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

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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 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:
  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
  o 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 extension1-3.
- 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 stresses3.
- 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**

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