer™ Digital Inclinometer

FUNDING AGENCIES (IF APPLICABLE): N/A

TYPE OF PROJECT (Check ALL that apply):
NEW PROJECT CONTINUATION RENEWAL DISSERTATION OR THESIS RESEARCH STUDENT RESEARCH PROJECT
 CHANGE IN PROCEDURE FOR A PREVIOUSLY APPROVED PROJECT

DISSERTATION/THESIS ADVISER, OR STUDENT ADVISER: Schawnn Decker

PROPOSED PROJECT: INVOLVES NEW DRUGS (IND) INVOLVES NON-APPROVED USE OF DRUG INVOLVES A COOPERATING INSTITUTION

IF ANY OF YOUR SUBJECTS FALL IN ANY OF THE FOLLOWING CLASSIFICATION, PLEASE INDICATE THE CLASSIFICATION(S):

MINORS (<18 YEARS) PREGNANT WOMEN MENTALLY DISABLED FETUSES PERSONS WITH MENTAL RETARDATION
 PRISONERS ABORTUSES UND STUDENTS (>18 YEARS)

IF YOUR PROJECT INVOLVES ANY HUMAN TISSUE, BODY FLUIDS, PATHOLOGICAL SPECIMENS, DONATED ORGANS, FETAL MATERIAL, OR PLACENTAL MATERIALS, CHECK HERE

IF YOUR PROJECT HAS BEEN/WILL BE SUBMITTED TO ANOTHER INSTITUTIONAL REVIEW BOARD(S), PLEASE LIST NAME OF BOARD(S):

Status: Submitted; Date _____ Approved; Date _____ Pending

1. ABSTRACT: (LIMIT TO 200 WORDS OR LESS AND INCLUDE JUSTIFICATION OR NECESSITY FOR USING HUMAN SUBJECTS.)

The American Medical Association (AMA) currently uses range of motion measurements of the low back (lumbar spine) obtained by an inclinometer as one of the methods for evaluating spine impairment. The AMA includes electronic inclinometers as one of the recommended methods of measuring low back range of motion (ROM). The purpose of this study is to establish reliability of the Dualer™ digital inclinometer owned by the UND Physical Therapy Department for measuring lumbar forward bending (flexion) and backward bending (extension) for individuals between the ages of 20 and 60 years.

PLEASE NOTE: Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Where appropriate attach sections from your proposal (if seeking outside funding).

2. PROTOCOL: (Describe procedures to which humans will be subjected. Use additional pages if necessary. Attach any surveys, tests, questionnaires, interview questions, examples of interview questions (if qualitative research), etc., the subjects will be asked to complete.)

University of North Dakota Physical Therapy students who have been trained in the use of the Dualer™ digital inclinometer will be testing each participant in the study. Two of the student researchers will perform the measurements, and two of the student researchers will document the results.

Criteria to be part of the study include:

1. Subject between 20 and 60 years of age.
2. No history of lumbar spine surgery.
3. No abdominal surgery within the last twelve months.
4. No back pain lasting longer than one week in the past twelve months.
5. The subject will not have undergone treatment by a health professional for back pain in the last twelve months.
6. The subject cannot be pregnant.
7. The subject must have adequate balance to bend forwards and backwards in a standing position without dizziness, nausea, or a loss of balance.

Procedure:

The subjects will be accepted for the study under a voluntary basis, including but not limited to UND students, UND faculty, and other members of the general public. The subjects will be recruited via e-mails to large groups, short presentations about the study to large groups, and signs posted around the UND campus and the community to invite individuals to participate in our study. The prospective subjects will be informed of the criteria that must be met to participate in the study. If the individuals are interested in participating and meet the criteria to the best of their knowledge, they may contact the researchers via e-mail or telephone to schedule an appointment with the researchers. The participants will be tested in the order by which they schedule an appointment to be tested. Subjects will be tested on two separate dates by two testers each date. At the initial scheduled testing time, each subject will be provided with an information and consent form to be read and signed prior to commencement of testing. Following signing of the consent form, the participants will fill out a short medical questionnaire. If they meet the criteria of the questionnaire, measurements will be taken next. The participants will be asked to expose the low back. If the low back cannot be adequately exposed subjects will be asked to change into a hospital gown. A total of 20 subjects will be sought for the study.

1. The subject will stand without shoes on a hard floor.
2. The subject will perform warm-up exercises consisting of bending forwards and backwards three times in each direction to reduce the risk of muscle strain occurring during testing.
3. The testers will place marks at bony landmarks (twelfth thoracic vertebrae and mid-sacrum) on the subject's low back with sticky dots, or in the case of an allergy to adhesives, a wax pencil.
4. The Dualer™ digital inclinometer will be placed on the subject's low back over the previously marked areas. The Dualer™ digital inclinometer is standard equipment that is approved for medical use to measure range of motion. The "master portion" of the Dualer™ gives the digital reading of the number of degrees of motion in the low back. The "slave portion" is connected to the "master portion" of the Dualer™ via a wire and acts in conjunction with the "master portion" to measure motion in the low back.
5. The subject will be asked to bend forwards as far as possible to try to touch their toes (lumbar flexion) and a measurement will be taken using the Dualer™. The subjects will be reminded to keep their knees straight while bending. This will be repeated no more than six times, with the subject returning to a normal upright position between each measurement.
6. The subject will be asked to bend backwards (lumbar extension) as far as possible and a measurement will be taken using the Dualer™. This will be repeated no more than six times, with the subject returning to a normal upright position between each measurement. The subject will be reminded to keep their knees straight.
7. The slave portion of the Dualer™ will be strapped to one of the subject's thighs. The master portion will be placed over the mid-sacrum. The subject will again be asked to bend forwards and then backwards to obtain measurements for hip flexion and extension. This will be repeated no more than six times.
8. The subject will be asked to lie on their back on a mat. The Dualer™ will be placed over the subject's shin near the ankle. The subject's leg will be raised up keeping the knee straight and a measurement will be taken. (Straight Leg Raise)
9. The values obtained from the hip flexion and extension will be subtracted from the Straight Leg Raise value to obtain validity results. The testing will be considered valid if the total is less than or equal to ten degrees.

The participants' names will only appear on the consent forms. The data obtained from the measurements and questionnaire will not be linked to the consent form in any way. Data obtained from the study will be reported in aggregate form. The participants in the study will not be identified in any manner.

The investigators may discontinue the testing procedures at anytime up until the final measurements are taken. The subjects may withdraw without penalty at any time during the testing procedures up until the final measurements are taken. Withdrawal from the study will not negatively influence the subject's relationship with UND or the department of physical therapy.

3. BENEFITS: (Describe the benefits to the individual or society.)

1. The subject will have the benefit of participating in a scientific research project.
2. The subject will have access to their personal range of motion measurements at the time of the testing upon request.
3. After establishing the levels of intra and intertester reliability for lumbar flexion and extension measured with the Dualer™ digital inclinometer, other health care professionals who perform impairment ratings will be able to make the decision about whether the Dualer™ digital inclinometer is an appropriate tool for this purpose.

4. RISKS: (Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self-respect, as well as psychological, emotional or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to protect the confidentiality of data obtained, debriefing procedures, storage of data, how long data will be stored (must be a minimum of three years), final disposition of data, etc.)

1. The low back will be exposed, which may cause embarrassment to the subject. To minimize embarrassment and exposure the subject will be tested in a private area and will be draped appropriately.
2. The subject may experience some discomfort in maintaining the positions of forwards and backwards bending. The testers will take the measurements as quickly as possible to minimize any discomfort.
3. The subject may experience muscular strain if the subject bends beyond his/her maximal limit. The subject will be informed prior to the testing that bending too far forwards or backwards may cause a muscle strain. The subject will also be asked to perform three warm-up exercises prior to testing.

The data will be kept for three years in a locked file cabinet in room number 2542 in the Physical Therapy department. It will be shredded for disposal at the end of the designated time period.

5. CONSENT FORM: Attach a copy of the **CONSENT FORM** to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no **CONSENT FORM** is to be used, document the procedures to be used to assure that infringement upon the subject's rights will not occur.

Describe where signed consent forms will be kept and for how long (must be a minimum of 3 years), including plans for final disposition or destruction.

The signed consent forms will be kept for three years in a locked file cabinet in room number 2542 in the Physical Therapy Department. They will be shredded for disposal at the end of the designated time period.

6. For **FULL IRB REVIEW** forward a signed original and fifteen (15) copies of this completed form, including fifteen (15) copies of the proposed consent form, questionnaires, examples of interview questions, etc. and any supporting documentation to the address below. An original and 19 copies are required for clinical medical projects. In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 7 copies if the proposal is clinical medical. If the proposed work is being conducted for a pharmaceutical company, 7 copies of the company's protocol must be provided.

Office of Research & Program Development
University of North Dakota
Grand Forks, North Dakota 58202-7134

On campus, mail to: Office of Research & Program Development, Box 7134, or drop it off at Room 105 Twamley Hall.

For **EXEMPT** or **EXPEDITED REVIEW** forward a signed original, including a copy of the consent form, questionnaires, examples of interview questions, etc. and any supporting documentation to one of the addresses above. In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form.

The policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of Human Subjects performed by personnel conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University's policies and procedures governing the use of human subjects.

SIGNATURES:

| | |
|--|---------------|
| _____ Principal Investigator | _____ Date |
| _____ Project Director or Student Adviser | _____ Date |
| _____ Training or Center Grant Director | _____ Date |

(Revised 2/2000)

STUDENT RESEARCHERS: As of June 4, 1997 (based on the recommendation of UND Legal Counsel) the University of North Dakota IRB is unable to approve your project unless the following "Student Consent to Release of Educational Record" is signed and included with your "Human Subjects Review Form."

STUDENT CONSENT TO RELEASE OF EDUCATIONAL RECORD¹

Pursuant to the Family Educational Rights and Privacy Act of 1974, I hereby consent to the Institutional Review Board's access to those portions of my educational record which involve research that I wish to conduct under the Board's auspices. I understand that the Board may need to review my study data based on a question from a participant or under a random audit. The study to

which this release pertains is Intra- and Inter-tester Reliability for Lumbar Flexion and Extension Using the Dualer™ Digital Inclinometer

I understand that such information concerning my educational record will not be released except on the condition that the Institutional Review Board will not permit any other party to have access to such information without my written consent. I also understand that this policy will be explained to those persons requesting any educational information and that this release will be kept with the study documentation.

Date

Signature of Student Researcher

¹Consent required by 20 U.S.C. 1232g.

APPENDIX B

INFORMATION AND CONSENT FORM

Intra-tester Reliability for Lumbar Flexion and Extension Using the Dualer™ Digital Inclinometer

You are invited by **Amber Flatland, Jennifer Johnson, Tracy Stommes, Kimberly Weeda, and Schawnn Decker** from the University of North Dakota to participate in this study to measure the amount of forward and backward bending of the low back (lumbar spine). This study will be conducted as fulfillment of Masters degree requirements. The purpose of this study is to examine reliability of the Dualer™ for the measurement of lumbar forward bending (flexion) and backward bending (extension). We hope the results of this study will aid physical therapists in determination of which instrument to use in measuring impairment ratings for low back patients.

Through e-mail, posted signs, or verbal communication you have learned about and volunteered to participate in this study. You have been asked to report to the Physical Therapy Department at the University of North Dakota, located in the Medical Science North Building. The criteria to participate in this study include: 1) you lack history of back or abdominal surgery in the past 12 months, 2) you lack history of recurrent low back pain, 3) you have not had back pain lasting longer than one week in the past 12 months, 4) you have not been treated by a health care professional for back pain in the past 12 months, 5) you are not pregnant, 6) you have adequate balance, and 7) you are between 20 and 60 years of age. These criteria and others are covered in a short medical questionnaire that you will be asked to fill out after signing this consent form and prior to testing. If you do not meet these criteria, we thank you for your participation. However, we will not be able to test you in this study. These criteria must be met in order to protect you from possible injury and to make our study as accurate as possible.

If there are no restrictions to participate, you will be asked to expose your mid-back. If you cannot expose your back properly, you will be asked to wear a hospital gown. Exposure of the mid-back is required so sticky dots can be placed on your spine at specific levels (T₁₂ and mid sacrum) to allow proper measurement to be taken by the researchers. If you are allergic to adhesives, marks will be made with a wax pencil. While standing, you will then be asked to bend forward and backwards during a warm-up session. The Dualer™ digital inclinometer will be placed on the marked areas. You will then repeat the forward and backward bending motions between 3-6 times for the test, and maintain the forward or backward position for a few seconds while measurements are taken. A straight leg test on each leg will also be measured while you are lying down. You will be measured on two separate occasions, by two separate testers each date. The testing should not take longer than 30 minutes.

Although the process of physical performance testing always involves some degree of risk, the investigators in this study feel the risk of injury or discomfort is minimal. To assess range of motion you will be asked to bend forward or backward and hold the position. Warm-up exercises will be performed prior to the measurement to reduce the risk of injury. These activities are consistent with current standards of medical assessment for low back pain.

In the event that this research activity results in physical injury, medical treatment will be available as it is to a member of the general public in similar circumstances. You and your third part payer must provide payment for any such treatment.

The benefits of participating in this study include: 1) the subject will have the benefit of participating in a scientific research project, 2) the subject will have access to their personal range of motion measurements at the time of testing upon request.

Your name will only appear on this consent form. The data obtained from your measurements and questionnaire will not be linked to your consent form in any way. The data obtained from your measurements will be reported in aggregate form. The investigators or participants may stop the experiment at any time for any reason. Your decision whether or not to participate will not prejudice your future relationship with the Physical Therapy Department at the University of North Dakota or the University of North Dakota School of Medicine. If you decide to participate, you are free to discontinue participation at any time, until final measurements are taken without prejudice.

The investigators involved are available to answer any questions you have concerning this study. In addition, you are encouraged to ask any questions concerning this study that you may have in the future. If you have questions regarding the study or the protocol please contact the researchers. You may call Shawnn Decker at (701) 777-6389 or Jennifer Johnson at (701) 746-8922. If you have any other concerns, contact the University of North Dakota Institutional Review Board at the Office of Research and Program Development at (701) 777-4279. You will be given a copy of this form for future reference. This consent form and data obtained will be destroyed three years after the completion of this study.

All of my questions have been answered and I am encouraged to ask any questions that I may have concerning this study in the future. I have read all of the above and willingly agree to participate in this study as it is explained to me by Amber Flatland, Jennifer Johnson, Tracy Stommess, or Kimberly Weeda.

Subject's signature _____ Date _____

Witness's signature _____ Date _____

APPENDIX C

Date: _____

Questionnaire

1. Have you had any back surgeries? Yes _____ No _____

If yes please describe type and date:

2. Have you had any back injuries? Yes _____ No _____

If yes please describe and date:

3. Have you had any abdominal surgeries? Yes _____ No _____

If yes please describe type and date:

4. Have you had any sudden loss of balance or dizziness when bending forward or backward?

Yes _____ No _____

5. Have you seen a physical therapist/chiropractor/physician for any back related problems in the past 12 months?

Yes _____ No _____

6. Have you had back pain lasting greater than 1 week in the past 12 months?

Yes _____ No _____

7. Are you currently pregnant? Yes _____ No _____

8. Do you feel that the testing procedure, as described in the consent form, will make a pre-existing condition worse?

Yes _____ No _____

Age: _____

Sex: _____

APPENDIX D

Date: _____

| Test | Trial 1 | | Trial 2 | | Trial 3 | | Trial 4 | | Trial 5 | | Trial 6 | |
|-------------------------|---------|--|---------|--|---------|--|---------|--|---------|--|---------|--|
| Lumbar Flexion | | | | | | | | | | | | |
| Lumbar Extension | | | | | | | | | | | | |
| Hip Flexion | | | | | | | | | | | | |
| Hip Extension | | | | | | | | | | | | |

Check the trials used.

Hip Motion

Flexion S_2 _____ + _____ = _____

Right SLR _____

Left SLR _____

Difference between SLR and hip motion _____

Valid Test **Yes:** _____ **No:** _____

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