

Novel Device to Quantify ACL Laxity

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Methods of assessing the ACL

There are approximately 250,000-300,000 anterior cruciate ligament (ACL) injuries per year in the USA. The clinical technique most commonly used to assess the ACL is the Lachman Test. This test is typically performed in a position of 20-30 degrees of knee flexion with an anterior translation of the tibia on the femur. The test is considered positive if the anterior translation of the involved knee is 5 mm greater than that of the uninvolved knee. In addition, a soft or mushy end feel is an indication of the failure of the ACL to limit translation. The end feel is an excellent qualitative parameter but it is most prominent when the ACL is ruptured, i.e. grade III sprain.

What if the ligament is stretched, i.e. grade I or grade II injury? Can clinicians really tell the difference between 4 or 5 mm of translation? To further challenge the assessment, one must be sure the hamstrings are relaxed and the knee is not flexed more than 30 degrees. Failure to do so could stop the translation of the tibia with muscular resistance or block the motion via the posterior horn of the meniscus, respectively. The sensitivity of the Lachman test ranges from 0.63-0.99, while the specificity has been reported to range from 0.42-1.00. Values under anesthesia are significantly better (sensitivity = 0.97; specificity 0.93). Thus, reflecting the influence of hamstring resistance.

Numbers are knowledge

To assist in the quantification of the laxity of the ACL, the KT1000 device was developed (Figure 1). This device positioned the knee correctly but presented different concerns. The uncomfortable counterforce against the patella and the Velcro straps compressing into the soft tissue of the gastrocnemius produced erroneous motion [1-4] have all cast doubt over the accuracy of the KT1000. Several studies have reported substantial variability in the measures with a false-negative rate as high as 28% [1,2,5,6]. The KT has been off the market since 2012. Thus, the ability to quantify the linear translation of the knee continued to be an issue. The Mobil-Aider is a class I exempt FDA cleared device engineered to address this issue.



Figure1: KT 1000.

Validity and reliability are essential

The development of a novel device does not mean it has clinical value. Validity and reliability must be established to use a device to render clinical decisions. The Mobil-Aider (Figure 2) was developed in 2019. It is a custom contoured device weighing 13 ounces and is used in a similar manner as the Lachman test. The device has been funded by a National Science Foundation Phase I and Phase II SBIR grant. To date, several bench studies have been completed using the Zeiss Smartzoom as the gold standard.

The data are as follows:

- Pearson correlation coefficients = 0.986 to 0.997
- The Pearson correlation is a linear index and demonstrate a strong relationship between the two measures but they do not confirm reliability or validity.
- Cronbach's alpha = 0.992 to 0.997. The Cronbach is a measure of reliability.
 - Independent one-sample t-tests was $p = 0.42$. The measures were not significantly different, i.e. they were the same.



Figure 2: Mobil-Aider.

In addition, a case report compared the Mobil-Aider measures with radiographs of the knee when performing a Lachman test. The translation of the tibia on the radiograph measured 6.96 mm while the digital reading of the Mobil-Aider was 7.10 mm. If one accepts the

radiograph as the gold standard in the assessment of osseous measures, the Mobil-Aider was within 2% of that measure. These data have been published in three peer-reviewed journals (Journal of Sport Rehab; International Journal of Sports and Exercise Medicine; Journal of Yoga, Physical Therapy and Rehabilitation). However, that is not enough. Clinical studies need to be conducted. Due to COVID issues, data has only been collected on three individuals but the data is interesting. The numbers of participants need to increase dramatically but one can begin to see our hypothesis developing.

Clinical application

No diagnosis should ever be made with just one sign or symptom. The assessment of the ACL should include mechanism of injury, swelling, range of motion, feeling of “instability” with weightbearing, and clinical testing. The Mobil-Aider is a new device currently undergoing clinical testing. Based on the bench testing, it has the potential to provide an objective measure of the linear translation of the knee to quantify knee laxity. This data may have an impact on the assessment and intervention of ACL injuries.

	Translation of Involved Knee	Translation of Uninvolved Knee	Translation Delta	MRI Results
Patient #1	6.2 mm	5.2 mm	1.0 mm	Intact
Patient #2	9.9 mm	5.9 mm	4.9 mm	Stretched not complete
Patient #3	8.4 mm	4.4 mm	4.0 mm	Torn

Disclosure

The development of the Mobil-Aider device is funded a Phase I and Phase II National Science Foundation SBIR Grant. The author is the CEO of Therapeutic Articulations, LLC. For more information or for interest in participating in clinical testing, please contact Dr. Gulick at info@iortho.xyz

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