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Soft Tissue Imbalance Resulting from a Simulated Measured Resection Model as Predicted by the Use of Robotic-Assisted Total Knee Arthroplasty Technology

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Abstract

In this study, patients undergoing RA-TKA were critically assessed to understand the accuracy and precision of a simulated MR model used historically in manually instrumented TKA surgery. Using a 3mm threshold of soft-tissue laxity, knees were identified that would have been expected to require the application of a "reactive" CI-TKA surgical technique to achieve adequate soft-tissue balance.

Introduction

Achieving a well-balanced knee has long been recognized as one of the most important goals of the surgical technique in total knee arthroplasty (TKA)^{1,2,3}. The techniques of measured resection (MR) and gap balancing (GB) have typically been used to dictate bone preparation in TKA surgery. With the introduction, first of computer-assisted navigation (CAS) TKA and more recently of robotic-assisted (RA) TKA, surgeons now have the ability to move beyond these two historical techniques. Specifically, with RA-TKA systems, an integrative, proactive approach to planning, evaluation and execution in TKA is now available.

The goal of this study was to utilize the predictive software embedded in the NAVIO RA-TKA technique to critically measure and assess the coronal instability gaps created following a simulated measured resection surgical model for TKA.

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Methods

Starting in August 2019, a longitudinal data collection series was initiated in a singlesurgeon total joint arthroplasty registry. One-hundred and fifteen patients, undergoing total knee arthroplasty with the NAVIO 7.0 RA-TKA technique, were enrolled. Baseline demographic information for all cases was recorded, including gender, age, and BMI.

Exposure of the knee was accomplished with a standard, quadricep-splitting, medial peripatellar arthrotomy. As part of the initial surgical exposure, all accessible peri-articular osteophytes that could potentially affect the ability to accurately assess coronal laxity were removed. NAVIO 7.0 surface mapping of the distal femur and proximal tibia was then performed to generate an "imageless", static 3-dimensional model of the knee. A "measured resection" TKA model, as dictated by the manufacturer's stated surgical technique, was then generated based solely on bone resection depths.

All knees were then taken through a 0-90° "stressed" range of motion- during which both the medial and lateral compartments were subjected to tensile, distractive forces. NAVIO utilizes the tension applied to track the femur and tibia positions in three-dimensional space during this collection, where the deformed specifics of the femur and tibia have been mapped into the system during registration.

Utilizing the planned position of the implant components, NAVIO generates the gap measurements expected in the joint, once the deformed bones are cut and presents that to the user in the planning stage prior to the physical act of preparation of the bone. Based on simulated joint distraction with a calibrated tensioner, the technique allows consistently applied force of approximately 120 Nm to measure soft tissue laxity. The medial and lateral displacements, as a measure of coronal soft tissue laxity or tautness/tightness, were recorded. These measurements were then integrated onto the simulated measured resection model. The validity of the planned gaps to achieved gaps have been studied to be within submillimeter accuracy⁴.

This assessment technique allows for predictive measurements of laxity or tightness in all four traditional positions assessed: medial/extension; lateral/extension; medial/flexion; and lateral/flexion poses. The measurements generated with this modeling technique provide objective information of the "balancing" that would then be required for a surgeon in a historical "reactive" model mandated by following a MR technique.

The NAVIO 7.0 software and the Journey II total knee prosthesis was used for all cases.

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Results

A total of 115 patients underwent primary, unilateral TKA surgery during the study period. No patients were excluded due to missing data.

Baseline demographic data demonstrated average patient age of 70.2 years (range 51-85 years); average patient BMI of 29.8 (range 19-48); with 48 male (42%) and 67 female patients (58%).

The average soft tissue gaps recorded in the extension pose were 1.2mm medially and 3.1mm laterally. At 90° of flexion, the gaps recorded were 1.1mm medially and 3.9mm laterally. In extension, the laxity noted in these poses ranged from -4.7 to +6.8mm medially, and from -3.2 to 7.3mm laterally. At 90° of flexion, the measured laxity ranged from -9.4 to 6.1mm medially, and from -3 to 9.7mm laterally.

When the cases were assessed for displacement >3mm on either the medial <u>or</u> lateral side in extension, however, 81/115 (58%) demonstrated greater than 3mm of instability. Similarly, at 90° of flexion, 81/115 (58%) of cases demonstrated greater than 3mm of laxity either on the medial <u>or</u> lateral side of the knee. When the knees were pooled collectively to assess for medial <u>or</u> lateral instability in either flexion <u>or</u> extension, 100/115 (85%) demonstrated instability of greater than 3mm in at least one of the four positions poses.

Discussion/Conclusion

Surgical techniques of measured resection (MR) and gap balancing (GB) have typically been used to dictate bone preparation in order to achieve symmetric, rectangular flexion and extension gaps. With the introduction, first of computer-assisted navigation (CAS) TKA and more recently of robotic-assisted (RA) TKA, surgeons now have the ability to move beyond these two historical techniques.

With the NAVIO RA-TKA system, an integrative approach to planning, evaluation and execution in TKA is now available. Through intra-operative 3-dimensional modeling, data related to the soft tissue envelope of the knee can be incorporated into the planning stages. In contra-distinction to the MR technique, RA-TKA allows for adjustments in the size, position and orientation of both the femoral and tibial components to drive soft tissue balance, prior to any bony resections. In so doing, minimization of, not necessarily elimination of, the need of actual soft tissue release can be achieved.

In this study, patients undergoing RA-TKA were critically assessed to understand the accuracy and precision of a simulated MR model used historically in manually instrumented TKA surgery ^{5,6}.

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Using a 3mm threshold of soft-tissue laxity, 85% of knees studied would have been expected to require the application of a "reactive" CI-TKA surgical technique to achieve adequate soft-tissue balance in at least one of the four positions assessed.

Further study will be necessary to assess whether this predictive/proactive modeling will demonstrate a reduction in the actual incidence of cases requiring a formal soft tissue release.

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