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TECHNICAL REPORT

Reliability and Validity of an Innovative Device for ACL Testing: The Mobil-Aider™

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Knee disorders prevalence is estimated at more than 50% in a lifetime. There are approximately 250,000 to 300,000 anterior cruciate ligament (ACL) injuries per year in the United States. There are over 175,000 ACL reconstructions annually. Athletes involved in high-demand sports have an increased risk of ACL injuries. Sports such as football, basketball, soccer, gymnastics, tennis, and skiing have been reported to elevate the risk of ACL injury. This study was a double-blinded design to establish the reliability and validity of a new orthopedic device to measure linear translation of the tibia on the femur (ACL testing). ***Methods:*** A Zeiss Smartzoom microscope was used as the gold standard to assess the ability of the Mobil-Aider™ to measure linear translation. Sixty blinded measures were taken with each of 6 different devices. ***Results:*** Both the intraclass correlation and the Pearson correlation were .986, indicating a strong correlation between the measures. The Cronbach alpha reliability analysis was 0.992. Independent 1-sample *t* tests were performed on the differences between the Mobil-Aider™ and the Zeiss values, and were not found to be significant ($P = .42$). This indicates the measures were not statistically different, that is, they are the same. Bland–Altman plot and a linear regression revealed no propositional bias. Finally, with 360 measures over 6 devices, the power of this study was calculated to be 100%. ***Discussion:*** The data collected in this study are the first step in establishing reliability and concurrent validity of a new device. As a result of the current data, the Mobil-Aider™ device is deemed a promising orthopedic tool for use in assessing the laxity of the ACL. Additional testing will need to be performed on both healthy and injured knees to assess the clinical value. Testing on humans is planned. ***Conclusions:*** At this time, clinical relevance is limited. Given the current results, there is potential for the Mobil-Aider™ to contribute to the assessment of ACL injuries, but additional human testing is needed.

Keywords: ACL injury, knee examination, knee stability testing

The prevalence of knee disorders is estimated at more than 50% in a lifetime.[1,2] There are approximately 250,000 to 300,000 anterior cruciate ligament (ACL) injuries per year in the United States.[2,3] There are over 175,000 reconstructions annually.[2,3] Athletes involved in high-demand sports have an increased risk of ACL injuries. Sports such as football, basketball, soccer, gymnastics, tennis, and skiing have been reported to elevate the risk of ACL injury.[2]

Although clinicians use a variety of examination techniques to assess the ACL,[1] there are 3 widely accepted clinical tests: anterior drawer, Lachman, and pivot shift.[1,4–9] These tests involve linear translation of the tibia on the femur. Meta-analysis and systematic reviews reported that these 3 tests have a wide range of diagnostic accuracy.[10,11] Individual modifications of the tests with varying degrees of tibial rotation and the magnitude of examiner experience have been reported to influence test accuracy.[12,13] The Lachman test is performed in the supine position with the knee in ~20° of flexion. Whether the test results are interpreted as dichotomous (positive = torn and negative = intact) or graded (grades I, II, and II), there is a subjective element to the data.[13,14] The clinician relies on the subjective assessment of end feel and being able to determine millimeters of translation to assign a grade of I (<5 mm), II (5–10 mm), or III (>10 mm).[14]

A study by Makhmalbaf et al[5] reported the sensitivity of the Lachman test to be 93.5% with a significant difference between men and women (66.7% vs 94.6%). A study by Guillodo et al[15] found the misdiagnosis of acute ACL injuries by emergency room physicians to be 74%. There are many reasons for these statistics. When there is a mismatch between the girth of the patient's leg and the size of the clinician's hand, it can be very challenging to perform a Lachman test. If the patient's knee is in too much flexion or if the hamstring musculature is not relaxed, false-negative results may be obtained. Furthermore, asymmetry in side-to-side laxity or a soft end point is considered abnormal. Even for the most experienced clinician, a criterion of 3 to 5 mm is extremely challenging to quantify by "feel." Having an instrument to quantify the linear translation of this ligament would be very valuable.[13,14]

Magnetic resonance imaging (MRI) is often used for ACL injury diagnosis.[3] However, an MRI is a static image and is best used in conjunction with instrumented laxity devices to assess biomechanical behavior.[16] Furthermore, the ability of MRI to identify partial ACL tears has been called into question.[17] Over the past 3 decades, there have been a few instruments reported to be able to assess ACL laxity. However, all of the devices have been met with challenges. The Hall effect strain transducer was implantable.[18] The Rottometer was a computer-assisted goniometer used to measure rotation of the tibial axis.[19] The Vermont knee laxity device was very bulky and required a significant amount of time to utilize.[20] The Lars rotational laxiometer was dependent on too many variables.[21] The Kinematic Rapid Assessment requires Bluetooth technology to measure acceleration of the tibia on the femur.[22] The Telos is used in conjunction with radiographs.[23–26] The Vernier dial test indicator has not been validated.[27] The Telos, GNRB, and KT1000/2000 require considerable set-up time and do not involve direct clinician contact with the patient.[28,29] The GNRB sells for $13,800, and the KT1000/2000 is no longer being

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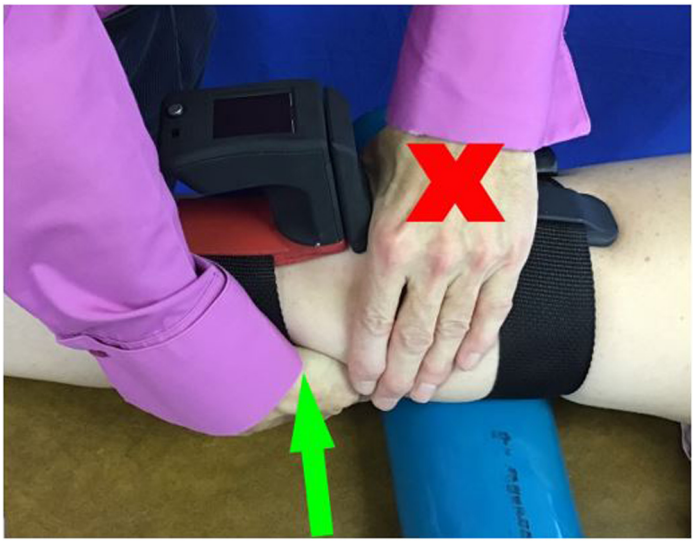

Figure 1 — Lachman test with Mobil-Aider device.

produced (only available through the resale market). Several studies have reported substantial variability in the measures using the KT1000/2000, with a false-negative rate as high as 28%.[27,30] Despite these drawbacks, the KT1000/2000 device did sell because it met an unfulfilled need. Several studies have reported substantial variability in the measures.[27,30–32]

To address this need, the Mobil-Aider™ (Therapeutic Articulations, LLC, Spring City, PA) was developed (Figure 1). The device is lightweight (<370 g; <13 oz) and used to measure linear translation of a joint. When the device is stabilized against the proximal joint surface with the axis aligned with the joint, the distal portion of the device is translated with the distal segment of the body. The device assesses the linear translation and displays it in an LED display in millimeters. The device permits the clinician to interface the device between the patient's skin and the clinician's hands, so there is no need to deviate from the standardized Lachman technique. In fact, the Mobil-Aider™ can even be used to perform a prone Lachman test. The contour of the device conveniently puts the knee in the optimal 20° to 30° knee-flexion position.[9] The nonelastic straps hold the device firmly in place to allow the clinician to attend to the technique and appreciate the qualitative end feel.[33] The LED reading (in millimeters) will allow for right and left comparisons, as well as serial measures of a given knee after surgery or throughout the rehabilitation process. The purpose of this study was designed to establish the reliability and validity of a new orthopedic device to measure linear translation of the tibia on the femur (ACL testing).

Methods

The gold standard used to assess the Mobil-Aider™ was the Zeiss Smartzoom 5 Microscope (Carl Zeiss Microscopy GmbH, Germany). The Zeiss is designed for metallographic analysis; inspection of aerospace, automotive, and electronic components; and device failure analysis. Magnification ranges from 10× to 1011× with coaxial illumination. All data were collected in the University of XXXXXXXXXX clean room. The Zeiss is self-calibrating. The metal measurement devices were positioned in parallel and secured to the Mobil-Aider™. The Mobil-Aider™ was positioned on the Zeiss stage. With the Mobil-Aider™ in focus, a screenshot of the baseline position of the device was obtained and saved as "Baseline1." The Mobil-Aider™ device was translated to a random distance. The translation was revealed on the Mobil-Aider™ LED screen (in millimeters) and recorded on the data sheet. Another Zeiss screenshot was taken and saved as "M1." The Mobil-Aider™ was reset, and the process was repeated for a total of 60× across 6 different serialized Mobil-Aider™ devices. Thus, a total of 360 measures were performed. The images saved from the Zeiss were then reviewed, measured, and recorded on a data collection sheet. At the conclusion of all measurements, the data sheets were matched for Mobil-Aider™ and Zeiss measures. This resulted in all measures being blinded.

Intraclass correlation coefficient and Pearson correlations were performed to determine how strongly the measures of the 2 devices resemble each other. A Cronbach alpha reliability analysis was performed to measure internal consistency (a measure of how well a test addresses different constructs and delivers reliable scores). Independent 1-sample *t* tests were performed to determine if the 2 sets of data were significantly different from each other. A Bland–Altman plot was also generated, and a linear regression was calculated to check for propositional bias. Finally, a power calculation was performed to determine the confidence in the data.

Results

The data analysis was performed with SPSS Statistics 23 software (IBM, Chicago, IL) and began with an intraclass correlation coefficient to measure the association of the measures as pooled means and SDs. Pearson correlation coefficients were calculated because it is deemed the best method of measuring the association between variables based on the method of covariance.[34] The Pearson correlation is a linear index. The correlations ranged from .986 to .997 and demonstrate a strong relationship between the 2 measures, but they do not confirm reliability or validity. Cronbach alpha is a measure of reliability. The analysis was performed on each device, as well as the overall measures of all devices. This was done because the alpha coefficient can be increased by simply increasing the number of items on the analysis. Cronbach alpha was ranged from 0.992 to 0.997. Independent 1-sample *t* tests were performed on the differences between the Mobil-Aider™ and the Zeiss values. This was performed to confirm that the measures were the same, that is, validity. The independent 1-sample *t* test for all devices was not found to be significant at the $P = .05$ level ($P = .42$). This indicates that the measures were not significantly different, that is, they were the same. In addition, the standard error of the mean was calculated because it is a measure of the dispersion of sample means around the population mean. A low value is a positive reflection of the accuracy of the data. A graph of the values is displayed in Figure 2. The Bland–Altman plot (Figure 3) displays the mean difference and the 95% upper and lower confidence limits. No propositional bias was identified. Finally, with 360 measures, the power of this study was calculated to be 100%.

Discussion

The results of this study demonstrate both the reliability and the concurrent validity of the Mobil-Aider™ in a laboratory setting. This is the first step in assessing the clinical viability of any device. The ability to quantify ACL laxity could be a valid component to

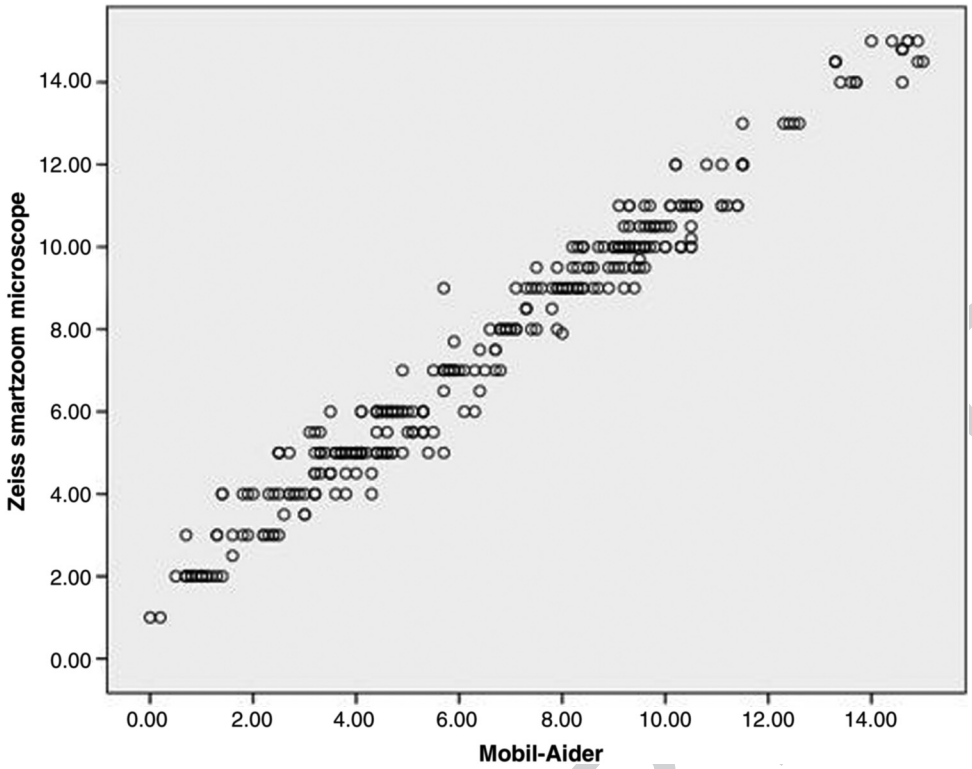

Figure 2 — Scatterplot of the Pearson correlation coefficient.

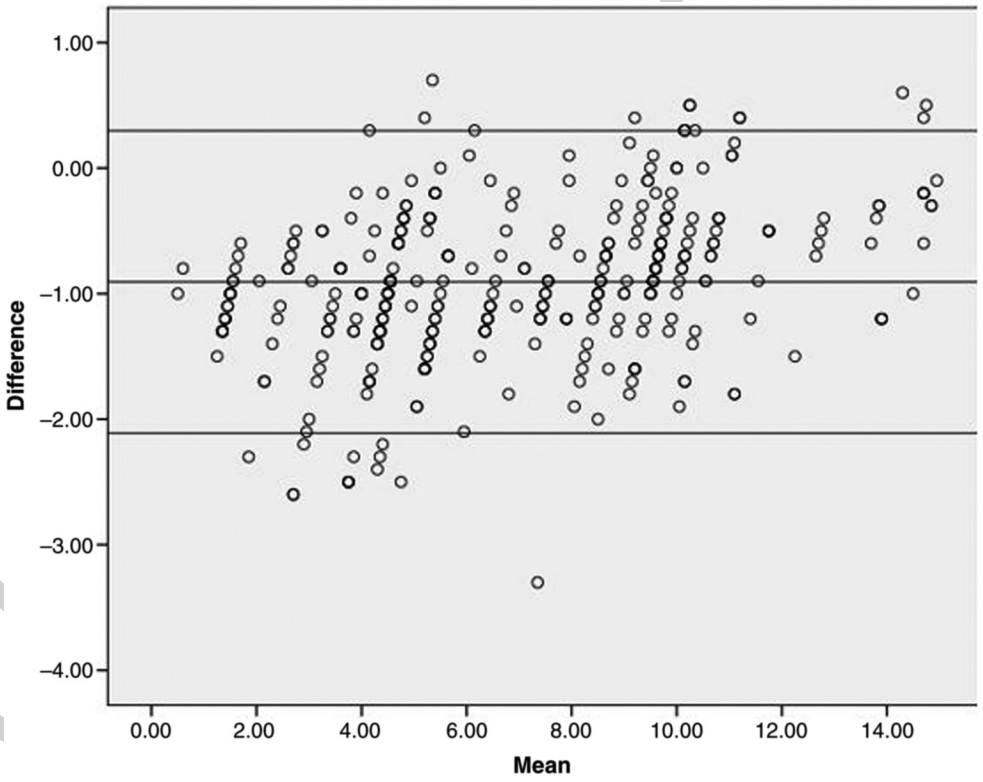

Figure 3 — Bland–Altman plot with 95% upper and lower confidence limits.

assessing the magnitude of an injury. Of course, the Mobil-Aider™ cannot identify the compromised bundles. However, with additional research, one may be able to relate the delta of the linear displacement of the involved versus the uninvolved knee to a grade of injury. Furthermore, the complete assessment of an ACL injury is based on the mechanism of injury, the clinical presentation, and imaging. The mechanism of injury can be contact or noncontact in nature. As the primary restrain to anterior translation of the knee, rapid deceleration, change in direction of movement, and knee hyperextension are just a few of the many ways the ACL can be damaged.[14] People report feeling a popping sensation and experiencing swift swelling with instability.

There are challenges in the clinical testing process: the subjective assessment of the Lachman test, the potential false negative if excessive knee flexion permits the posterior horn of the meniscus to influence anterior linear translation, and the mismatch of the size of the patient's limb to that of the clinician's hand can make translating the tibia on the femur very difficult. In addition, detecting millimeters of excessive translation while firmly grasping the limb can be difficult.

Magnetic resonance imaging is often used for ACL injury diagnosis.[3] These images only provide a "static" assessment of the ACL condition. It does not provide any information about the biomechanical behavior of the ligament or the joint.[16] Furthermore, the ability of MRI to identify partial ACL tears has been called into question by the research of Mikashima,[17] and the imaging process is very expensive.

The KT2000 device was available until 2012 but was large and cumbersome, with the need for 2 additional stabilizing components for proper positioning. The KT2000 used a handle to translate the tibia. The interface between the poorly contoured patella counterforce, the Velcro straps on the femur and tibia, and the handle through which the force was translated all contribute to potential error in the measurements. Several studies have reported substantial variability in the measures using the KT2000, with reports suggesting a false-negative rate as high as 28%.[27,30–32] Despite these drawbacks, the KT1000/2000 device met an unfulfilled need until 2012. Since that time, it is no longer on the market. The desire to address these clinical issues led to the development of the Mobil-Aider™ device to quantify tibial anterior translation with a simple handheld device that mimics the classic Lachman test. The contoured components allow the clinician to be in direct contact with the patient. The ability to provide a quantified, digital readout can provide significant assistance to the clinician assessing the ACL of the involved knee to that of the uninvolved knee.[33]

Conclusions

The data collected in this study are the first step in establishing reliability and concurrent validity of a new device. As a result of the current data, the Mobil-Aider™ device is a promising orthopedic tool for use in measuring the linear translation of the tibia on the femur. Increased anterior translation of the knee may indicate underlying knee pathology, which may include an ACL injury. Additional testing will need to be performed on both healthy and injured knees. This is the next reasonable step.

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Queries

Q1. Per style, 250 words are allowed in Abstract section. Please consider rephrasing abstract section.

Q2. Please check if the keywords inserted are correct.

Q3. Please ensure author information is listed correctly here and within the byline.

Q4. Please provide expansion for "GNRB."

Q5. The sentence “Several studies have reported substantial variability in the measures” has been duplicated (also see the previous sentence beginning “Several studies have reported . . . ”. Can this be removed, with the citation moved to the previous sentence?

Q6. Please provide expansion for "LED."

Q7. Please provide the city name for the manufacturer "Carl Zeiss Microscopy GmbH."

Q8. Please mention name of the university in the sentence “All data were collected. . . .”

Q9. Originally, Refs. 5 and 15 were identical. Hence, the duplicate reference has been removed from the reference list and the subsequent references have been renumbered both in text and in reference list. Please verify.

Q10. Please verify if edits to Ref. 17 are correct.