

THE RELIABILITY OF INSTRUMENTED KNEE AND ANKLE ORTHOPEDIC  
SPECIAL TESTS PERFORMED WITH A LIGMASTER™  
MULTIJOINT ARTHROMETER

by

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A thesis submitted to the Graduate Council of  
Texas State University in partial fulfillment  
of the requirements for the degree of  
Master of Science  
with a Major in Athletic Training  
December 2015

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## **ACKNOWLEDGEMENTS**

I would like to take this opportunity to thank my committee members Dr. Joni Mettler and Dr. Rodney Rohde, and especially my thesis chair Dr. Rod Harter. Your guidance and patience have been greatly appreciated and I have learned a lot of very valuable information from each of you.

I would like to thank you Dr. Mettler and Dr. Rohde to agree with changing the thesis topic in order to completing this thesis.

Dr. Harter thank you for agreeing to be my thesis chair, your assistance in the grant application, funds and effort of solving technical issue on the LigMaster<sup>TM</sup> unit are greatly appreciated. I truly value and appreciate the level of expertise you have brought to the table regarding this topic.

I would like to thank you Dr. Duane Knudson, the Chair of the Department of Health and Human Performance and Martin Zavala, the Administrative Assistant of the Department of Health and Human Performance for your assistance and financial support in sending the LigMaster<sup>TM</sup> unit for repair and calibration.

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## ABSTRACT

**Context:** Knee and ankle joint arthrometers are designed to increase the precision and objectivity of clinical measures of joint laxity and mechanical stiffness. The LigMaster™ is a relatively new multijoint arthrometer that can be used to perform instrumented orthopedic special tests at the knee, ankle, shoulder and elbow. To date, few lower extremity studies have been conducted with this device. **Objective:** To establish the intrarater test-retest reliability of measuring the mechanical properties of knee and ankle ligaments with the LigMaster™ multijoint arthrometer. **Design:** Cross-sectional study. **Setting:** Research laboratory. **Participants:** 40 healthy, physically-active adults (20 women, 20 men; age =  $22.7 \pm 2.0$  yrs; height =  $171.1 \pm 12.1$  cm; mass =  $71.1 \pm 13.9$  kg). **Main Outcome Measures:** At the knee, the Lachman, posterior drawer, varus and valgus stress tests were performed, with displacement and slope values obtained at loads of 90 N and 130 N. At the ankle, the anterior drawer test and inversion talar tilt test were performed, with displacement and slope values obtained at 125 N and 150 N loads. For each participant, these 6 tests were performed on two occasions on the same day and test results were used to calculate intrarater test-retest reliability. **Results:** The test-retest reliability of one examiner performing instrumented Lachman, posterior drawer, varus and valgus stress tests ranged from “excellent” to “good to fair” ( $ICC_{3,1} = 0.85$  to  $0.53$ ). The intrarater reliability of the knee slope values for the posterior drawer test, varus and valgus stress tests were also “excellent” to “good to fair” ( $ICC_{3,1} = 0.82$  to  $0.51$ ). The

intrarater reliability of the degrees of inversion with the talar tilt test and ankle displacement for ankle anterior drawer test at 125N and 150N were between “excellent” and “good to fair” ( $ICC_{3,1} = 0.79$  to  $0.62$ ). The intrarater reliability of the ankle slope value for the ankle anterior drawer test was “good to fair” ( $ICC_{3,1} = 0.54$ ). **Conclusion:** The instrumented Lachman, valgus, and varus stress tests at the knee and inversion talar tilt test as performed with the LigMaster™ arthrometer on healthy, physically-active adults had moderate reliability. Conversely, the posterior drawer test and the ankle anterior drawer test had lower levels of intrarater reliability. While this device has capabilities unlike any other commercially-available arthrometer, the LigMaster™ software generates joint displacement and mechanical stiffness values that are proprietary and thus unique to this device. These non-standard values do not correspond with output from other commercially-available arthrometers, making direct comparisons with published knee and ankle arthrometer studies difficult, if not impossible.

## CHAPTER I

### INTRODUCTION

According to recent NCAA injury surveillance data, lower extremity injuries account for 54% of all injuries in practices and games.<sup>1</sup> More specifically, 27,117 ankle ligament sprains (15% of all injuries) and 4,800 anterior cruciate ligament (ACL) injuries (3% of all injuries) were reported over a 16-year period.<sup>1</sup> In a recent epidemiological study of 246 elite women basketball players, ankle injuries accounted for 70% and ACL injuries accounted for 22% of all injuries sustained.<sup>2</sup>

Clinicians frequently employ manual orthopedic tests such as the Lachman, posterior drawer, varus and valgus stress tests at the knee, and the anterior drawer and inversion talar tilt tests at the ankle to determine the severity of injury. However, the results of these manual orthopedic special tests are highly variable and strongly influenced by the clinician's experience and the wide range of force that is applied.<sup>3-5</sup> One recent systematic review reported the intrarater and interrater reliability of manual orthopedic tests for anterior cruciate ligament (ACL) injury ranged widely—from poor to nearly perfect (Cohen's kappa = 0.02 to 1.00).<sup>5</sup> With regard to the ankle, Wilkin et al<sup>6</sup> reported poor interrater reliability with four different manual ankle special test tests. These authors found ICC values that ranged from 0.06 and 0.33 for the anterior drawer test in supine, anterior drawer test in crook lying, talar tilt and inversion tilt.<sup>6</sup>

Orthopedic researchers have long been working to develop and ultimately market mechanical devices known as *arthrometers* that utilize protocols that standardize the joint positions and external loads applied in order to measure joint laxity and mechanical

stiffness more accurately. One of the first knee arthrometers was developed by Markolf et al<sup>7</sup> at UCLA in 1978. They used this arthrometer to obtain in vivo measurements of anterior and posterior force-versus-displacement at 0, 20 and 90 degrees of knee flexion among participants with no previous history of knee injury.<sup>7</sup>

A commercial knee joint arthrometer known as the KT-1000 (MEDmetric Corp., San Diego, California) was developed in 1985 by Malcom et al.<sup>8</sup> The KT-1000 was used initially to measure anterior and posterior tibial translations on the femur by placing on the anterior aspect of the tibia center over the patella with 2 straps around the tibia. The device emitted different audible tones when anterior and posterior loads of 68 N and 90 N were applied with a force-sensing handle with the knee positioned different angles of knee flexion.<sup>9</sup> Later, these researchers modified the KT-1000 to become the KT-2000 with a graphic documentation via an X-Y plotter which could record the tibial displacement in relation to the force applied.<sup>10</sup>

The Genucom™ Knee Analysis System (FARO Medical Technologies Inc., Montreal, Canada) was a commercial knee arthrometer marketed in the 1990's that measured the knee laxity in 6 degrees of freedom.<sup>11</sup> This complex computerized device was comprised of an electrogoniometer for measuring the knee displacement and a 6-component force dynamometer used to measuring the force and moments applied to the knee.<sup>11</sup>

At approximately the same time, the Stryker Knee Laxity Tester™ (Stryker, Kalamazoo, Michigan) also became commercially available. The Stryker arthrometer was much less complicated than the KT-1000 or the Genucom arthrometers.<sup>12</sup> The Stryker arthrometer measured the anterior-posterior displacement of the tibia relative to the femur

and had a bar that was applied to the front of the tibia by two elastic straps and pillars with 4 cm apart.<sup>12-13</sup>

Very few studies were published to establish the test-retest reliability of those knee joint arthrometers.<sup>12</sup> Of the knee arthrometers reviewed, the KT-1000/2000 arthrometer demonstrated the best reliability with intrarater ICCs ranging from 0.46 to 0.84, and interrater ICCs ranging from 0.65 to 0.92.<sup>12</sup>

Before a portable instrumented ankle arthrometer was invented, clinicians who wanted objective assessment of the severity of ankle ligament injury used a Telos (Telos, Marburg, Germany) positioning apparatus during stress radiographs.<sup>14</sup> The Telos apparatus is primarily an ankle stabilizer with a pressure actuator that can be used to apply gradually increasing force to the ankle joint during stress radiographs.<sup>14</sup> The stress radiographs is a common tool for examining the severity of ligament laxity.<sup>14</sup> However, the accuracy of the stress radiograph is controversial. Some studies have more than 50% agreement on ankle ligament laxity between stress radiographs and surgical observation.<sup>15,16</sup> However, other studies indicated that the stress radiographs could detect less than 50% of ankle ligament laxity as compared to arthrography, clinical examination and MRI imaging.<sup>17,18</sup> Only one study has investigated the reliability of the ankle anterior drawer test and inversion talar tilt test. The interrater reliability for the talar tilt test and anterior drawer test were ICC of 0.86 to 0.92 and 0.73 to 0.87, respectively. The intrarater reliability for the talar tilt test and anterior drawer test were ICC of 0.78 and 0.95, respectively.<sup>19</sup>

A first portable, commercially-available instrumented ankle arthrometer, the Hollis Ankle Arthrometer (Blue Bay Research Inc., Navarre, FL) was described in 1995

in a study investigating the laxity at the ankle joint.<sup>20</sup> This ankle arthrometer features a 6-degrees-of-freedom spatial kinematic linkage, an adjustable plate fixed to the foot, a load-measuring handle attached to the footplate through which the load is applied, and a reference pad attached to the tibia.<sup>21</sup> The Hollis ankle arthrometer has “excellent” interrater (ICC = 0.80 to 0.91) and intrarater (ICC = 0.83 to 0.97) reliability with regard to the ankle anterior drawer test at 125N loads.<sup>22-24</sup>

The LigMaster™ (Sports Tech, Charlottesville, VA) is a relatively new multijoint arthrometer that can be used to evaluate the ankle, knee, elbow and shoulder joints.<sup>25</sup> This device is a modification of the Telos apparatus that includes an electronic sensor and used in the evaluation of the mechanical properties of the joints without the use of stress radiographs. To our knowledge only two studies have been published on the reliability of LigMaster™ measurements--one concerning the knee and the other involving the ankle.<sup>26,27</sup> To date, no studies of the reliability of the Lachman test, posterior drawer test or valgus stress test of the knee using the LigMaster™ have been published. Therefore, the purpose of this study was to establish the test-retest reliability of 6 knee and ankle orthopedic special tests that can be performed with a LigMaster™ multijoint arthrometer.

Following the completion of this thesis, an abstract of the findings will be submitted by November 15, 2015 for a peer-reviewed presentation at the 2016 annual meeting of the National Athletic Trainers' Association to be held in Baltimore, Maryland in June 2016. In the interim, the primary manuscript from this thesis will be submitted for publication to the *Journal of Athletic Training*.

## **CHAPTER II**

### **MANUSCRIPT**

**THE RELIABILITY OF INSTRUMENTED KNEE AND ANKLE ORTHOPEDIC  
SPECIAL TESTS PERFORMED WITH A LIGMASTER™  
MULTIJOINT ARTHROMETER**

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Formatted for publication in the:

*Journal of Athletic Training*

## Abstract

**Context:** Knee and ankle joint arthrometers are designed to increase the precision and objectivity of clinical measures of joint laxity and mechanical stiffness. The LigMaster™ is a relatively new multijoint arthrometer that can be used to perform instrumented orthopedic special tests at the knee, ankle, shoulder and elbow. To date, few lower extremity studies have been conducted with this device. **Objective:** To establish the intrarater test-retest reliability of measuring the mechanical properties of knee and ankle ligaments with the LigMaster™ multijoint arthrometer. **Design:** Cross-sectional study. **Setting:** Research laboratory. **Participants:** 40 healthy, physically-active adults (20 women, 20 men; age =  $22.7 \pm 2.0$  yrs; height =  $171.1 \pm 12.1$  cm; mass =  $71.1 \pm 13.9$  kg). **Main Outcome Measures:** At the knee, the Lachman, posterior drawer, varus and valgus stress tests were performed, with displacement and slope values obtained under loads of 90 N and 130 N. At the ankle, the anterior drawer test and inversion talar tilt test were performed, with displacement and slope values obtained at 125 N and 150 N loads. For each participant, these 6 tests were performed on two occasions on the same day and test results were used to calculate intrarater test-retest reliability. **Results:** The test-retest reliability of one examiner performing instrumented Lachman, posterior drawer, varus and valgus stress tests ranged from “excellent” to “good to fair” ( $ICC_{3,1} = 0.85$  to  $0.53$ ). The intrarater reliability of the knee slope values for the posterior drawer test, varus and valgus stress tests were also “excellent” to “good to fair” ( $ICC_{3,1} = 0.82$  to  $0.51$ ). The intrarater reliability of ankle degree for the inversion talar tilt test and ankle displacement for ankle anterior drawer test at 125 N and 150 N were between “excellent” and “good to

fair” ( $ICC_{3,1} = 0.79$  to  $0.62$ ). The intrarater reliability of the ankle slope value for the ankle anterior drawer test “good to fair” ( $ICC_{3,1} = 0.54$ ). **Conclusion:** The instrumented Lachman, valgus, and varus stress tests at the knee and inversion talar tilt test as performed with the LigMaster™ arthrometer on healthy, physically-active adults had moderate reliability. Conversely, the posterior drawer test and the ankle anterior drawer test had markedly lower levels of intrarater reliability. While this device has capabilities unlike any other commercially-available arthrometer, the LigMaster™ software generates joint displacement and mechanical stiffness values that are proprietary and thus unique to this device. These non-standard values do not correspond with output from other commercially-available arthrometers, making direct comparisons with published knee and ankle arthrometer studies difficult, if not impossible.

**Word count:** 416

**Key Words:** joint laxity, mechanical stiffness, intraclass correlation coefficients

## Introduction

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measuring handle attached to the footplate through which the load is applied, and a reference pad attached to the tibia.<sup>21</sup> The Hollis ankle arthrometer has “excellent” interrater (ICC = 0.80 to 0.91) and intrarater (ICC = 0.83 to 0.97) reliability with regard to the ankle anterior drawer test at 125 N loads.<sup>22-24</sup>

The LigMaster™ (Sports Tech, Charlottesville, VA) is a relatively new multijoint arthrometer that can be used to perform instrumented evaluations of ankle, knee, elbow and shoulder joint stability.<sup>25</sup> This device is a modification of the Telos apparatus that includes a force sensor and is used in the evaluation of the mechanical properties of the joints without the use of stress radiographs. To our knowledge, only 2 studies have been published on the reliability of LigMaster™ measurements—one involving the knee and the other involving the ankle.<sup>26,27</sup> To date, no studies of the reliability of the Lachman test, posterior drawer test or valgus stress test of the knee using the LigMaster™ have been published. Therefore, the purpose of this study was to establish the test-retest reliability of 6 knee and ankle orthopedic special tests that can be performed with a LigMaster™ multijoint arthrometer.

## Methods

### Participants

Forty-five volunteers were recruited from the general student body at Texas State University through the use of posted flyers and announcements in classes in the Department of Health and Human Performance. These volunteers were screened for eligibility for participation with questions that asked about their general health and any past or recent injuries to their knees and ankles. A certified athletic trainer (JSN)

performed standard orthopedic evaluations of their knee and ankle joints to verify the accuracy of the information obtained in the questionnaire.

Five volunteers were excluded from participation because two volunteers have a knee surgery, two volunteers has a grade 2 ankle sprain and one volunteer has more than one ankle sprains. Forty participants (20 males, 20 females; age =  $22.8 \pm 2.0$  yrs, height =  $171.1 \pm 11.65$  cm, mass =  $70.7 \pm 13.46$  kg) met our inclusion criteria. The complete list of inclusion and exclusion criteria is presented in Table 1. The Institutional Review Board at Texas State University approved this study, and written consent was obtained from each participant before testing.

#### Instrumentation

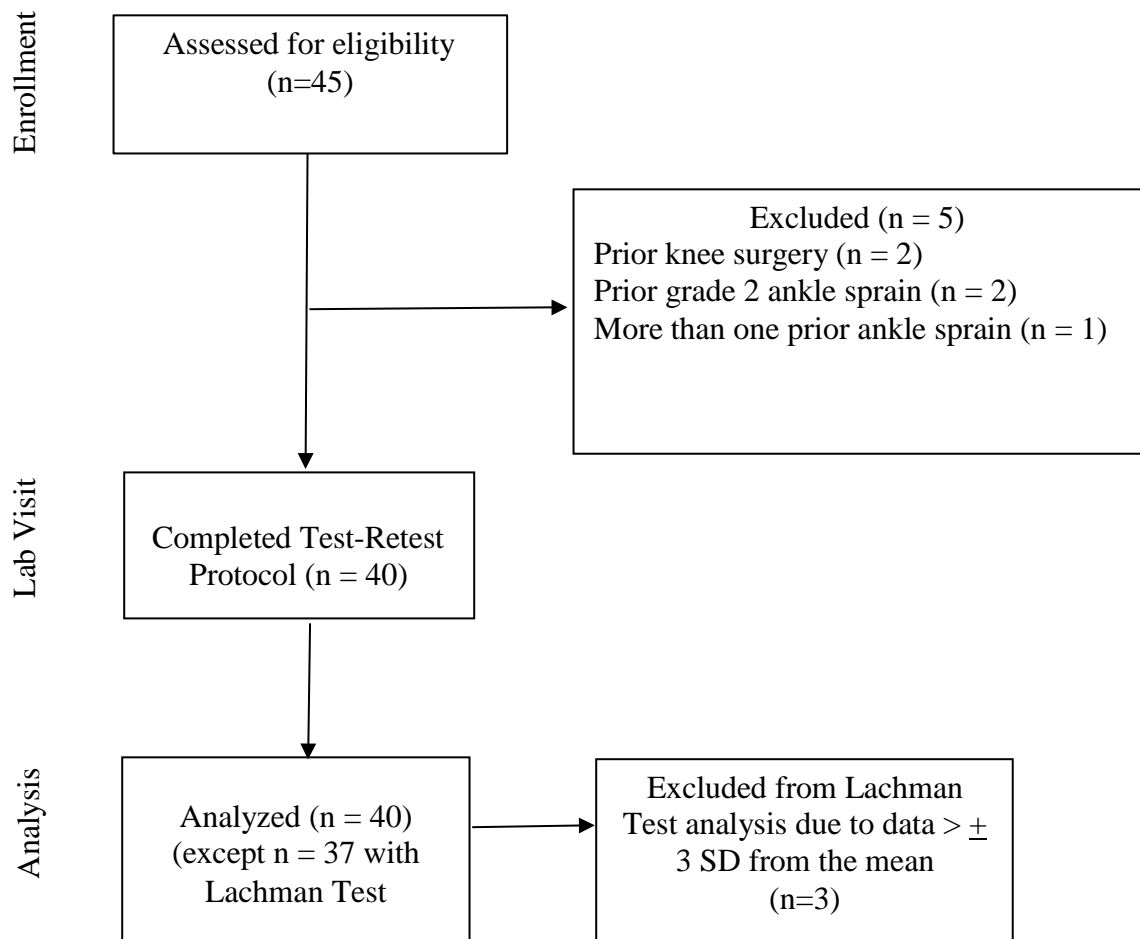
A multijoint arthrometer (LigMaster™, version 1.26; Sports Tech, Charlottesville, VA) was used to measure displacements (mm) of the tibiofemoral joint under 90 N and 130 N loads during the Lachman, posterior drawer, valgus stress and varus stress tests at the knee.<sup>28</sup> Similarly, we quantified displacement of the ankle joint during the anterior drawer test and inversion talar tilt test under 125 N and 150 N loads.<sup>27,29</sup>

**Table 1. Inclusion Criteria**

<b>Criteria</b>
Age 18 to 34 years old
No history of previous American Medical Association grade 2 (“moderate”) or grade 3 (“severe”) ankle or knee sprains
No prior history of knee or ankle surgery

A LigMaster™ proprietary outcome measure, *slope value*, is substituted for the typical mechanical stiffness outcome measure on other arthrometers. According to the LigMaster™ operating manual, the slope value is calculated from the encoder's record of force-displacement (load-deformation) data that the software subsequently processes to produce second-order plots of applied force against induced strain, rather than stress against strain.<sup>25</sup> The LigMaster employs graded stress technology to calculate the stressed ligament and the formula  $F = G(\alpha - 1/\alpha^2)$  which the force F, applied to the ligaments,  $\alpha$  is  $l/l_0$ , the ratio of the lengths of the stretched (l) and unstretched ( $l_0$ ) ligaments. The proportionality factor G represents the 'equivalent' elastic modulus.<sup>25</sup> As a result, the slope of the initial linear part equals the product of the cross-sectional area of the unstretched ligament and its elastic modulus when plotting force against strain.<sup>30</sup> However, the manufacturer proposes that increased slope values are likely due to a higher values for the elastic modulus, as normally seen in the chronic injuries when scar tissue has replaced much of the normal elastin or when calcification has occurred.<sup>25</sup>

A standard 360° goniometer (Model G 800; Whitehall Manufacturer, City of Industry, CA) was used to position the participant's knee at approximately 20° to 25° flexion for the Lachman, valgus stress, and varus stress tests. The participant's knee was positioned at approximately between 30° and 55° flexion for the posterior drawer test at the knee. The participant's ankle was positioned at approximately 15° plantar flexion for the inversion talar tilt and ankle anterior drawer tests.



**Figure 1. Study Flow Chart**

### Experimental Protocol

The primary investigator (JSN) scheduled a one-time laboratory visit with each of the participants. During this single visit to our research lab, a group of 6 LigMaster™ passive ligament tests (4 at the knee, 2 at the ankle) were performed using a “Test/Rest/Retest” experimental paradigm. Approximately 30 to 45 minutes were required to complete the 6 instrumented orthopedic special tests after the initial data collection. Participants used isopropyl alcohol swabs to remove the ink markings on their

knee and ankle joint landmarks applied in the first test session at the conclusion of the test session. A 30 minute quiescent period was then imposed, and following that rest period, the 6 orthopedic special tests were repeated in the identical order.

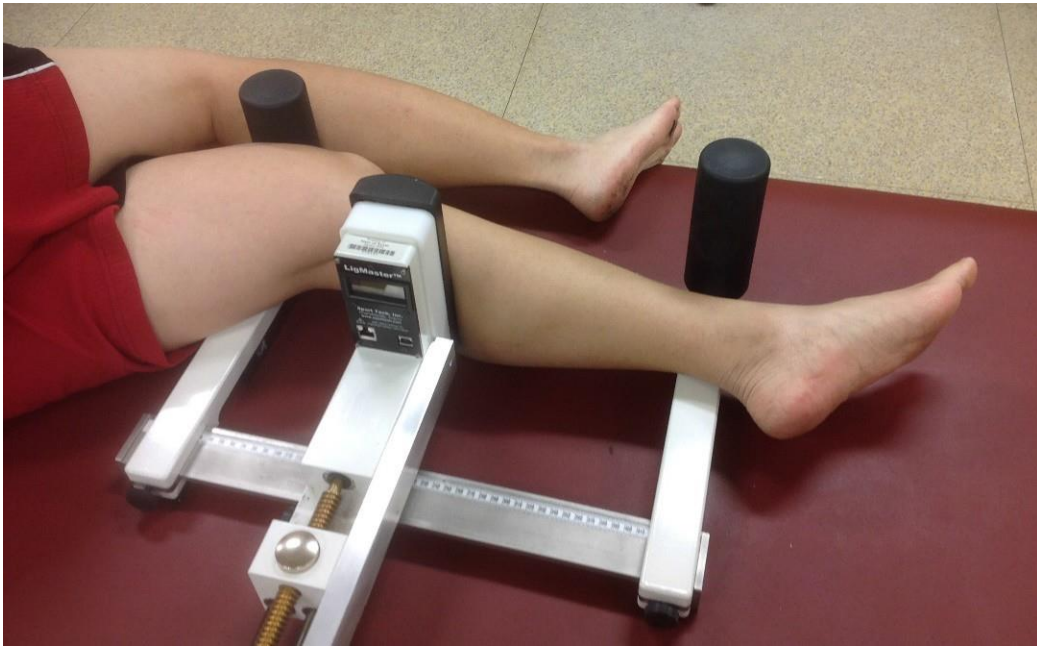
For this study, only the knee and ankle of the participant's dominant limb were evaluated. Limb dominance was determined by asking the participant which leg she/he would prefer to use to kick a soccer ball.

A certified athletic trainer (JSN) performed all the LigMaster™ testing and each test was repeated 4 times for each session. The first trial for each of the 6 orthopedic special tests was considered a conditioning trial and was not analyzed. We calculated 3-trial averages from the experimental values obtained during the second, third and fourth trials of each of the 6 orthopedic tests.

The order of the testing for the same for all participants: (1) Lachman test, (2) varus stress test of the knee, (3) ankle inversion talar tilt test, (4) posterior drawer test of the knee, (5) valgus stress test of the knee, and (6) anterior drawer test at the ankle. The order of these tests was purposeful and intended to minimize the time required to adjust the set-up of the arthrometer. We performed all testing procedures and participant positioning in accordance with the LigMaster™ instruction manual.<sup>25</sup>

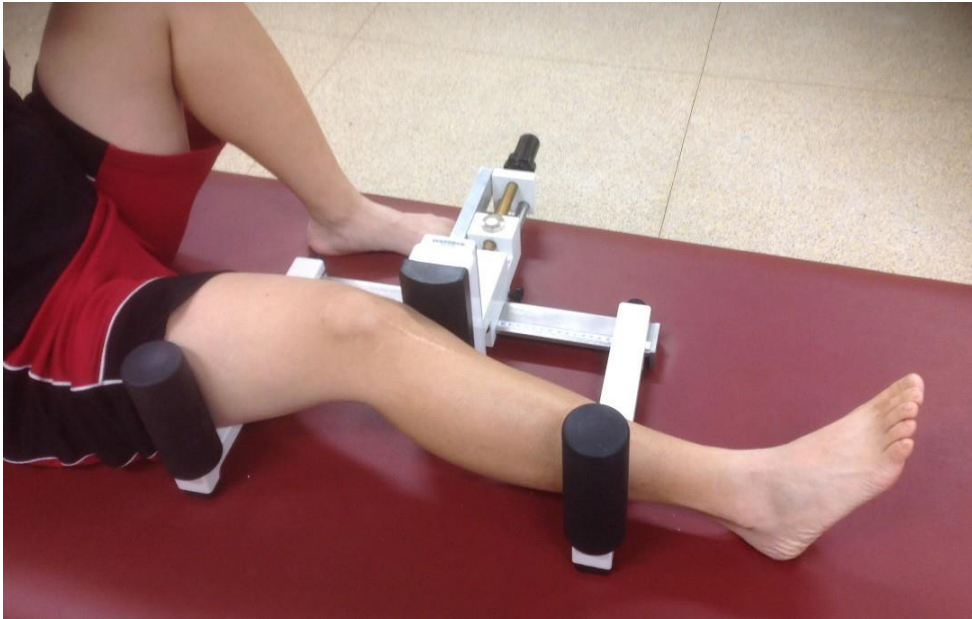
The anterior displacement of the tibia relative to the femur of the participant's dominant leg was obtained using a modified (side-lying) Lachman test with the knee positioned in 25° of flexion (Figure 2). For the second test, the varus stress test of the knee, the participant was positioned supine with the knee in 25° of flexion and 130 N loads were applied (Figure 3).

The inversion talar tilt test was the third test performed in both the test and retest protocol. Each participant was placed in a seated position with ankle at approximately 15° of plantar flexion; we then measured the number of degrees of passive inversion at the subtalar joint obtained under 125N and 150 N loads (Figure 4). The fourth test administered was the posterior drawer test of the knee. We obtained the posterior

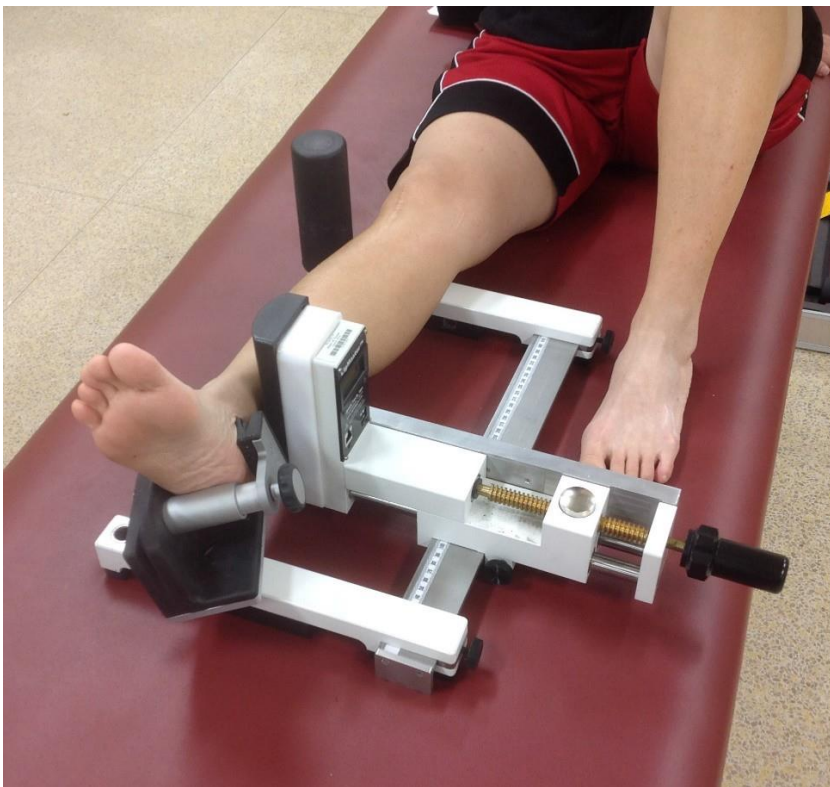


**Figure 2. Instrumented Lachman Test using the LigMaster™ Arthrometer.**

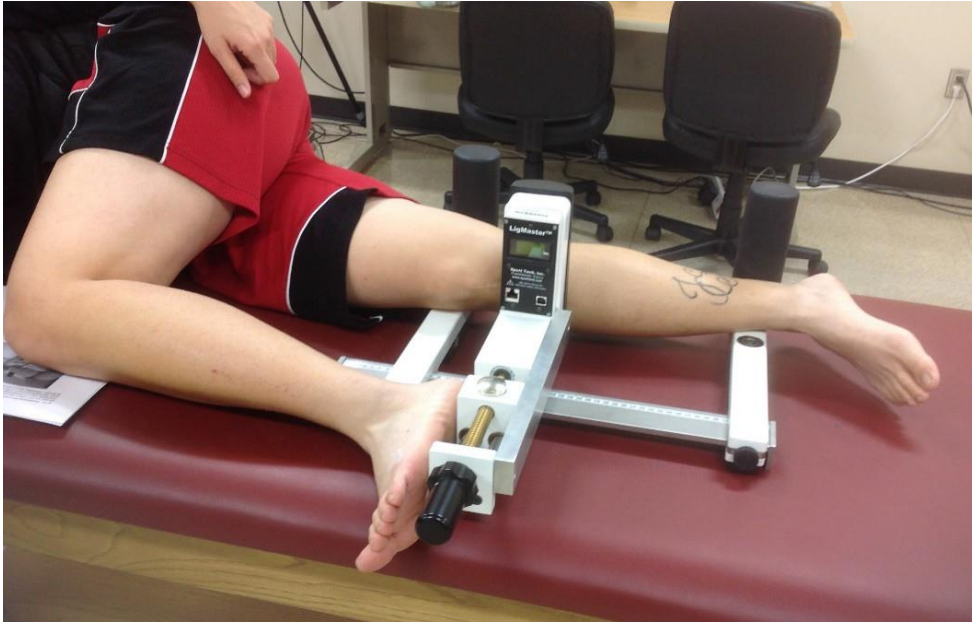
displacement of the tibia relative to the femur of the participant's dominant leg using a modified (side-lying) posterior drawer test with the knee at 90° knee flexion (Figure 5). For the valgus stress test at the knee, the participant was positioned supine with his/her knee in approximately 25° of flexion, and then 130 N loads were applied (Figure 6). For the sixth and final special test, the anterior drawer sign at the ankle, we positioned the ankle of the dominant limb at approximately 10° to 20° plantar flexion to measure anterior displacement of the talus relative to tibia under loads up to 150 N (Figure 7).



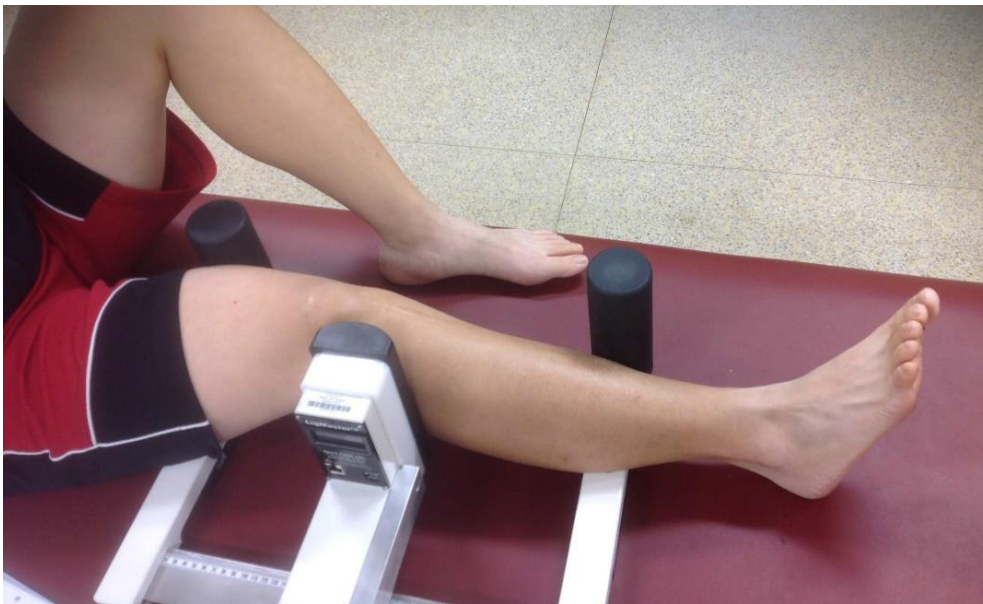
**Figure 3. Instrumented Varus Stress Test using the LigMaster™ Arthrometer.**



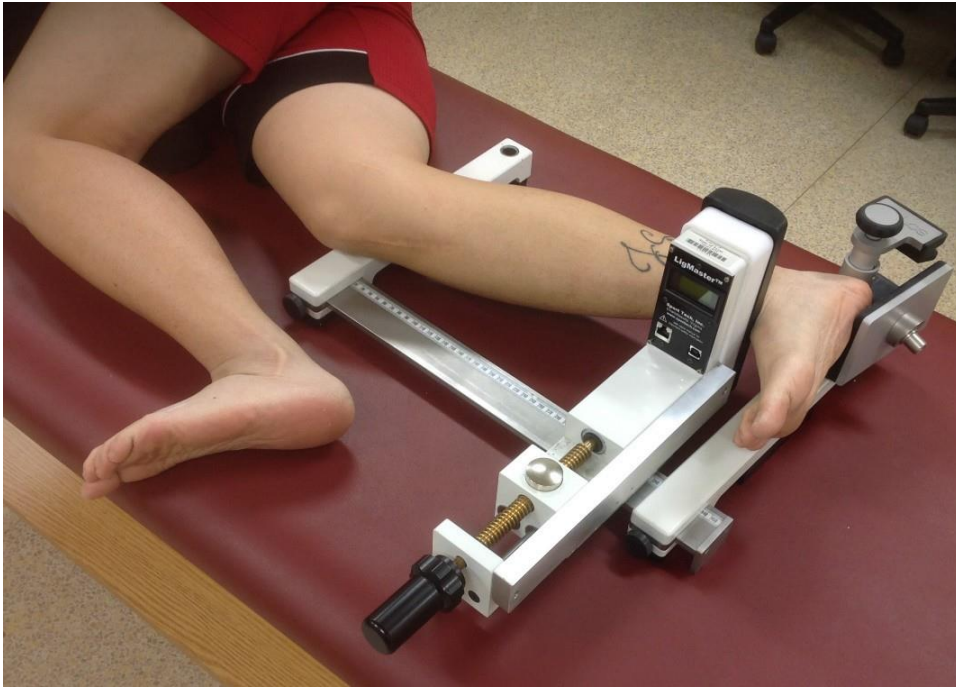
**Figure 4. Instrumented Inversion Talar Tilt Test using the LigMaster™ Arthrometer.**



**Figure 5. Instrumented Posterior Drawer Test using the LigMaster™ Arthrometer.**



**Figure 6. Instrumented Valgus Stress Test using the LigMaster™ Arthrometer.**



**Figure 7. Instrumented Anterior Drawer Test using the LigMaster™ Arthrometer.**

In effort to compare our findings with those in the arthrometry literature, we identified knee joint displacements during the 4 orthopedic special tests at 90 N and 130 N loads, and used these values to calculate our test-retest reliability scores. Following a similar logic, we identified the amounts of anterior ankle joint displacement and inversion passive range of motion under 125 N and 150 N loads, and used these values to calculate our intrarater ICCs.

The total time commitment to this study ranged from 90 to 120 minutes and at the conclusion of the data collection session each participant was compensated with a \$20 gift card from Wal-Mart.

#### Experimental Design and Statistical Analyses

For this cross-sectional study to determine intrarater test-retest reliability, we used a repeated measures ANOVA design. The intrarater reliability for the Lachman test,

posterior drawer test, valgus stress test, varus stress test, ankle anterior drawer test and inversion talar tilt test were assessed by calculating intraclass correlation coefficients (ICC<sub>3,1</sub>). Standard error of measurement (SEM) was calculated to provide an estimate of precision of measurement.<sup>31</sup> One-way ANOVAs were performed on 12 displacements and 6 slope values to evaluate for significant differences between the test and retest values ( $\alpha = 0.05$ ).

Utilizing the well-established rating scale of Shrout and Fleiss<sup>32</sup>, ICC values equal to or greater than 0.75 were considered “excellent”, ICC values between 0.40 and 0.74 were rated “good to fair” and ICC values less than 0.40 represented “poor” reliability. All statistical analyses were calculated by using version 22.0 of IBM SPSS statistical software (IBM SPSS Inc., Chicago, IL).

## Results

The key outcome measures in this study were the displacement values obtained from the instrumented assessment of knee and ankle joint laxity, and the slope values calculated from the differences in laxity values between loads of 90 N and 130 N at the knee, and between 125 N and 150 N loads at the ankle. Intra-examiner test-retest values for all 6 instrumented orthopedic special tests are also presented in the following section.

### Displacement

**Knee displacement values.** There were no significant differences between test and retest displacement values for the Lachman tests, varus stress tests, or valgus stress tests at 90 N and 130 N ( $p > 0.05$ ). However, ANOVA analysis of the test-retest displacement values for the instrumented posterior drawer tests revealed significant differences between test and retest at 90 N ( $p = 0.04$ ) and at 130 N ( $p = 0.01$ ). The means

and standard deviations for all 4 knee special orthopedic tests are presented in Table 2.

The intrarater reliability for the displacement values obtained with these instrumented knee special tests ranged from “excellent” for the varus stress test at 130 N ( $ICC_{3,1} = 0.85$ ) to “good to fair” for the posterior drawer test at 130 N ( $ICC_{3,1} = 0.41$ ), with the remaining values for all 4 special tests summarized in Table 2.

**Ankle displacement values.** There were no statistically significant differences between test and retest values for the instrumented inversion talar tilt or the anterior drawer tests at the ankle under 125 N and 150 N loads ( $p > 0.05$ ). The means and standard deviations for both of these ankle special tests are summarized in Table 3.

The intrarater reliability for all ankle displacement tests ranged from 0.79 for the inversion talar tilt test at 150 N (“excellent”) to 0.62 (“good to fair”) for the anterior drawer test, with all ICC values presented in Table 3.

#### Slope Values

**Knee slope values.** There were no statistically significant differences between test and retest slope values for the Lachman test or the valgus stress test ( $p > 0.05$ ). However, ANOVA analysis of the test-retest slope values indicated significant differences between test and retest slope values for the instrumented posterior drawer tests ( $p = 0.01$ ) and the instrumented varus stress tests ( $p = 0.05$ ). The means and standard deviations for the slope values for all 4 knee special orthopedic tests are presented in Table 4.

The intrarater reliability for the slope values obtained with these instrumented knee special tests ranged from “excellent” for the varus stress test ( $ICC_{3,1} = 0.82$ ) to “good to fair” for the Lachman test ( $ICC_{3,1} = 0.41$ ), with the remaining values for all 4

special tests summarized in Table 4.

**Ankle slope values.** There were no significant differences between test and retest slope values for the instrumented inversion talar tilt or the anterior drawer tests at the ankle ( $p > 0.05$ ). The means and standard deviations for the slope values for both ankle special tests are summarized in Table 5.

The intrarater test-retest reliability for ankle test slope values ranged from “good to fair” ( $ICC_{3,1} = 0.54$ ) with the anterior drawer test to “poor” ( $ICC_{3,1} = 0.38$ ) for the inversion talar tilt test (Table 5).

### Discussion

The purpose of this study was to establish the test-retest reliability of 6 knee and ankle orthopedic special tests that can be performed with a LigMaster™ multijoint arthrometer. Reliability of Knee Arthrometry

**Slope Values.** Only 2 previous studies have been conducted with the intent to determine the reliability of the slope value parameter (mechanical stiffness) with the LigMaster™ for the valgus stress test at the knee. These 2 studies reported ICC values of 0.99 and 0.80 respectively.<sup>26, 33</sup> compared to the  $ICC_{3,1}$  value of 0.62 found in the present study. The higher ICCs values reported on the Aronson et al studies were categorized as “excellent” compared to our “good to fair” Shrout and Fleiss reliability classification. These differences could be attributed to the fact that, in the Aronson studies, the participant’s foot was secured to a footplate that is not part of the LigMaster™ system designed to control rotation of tibia and femur during testing. Furthermore, these authors attached a biofeedback device to their participant’s vastus medialis and the medial hamstring muscles to make sure those muscles were relaxed.<sup>26</sup> The participants in our

**Table 2. Joint Laxity (Displacement) Results with Instrumented Orthopedic Special Tests at the Knee (Means  $\pm$  Standard Deviations, Standard Errors of Measurement, ANOVA Results, p values and ICC<sub>3,1</sub> Values) [ $*$  =  $p \leq 0.05$ ]**

Orthopedic Special Tests		Mean $\pm$ SD (mm)	SEM ( $\pm$ ) (mm)	F	p	ICC
Lachman Test at 90 N	Test	24.21 $\pm$ 3.23	0.51	<1	0.92	0.75
	Retest	24.17 $\pm$ 3.20	0.51			
Lachman Test at 130 N	Test	31.12 $\pm$ 3.40	0.54	<1	0.84	0.71
	Retest	31.03 $\pm$ 3.42	0.54			
Posterior Drawer Test at 90 N	Test	21.40 $\pm$ 4.48	0.71	4.67	0.04*	0.63
	Retest	20.15 $\pm$ 4.24	0.67			
Posterior Drawer Test at 130N	Test	29.44 $\pm$ 4.89	0.77	6.61	0.01*	0.53
	Retest	27.64 $\pm$ 4.52	0.71			
Varus Stress Test at 90 N	Test	24.52 $\pm$ 6.28	0.99	3.33	0.08	0.84
	Retest	23.59 $\pm$ 5.40	0.85			
Varus Stress Test at 130 N	Test	34.68 $\pm$ 7.25	1.15	3.51	0.07	0.85
	Retest	33.59 $\pm$ 6.27	0.99			
Valgus Stress Test at 90 N	Test	24.16 $\pm$ 3.75	0.59	2.01	0.16	0.71
	Retest	24.92 $\pm$ 5.10	0.81			
Valgus Stress Test at 130 N	Test	33.87 $\pm$ 4.48	0.71	1.97	0.17	0.71
	Retest	34.74 $\pm$ 5.80	0.92			

**Table 3. Joint Laxity (Displacement) Results with Instrumented Orthopedic Special Tests at the Ankle (Means  $\pm$  Standard Deviations, Standard Errors of Measurement, ANOVA Results, p values and ICC<sub>3,1</sub> Values) [\* = p  $\leq$  0.05]**

Orthopedic Special Tests		Mean $\pm$ SD	SEM ( $\pm$ )	F	p	ICC <sub>3,1</sub>
Inversion talar Tilt Test at 125 N (deg)	Test	31.84 $\pm$ 6.70	3.28	<1	0.44	0.76
	Retest	32.42 $\pm$ 6.86	3.36			
Inversion talar Tilt Test at 150 N (deg)	Test	36.39 $\pm$ 6.88	3.15	2.73	0.11	0.79
	Retest	37.53 $\pm$ 6.96	3.19			
Anterior Drawer Test at 125 N (mm)	Test	29.22 $\pm$ 6.24	3.80	2.03	0.16	0.63
	Retest	28.04 $\pm$ 6.01	3.66			
Anterior Drawer Test at 150 N (mm)	Test	31.07 $\pm$ 5.97	3.68	1.92	0.17	0.62
	Retest	29.94 $\pm$ 5.94	3.66			

study were only verbally instructed to avoid any limb movement and to relax their muscles during testing.

When comparing the actual mean slope values obtained with the valgus stress test of the knee among participants with similar demographic characteristics, we had a higher mean slope values at both the test (16.68) and retest (16.78), whereas the 3 published studies by Aronson et al reported a lower range of slope values, between 11.7 and 14.82.<sup>26, 34, 35</sup> One of Aronson's studies calculated the slope values of the valgus stress test of the knee among children, young adults and older adults.<sup>26</sup> These authors reported no significantly differences between the young and older adults' slope values of the valgus stress tests, but found that children have significantly different (lesser) knee valgus slope values than the young and older adults they tested.<sup>26</sup>

**Table 4. Slope Value Results with Instrumented Orthopedic Special Tests at the Knee (Means  $\pm$  Standard Deviations, Standard Errors of Measurement, ANOVA Results, p values and ICC<sub>3,1</sub> Values) [\* = p  $\leq$  0.05]**

Orthopedic Special Tests		Mean $\pm$ SD (mm)	SEM ( $\pm$ ) (mm)	F	p	ICC
Lachman Test	Test	16.25 $\pm$ 1.12	0.18	<1	0.83	0.41
	Retest	16.29 $\pm$ 0.82	0.14			
Posterior Drawer Test	Test	7.47 $\pm$ 0.84	0.13	5.56	0.02*	0.51
	Retest	7.86 $\pm$ 1.01	0.16			
Varus Stress Test	Test	16.96 $\pm$ 2.70	0.43	4.09	0.05*	0.82
	Retest	17.43 $\pm$ 2.76	0.44			
Valgus Stress Test	Test	16.68 $\pm$ 1.61	0.25	<1	0.55	0.62
	Retest	16.78 $\pm$ 2.19	0.35			

**Table 5. Slope Value Results with Instrumented Orthopedic Special Tests at the Ankle (Means  $\pm$  Standard Deviations, Standard Errors of Measurement, ANOVA Results, p values and ICC<sub>3,1</sub> Values) [\* = p  $\leq$  0.05]**

Orthopedic Special Tests		Mean $\pm$ SD	SEM ( $\pm$ )	F	p	ICC <sub>3,1</sub>
Anterior Drawer Test (mm)	Test	5.36 $\pm$ 0.90	0.14	<1	0.35	0.38
	Retest	5.18 $\pm$ 1.04	0.17			
Inversion Talar Tilt Test (deg)	Test	106.36 $\pm$ 87.64	13.86	1.92	0.17	0.54
	Retest	121.72 $\pm$ 104.38	16.50			

We could find no published studies that have reported the reliability of LigMaster™ slope values for the Lachman, posterior drawer or valgus stress tests at the knee. Of these 3 instrumented knee special tests, our ICC values were best for the varus stress test (0.82), and to our surprise and disappointment, lowest for the instrumented Lachman test (0.41).

**Displacement Values.** When comparing our LigMaster™ Lachman test results with those obtained with the KT-1000 arthrometer, we noted that Hanten and Pace<sup>36</sup> reported an intrarater reliability of 0.84 for instrumented Lachman tests performed at 89 N loads. This value was slightly higher but similar in categorization (“excellent”) to the ICC value of 0.75 that we observed with LigMaster™ Lachman testing with 90 N loads. A similar study used the KT-1000 to perform instrumented Lachman tests at 89 N on individuals with ACL ruptures and reported much lower test-retest (ICC) reliability of 0.47.<sup>37</sup>

When comparing the test-retest reliability of our LigMaster™ knee displacement values (0.75 at 90 N) with those obtained with KT-2000 arthrometers, one group reported ICC values for the 89 N Lachman test of 0.95 and 0.93 for 134 N tests performed on healthy participants.<sup>38</sup> Similarly, the other study measured the ICC values of the Lachman test on healthy and ACL-deficient knees at 89 N were 0.92 and 0.95 respectively.<sup>39</sup>

While the test-retest reliability for displacement values obtained with instrumented Lachman tests are our study and most studies in the literature can be classified as “excellent”, there are large differences in the experimental procedures used to collect LigMaster™ and KT-1000/2000 data. With KT-1000/2000 arthrometer testing the participants are positioned supine, knee flexion angle is held constant with a rigid

bolster, tibial rotation is constrained by a foot plate, and the force is applied by pulling the tibia anteriorly through the device's force-sensing handle. In contrast, when performing instrumented Lachman tests with the LigMaster™, participants are in a side-lying position and a posteriorly-located pressure plate pushes the proximal tibia forward on the femur.

We could find only one study that used the KT-1000 arthrometer to determine the intrarater reliability of the displacement values obtained with the posterior drawer test at 89 N; these authors reported ICC values of 0.70 for the novice examiner and 0.74 experienced examiner.<sup>40</sup> Their KT-1000 ICC values compare closely with our ICC<sub>3,1</sub> value of 0.63 obtained when a novice examiner (JSN) performed LigMaster™ instrumented posterior drawer testing.

#### Reliability of Ankle Arthrometry

**Displacement Values.** In a similar and only previous study using a LigMaster™, Docherty et al<sup>27</sup> reported test-retest reliability ICC values of 0.74 for the inversion talar tilt test and 0.65 for the anterior drawer test. Our intrarater reliability results for ankle joint displacement measures with the LigMaster™ at 150 N were almost identical, with ICC<sub>3,1</sub> values of 0.79 for the inversion talar tilt test and 0.62 for the anterior drawer test.

Several other studies have conducted to determine the reliability of other ankle arthrometers, specifically the Hollis Instrumented Ankle Arthrometer.<sup>22-24</sup> This device has demonstrated high intrarater reliability of both anterior-posterior (AP) displacement and internal-external (IE) rotation values. In all 3 published studies<sup>22-24</sup>, intrarater reliability of AP displacement (ICC range = 0.82 to 0.97) and I-E rotation (ICC range = 0.82 to 0.99) values were “excellent” by Shrout and Fleiss<sup>32</sup> standards.

In comparison with ankle anterior drawer tests performed with the LigMaster™ the Hollis Instrumented Ankle Arthrometer displacements had substantially higher test-retest reliability. These differences are mostly likely attributed to the increased level of control of extraneous motion that the Hollis arthrometer in comparison to the LigMaster™, e.g., a foot plate, additional linkages that stabilize the ankle.

### Limitations

We acknowledge that there are several limitations to this study. The level of tension in the participant's limb muscles throughout testing was not quantified with electromyography or biofeedback in other studies. The primary investigator (JSN) instructed all the participants to relax their muscles during the tests, and the participants claimed that they were relaxed.

There were several patient positioning and testing issues due to the participants' morphology, i.e., the size of the knee and ankle joints and bones. For example, the size of the calcaneus of some participants was too small to conduct the inversion talar tilt test at the full 150 N load. We also found that we could not complete 150 N ankle laxity testing on some female participants, as the LigMaster™ device could not accommodate individuals with smaller lower leg bones, e.g., tibia, calcaneus.

### Conclusions

The instrumented Lachman, valgus, and varus stress tests at the knee and inversion talar tilt test as performed with the LigMaster™ arthrometer on healthy, physically-active adults had moderate test-retest reliability. Conversely, the posterior drawer test and the ankle anterior drawer test had markedly lower levels of intrarater

reliability. While this device has capabilities unlike any other commercially-available arthrometer, the LigMaster™ software generates joint displacement and mechanical stiffness values that are proprietary and thus unique to this device. These non-standard values do not correspond with output from other commercially-available arthrometers, making direct comparisons with published knee and ankle arthrometer studies difficult, if not impossible.

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## CHAPTER III

### SUMMARY AND RECOMMENDATIONS FOR FUTURE RESEARCH

#### Summary

The purpose of this study was to establish the test-retest reliability of 6 instrumented orthopedic special tests at the knee (Lachman test, posterior drawer test, varus and valgus stress tests) and ankle (anterior drawer test, inversion talar tilt test) performed with a LigMaster™ multijoint arthrometer. The LigMaster™ is relatively new arthrometer, the only arthrometer currently on the market that has the capacity to objectively quantify joint laxity and mechanical stiffness values at 4 joints (knee, ankle, shoulder and elbow). We found that the intrarater reliability of the joint laxity (displacement) for all knee tests and ankle test ranged from “good to fair” to “excellent”. The intrarater reliability of the slope values (stiffness) for all knee tests were range “good to fair” to “excellent”, whereas all the ankle tests were range “poor” to “good” to “fair”.

We acknowledge that our study had several limitations. We could not confirm that the participants’ muscles were completely relaxed during LigMaster™ testing, although they claimed that they were. Previous test-retest studies with this device have employed biofeedback units to make sure that the antagonist muscles to the ligamentous stress test are inactive. In addition, Aronson and associates added a foot plate that is not part of the LigMaster system to hold the foot stationary and minimize rotation of the lower leg during testing. Muscle activation is known to provide dynamic stability to the joint and reduce the magnitude of the laxity present and/or observed during orthopedic

special tests.

Prior to formal data collection the primary investigator (JSN), a novice LigMaster™ examiner, conducted a full-scale pilot study of the reliability of the 6 knee and ankle special test with 11 volunteers, performing over 400 instrumented tests at the knee and ankle to gain experience with the device. From these data we learned that found our LigMaster™ unit likely had calibration problems as it provided valid data. After consulting the manufacturer and numerous attempts to resolve the problems we were experiencing, we sent the device to Virginia for evaluation and calibration before we began our formal data collection. The manufacturer claimed that our LigMaster™ unit was repaired and tested it before sending back to us for use in our reliability study.

The differing sizes of the participants' knee and ankle joints also turned out to be problematic for instrumented knee and ankle stress testing with the LigMaster™. The primary investigator (JSN) had some difficulties with positioning several of the female participants' knees (varus and valgus stress tests) and ankle (anterior drawer and inversion talar tilt tests). For example, some participants had ankles so small in dimension that the LigMaster™ calcaneus clamp did not constrain the ankle, e.g., the ankle slid off the device, during the inversion talar tilt test.

#### Recommendations for Future Study

- Repeat this test-retest reliability study bilaterally on the healthy, physically-active adult participants.
- Conduct the test-retest reliability study bilaterally on the participants with medical histories that include previous knee/ankle injuries, and knee/ankle surgeries.
- Employ a biofeedback unit to ensure minimal activity/tension in the muscles that

are antagonistic to the ligamentous stress tests being performed.

- Consider the design and fabrication of a “foot plate” for the LigMaster™ that constrains the foot and limits unwanted limb rotation during testing.
- For the Lachman and posterior drawer tests at the knee, directly compare the results of KT-2000™ and LigMaster™ instrumented tests, and determine the correlation between the joint laxity (displacement) and mechanical stiffness (slope value) measures for each special test with each device.
- For the anterior drawer test at the ankle, directly compare the results of Hollis Instrumented Ankle Arthrometer™ and LigMaster™ testing, and report the correlations between the displacement (joint laxity) and mechanical stiffness (slope value) measures obtained with each device.

## APPENDIX SECTION

### IRB DOCUMENTS

#### INSTITUTIONAL REVIEW BOARD SYNOPSIS

##### **Reliability of measuring the mechanical properties of knee and ankle ligaments with a LigMaster™ Multijoint Arthrometer**

1. *Identify the sources of the potential subjects, derived materials or data. Describe the characteristics of the subject population, such as their anticipated number, age, sex, ethnic background, and state of health. Identify the criteria for inclusion or exclusion. Explain the rationale for the use of special classes of subjects, such as fetuses, pregnant women, children, institutionalized mentally disabled, prisoners, or others, especially those whose ability to give voluntary informed consent may be in question.*

Volunteers for this study will be recruited from general student population at Texas State University. Our goal is to recruit 40 apparently healthy participants (20 females and 20 males) between the ages of 18 and 34 years.

Volunteers will be screened to determine whether they meet all of the following inclusion criteria for participation in the study:

##### Criteria for Inclusion

- Age 18 to 34 years old
- No history of a previous American Medical Association grade 2 (“moderate”) or grade 3 (“severe”) ankle or knee sprains

2. *Describe the procedures for recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be solicited and obtained, who will seek it, the nature of information to be provided to prospective subjects, and the methods of documenting consent. (Include applicable **Consent Form** (s) for review.) If written consent is not to be obtained, this should be clearly stated and justified.*

##### **Procedures for recruitment of participants:**

Volunteers will be recruited through the use of flyers and oral announcements in Texas State University classes and instructional labs. After obtaining the necessary permission from Campus Activities and Student Organizations, flyers will be posted on bulletin boards around fitness facilities and classrooms at Texas State University. Similarly, after obtaining permission from individual instructors

in the Department of Health and Human Performance, verbal recruiting announcements will be made in classes. Both recruiting methods will provide prospective volunteers with the essential information about the research project, including the purpose of the study, study procedures, time commitment, and investigator contact information. Individuals who are interested in study participation will be responsible for contacting the principal investigator (JSN).

**Procedures for obtaining consent:**

Volunteers will contact the study's principal investigator to arrange an initial meeting in the Biomechanics/Sports Medicine Laboratory in Jowers Center at Texas State University. At this meeting, the volunteer will be given a written Consent Form that will be used as a guide for the conversation. The study's purpose and all procedures will be verbally explained, and then the volunteer will have as much time as she needs to read the form. Each volunteer's level of understanding about the study will be assessed before being asked to sign the IRB-approved Consent Form. In cases in which English is not the volunteer's first language, additional time will be provided for questions to ensure that the potential participant fully understands all of the elements of the study. Participation in the study will not begin until a signed Consent Form is returned to the principal investigator.

3. *If your planned recruitment process involves emailing Texas State students, staff, faculty or other individuals using their active Texas State email address, provide details in the **Synopsis**. (In addition, the IRB will require a draft of your recruitment email, using the enclosed template and formatted as illustrated in the example in this document, submitted in addition to other required documents.*

The recruitment process for this study will not involve the use of e-mails to any Texas State University student, staff, faculty or other member of our academic community.

4. *If you plan to distribute a survey to collect information directly from individuals who comprise a significant proportion of one or more Texas State affiliation groups, as defined in Section 04 of [UPPS No. 04.01.02, Information Resources Identity and Access Management](#), you must follow the review and approval procedures outlined in [UPPS No. 01.03.05, Administrative Surveys](#), and provide information in your **Synopsis** [regarding review and approval](#).*

The proposed study does not include a survey research component.

5. *Describe the project's methodology in detail. If applicable, detail the data collection procedures, the testing instruments, the intervention(s), etc. If using a survey, questionnaire, or interview, please provide a copy of the items or questions.*

### **Study Overview**

The proposed research project will employ a test-retest design which the participants will have the laxity and mechanical stiffness of 4 knee and 2 ankle ligaments measured twice during one data collection session. The purpose of this study will be to establish the reliability of measuring the mechanical properties of the major ligaments of the knee and ankle with a relatively new, sophisticated biomedical device known as a multi-joint arthrometer (LigMaster™, Sport Tech, Inc., Charlottesville, VA; cost = \$20,000). At present, there are only three other published studies utilizing this device to quantify the laxity of the medial collateral ligament of the knee, and two published studies using the LigMaster™ to measure ankle ligament laxity. No previous studies have established the test-retest reliability for the LigMaster™ measures for the anterior cruciate ligament, posterior cruciate ligament, or lateral collateral ligament of the knee.

### **Orthopedic Injury History Screening**

We will screen all volunteers for eligibility to participate in this study by asking them to complete a questionnaire that will ask questions about their general health and any past or recent injuries to the knees and ankles. Next, a licensed athletic trainer (JSN) will perform a standard orthopedic evaluation of their knee and ankle joints to verify the information obtained in the questionnaire.

### **Data Collection Procedures**

After obtaining written consent from the volunteer, the participants will schedule a one-time lab visit with the primary investigator. The 6 passive ligament tests (4 at the knee, 2 at the ankle) to be performed using the LigMaster™ require about 30 minutes to complete. A 30 minute “quiet” period will be imposed, and then the 6 ligament tests will be repeated. Only the knee and ankle ligaments of the participant's dominant limb will be evaluated. A participant's total time commitment to this study will be approximately 90 minutes.

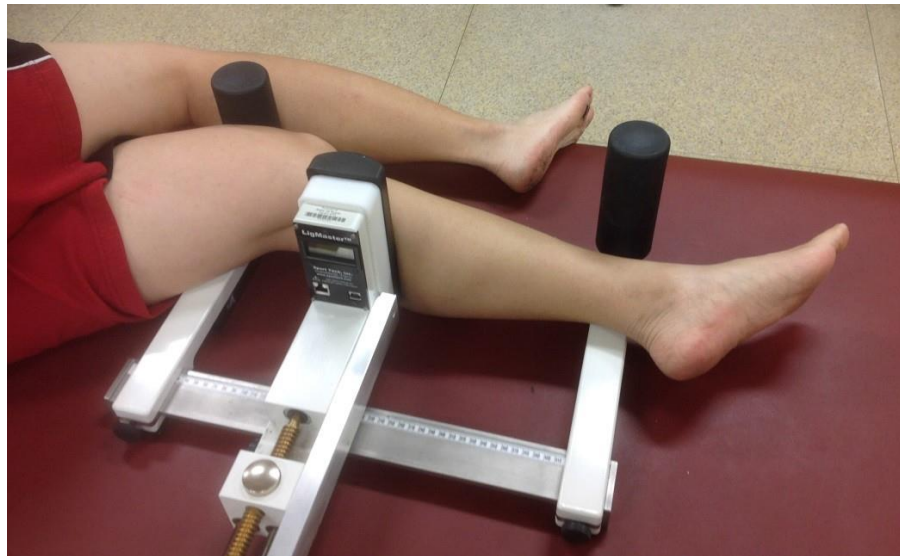
### **Knee Arthrometry Data Collection**

We will use a biomedical device known as a multi-joint arthrometer (LigMaster™) to perform instrumented versions of 4 standard orthopedic tests of ligamentous laxity of the participant's dominant limb knee joint. This computerized device gives us the capacity to measure the inherent laxity (“looseness”) of the knee ligaments very precisely, down to the nearly one-tenth of a millimeter.

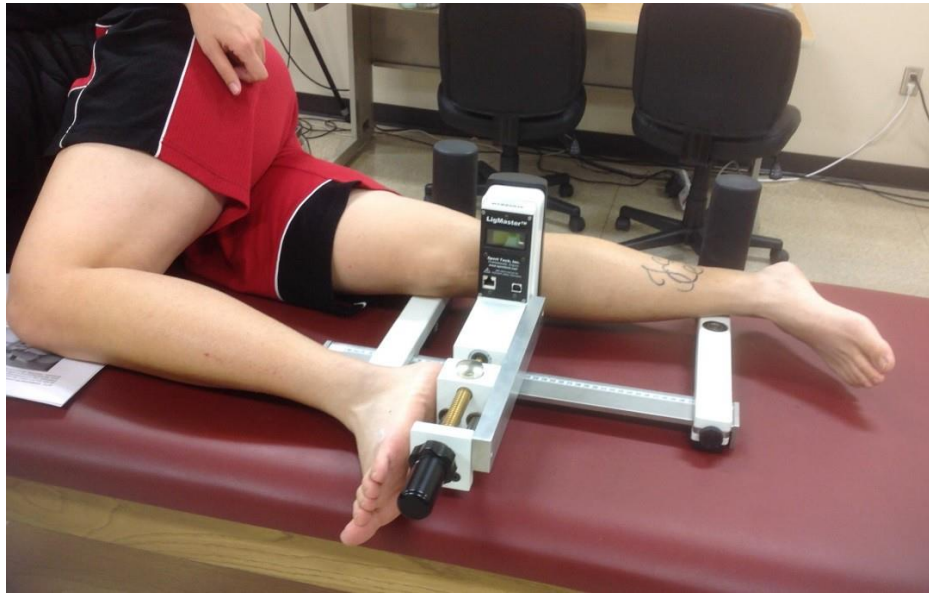
To perform these orthopedic tests, we will ask participants to lie on her side or supine on an examination table while wearing gym shorts or similar clothing that exposes their knees and ankles. The 4 passive orthopedic tests of knee ligament laxity that we will perform with the help of the arthrometer are the:

- **Lachman Test** – primarily tests the anterior cruciate ligament (Figure 1).
- **Posterior Drawer Test** – primarily tests the posterior cruciate ligament (Figure 2).
- **Valgus Stress Test** – primarily tests the tibial collateral ligament and medial joint capsule of the knee (Figure 3).
- **Varus Stress Test** – primarily tests the fibular collateral ligament and lateral joint capsule of the knee (Figure 4).

The participant's dominant knee will be placed in different angles with each of these 4 tests. A “test” will consist of using the arthrometer to apply a safe, controlled amount of load to the knee ligaments, ranging from 0 up to 30 pounds of force. Each test will be repeated 4 times during each of the 2 rounds of data collection.



*Figure 1. Instrumented Lachman Test using the LigMaster™ arthrometer*



*Figure 2. Instrumented Posterior Drawer Test using the LigMaster™ arthrometer*



*Figure 3. Instrumented Valgus Stress Test using the LigMaster™ arthrometer*



*Figure 4. Instrumented Varus Stress Test using the LigMaster™ arthrometer*

### **Ankle Joint Arthrometry Data Collection**

We will reconfigure our multi-joint arthrometer (LigMaster™) in order to perform instrumented versions of 2 standard orthopedic tests of ligamentous laxity of the participant's ankle joint. This computerized device gives us the capacity to measure the laxity in the ligaments to the nearly one-tenth of a millimeter.

To perform these orthopedic tests, we will again ask the participant to lie on her side or be seated on an examination table while wearing gym shorts or similar clothing that exposes the knee and ankle joints.

The 2 passive orthopedic tests of ankle ligament laxity that we will perform with the help of the arthrometer are the:

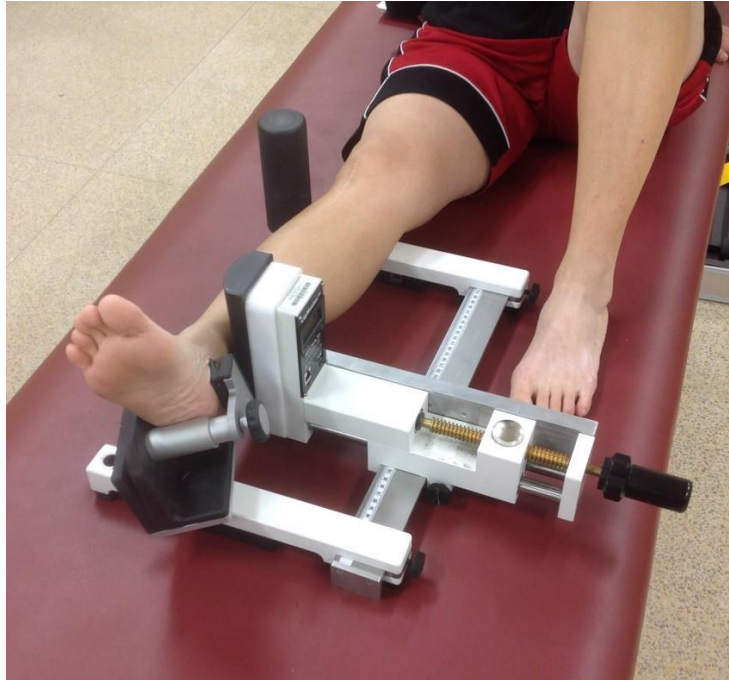
1. **Anterior drawer test** – primarily tests the anterior talofibular ligament (Figure 5)
2. **Inversion talar tilt test** – primarily tests the calcaneofibular ligament (Figure 6)

The participant's dominant ankle will be placed in different positions and angles with each of these tests. A "test" will consist of using the arthrometer to apply a

safe, controlled amount of load to the ankle ligaments, ranging from 0 up to 35 pounds of force. Each test will be repeated 4 times during each data collection session.



***Figure 5. Instrumented Anterior Drawer Test using the LigMaster™ arthrometer***



***Figure 6. Instrumented Inversion Talar Tilt Test using the LigMaster™ arthrometer***

### **Additional Considerations**

Limb dominance will be determined by asking the participant which leg he/she would prefer to use to kick a soccer ball into a goal.

Given the viscoelastic nature of the human soft tissues, participants will be instructed not to engage in any significant physical activity, e.g., running, weight lifting, yoga, bicycling to campus, within 2 hours of their scheduled data collection session. Elevated core body temperature from exercise has been shown to increase joint laxity at the knee (Perrin et al., 1990).

6. *Describe any potential risks — physical, psychological, social, legal or other — and state their likelihood and seriousness. Describe alternative methods, if any, that were considered and why they will not be used.*

The potential risks of injury associated with this study are minimal, but the participants may feel a stretching sensation or mild discomfort during data collection with the computerized multijoint arthrometer. Muscles around the knee and ankle joint may reflexively tighten with the passive testing, and cause the mild muscle soreness 24 to 48 hours after testing. The participants may also feel anxious at the outset of testing because they have no previous experience these standard orthopedic tests of knee and ankle joint laxity.

The principal investigator, a nationally certified athletic trainer skilled in sports injury prevention, orthopedic injury assessment, as well as emergency medical care, will be present to provide the participants with any medical advice needed.

7. *Describe the procedures for protecting against or minimizing any potential risks and include an assessment of the likely effectiveness of those procedures. Include a discussion of confidentiality safeguards, where relevant, and arrangements for providing mental health or medical treatment, if needed.*

### **Procedures for Participants Safety**

At all times, the principal investigator (JSN) will be responsible for the safety of the study participants during the arthrometry data collection. The principal investigator will ensure that a participant's knee and ankle joints are in the proper positions on the multijoint arthrometer in accordance with manufacturer's instructions. The participants will give verbal feedback about whether their knee, ankle and trunk are in comfortable positions. To minimize the potential risks, the principal investigator will stand nearby the arthrometry, instruct the participants relax their leg and knee muscles, and visually observe proper position of the knee

and ankle joint during the each arthrometer test.

### **Confidentiality Safeguards**

Each participant will be assigned a code number that will insure the confidentiality of the information that they provide to this study. All study documents will be kept secure in a file cabinet in a locked room within the Biomechanics/Sports Medicine Laboratory at Texas State University. Only the investigators for the study will have access to the study materials. A document with individually-identifiable data such as a Consent Form will be kept separately from others that do not have identifying information. All electronic data will be stored on a computer that requires a unique log-in ID and password to gain access to the data, which will be kept confidential by the study investigators. All electronic data obtained through this study will be kept for no more than three years before being destroyed. For permanent destruction, the electronic data files will be moved to the "Recycle Bin" on the PC computer's desktop, and then the Recycle Bin will be emptied to ensure complete removal from the system.

8. *Describe and assess the potential benefits to be gained by the subjects, as well as the benefits that may accrue to society in general as a result of the proposed study.*

By participating in this study, the participants will learn about the value of laxity and mechanical stiffness of their knee and ankle joint and knowledge of the LigMaster™ multijoint arthrometer.

9. *Clearly describe any compensation to be offered/provided to the participants. If extra credit is provided as an incentive, include the percentage of extra credit in relation to the total points offered in the class. Also, if extra credit is provided, describe alternatives to participation in your research for earning extra credit.*

All volunteers who qualify for participation in this study will receive \$20 Wal-Mart gift card if they complete all aspects of the study.

10. *Discuss the risks in relation to the anticipated benefits to the subjects and society.*

There are minimal risks associated with participation in this study. There is a large potential benefit to orthopedic research through determination of the test-retest reliability of the LigMaster™ for measuring male and female knee and ankle joint laxities and mechanical stiffness. There are potential risks including knee and ankle joints experiencing momentary mild discomfort during the arthrometry data collection. We believe the risk-benefit ratio is acceptable.

- 11. Identify the specific sites/agencies to be used as well as approval status. Include copies of approval letters from agencies to be used (note: these are required for final approval). If they are not available at the time of IRB review, approval of the proposal will be contingent upon their receipt.*

All data collection sessions will take place in the Texas State University's Biomechanics/Sports Medicine Laboratory. No agencies or sites outside of Texas State University will be used for subject recruitment, data collection, or exercise session supervision.

- 12. If you are a student, indicate the relationship of the proposal to your program of work and identify your supervising/sponsor faculty member.*

Dr. Rod Harter is a Professor of Athletic Training and Associate Dean for Research in the College of Education at Texas State University, where I am currently a graduate student in the Master of Science Post-Professional Program in Athletic Training.

- 13. In the case of student projects, pilot studies, theses, or dissertations, evidence of approval of Supervising Professor or Faculty Sponsor should be included. Thesis and dissertation proposals must be approved by the student's committee before proceeding to the IRB for review.*

My thesis committee consists of Dr. Rod Harter (chair) and Dr. Joni Mettler, members of the Department of Health and Human Performance faculty, and Dr. Rodney Rohde, chair of the Department of Clinical Laboratory Sciences, all at Texas State University. A successful public meeting was held on November 21, 2014, at which time my committee approved my thesis proposal, and these revisions were approved by my thesis committee on June 10, 2015.

- 14. If the proposed study has been approved by another IRB, attach a copy of the letter verifying approval/disapproval and any related correspondence. If the proposed study has not been reviewed/approved by another IRB, please state this explicitly.*

The proposed study protocol has not been reviewed by any other IRB.

- 15. Identify all individuals who will have access, during or after completion, to the results of this study, whether they be published or unpublished.*

No persons, except the principal investigators, will have access to the raw data or

personal identifying information. All interested individuals or groups may contact the principal investigators for the results of this study.

*16. Provide date of completion of the required CITI training on the protection of human subjects. Applicants must provide training dates for themselves and for supervising faculty member. All training must be current and not expired.*

Dr. Rod Harter, Faculty, completed the CITI refresher course training on 2/11/2014; (Reference ID #7054667)

JyeShuang Ng, Graduate Student, completed the CITI training on 11/29/2014 (Ref ID# 14663463)

## Consent Form

*In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study. In this form "we" means the researchers and staff involved in running this study at Texas State University.*

**Principal Investigator:** JyeShuang Ng, ATC, LAT, CES  
Department of Health and Human Performance  
B128 Jowers Center  
San Marcos, TX 78666  
shuang99186@txstate.edu  
903-752-9064

Rod Harter, PhD, ATC, LAT, FNATA  
Professor of Athletic Training  
Department of Health and Human Performance  
A132 Jowers Center  
San Marcos, TX 78666  
rod.harter@txstate.edu  
512-245-2972

### **What is the purpose of this form?**

This form will help you decide if you want to be in the research study. You need to be informed about the study before you can decide whether you want to be in it. You do not have to participate in this study if you do not want to. You should have all your questions answered before you give your permission or consent to be in the study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will get a copy of this signed form.

### **Why is this research being done?**

The purpose of this study is to establish the reliability of measuring the mechanical properties of knee and ankle ligaments using a relatively new biomedical device known as a multi-joint arthrometer (LigMaster™; cost = \$20,000) to measure the laxity ("looseness") of knee and ankle ligaments. There are only three published studies that have used this device to evaluate the ligaments of the knee, and just two studies that have measured ankle ligament laxity.

### **How long will this study take?**

Your participation in this study will require you to visit the Biomechanics/Sports Medicine Lab in Jowers Center at Texas State University once for approximately 90 minutes. After you have read and signed this Consent Form, initial data will be collected,

requiring approximately 30 minutes. A 30 minute rest period will be imposed, and then the identical data collection process will be repeated.

### **What will happen if you are in the study?**

As a volunteer, you will be screened for eligibility to participate in this study by completing a questionnaire that will ask about your general medical status and any past or recent injuries to your knees and ankles. Next, a licensed athletic trainer (JSN) will perform a standard orthopedic evaluation of your knee and ankle joints. If you meet all of the inclusion criteria and agree to participate, you will sign this consent form before any study procedures take place.

### **Knee Joint Data Collection:**

We will use a biomedical device known as a multi-joint arthrometer (LigMaster™) to perform instrumented versions of 4 standard orthopedic tests of ligamentous laxity of your knee joint. This computerized device gives us the capacity to measure the inherent laxity (“looseness”) of your ligaments very precisely, down to the nearly one-tenth of a millimeter.

To perform these orthopedic tests, we will ask that you lie supine on an examination table while wearing gym shorts or similar clothing that exposes your knees and ankles. We will only evaluate the knee of your dominant limb.

The 4 passive orthopedic tests of knee ligament laxity that we will perform with the help of the arthrometer are the:

1. **Lachman test** – primarily tests the anterior cruciate ligament (ACL)
2. **Posterior drawer test** – primarily tests the posterior cruciate ligament (PCL)
3. **Valgus stress test** – primarily tests the tibial collateral ligament and medial joint capsule of the knee
4. **Varus stress test** – primarily tests the fibular collateral ligament and lateral joint capsule of the knee

Your dominant knee will be placed in different angles with each of these 4 tests. A “test” will consist of using the arthrometer to apply a safe, controlled amount of loading on your knee ligaments, ranging from 1 up to 30 pounds of force. Each test will be repeated 4 times during each data collection session.

### **Ankle Joint Data Collection:**

We will reconfigure our multi-joint arthrometer (LigMaster™) to perform instrumented

versions of 2 standard orthopedic tests of ligamentous laxity of your ankle joint. This computerized device gives us the capacity to measure the laxity in your ligaments to the nearly one-tenth of a millimeter.

To perform these orthopedic tests, we will again ask that you lie supine on an examination table while wearing gym shorts or similar clothing that exposes your knees and ankles. We will only test the ankle of your dominant limb.

The 2 passive orthopedic tests of ankle ligament laxity that we will perform with the help of the arthrometer are the:

3. **Anterior drawer test** – primarily tests the anterior talofibular ligament (ATF)
4. **Inversion talar tilt test** – primarily tests the calcaneofibular ligament (CF)

Your dominant ankle will be placed in different positions and angles with each of these tests. A “test” will consist of using the arthrometer to apply a safe, controlled amount of loading on your ankle ligaments, ranging from 1 up to 35 pounds of force. Each test will be repeated 4 times during each data collection session.

**What are the benefits of being in the study?**

There are minimal benefits associated with participation in this study. However, you will also learn about the amount of laxity and stability in your knee and ankle joints and knowledge of the LigMaster™ Multi-Joint Arthrometer.

**What are the risks of being in this study?**

There are few minor risks or possible discomforts associated with participation in this study. You may experience mild joint discomfort or soreness after the arthrometer testing. To guard against this occurrence, we are using standard clinical orthopedic tests for the knee and ankle ligaments as approved by the American Medical Association (AMA) and the American Academy of Orthopaedic Surgeons (AAOS).

**What if you are hurt in this study?**

Please be advised that medical treatment is available upon the event of physical injury resulting from the study. Medical treatment will be limited to first aid and ice. In the event that you sustain an injury needing medical treatment beyond that of first aid and ice, you will need to seek appropriate medical attention. Texas State University students may choose to go to the Student Health Center free of charge. Please call 512-245-2161 to schedule an appointment or speak to a health care provider at the Student Health Center. We will report any adverse events per institutional policy. In the event that you believe you have suffered injury not apparent immediately after testing, please contact the IRB chairperson Dr. Jon Lasser at 512-245-3413, who will review the matter with

you and identify any other resources that may be available to you.

**Will you be compensated/helped for being in this study?**

If you qualify for participation in this study, you will receive a \$20 Wal-Mart gift card if you complete all aspects of the study.

**Who funds the study?**

The study is being partially funded by a \$500 Graduate Student Research Grant sponsored by Texas State University's College of Education.

**Who will see your information?**

Your participation in this study is confidential. Only the investigators will have access to your personal identifiers and to any information that may be linked with your identity. All information that you provide will be assigned an identification number rather than your name to ensure your confidentiality. All electronic data will be stored in a locked cabinet in Texas State University's Biomechanics/Sports Medicine Laboratory for up to three years following the conclusion of this study before being destroyed. In the event of this study being published, none of your personal identifying information will be disclosed.

**If you want to know about the results before the study is done:**

We cannot disclose any information to you until the end of the duration of the study and the results have been analyzed. After that point in time, we will be happy to discuss your individual results with you. You may also ask any questions you may have regarding the overall findings of this study.

**Right to ask questions:**

You may ask questions about the research procedures at any time and will receive immediate responses. If you have any further questions, please direct these to the graduate student researcher, Jye Shuang Ng at [shuang99186@txstate.edu](mailto:shuang99186@txstate.edu) (mobile phone: 903-752-9064) or Dr. Rod Harter at [rod.harter@txstate.edu](mailto:rod.harter@txstate.edu) (office phone: 512-245-2972).

**Principal Investigator:**

JyeShuang Ng, ATC, LAT, CES  
Graduate Student Researcher  
Department of Health and Human Performance  
B128 Jowers Center  
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**Co-Principal Investigator:** Rod Harter, PhD, ATC, LAT, FNATA  
Professor of Athletic Training  
Department of Health and Human Performance  
A132 Jowers Center  
San Marcos, TX 78666  
[rod.harter@txstate.edu](mailto:rod.harter@txstate.edu)  
512-245-2972

**Voluntary Participation:**

Your participation in this study is completely voluntary. You may withdraw from this study at any time without any negative consequences from anyone associated with the study.

**What if you have a concern about a study?**

This project [IRB #2014J6451] was approved by the Texas State IRB on June 15, 2015. Pertinent questions or concerns about the research, research participants' rights, and/or research-related injuries to participants should be directed to the IRB chair, Dr. Jon Lasser (512-245-3413 - [lasser@txstate.edu](mailto:lasser@txstate.edu)) and to Becky Northcut, Director, Research Integrity & Compliance (512-245-2314 - [bnorthcut@txstate.edu](mailto:bnorthcut@txstate.edu)).

**What does your signature mean?**

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you understand the information given to you about the study and in this form. If you sign the form it means that you agree to join the study pending eligibility.

**You will be given a copy of this consent form for your records.**

\_\_\_\_\_  
Participant Name (please print in all caps)

\_\_\_\_\_  
Participant Signature

\_\_\_\_\_  
Date

I, the undersigned, verify that the above informed consent procedure has been followed.

\_\_\_\_\_  
Investigator Signature

\_\_\_\_\_  
Date

## REVIEW OF LITERATURE

### Introduction

According to recent NCAA injury surveillance data, lower extremity injuries account for 54% of all injuries in games and practices, respectively.<sup>1</sup> An average of 313 anterior cruciate ligament (ACL) injuries per year and an average of 1,688 ankle ligament sprains were reported over a 16-year period of NCAA collegiate sports seasons.<sup>1</sup> Similarly, a survey showed that ankle injuries account for 70% of total injuries and ACL injuries account for 22% among 246 elite women basketball players.<sup>2</sup>

Clinicians frequently employ manual orthopedic tests such as the Lachman test, posterior drawer test on the knee, varus and valgus stress test, ankle anterior drawer test, and inversion talar tilt test to determine the severity of the knee and ankle sprains and their mechanical properties. However, the results of these manual orthopedic special tests are highly inconsistent, and based on clinician's skill and wide range of force that is applied.<sup>3,4</sup> In addition, the manual orthopedic special tests often lack of objectivity such as the grading of the ligaments, the position or the joint angle during testing, and the accuracy of estimation of the displacement.<sup>5</sup> One recent systematic review reported the intrarater and interrater reliability of the Lachman test for anterior cruciate ligament (ACL) tear ranged from fair to nearly perfect (Cohen's kappa = 0.22-1.00) and slight to nearly perfect (Cohen's kappa = 0.02-0.81), respectively.<sup>4</sup>

Only one *in vivo* study has reported a poor interrater reliability of four ankle orthopedic tests. The ICC value ranged between 0.06 and 0.33 for the anterior drawer in supine, anterior drawer in crook lying, talar tilt and inversion tilt.<sup>6</sup> On the other hand, *in vitro* study has shown excellent intrarater reliability and fair-to-good interrater reliability

the anterior drawer test (ICC= 0.94 and 0.54 respectively for the anterior drawer test).<sup>7</sup>

### **Biomechanics of the Knee**

Orthopedic special tests or examination have been using by clinicians to assess the laxity of joints. Noyes et al explained that a stability of a joint is consisted of ligaments and capsular structures to “work as a system, interdependent and related one to another.”<sup>8</sup> A concept of primary and secondary restraints of ligaments was described in Noyes et al paper to assist the clinicians accurately interpret results the orthopedic special tests.<sup>8</sup> Biomechanical studies have clarified that only one or two ligaments deliver the primary restraint for each place of knee stability and the other ligaments provide the secondary restraint.<sup>8</sup> Both the primary and secondary restraints cooperate to stabilize the joints and resist an external force.<sup>8</sup> When a primary ligament restraint is lost or rupture, the weaker secondary ligament restraint will play the role of resisting the external force.<sup>8</sup> The secondary ligament is not designed for resisting the same amount of force as the primary ligament.<sup>8</sup> As the result, the laxity of the joint is increased and the orthopedic special test will become more positive.<sup>8</sup>

**Anterior Stability.** Butler et al tested primary and secondary ligament restraints to anterior-posterior motion in fourteen human knee.<sup>9</sup> Butler et al concluded that ACL is the primary restraint to anterior stability of the knee.<sup>9</sup> At 90° knee flexion, the ACL provided 85.1% of restraining force to the anterior translation of the tibia whereas 87.2% at 30° knee flexion.<sup>9</sup> Secondary ligament restraints for anterior stability are iliotibial track and band, middle medial capsule, middle lateral capsule, medial collateral ligament (MCL) and lateral collateral ligament (LCL).<sup>9</sup> The iliotibial band provided 24.8% of anterior resistance while middle lateral capsule and middle lateral capsule have provided

22.3% and 20.8%.<sup>9</sup> The MCL and LCL contributed 16.3% and 12.4%, respectively.<sup>9</sup>

**Posterior Stability.** The posterior cruciate ligament (PCL) is the primary ligament restraint to posterior translation of the tibia on the femur.<sup>10</sup> The PCL provided 90% to 95% of the resistance to posterior translation at 30° and 90° knee flexion. No other structures contributed more than 2% of total restraint.<sup>9</sup> Posterior lateral capsule and popliteus tendon (58.2%) and MCL (15.7%) provided the greatest force as the secondary restraint.<sup>9</sup> Other secondary ligament restraints were the posterior medial capsule (6.9%), LCL (6.3%) and middle medial capsule (6.2%) that contributed less posterior restraint.<sup>9</sup>

**Medial Stability.** The MCL is the primary ligament resist valgus displacement with knee and provides the medial knee stability.<sup>11</sup> Grood et al indicated the MCL contributed 57.4% of total valgus stress at 5° knee flexion and 78.2% at 25° knee flexion. ACL and PCL in combination were the majority of the secondary ligament restraint and they provided total 14.8% of total valgus stress at 5° knee flexion and 13.4% at 25° knee flexion.<sup>11</sup> Anterior, middle and posterior parts of the medial half of the capsule were other secondary restraints contributed 25.2% of total valgus stress at 5° knee flexion and 7.6% at 25° knee flexion.<sup>11</sup> This explains that the role of MCL becomes important as the knee flexion increases.<sup>11</sup>

**Lateral Stability.** The LCL is the primary ligament resist varus displacement with knee and provides the lateral knee stability.<sup>11-13</sup> The LCL contributed 54.8% of total varus stress at 5° knee flexion and 69.2% at 25° knee flexion. ACL and PCL in combination were the majority of the secondary ligament restraint and they provided total 22.2% of total varus stress at 5° knee flexion and 12.3% at 25° knee flexion.<sup>11</sup> Anterior, middle and posterior parts of the medial half of the capsule contributed 17.2% of total

valgus stress at 5° knee flexion and 8.8% at 25° knee flexion at part of the secondary restraint structures.<sup>11</sup>

### **Biomechanics of the Ankle**

Bahr et al evaluated the ATF and CF ligaments forces changes during the anterior drawer and talar tilt test and ankle joint motion during the test and repeated with an isolated lesion of the ATF ligament or a combined lesion of the ATF and CF ligament on eight cadaver specimen.<sup>14</sup> The test was repeated at 10° dorsiflexion, neutral, and 10° and 20° plantar flexion. Bahr et al found out that when the ATF and CF ligaments were intact, the ATF ligament had the greatest forces increased at 20° plantar flexion whereas the CF ligament has biggest forces increased at 10° dorsiflexion during the anterior drawer test.<sup>14</sup> Similarly, during the talar tilt test, the ATF ligament had the greatest forces changes at 20° plantar flexion and the CF ligament at 10° dorsiflexion.<sup>14</sup> When the both ligaments had been cut, the joint motions were significantly increased including anterior translation, internal rotation and supination at all flexion angles during the both tests.<sup>14</sup> The results indicated that the best position to detect an ATF ligament injury is in plantar flexion whereas a CF ligament injury is in dorsiflexion. A previous biomechanics study also supported the ankle motions were increased without those ligaments<sup>15</sup> and the other study suggested that the ankle in plantar flexion is the best position to detect the ATF ligament injury.<sup>16</sup>

However, other studies have shown that detecting the ATF ligament injury was greater in dorsiflexion than plantar flexion.<sup>17,18</sup> Bahr et al explained that those biomechanics studies have controversial findings could be individual variations in ligament orientation on the cadaver specimen and it is impossible to create a universal

reference of the best flexion angles for testing.<sup>14</sup>

### **Knee Orthopedic Special Tests**

**Lachman Test.** There are several special tests to assess anterior instability of the knee. John W. Lachman, MD, Chairman and Professor of Orthopedic Surgery at Temple University had taught a simple and reliable clinical test to indicate ACL instability which was first described by Joseph S. Torg and colleagues.<sup>19</sup> The Lachman test is performed as a patient lying on their back and the examiner hold the patient's knee between full extension and 15° flexion. The femur is stabilized with one hand while the one hand applies firm pressure anteriorly to the posterior aspect of the proximal tibia.<sup>19</sup> Torg believed that testing the disruption of the anterior cruciate ligaments with the knee held between 0° and 15° was reliable after examining 250 injured knees in athletes.<sup>19</sup> A positive test indicating the ACL injury for the Lachman test is a proprioceptive and/or visible anterior translation of the tibia beyond the femur with a “mushy” or “soft” endpoint.<sup>19</sup> The positive test may indicate other structures have some degree of injured: posterior oblique ligament and arcuate-popliteus complex.<sup>19,20</sup> In contrast, the “hard” endpoint indicates the ACL is intact.<sup>19</sup>

Holding the knee in 30° flexion is common as performing the Lachman test nowadays. Butler et al applied anterior-posterior force to cadaveric knee specimens and concluded that the ACL is the primary restraint to anterior translation of the tibia.<sup>21</sup> At 90° knee flexion, the ACL contributed 85.1% of restraint force to the anterior translation of the tibia whereas 87.2% at 30° knee flexion.<sup>21</sup> Similarly, *in vivo* study showed that the ACL sustained larger strain at 30° than 90° knee flexion when applying anterior force.<sup>22</sup> A study has reported that almost 100% positive result of the Lachman test on the patients

under anesthesia and 80% on the patients without anesthesia compared to the anterior drawer test (90° knee flexion) just has 50% positive result on the patients under anesthesia and 10% on the patients without anesthesia.<sup>23</sup>

**Posterior Drawer Test.** The origin of the posterior drawer test was unclear and it is one of the tests to assess posterior instability of the knee. This test has 90% sensitivity and 99% specificity for evaluating PCL.<sup>24</sup> This test is almost the same as the anterior drawer test. The examiner places both hands on the anterior aspect of the proximal tibia with the thumbs lying on the anterior joint line of both the medial and lateral compartments. The anterior force is applied to the proximal tibia with the patient lying on their back and knee flexes at 90° for the anterior drawer test. Instead, a posterior force is applied to the proximal tibia for performing the posterior drawer test.<sup>24</sup> Posterior translation and the quality of the end point are the guidelines for distinguishing a posterior drawer test. A grade I PCL injury was discussed as “increased posterior tibial displacement but the tibia not being flush with femoral condyles”.<sup>25</sup> A grade II PCL injury was “the posterior tibial displacement was flush with femoral condyles”.<sup>25</sup> A grade III PCL injury was “the anterior tibia was subluxated posterior to the anterior surface of the femoral condyles”.<sup>25</sup> A “firm” endpoint may return after two weeks of PCL injuries as other intact structures starts supporting.<sup>24</sup> The positive test may indicate other structures have some degree of injured: posterior oblique ligament, ACL and arcuate-popliteus complex.<sup>20</sup>

**Valgus Stress Test.** The valgus stress test is used to evaluate the medial instability of the knee. The procedures of this test are the patient lying on their back and the examiner places one hand over the lateral aspect of the knee and stabilizes the ankle

with the other hand.<sup>24,20</sup> A valgus force is applied by the hand on the lateral aspect of the knee.<sup>24,20</sup> This test can be done at knee extension and knee flexion between 20° and 30°. <sup>20</sup> One study reported this test has sensitivity of 86% with medial collateral ligament (MCL) tears.<sup>24</sup> The positive test for this test is “the tibia moves away from the femur an excessive amount when a valgus stress is applied”.<sup>20</sup> When the test is positive at knee extension, the following structures might be injured to some degrees: medial collateral ligament (superficial and deep fibers), posterior oblique ligament, posteromedial capsule, ACL, PCL, medial quadriceps expansion and semimembranosus muscle.<sup>20</sup> On the other hand, the positive test at knee flexion between 20° and 30°, the following structures might be injured to some degrees: MCL, posterior oblique ligament, PCL and posteromedial capsule.<sup>20</sup> The grading for the valgus stress test integrate with the amount of medial joint opening and the quality of the ending point.<sup>24</sup> A grade I is defined as the knee joint opens 5 mm or less and a solid endpoint.<sup>24</sup> A grade II is defined as a knee joint opens 6 mm to 10 mm with a good endpoint and a grade III has a more than 10 mm of a knee joint open and a soft endpoint.<sup>24</sup>

**Varus Stress Test.** The varus stress test is used to evaluate the lateral instability of the knee and mainly detect lateral collateral ligament (LCL). The procedures of this test are similar to the valgus stress test. Instead, the examiner places one hand over the medial aspect of the knee and stabilizes the ankle with the other hand.<sup>20, 24</sup> A varus force is applied by the hand on the medial aspect of the knee. The positive test for this test is “the tibia moves away from the femur an excessive amount when a varus stress is applied”.<sup>20</sup> This test also can be done at knee extension and knee flexion between 20° and 30° and same positive test as the valgus stress test. When the test is positive at knee

extension, the following structures might be injured to some degrees: LCL, posterolateral capsule, arcuate-popliteus complex, biceps femoris tendon, PCL, ACL, lateral gastrocnemius muscle and iliotibial.<sup>20</sup> On the other hand, the positive test at knee flexion between 20° and 30°, the following structures might be injured to some degrees: LCL, posterolateral capsule, arcuate-popliteus complex, iliotibial band and biceps femoris tendon.<sup>20</sup> The grading system is the same as the valgus stress test. No sensitivity and specificity has been assessed.

### **Ankle Orthopedic Special Tests**

**Ankle Anterior Drawer Test.** This is mainly designed to detect anterior talofibular (ATF) ligament. When the patient lying on their back, the examiner stabilizes the tibia and fibula, grasps the patient's foot in 20° of plantar flexion and draws the talus forward in the ankle mortise.<sup>20</sup> The positive test of this test is an increased anterior translation of the ankle and it indicates a tear of ATF ligament. If the anterior translation is greater, ATF ligament and calcaneofibular (CF) ligament are torn.<sup>20</sup>

**Inversion Talar Tilt Test.** This is mainly designed to detect CF ligament. The patient can be either lying back or side lying position with foot relaxed. The examiner cups the patient's heel and applies inversion force with the other hand holds mid foot to move the ankle into inversion.<sup>6</sup> The positive test is the inversion degree of the testing ankle is greater than the normal ankle and indicates the injury of CF ligament.<sup>20</sup>

### **Biomechanics of the Ligamentous Stress-Strain Curve**

Strain is described as “the deformation per unit length of a ligament” whereas stress is described as the load per unit cross-sectional area of a ligament.<sup>26</sup> A stress-strain curve shows how the ligament can be stretched as the load increases.<sup>26</sup> The stress-strain

curve for a ligament is nonlinear and it has two regions.<sup>26</sup> The first region is the nonlinear region.<sup>26</sup> The second region is “the stress is linearly proportional to the strain and the slope of this region is called the Young’s (tangent) modulus or stiffness” and the line is linear.<sup>26</sup> A higher Young’s modulus or slope can indicate several meanings: the ligament contains stiffer material, more collagen per unit area or collagen fibrils have larger diameters.<sup>26</sup> Almost all biomechanics studies especially ligaments have used this stress-strain curve to represent the stiffness of the ligament. However, Rijke et al had described the graded stress radiography technique (force against strain) which uses in the LigMaster™ arthrometer to detect the “stiffness” of the joint.<sup>27</sup> This study had used modified KT-1000 to calculate the stressed ligament using the formula  $F = G(\alpha - 1/\alpha^2)$  which the force F, applied to the ligaments,  $\alpha$  is  $l/l_0$ , the ratio of the lengths of the stretched (l) and unstretched ( $l_0$ ) ligaments.<sup>27</sup> The proportionality factor G represents the ‘equivalent’ elastic modulus. As the ACL is injured, the value of G will be decreased and the “stiffness” (slope) of the ligament will be less compared to the healthy ligament.<sup>27</sup>

### **Knee and Ankle Joint Arthrometry**

Orthopedic researchers have long been working to develop and ultimately market mechanical devices known as *arthrometers* that utilize protocols that standardize the joint position(s) and load(s) applied to accurately measure joint laxity and mechanical stiffness.

**Knee Joint Arthrometry.** Researchers have been developing a machine or apparatus that test knee laxity and stiffness accurately especially testing ACL in the past forty years. Markolf et al. used a modified dental chair to measure anterior-posterior force-versus-displacement on forty nine subjects with no previous history of knee injury at 0, 20 and 90 degrees knee flexion.<sup>28</sup> This was the clinically instrument at the University of California-Los Angeles (UCLA). They reported that the greatest laxity was shown when placing the knee at 20 degrees.<sup>28</sup> Similarly, Markolf had conducted other study which tested patients with the anterior cruciate ligament deficient and their healthy knees and establish the protocol of testing ACL clinically.<sup>29</sup> The authors have the patients in 20 degrees and 90 degrees knee flexion with the Velcro strap on the tibia, four-point fixation pads and the foot was tied to the foot-plate.<sup>29</sup> Force was applied to the tibia during the experiment. The result reported that the knee without the ACL has greatest anterior-posterior laxity and less anterior stiffness at 20 degrees of flexion.<sup>29</sup> In addition, low level of force (100N or less) was the best to test the stiffness changes.<sup>29</sup> This knee flexion position is used in Lachman test which has higher sensitive in detecting a torn ACL than the anterior drawer test at 90 degrees knee flexion.<sup>19</sup>

A knee joint arthrometer known as the KT-1000 (MEDmetric Corp., San Diego, California) was developed later by Malcom, Daniel, Stone, and Sachs.<sup>30</sup> The KT-1000 was used initially to measure tibial translations by applying forces on tibial tubercle at  $20 \pm 5$  degrees at knee flexion.<sup>31</sup> The device emitted different audible tones when anterior and posterior loads of 68 Newton (N) and 90N were applied with a force-sensing handle with the knee positioned different angles of knee flexion. The authors measured the normal knee anterior laxity on subjects' with acute ACL disruption and reported  $7.2 \pm 1.9$

mm under 89 newton.<sup>31</sup> On the same year, same authors had modified the KT-1000 to KT-2000 with a graphic documentation via an X-Y plotter which could observe the tibial displacement as applying the force.<sup>32</sup> The KT-2000 measured tibial translations by applying forces on tibial tubercle at  $20 \pm 5$  degrees at knee flexion on human subjects and thirty-three cadaver specimens.<sup>32</sup> In *vitro* study, the anterior displacement on the cadaver specie was  $5.8 \pm 2.7$  millimeters (mm) under 89 newton force.<sup>32</sup> In *vivo* study, the anterior displacement on the normal human subjects was  $5.8 \pm 1.9$  and  $5.5 \pm 1.8$  mm under 89 newton force on their left and right knee respectively.<sup>31</sup> The authors reported that the knees without ACL have more than 2 millimeter anterior displacement than the knee with ACL.<sup>31</sup> Several studies have replicated Daniel et al. (1985)'s study and some of them compared KT-1000 to other knee joint arthrometer.

The Genucom Knee Analysis System (FARO Medical Technologies Inc, Montreal, Canada) is the other common commercial knee joint device that measured knee laxity in 6 degrees of freedom in the 1990s. This complex computerized device is made up of an electrogoniometer for measuring the knee displacement and a 6-component force dynamometer for measuring the force and moments applied to the knee.<sup>33</sup> It tested on one hundred subjects with some kind of knee injury and measured the laxity on the 90 degrees anterior-posterior (AP) drawer, the 30 degrees (AP) and the varus/valgus stress test. The authors revealed that.

At approximately the same time, the Stryker Knee Laxity Tester (Stryker, Kalamazoo, Michigan) also became commercially-available. This device is less complicated than the KT-1000 or the Genucom arthrometers.<sup>34</sup> The Stryker Knee Laxity Tester measured the anterior-posterior displacement of the tibia relative to the femur.<sup>34</sup>

This device had a bar that was applied to the front of the tibia by two elastic straps and pillars with 4 cm apart.<sup>35</sup> A plunger that was perpendicular to the bar contained a piston was preloaded on the patella.<sup>35</sup> Studies have been done to establish the reliability of those knee joint arthrometers and only the KT-1000 knee joint arthrometer has provided the best reliability among the knee joint arthrometer (ICC interrater = 0.65 to 0.92, ICC intrarater = 0.46 to 0.84).<sup>35</sup>

**Ankle Joint Arthrometry.** Before a portable instrumented ankle arthrometer was invented, clinicians who wanted objective assessment of the severity of ankle ligament injury used a Telos (Telos, Marburg, Germany) positioning apparatus during stress radiographs.<sup>36</sup> The Telos apparatus is a primarily stabilizer and it has a pressure actuator that provide a gradual force to the ankle joint during stress radiographs.<sup>36</sup> The stress radiographs is a common tool for examining the severity of ligament laxity.<sup>36</sup> However, the accuracy of the stress radiograph is controversial. Some studies have more than 50% agreement on ankle ligament laxity between stress radiographs and surgical observation.<sup>37,38</sup> However, other studies indicated that the stress radiographs could detect less than 50% of ankle ligament laxity as compared to arthrography, clinical examination and MRI imaging.<sup>39,40</sup> Only one study has investigated the reliability of the ankle anterior drawer test and inversion talar tilt test. The interrater reliability for the talar tilt test and anterior drawer test were ICC of 0.86 to 0.92 and 0.73 to 0.87, respectively; the intrarater reliability for the talar tilt test and anterior drawer test were ICC of 0.78 and 0.95, respectively.<sup>41</sup>

A first portable, commercially-available instrumented ankle arthrometer, the Hollis Ankle Arthrometer (Blue Bay Research Inc., Navarre, FL) was invented and

described in 1995 to investigate laxity at the ankle joint.<sup>42</sup> This ankle arthrometer features a 6-degrees-of-freedom spatial kinematic linkage, an adjustable plate fixed to the foot, a load-measuring handle attached to the footplate through which the load is applied, and a reference pad attached to the tibia.<sup>43</sup> Hollis's study has indicated that different flexion angle and ankle ligaments sectioned could affect the motion and laxity of the ankle and subtalar joint.<sup>42</sup> Subsequently, the measurement reference position has been defined to the ankle was positioned at zero anteroposterior (AP) load and zero inversion-eversion (I-E) moment at a neutral (0 degrees) flexion angle and researchers have used it to study the ankle joint laxity.

Kovaleski et al were the first *in vivo* study to establish the reliability of the portable instrumented ankle arthrometer at three different forces. The intraclass correlation coefficients (ICC) for intrarater reliability of AP displacement and I-E rotation ranged from 0.82 to 0.89, and from 0.86 to 0.97, respectively.<sup>44</sup> Similarly, few studies also showed the high intrarater and intertester reliability of the Hollis Ankle Arthrometer; intrarater reliability of AP displacement and I-E rotation were .91 and .99 in Hubbard's study<sup>45</sup> and .97 and .82 in the Kovaleski study.<sup>46</sup> These findings suggest that the Hollis Ankle Arthrometer could be the suitable and reliable diagnostic tool for examining lateral ankle ligament laxity.<sup>45,46</sup>

### **LigMaster™ Instrumented Arthrometry**

The LigMaster™ (Sports Tech, Charlottesville, VA) is a relative new multijoint arthrometer that can be used to evaluate the ankle, knee, elbow and shoulder joints.<sup>47</sup> This device is a modification of the Telos apparatus that includes an electronic sensor and used in the evaluation of the mechanical properties of the joints without the use of stress

radiographs. In addition, the LigMaster<sup>TM</sup> used the graded stress technique to show the force-displacement data that to produce a plots of applied force against induced strain, rather than stress against strain.<sup>27</sup> Only three studies investigated the mechanical properties of tibiofemoral joint in slope values. First study was to test whether the bilateral medial tibiofemoral joint stiffness would be greater in full knee extension or 20 degrees of knee flexion. As the result, the slope value was greater in full knee extension (left  $15.8 \pm 3.1$  N/mm; right  $16.1 \pm 3.3$  N/mm) than 20 degrees of knee flexion (left  $11.7 \pm 2.8$  N/mm; right  $12.2 \pm 3.1$  N/mm) and no difference between both limb.<sup>48</sup> To extend the first study, second study has been conducted to exam the slope value at 0, 5, 10, 15 and 20 degrees knee flexion angle. Authors reported that the slope value at 0 degrees was 17.62. This indicated that different degrees of knee sagittal motion involves different medial tibiofemoral joint structures that affect the knee joint stiffness.<sup>49</sup> Her third studies was about investigating the medial tibiofemoral-joint stiffness across the lifespan in gender. The authors compared the slope value at three different age groups and at knee extension and 20 degrees knee flexion. Results have revealed that ligament stiffness was no significant difference between genders.<sup>50</sup> However, children have less medial tibiofemoral-joint stiffness than younger adults and older adults.<sup>50</sup>

Similarly, only one study established the intrarater and intertester reliability of the LigMaster during anterior drawer testing and talar inversion test of the ankle joint. Results have shown that the intrarater reliability of talar inversion test was 0.74 and anterior drawer test was 0.64 whereas the intertester reliability of talar inversion test was 0.76 and anterior drawer test was 0.81.<sup>51</sup>

## Summary

The review literature has specifically focused on the history of joint arthrometers in the past thirty years, description of the knee and ankle special test and the biomechanics of the knee and ankle joint. Each topic in this review literature provided the valuable knowledge to understand the purpose of designing the joint arthrometer. The joint arthrometer can be a reliable tool to assess objectively the laxity joint especially after surgically repair. The LigMaster<sup>TM</sup> was the focus of this study and its reliability was conducted.

The outcomes of this study could provide valuable information to know the reliability of the LigMaster<sup>TM</sup> for the Lachman test, posterior drawer test, valgus and varus stress test at the knee and ankle anterior drawer test and inversion talar tilt test at the ankle. Unlike other joint arthrometers, the LigMaster<sup>TM</sup> is a multijoint arthrometer that can be used to evaluate the ankle, knee, elbow and shoulder joints. However, only three knee studies and two ankle studies using the LigMaster. This study provided significant information regarding the intrarater reliability of this device.

This was a first study examining the reliability of the LigMaster<sup>TM</sup> for the Lachman test, posterior drawer test, valgus and varus stress test at the knee and ankle anterior drawer test and inversion talar tilt test at the ankle. Therefore, this paper will provide the crucial information about the value of this unit and may bring some attentions from other researchers to conduct more studies.

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