A case-control study of Clinical Outcomes, Functional Performance, and Patient Satisfaction in Kinematically Aligned vs. Mechanically Aligned Total Knee Arthroplasty using Medial pivot implants.

Background

For nearly two decades now, Total Knee Arthroplasty (TKA) has been recognized as the primary method of treatment for relieving the challenges brought forth by advanced knee osteoarthritis (OA). During this period, we have witnessed a steady global uptick in TKA treatments. The frequency of TKA in developed nations falls within the band of 150 to 200 cases per 100,000 (1). Total knee arthroplasty (TKA) is one of the most effective, cost-efficient, and consistently successful surgeries in orthopedics. Patient-reported outcomes underscore its significant impact on pain relief, functional restoration, and improved quality of life(2).

Regrettably, post-TKA happiness levels hover around only 80%, leaving almost one-fifth of the patients less than perfectly content,particularly(3), younger patients who desire to quickly resume demanding recreational activities like cycling or hiking after their procedure(4).

Traditionally, the mechanically aligned (MA) TKA has been the gold standard, aiming for a neutral alignment of the knee joint to optimize prosthesis longevity. However, kinematically aligned (KA) TKA has emerged as an alternative approach, aiming to restore the knee's natural, pre-arthritic alignment.

The mechanically aligned TKA procedure directs the surgeon to execute cuts according to the perpendicular lines drawn from the femoral and tibial mechanical axes.
The cuts thus made alter the angle and positioning of the inherent joint line - a compromise, as stated by Insall.An adjustment in an integral angle and positioning of the joint line results in irregular tightening or loosening of the collateral, retinacular, and posterior cruciate ligaments. In contrast, in kinematically-aligned TKA the surgeon cuts the distal femur and proximal tibia to restore the natural angle and level of the joint lines thereby minimising these undesirable consequences(5).

In addition , the medial pivot (MP) knee system is designed to mimic the physiological medial center of rotation of the native knee. A greater medial conformity is provided by a concave surface on the medial compartment of the tibial insert with an anterior lip that stabilizes the knee from full extension through deep flexion confining the anterior sliding with a greater anterior constraint and a subluxation resistance. In contrast, the lateral condyle is designed to move more freely along an arcuate path..(6)

The combination of benefits of medial pivot kinematics and kinematic alignment to individualize knee implantation for each patient offer better functional outcomes and patient satisfaction.

This study aims to provide clinical and radiological data comparing the two techniques, in terms of radiological outcomes, functional performance and postoperative outcomes in a 2-year span.

Objectives

- Comparison of pre-operative and postoperative radiological image using the Coronal Plane Alignment of the Knee (CPAK) classification.(7)
- Patient reported outcomes that include pain, satisfaction rate and quality of life.
- Comparison of Functional Performance: Range of Motion (ROM), results between the two groups.
- Postoperative complications: implant wear, implant malalignment, revision rates.

Hypothesis

Null Hypothesis: No significant difference between those undergoing KA-TKA and MA-TKA with Medial Pivot knee system in clinical outcomes, postoperative complications.
Alternative Hypothesis: Better patient reported outcomes on those undergoing KA-TKA using MP knee system than those undergoing MA-TKA and MP knee system.

Study Design

Study type: Case-Control study
Study population: Patients with primary knee osteoarthritis matching on relative varus or valgus deformity with no history of arthrotomy.
Duration: 3 years (1 year for patient recruitment and surgery, 2 years postoperative follow-up).

Inclusion and exclusion criteria

Inclusion criteria

- Adults between 65-80 years old.
- Patients with end stage (K-L 3,4) primary knee osteoarthritis.
- Indicated for TKA
- Eager and able to comply with the 2-year study's follow-up.

Exclusion criteria

- Severe valgus or varus deformity (>15°)
- Previous knee surgery.
- Inflammatory joint disease affecting the knee joint.
- Neuromuscular disorder affecting gait.
- BMI > 40 kg/m^2

Intervention

- Group 1 (KA TKA): Patients will undergo kinematically aligned total knee arthroplasty using **Evolution® Medial-Pivot Knee-Microport, Shangai, China**. The surgical technique will involve aligning the knee components based on the patient's native knee anatomy and kinematics, with the goal of restoring the pre-arthritic alignment.
- Group 2 (MA TKA): Patients will undergo mechanically aligned total knee arthroplasty using **Evolution® Medial-Pivot Knee-Microport, Shangai, China**. The surgical technique will involve aligning the knee components to achieve a neutral mechanical alignment, with the limb alignment set to 0°.

Outcome measures

Primary Outcome Measure:

- Patient-Reported Outcomes:Visual Analog Scale (VAS) for pain, Forgotten Joint Score for the Knee (FJS)(8), KOOS jr.(9), Oxford Knee Score (10)

Secondary Outcome Measures:

1. Psychological distess of the Patients: Short-form-health survey-questionnaire. (11)
2. Pre and postoperative coronal limb and knee alignments measured on single-leg standing long-leg radiographs(12).
3. Complications: Incidence of surgical complications, implant malalignment, wear, and revision surgery rates.

Randomization and Blinding

- Randomization: Patients will be randomized 1:1 to either the KA TKA or MA TKA group using a computer-generated randomization sequence.

- Blinding: The surgeon will not be blinded due to the nature of the procedure, but the outcome assessors and patients will be blinded to the group allocation.

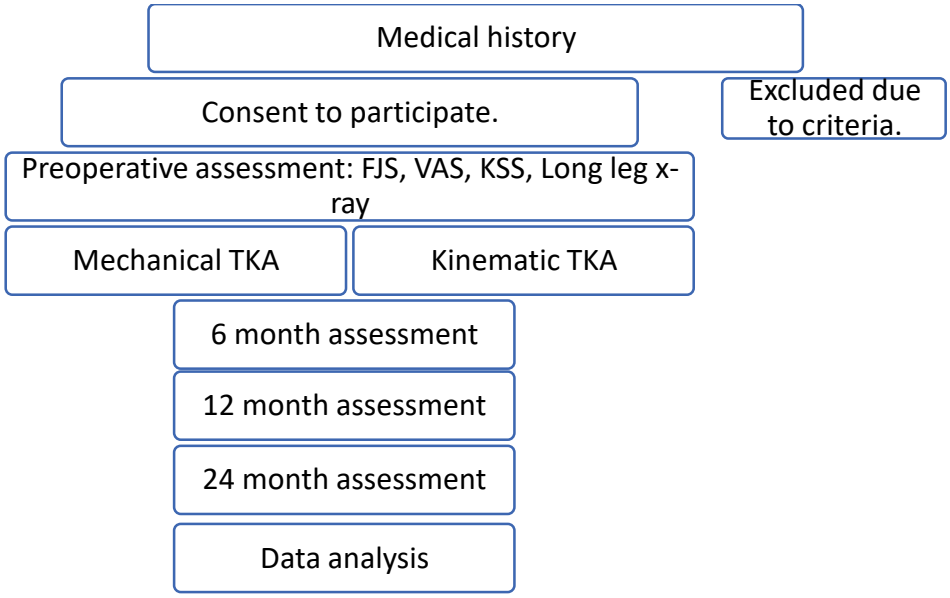
Data Collection and Analysis

Data Collection: Baseline data, intraoperative data, and follow-up data will be collected using standardized forms. Follow-up assessments will be conducted 6 months, 12 months and 24 months postoperatively.

Ethical Considerations

The study will be conducted in accordance with the Declaration of Helsinki (13). Ethical approval will be obtained from the institutional (University of Patras) review board (IRB) prior to study commencement.
Informed consent will be obtained from all participants.
Any adverse events will be reported and managed according to institutional protocols.

Timeline



Month 1-3: Study setup, recruitment of participants
Month 4-23: Patient recruitment and surgery
Month 24-36: Follow-up assessments and data analysis

Dissemination of Results

Results will be published in peer-reviewed orthopedic journals and presented at relevant conferences. A summary of findings will be shared with study participants.

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