

Validation of a Prototype Knee Arthrometer to Gold Standard Arthrometry and Radiographs

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Disclosures: S.J. Shultz: 3B; ArthroLax Solutions, LLC. E. Foli: None. R.J. Schmitz: 3C; ArthroLax Solutions, LLC.

INTRODUCTION: Knee injuries continue to be a growing concern of the physically active resulting in short- and long-term health consequences. Greater knee laxity is a key indicator of anterior cruciate ligament (ACL) size and integrity^{1,2} and predictor of future injury risk.^{3,4} Validated, clinically accessible tools to assess knee joint laxity can support clinician efforts to screen individuals for injury potential (prompting proactive interventions), diagnose ligament injuries, confirm ligament integrity post-surgery and during rehabilitation, and monitor joint health over time. The KT-1000/2000TM has long been considered the “gold standard” for knee arthrometry in the US. However, this device is no longer available, and there has been little innovation in the US since. The GMetric3D (Figure 1; US Patent No. US 12,285,273B2 awarded April 29, 2025) is being developed to address two critical shortcomings of prior devices by: 1) improving limb stabilization to obtain precision measures reflecting true joint motion, 2) optimizing ease of use / training to minimize sources of tester measurement error. The purpose of this laboratory validation study was to establish early proof of concept by assessing absolute agreement between the GMetric3D (technology readiness level 3-4) with gold standard arthrometry and radiographs. Success metrics were set a-priori at ICCs ≥ 0.80 for absolute agreement and ≤ 1.0 mm for measurement error.

METHODS: 18 participants (9F, 23.2 \pm 3.5 yrs, 169.9 \pm 7.3 cm, 67.0 \pm 6.2 kg; 9M, 27.3 \pm 5.9 yrs, 179.2 \pm 9.6 cm, 86.2 \pm 14.2 kg) were measured with the KT-2000TM (Tester 1) followed by the GMetric3D prototype (Testers 1 and 2). Tester 1 was proficient with the KT-2000TM (Intratester reliability ICC \pm SEM, 0.95 \pm 0.55 mm) but novice with the GMetric3D, Tester 2 was proficient with the GMetric3D (Tester 2 Intratester reliability ICC \pm SEM, 0.99 \pm 0.17 mm). Load and displacement measures were obtained from 3 consecutive cycles of posterior (89N) to anterior (130N) directed loads with each device, and anterior tibial displacement (ATD) was defined as the change in displacement from zero baseline to 130N, averaged over the last 2 cycles. While positioned in the GMetric3D, a portable x-ray (OrthoScan Mobile DI Mini C Arm) obtained lateral views of the knee joint under neutral (no load) and a sustained 130N anterior directed load (Tester 2). Measures of absolute (tibial displacement) and relative (tibial displacement – femur displacement) ATD were obtained from sagittal plane digital radiographs using MIPAV software (Intratester ICC \pm SEM: 0.98 \pm 0.50, 0.96 \pm 0.70 mm). Absolute agreement was assessed using Intraclass Correlation Coefficients 2-way random effects models and the average of 2 measurements for comparisons (ICC 2,2). Precision was assessed with the standard error of measurement (SEM). This study was approved by the University Institutional Review Board and informed consent was obtained prior to testing.

RESULTS SECTION: Table 1 provides the means \pm sd obtained from each device and tester, and the absolute agreements between device measures. Anterior displacement measures from the GMetric3D Prototype were in strong agreement with those obtained from the KT-2000 and radiographs. Agreement between the novice and experience testers using the GMetric3D were also very strong (0.93 \pm 0.6 mm). Measurement errors largely met or neared the threshold of 1.0mm.

DISCUSSION: Despite its early prototypic stage, the GMetric3D knee arthrometer performed similarly to a long-standing predicate device, with values strongly representative of true tibiofemoral motion obtained from radiographs. Mean values obtained from the GMetric3D more closely approximated true tibiofemoral motion than the KT-2000TM, suggesting greater proximal stabilization of the femur was achieved. Strong agreement between a novice and experienced tester supports the intention that accurate values can be obtained from GMetric3D with limited training. While measurement errors largely met or neared success metrics for this stage of development, further reductions in measurement error are needed to provide clinicians with the necessary precision to accurately assess ligament integrity for screening and clinical decision making.

SIGNIFICANCE/CLINICAL RELEVANCE: Clinicians need accessible, easy to use precision measurement tools to accurately assess knee ligament integrity for purposes of injury risk screening, injury diagnosis, return to play decisions and monitoring healing and long-term joint health. Addressing limb stabilization and tester influences to improve measurement accuracy and consistency over time and between clinicians would enable greater generalization of knee laxity values and their clinical utility for benchmarking an individual’s joint health and potential risk.

REFERENCES: ¹Fleming et al, *J Biomech.* 2011; 44:2843-2846; ²Wang et al, *Orthop J Sports Med* 2021; 9(2):2325967120979986; ³Uhorchak et al, *Am J Sports Med* 2003; 31:831-842; ⁴Vacek et al, *Am J Sports Med* 2016; 44:1492-1501

ACKNOWLEDGEMENTS: This material is based upon work supported by the North Carolina Biotechnology Center

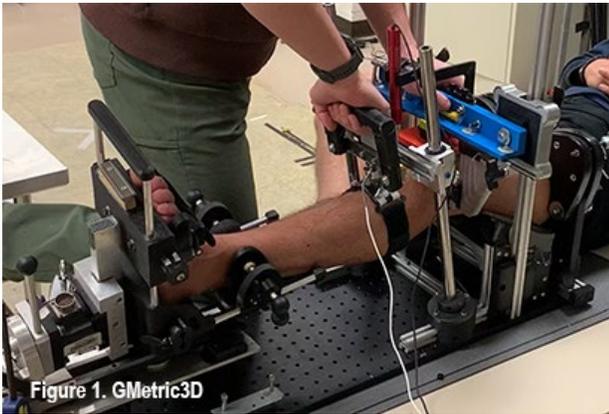


Table 1. Results	Absolute Agreement		
	(Mean \pm Sd)*	ICC (2,1)	SEM*
Radiographic Absolute ATD_T2	6.2 \pm 3.6		
vs. Gmetric_T1	5.2 \pm 2.3	0.87	1.1
vs. Gmetric_T2	5.1 \pm 2.0	0.90	0.9
vs. KT-2000_T1	6.1 \pm 3.3	0.91	1.0
Radiographic Relative ATD_T2	4.4 \pm 3.7		
vs. Gmetric_T1	5.2 \pm 2.3	0.84	1.2
vs. Gmetric_T2	5.1 \pm 2.0	0.86	1.1
vs. KT-2000_T1	6.1 \pm 3.3	0.88	1.2
KT-2000_T1	6.1 \pm 3.3		
vs. Gmetric_T1 (N=21)	5.1 \pm 2.3	0.82	1.2
vs. Gmetric_T2	5.1 \pm 2.0	0.80	1.2

T1, T2 = Testers 1 & 2; ATD = anterior tibial displacement; *values in mm