

Mako Total Knee 2.0

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Clinical Summary

Title

Robotic-assisted total knee arthroplasty technology helps provide a repeatable and reproducible method of assessing soft tissue balance

Authors

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Reference

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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 preresection assessments (≥0.96)
- For reproducibility between the surgeons, the median ICC values were also excellent (\geq 0.90)
- When comparing each surgeon to themselves:
 - o Average variation was 0.35mm
 - o Variation was within 1mm 96% of the time
- When comparing the surgeons to each other,
 - o 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 laxity¹.
	• 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
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	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

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