Next-Generation Hinge Knee System

Outline.

- **A long history.** Hinge knee designs have a long history of use for multiple indications including revision arthroplasty and primary arthroplasty applications.
- **Multiple solutions, mixed results**. Despite multiple generations of implant designs introduced for use, results have been mixed.
- Unmet clinical need. Our hypothesis is that implant and instrument design is not done – an unmet clinical need remains. Implant design improvements are required for hinge knee systems to become an optimal solution for the right patient.
- A new option. United Orthopedic has introduced our next-generation Hinge Knee System with the goal of increasing the value of hinge knee replacement systems and to provide a more viable solution than currently available systems.

Existing Solutions. Hinge knees have been an implant option for knee arthroplasty for over 70 years, and there have been multiple generations of systems introduced to the market for use [1]. Early generation systems featured fixed rotation, posterior hinge engagement position, larger femoral bone resections that often removed the femoral condyles, and multiple hinge components that required inter-operative assembly [2,3]. (See images of hinge knee designs over time).

Subsequent generations included rotating-hinge designs, more centralized hinge engagement positions, and/or smaller resections. New features were added, such as new designs of the articulating surface, which were introduced to transfer force through the femoral condyles [4,5].

Indications and Results. One primary indication has been for revision knee arthroplasty where multiple studies have reported on results for patients revised for multiple reasons including (a) septic loosening and (b) persistent ligamentous instability. Some studies have reported positive results with higher rates of survivorship, while others have reported survivorship is significantly lower in rotating-hinge devices compared to other types of implants [6,7,8,9,10).

Hinge Knee Designs Over Time

In addition, multiple studies have reported on the use of hinge knee systems for primary knee arthroplasty resurfacing applications. Typical indications reported include patients with greater than 20 degrees varus or valgus deformity and/or significant ligamentous instability. Like in revision knee procedures, the use of hinge-knee systems has had been a varied range of positive and negative survivorship results reported [1,5,11].

Reasons for failure of hinge knee systems in both primary and revision applications include wear, osteolysis, infection and fracture, and mechanical failure of the hinge mechanism [11,12].

Summary. It is evident that there remains an unmet need for new clinical options for primary and revision patients for whom a hinge-knee system is the optimal solution.

References

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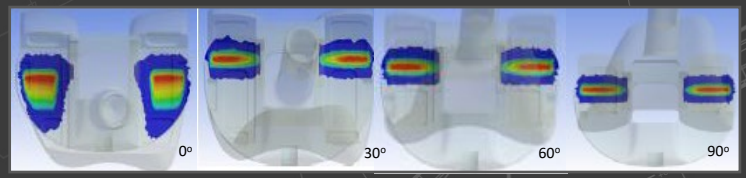
Overview -A *next*-generation, rotating-platform, hinge knee system.

- **Designed to have an optimal condylar loading design.**
- **Features a small profile, pre-assembled hinge mechanism centered on the femur and tibia.**
- **Connected intra-operatively by a single screw.**
- **The system has a reduced femoral profile to preserve bone with distal and posterior condyle resections similar to a primary total knee**

Rotating Platform. Designed with a built-in tibial rotation stopper allows ±25° of tibial insert rotation for improved movement. The central location of the hinge mechanism is placed closer to the axis of the tibial component creating the potential for more natural and consistent tibiofemoral kinematics when compared to posterior hinge knee designs. (See axial view of the hinge knee system.)

Axial view of hinge knee system.

This modern rotating hinge system is designed to maximize contact between the femoral component and articular surface throughout range of motion ("ROM"). This passes over 95% of the load to the central portion of the tibial condyles (See Finite Element Analysis (FEA) model showing condyles bearing weight throughout ROM.)



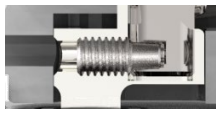
Hinge mechanism centered on the femur and tibia. Designed to provide a femoral-tibial engagement point more comparable to a primary PS knee vs. the traditional "book-end" engagement design of earlier generation systems. (See expanded view of the system.)

Connected Intra-operatively by a Single Screw. The set screw is pre-positioned in the tibial insert to reduce surgical time and is designed to prevent back-out. (See close-up image of the set screw assembly engaged in the femoral hinge assembly.)

Small profile, pre-assembled hinge mechanism. The hinge mechanism is provided pre-assembled to allow the opportunity for reduced surgical time by reducing procedural steps. In addition, the assembly is enclosed inside the femoral component to reduce the potential for wear and cement debris. (See cut-away view of pre-assembled femoral hinge mechanism.)


Expanded view of the system.


Cut-away view of pre-assembled femoral hinge mechanism.


Close-up image of set screw assembly engaged in the femoral hinge assembly.

Consistent implant design. Designed to provide improved flexibility and a platform-based approach, the multiple knee systems feature matching AP, ML and chamfer resections on the femur for primary posterior-stabilized (PS), revision, and hinge total knee replacement systems. In addition, femoral box widths are constant across implant systems. Note: box depth and heights vary.

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