Mako Total Knee 2.0
Scholl et al. 2023
Clinical Summary

Title	**Robotic-assisted total knee arthroplasty technology helps provide a repeatable and reproducible method of assessing soft tissue balance**
Authors	Laura Scholl, Melanie Caba, Emily Hampp, Azar Ali, James Crutcher, Michael Mont and Ormonde Mahoney
Reference	Poster Presentation 1683. Presented at: Orthopaedic Research Society Annual meeting; Feb 10-14, 2023; Dallas, Texas.
Objectives	To assess the repeatability and reproducibility in balancing ligament laxity (LL) when using Mako Total Knee 2.0, a robotic-assisted TKA (RATKA) surgical workflow
Design	Cadaveric
Duration	NA

Key Points	**Methods:**
	• Three high-volume, fellowship-trained surgeons with RATKA experience assessed LL of six human cadaveric knees.
	• Prior to bone cuts, the surgeons assessed pre-resection LL three times, in extension and flexion, as they rotated between cadavers for randomization.
	• Mako Total Knee 2.0 provided visual and audible feedback on the change of LL displacement in 0.5mm increments, and visual input on tibio-femoral alignment as well as collecting gap values for data analysis, through the digital tensioner.
	• Intraclass correlation coefficient (ICC) analysis was performed on the LL to determine the repeatability within a single surgeon and reproducibility between the three surgeons. ICC estimates greater than or equal to 0.75 represented excellent agreement beyond chance.
	
	Results:
	• Based on ICC values, the surgeons had excellent repeatability for pre-resection assessments (≥0.96)
	• For reproducibility between the surgeons, the median ICC values were also excellent (≥0.90)
	• When comparing each surgeon to themselves:
	  ○ Average variation was 0.35mm
	  ○ Variation was within 1mm 96% of the time
	• When comparing the surgeons to each other,
	  ○ Average variation was 0.6mm
	  ○ Variation was within 1mm 98% of the time
	
	Conclusion:
	"Standard soft tissue balancing techniques during TKA can be subjective and unpredictable. Establishing a repeatable and reproducible method to balance a TKA may lead to a more predictable surgery"

Limitations	The data in this study is derived from a cadaveric lab. As such, the findings may not reflect clinical practice.
Discussion	**Why is this important?** • The results conclude that the Mako Total Knee 2.0 digital tensioner provides repeatable ligament laxity assessments and reproducible ligament assessments within 1mm. • The information from the Mako Total Knee 2.0 digital tensioner is designed to aid a surgeon in dynamic joint balancing. • For this to be effective, the data needs to have low intra-user variability (i.e. be repeatable) and low inter-user variability (i.e. be reproducible). **Why was this study carried out?** • Standard soft tissue balancing techniques utilized in total knee arthroplasty (TKA) often include a surgeon intraoperatively applying stresses to the knee in varying degrees of flexion and extension[1-3]. • These techniques can be performed manually or with the aid of instruments such as spacers, and can be subjective, centered around a surgeon's feel of ligament laxity[1]. • In addition to this subjectivity, tibio-femoral alignment also influences balancing assessments, so a surgeon must be conscious of alignment while applying manual stresses[3]. • With the emergence of robotic technology, there are opportunities for improved soft tissue balancing methods to allow for surgeons to achieve more predictable results. • The objective of this study was to assess the repeatability and reproducibility in balancing ligament laxity (LL) when using Mako Total Knee 2.0, a robotic-assisted TKA (RATKA) surgical workflow. **What is the difference between repeatability and reproducibility?** • Repeatability compares data from the same surgeon carrying out multiple assessments. This is sometimes referred to as **intra**-user variability • Reproducibility compares data from assessments carried out by different surgeons. This is sometimes referred to as **inter-**user variability
References	1. Kwak DS, Kong CG, Han SH, Kim DH, In Y. Development of a pneumatic tensioning device for gap measurement during total knee arthroplasty. Clin Orthop Surg. 2012;4(3):188-192. doi:10.4055/cios.2012.4.3.188 2. Aunan E, Kibsgård T, Clarke-Jenssen J, Röhrl SM. A new method to measure ligament balancing in total knee arthroplasty: laxity measurements in 100 knees. Arch Orthop Trauma Surg. 2012;132(8):1173-1181. doi:10.1007/s00402-012-1536-1 3. Fary C, McKenzie D, Steiger R. Reproducibility of an Intraoperative Pressure Sensor in Total Knee Replacement. Sensors (Basel). 2021;21(22):7679. Published 2021 Nov 18. doi:10.3390/s21227679

The information presented is intended to demonstrate the breadth of Stryker's product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any of Stryker's products. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your sales representative if you have questions about the availability of products in your area.

JR-GSNPS-STUD-607791