ATTUNE® Knee System: GLIDERIGHT™ Articulation

Attune® Knee System

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INTRODUCTION

Total Knee Replacement (TKR) is a widely adopted and clinically successful procedure for the treatment of pain and restoration of mobility in patients suffering from osteoarthritis. However, challenges still exist in the area of patellar function. Anterior knee pain following TKR remains a common occurrence for some patients, leading to decreased mobility and patient satisfaction. Also, complications related to the patello-femoral joint remain a common cause for revision of TKRs.[1-3]

Implant design, alignment of the patellar and femoral components, and patient variation have been identified as key factors affecting patella kinematics, contact mechanics, and ultimately, the clinical outcome of TKRs.[4-7] Several of these factors, such as the design of the implants and surgical instruments can be controlled. Published literature has shown improvements in TKR design and alignment accuracy can lead to improved patello-femoral performance and significant reduction of patello-femoral complications after knee replacement.[6-9]

Since the patello-femoral joint is subjected to a wide range of variation across the spectrum of knee replacement patients, the design of an implant's patello-femoral joint and the system's instrumentation must be optimized to provide a good clinical outcome for each patient.

BACKGROUND

The Native Patella and Trochlear Groove

The anatomy of the native patella is asymmetric with a longer lateral facet and a shorter, steeper medial facet. The apex of the patella is situated medially, which causes the patella to track lateral and reduces the strains in the lateral patella-femoral ligament and retinaculum. The position of this apex varies from individual to individual. The depth of cartilage on the patella is some of the deepest seen in the body, reflecting the loads to which the patella is subjected.

The trochlear groove of the femur is also variable across patients. The most superior part of the trochlea in early flexion is virtually flat and the orientation of the trochlear groove is largely dependent on the direction of patella travel. Between 0-30 degrees, the patella is guided by the presence of medial and lateral retinacular ligaments, which control the kinematics to deliver the patella into the central groove of the trochlea. The trochlea then deepens at 45 degrees of flexion.[10] The direction of patella travel is also dictated by the positioning of the tibial tubercle, the distribution of forces across the hip flexors and extensors, the degree of femoral rotation, development of the femoral condyles and posture and orientation of the hind foot and ankle.

As the knee flexes, the patella becomes more loaded and the trochlea deepens to constrain and stabilize the patella. The medial and lateral retinacular ligaments become progressively more lax from 35 degrees of flexion onwards. Patella tracking then becomes more conforming and predictable as the patella enters the highly constrained trochlear groove and dislocation or variation in tracking is minimized.

Historical Review of Patella Tracking in TKA

Early knee replacement designs did not consider the importance of the patello-femoral joint and indeed the patello-femoral joint was not included in very early designs (Manchester Knees, Stanmore Implants Worldwide, Ltd Total Knee Replacement). As condylar knee designs developed, the complication of patella dislocation required a lateral release rate of up to 30% in some studies.[2,3,11] Poor design of the patello-femoral joint and incomplete understanding of patella tracking may have contributed to this high rate of lateral releases. In the presence of high rates of patella subluxation, symmetric femoral condylar knee designs incorporated deepening of the trochlear groove with the intention to 'capture' the patella to reduce patella subluxation and patella complications.

The incorporation of a very deep trochlear groove during early flexion in a symmetrical femoral condylar replacement is now understood to compromise the variable patello-femoral kinematics observed across patients. Due to this non-physiological groove, resurfacing the patella with a corresponding symmetric patellar component was recommended. This technique was more readily accepted in markets like the US where 95% of patellae are resurfaced. However, in the United Kingdom, Australia, Germany and South Africa, where the majority of patellae are unresurfaced, this design feature was less ideal because a deepened or U-shaped trochlear groove design does not match the contour of native patellae. Surgeons who leave the native patella intact have expressed concern regarding the kinematics and contact forces resulting from this non-congruent fit.

Current Designs

Unmet patient needs remain with respect to performance of the patello-femoral articulation in total knee surgery today. Many studies indicate that almost 50% of patients have difficulty kneeling or climbing stairs after knee replacement surgery[2,3,11] and there is a recognized incidence of grinds and clicks from the patello-femoral articulation, in addition to the well described patello-femoral 'clunk' syndrome.[12-14]

The majority of femoral condylar replacements are now asymmetric to incorporate the orientation of the trochlear groove. These may be broadly divided into two categories, those with a U-shaped trochlear groove to accommodate planned patella resurfacing (PFC® SIGMA® Knee System, Stryker® Triathlon®) and those with a more physiological trochlear groove design to accommodate the un-resurfaced patella (LCS® Knee, Zimmer® NexGen®).

ATTUNE® KNEE SYSTEM - GLIDERIGHT ARTICULATION

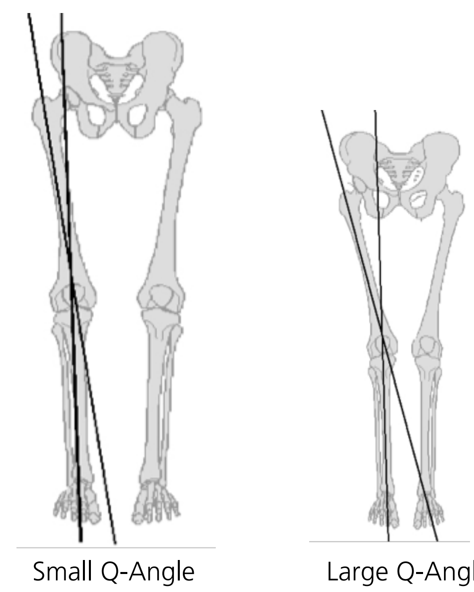
Trochlear Groove Design

Development of the GLIDERIGHT™ Articulation, or patello-femoral articulation of the ATTUNE® Knee, was a significant focus of the project with the goal of improving patient satisfaction and addressing the recognized anatomic discomfort that patients may suffer related to knee replacement surgery. Understanding the anatomy and kinematics of the trochlea and patella interaction led to the development of the funnel effect, which enables the ATTUNE Knee design to more accurately replicate normal patello-femoral kinematics. As in the native knee, the relatively flat trochlear groove in early flexion allows the patella to be guided by the retinacular ligaments while accommodating variation due to tibial rotation during gait and differential medial/lateral forces across the extensor mechanism.[15] This allows the patella to enter the trochlear groove with different positions and angles.

As the patella becomes progressively loaded through 35 to 45 degrees, the ATTUNE Knee trochlea deepens, mimicking the increasing constraint on the patello-femoral joint seen naturally (Figure 1).

Figure 1: ATTUNE Knee femoral and patella components viewed at 0, 15, 30, and 45 degrees of flexion with coronal cross-sections taken through patella mid-section. The cross-sections highlight the funnel effect of the ATTUNE Knee patello-femoral joint from 0 to 45 degrees with progressive conformity as flexion increases.

In addition to the progressive patella capture found within the ATTUNE Knee trochlea design, the angle of the trochlea incorporates a physiological angle to enable the patella to track more lateral in early-mid flexion, reducing the strain in the lateral retinacular tissues. Since a patient's Q-angle is largely proportional to height, the trochlear angle in the ATTUNE Knee design is proportional throughout the femoral sizing line (Figure 2).



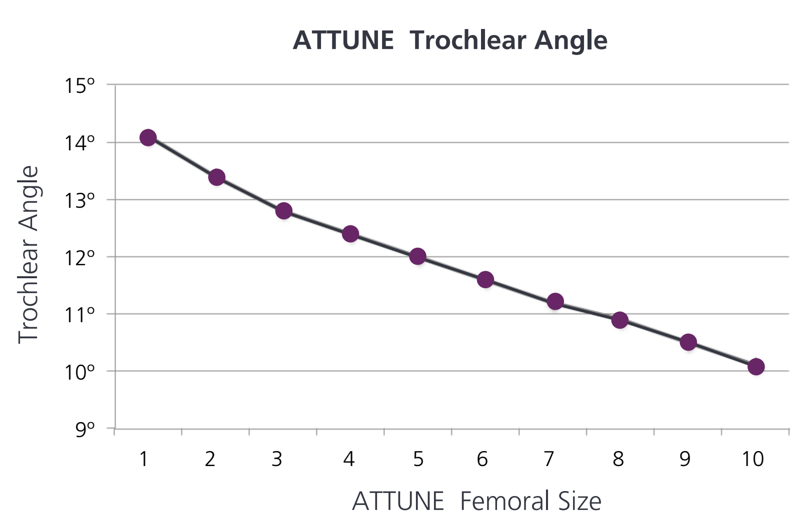


Figure 2: The physiologically proportional angle of the ATTUNE Knee trochlea.

Many surgeons, particularly in Europe and Asia, do not routinely resurface the patella. As a result, the ATTUNE Knee trochlear groove is designed to be similar to the natural trochlear groove to articulate with the native patella.

To assess the ability of the ATTUNE Knee trochlear groove to articulate with the native patella, it was compared with the LCS Knee System, which has a clinical history of being implanted with the native patella. When tested with a native patella, the ATTUNE Knee femoral component produced similar levels of contact pressure as the LCS Knee femoral component.[16]

Patella Design

The use of a circular patella footprint, which may require medialization of the dome to optimize patellar tracking, has been associated with large areas of exposed bone, resulting in lateral facet impingement syndrome.[17] The ATTUNE Knee System offers patellar components which have peripheral shapes that maximize bone coverage and may help avoid lateral facet patella impingement syndrome.

In recognition of the longer lateral facet and often medialized apex of the native patella, the ATTUNE Knee patella component has a medialized dome enabling full bone coverage while replicating the natural position of the patient's own patella apex. This promotes physiological patella tracking[17] and allows replication of physiological extensor hood soft tissue tensions within the replaced knee (Figure 3).

Central Dome Design ATTUNE Knee Medialized Dome

Figure 3: The effect of medialization of a central dome design with resultant femoral impingement (left) versus resolution with the ATTUNE Knee medialized dome patella (right).

The ATTUNE Knee also offers a medialized anatomic patella component, which replicates the anatomic contours of the native patella, similar to the all-polyethylene patella prosthesis in the LCS Total Knee System. The conforming lateral facet, domed medial facet, and medialized apex provides increased contact area between the patella component and the trochlear groove. As a result of the increased contact area, there is a reduction in flexion/extension tilt of the patella as compared to a dome design (Figure 4).[18]

Figure 4: The ATTUNE Knee medialized anatomic patella provides increased contact area and reduced flexion/extension tilt.

Reducing Patello-femoral Complications in Posterior Stabilized Prostheses

Patello-femoral tracking is commonly associated with soft tissue contact at the front of the femoral prosthesis which historically has been a problem with all total knee replacements, particularly Posterior Stabilized (PS) prostheses. The proximity of this contact relative to the PS box/trochlea transition has been correlated to clinical patello-femoral complications.[9] The femoral component of the ATTUNE Knee has incorporated numerous design improvements to reduce non-physiological patello-femoral soft tissue contact. The trochlear groove has been lengthened to provide a smoother engagement of the extensor hood, the femoral box has been blended into the trochlear contour and the box sizes are now proportional to the size of the implant to minimize the possibility of soft tissue irritation in some of the smaller size ranges (Figure 5).

Figure 5: The ATTUNE Knee femoral component is designed with an extended trochlear groove, blended PS box transition, and proportional PS box sizes to reduce the potential for soft tissue irritation.

The unique contours of the medialized anatomic patella component may also reduce some of the unwanted interaction between the soft tissue at the superior pole of the patella and the femoral component (Figure 6).

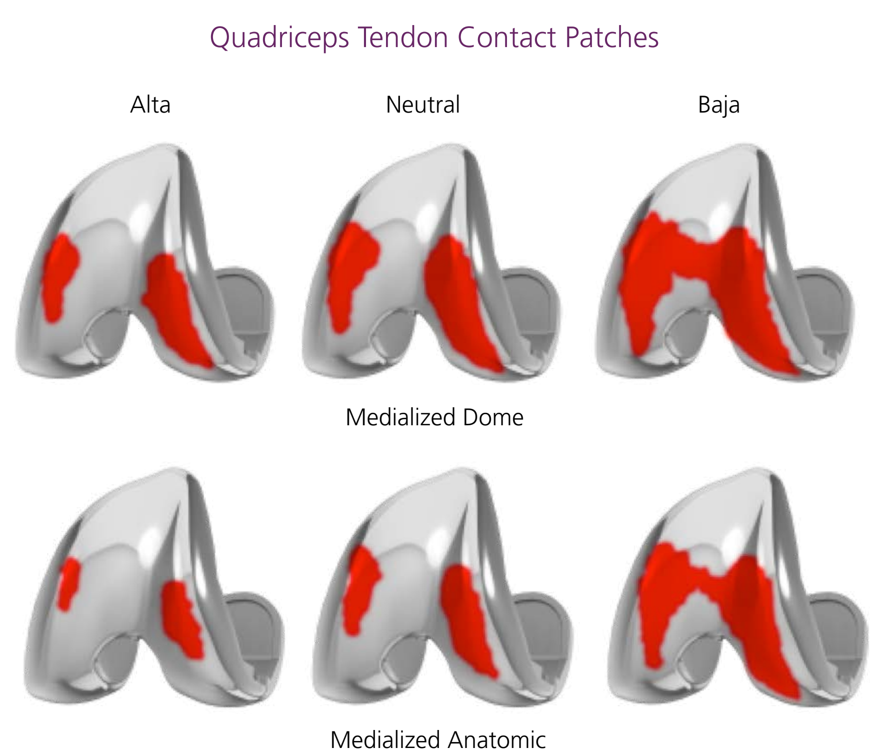


Figure 6: The ATTUNE Knee patella components were designed to maintain adequate separation between the quadriceps mechanism and the entrance to the femoral box.

Combined Impact Upon Soft Tissue Tension & Anterior Knee Pain

The above descriptions of the funnel effect, Q-angle, patella design, and PS design improvements illustrate the multi-faceted and comprehensive approach that was used to develop the new patello-femoral articulation of the ATTUNE Knee System. All of the features are designed to work together to reduce anterior pain by providing more physiological tracking/forces and avoid excessive tensions within the soft tissue of the patient's extensor hood.

ATTUNE Knee Design Validation

Both the ATTUNE Knee medialized dome and medialized anatomic patella components have a medialized apex, which, as stated previously, is intended to promote physiological patella tracking. In order to validate the effect of medialization on patella kinematics, cadaveric testing was completed using the Kansas knee simulator (Experimental Joint Biomechanics Research Lab, University of Kansas).[17,19] Seventeen cadaveric knees were subjected to a deep knee bend in which the patella motion and length of the Lateral Patello-Femoral Ligament (LPFL) were measured. After the natural knee evaluations, each knee received a posterior stabilized TKR with either a centralized patella (SIGMA Knee, *DePuy Synthes Joint Reconstruction*) (n=7) or a medialized dome patella (ATTUNE Knee, *DePuy Synthes Joint Reconstruction*) (n=10). Both patellae had identical outer profiles, but the articular peak of the medialized patella was offset 2-3 mm medially. Both femoral components had equivalent trochlear angles.

Results showed that tracking of the natural patella started centrally and moved slightly lateral in flexion, whereas the centralized and medialized patella groups moved medially with flexion. However, the medialized patella group consistently tracked 2-3 mm lateral of the centralized patella group, resulting in a position more similar to the natural patella at 90° flexion (Figure 7).

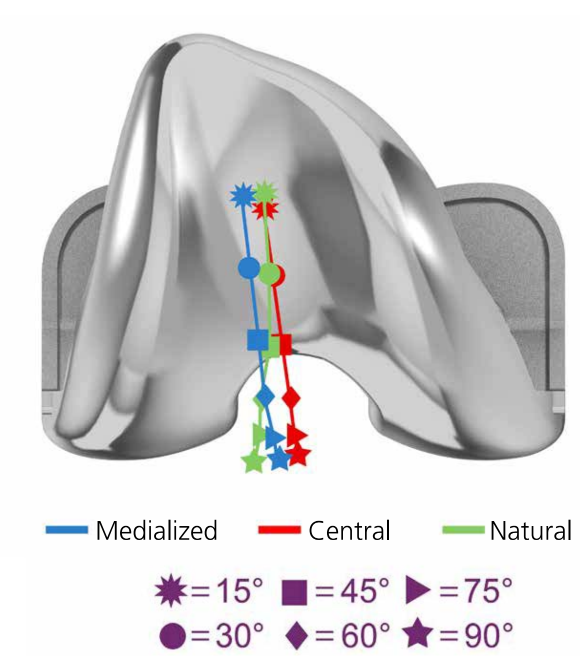


Figure 7: Patella motion with natural (green), central dome (red), and medialized dome (blue) patellae.

Medialization of the patella component also reduced the length of the LPFL, particularly from 15° to 35° knee flexion. These results are consistent with surgical techniques which release the LPFL to address lateral patella tracking[20] and suggest that medialization of the patella may reduce lateral soft tissue strain during TKR.

Additional performance testing utilizing previously validated methods [21,22] was conducted to examine the robustness of the ATTUNE Knee patello-femoral design to patient and surgical variation (Figure 8).

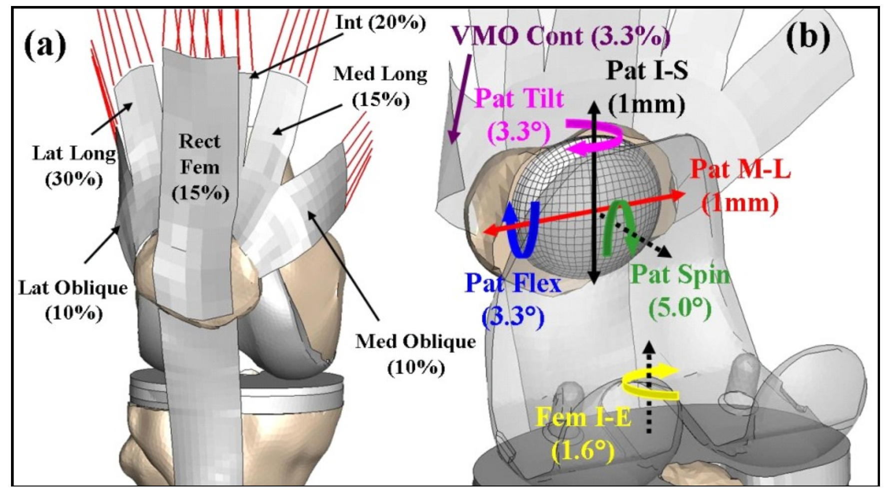


Figure 8: The isolated patello-femoral model with a) the quadriceps load distribution and b) the variables included in the probabilistic analysis:

- femoral internal/external (I/E) alignment
- patellar I/E
- flexion/extension (F/E) alignment
- adduction/abduction (A/A) alignment
- patellar medial/lateral (M/L) translations
- superior/inferior (S/I) translations patella alta/baja
- percentage of the quadriceps load on the VMO tendon

Four implant combinations were included: ATTUNE Knee with a medialized dome patella, ATTUNE Knee with a medialized anatomic patella, SIGMA Knee, and NexGen®.

Results showed that the ATTUNE Knee patella components experienced less lateral shear force (Figure 9) than the SIGMA Knee or NexGen®.

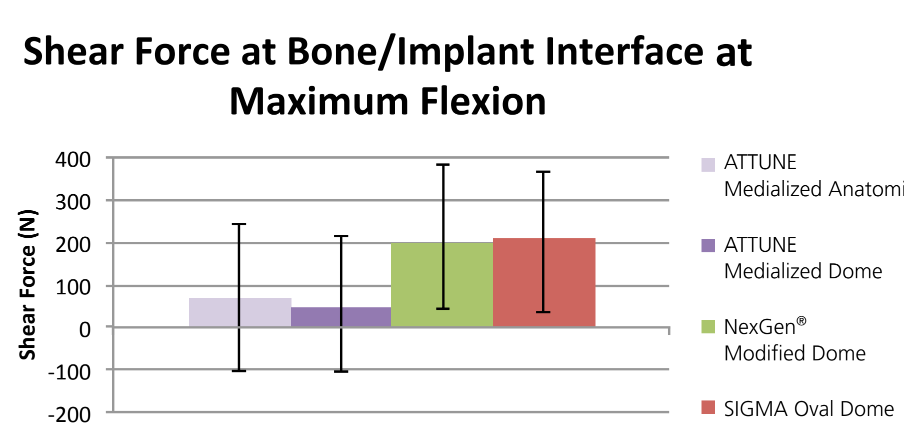


Figure 9: Shear force at the bone/implant interface at maximum flexion.

Although the SIGMA Knee and ATTUNE Knee have similar trochlear angles in the frontal plane, the medial offset built into the ATTUNE Knee medialized dome and medialized anatomic patella components allows the patellae to track laterally, reducing the shear forces at the implant-bone interface.[22] The ATTUNE Knee patella components also experienced lower peak contact pressures than NexGen® through the majority of a deep knee bend (Figure 10), demonstrating the robustness of the ATTUNE Knee patella components to the range of potential surgical and patient factors.[22]

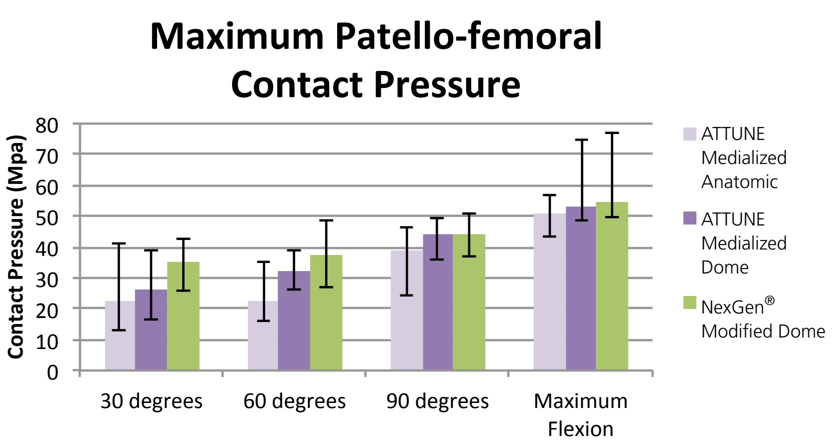


Figure 10: Maximum Patello-femoral contact Pressure.

Early Clinical Experience

Tens of thousands of ATTUNE Knee replacements have been provided for patients worldwide. Surgeon feedback to *DePuy Synthes Joint Reconstruction* has been excellent with particular remarks on the tibio-femoral kinematics and the patello-femoral tracking which are interlinked. In the experience of the surgeon author, the patello-femoral tracking has been smooth and there have been no issues of high rates of lateral release, patella complications, or dislocations.

SUMMARY

In the ATTUNE Knee development program, considerable progress has been made in understanding patello-femoral kinematics with innovative experimental and computer software techniques. This has led to the design of a physiological trochlear groove and patella resurfacing options to more accurately mimic natural patello-femoral function and performance.

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