ATTUNE™ KNEE SYSTEM: SOFCAM™ CONTACT

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Historically, sagittal plane instability following Total Knee Arthroplasty (TKA) due to insufficiency or resection of the posterior cruciate ligament resulted in the development of posterior cruciate substituting (PS) TKA designs. These devices incorporate a cam-spine mechanism to provide posterior stability and assure posterior femoral translation to enhance flexion following TKA. Many PS TKA designs have been developed which, while similar in concept, differ in many areas including the degree of flexion at which cam-spine engagement occurs, location, size and shape of the cam and spine, location of spine contact, freedom of axial rotation, and the amount of bone resection required to accommodate the intercondylar box of the femoral component.

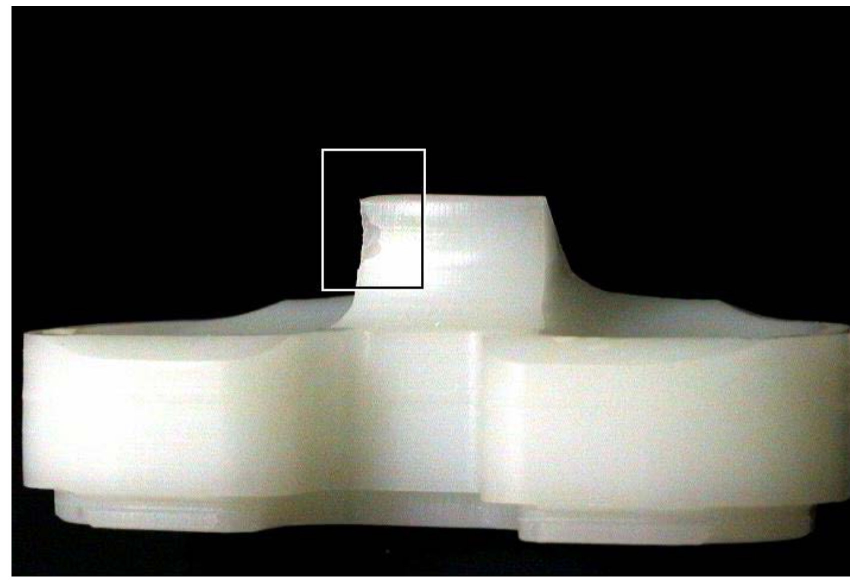

Figure 1. Photograph of a retrieved PS polyethylene insert demonstrating eccentric medial spine wear.

Numerous long term clinical reports of subjects implanted with PS TKA have demonstrated excellent results[1,2] as well as better weight bearing knee flexion compared to CR knees; however, despite these results, in vivo kinematic analyses still demonstrate wide variations in cam-spine mechanics. Some designs engage earlier providing kinematic control of anterior-posterior (A/P) translation during gait. In others, cam-spine engagement occurs later in flexion (65-100 degrees) and in some cases, cam-spine engagement never occurs throughout knee flexion.

Additionally, there are other considerations that must be taken into account. Cam-spine engagement may occur at flexion angles which differ from that reported by implant manufacturers due to varying patient kinematics or surgical placement which may cause cam-spine contact on the medial, lateral, or anterior aspect of the spine rather than centrally on the posterior aspect resulting in increased spine stresses and premature spine wear (Figure 1).[4] The velocity of the cam at the time of spine engagement varies and is affected by the condylar control of A/P femoral-tibial translation before engagement occurs. High engagement velocities result in elevated "collision" impact forces rather than a softer controlled pattern of cam-spine engagement. Some of these kinematic variances likely play a significant role in premature failures of PS TKA designs that have been reported due to excessive spine wear or fracture.[4-6]

Anterior impingement can also occur with knee hyperextension or malpositioning of the femoral and/or tibial components. It is typically caused by the femoral component being placed in flexion and excessive posterior slope added to the tibia (Figure 2). Anterior impingement increases spine stresses and wear and adds additional stress to modular tibial insert locking mechanisms.[9] Cam-spine mechanisms must be robust to allow for surgical variation without the development of anterior spine impingement.

Opponents of posterior cruciate substitution often object to the amount of bone removed from the intercondylar notch of the femoral component which affects available bone mass should later revision TKA become necessary. Historically, the shape of bone resection has been rectangular and the quantity of bone resection has not been proportional based on femoral component size.

As a result, PS knees should be designed with the goal of reducing these issues by incorporating the following concepts. PS knees should have consistent cam-spine contact at a higher flexion angle than occurs during gait to lessen the frequency of cam-spine contact and enhance longevity of the cam-spine mechanism. Loads on the spine increase during progressive knee flexion;[7] therefore, it is desirable to have the location of cam-spine contact in deep flexion at the base of the spine where the strength is greatest. The geometry of the cam and spine must be forgiving of variances in axial rotation to avoid high eccentric spine stresses. The articular geometry of both the femoral component (J Curve) and tibial insert must produce A/P femoral-tibial translation patterns that assure the cam engages with the spine in a soft manner with minimized impact. And the amount of bone resection from the intercondylar notch should be minimized and proportional based on size of the femoral component.

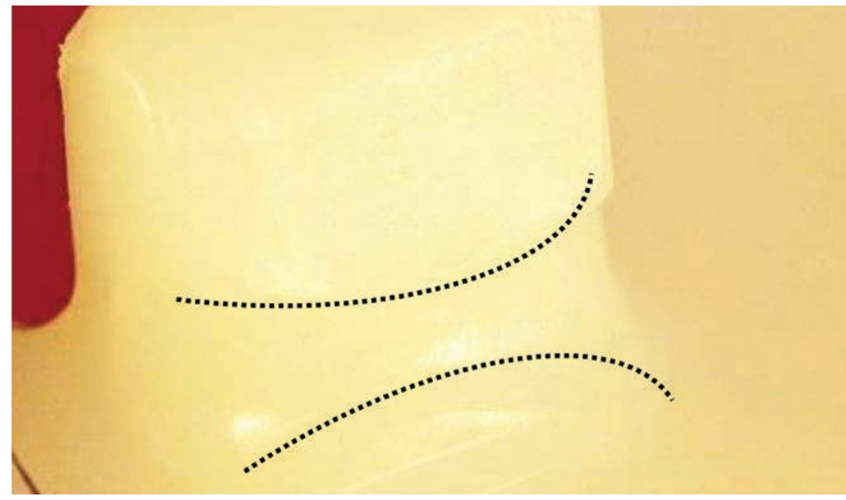

Figure 2. Photograph of a retrieved PS polyethylene insert demonstrating anterior spine impingement and subsequent wear.

ATTUNE™ KNEE SYSTEM CAM-SPINE MECHANISM (SOFCAM™ CONTACT)

Extensive research analyses using multiple analytical methodologies were performed to determine the ideal cam-spine mechanism for the ATTUNE™ Knee System posterior cruciate substituting TKA. Multiple design prototypes were developed as a part of the project in order to evaluate the parameters that affect the functional characteristics of the cam-spine engagement. Each design was evaluated for the factors mentioned above using computer modeling at the University of Denver and *DePuy Synthes Joint Reconstruction*, weight bearing cadaveric testing at the University of Kansas in a highly modified Oxford rig, and through multiple surgeon cadaveric and intra-operative evaluations. Ultimately, the SOFCAM™ Contact design best accomplished the design goals.

Initially, the J Curve of the femoral component was determined. As is present in the native knee, a multi-radius concept was selected. Review of pre-existing multi-radius femoral component designs showed abrupt changes in the radius of curvature in most femoral components.[10]

These abrupt changes result in a loss of control of A/P femoral-tibial translation and subsequent control of cam-spine engagement. To address this the ATTUNE GRADIUS™ Curve (gradually reducing femoral radius of curvature) was developed. The ATTUNE GRADIUS incorporates smooth transitions between radius changes which enhances the desired control of cam-spine engagement and lessens paradoxical anterior femoral translation seen in many current implants (Figure 3). The end result is that A/P femoral-tibial translation is initially controlled by a condylar geometry which gives rise to the femoral component translating slowly into engagement with the tibial spine, providing a smooth transition from condylar to cam-spine control.[7] This smooth (soft) engagement of the cam and spine occurs after the gait cycle (between 65 and 75 degrees of flexion) to eliminate excessive repetitive contact during each gait cycle which could lead to premature spine wear.

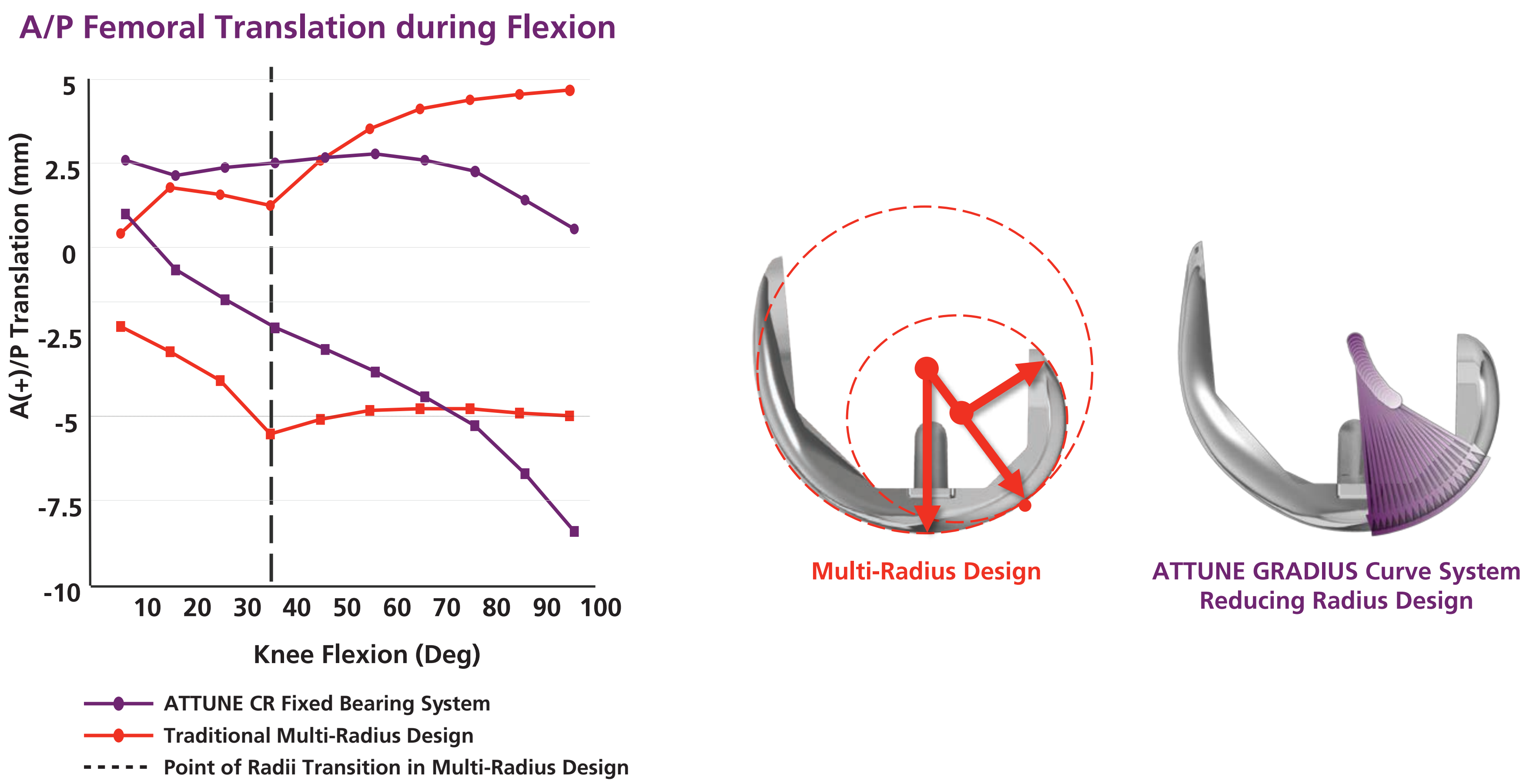

Figure 3. Diagrams demonstrating the traditional multi-radius design versus the ATTUNE GRADIUS Curve design and the kinematic profiles of A/P translation of each demonstrating elimination of paradoxical anterior femoral translation in the ATTUNE Knee design.[10]

The shape of the cam and spine has a significant impact on the contact and torsional stresses applied to the tibial spine and the tibial base fixation interface. With this in mind, the patented 'S-shape' of the ATTUNE Knee cam and spine was created to provide a large contact area as the cam initially engages broadly on the spine (Figure 4A) and then quickly translates to the distal base of the tibial spine as the knee moves into deeper flexion (Figure 4B). The low contact position in high flexion directs the forces through the thickest portion of the tibial insert instead of through the upper spine which lessens spine stresses, the subsequent risk of spine fracture, and the danger of cam-spine dislocation.[7] The shape of the cam and spine also direct forces more distally, versus anteriorly, creating compressive forces at the tibia which are more protective of the tibial/bone interface.[8]

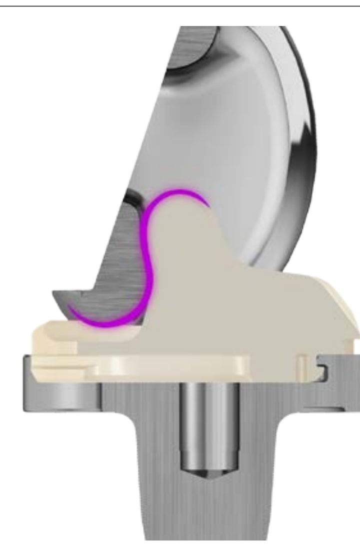

Figure 4A: Cross-sectional diagram of the SOFCAM at 70° of flexion demonstrating broad levels of cam-spine contact.

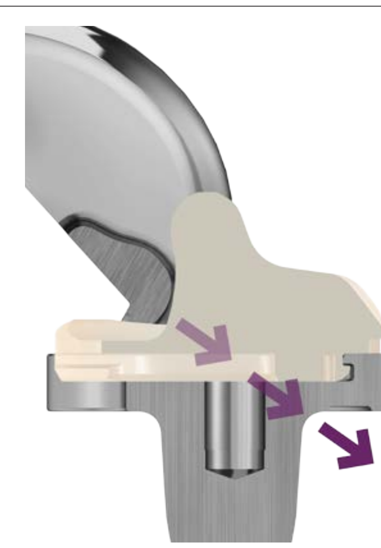

Figure 4B: Cross-sectional diagram of the SOFCAM at 145° of flexion demonstrating contact at the base of the spine where polyethylene strength is maximized.

Furthermore, several publications describe a spine that does not allow rotational freedom as a driver for tibial spine impingement and fracture.[6,9] With the ATTUNE Knee, the anterior surface and side of the tibial post, along with the corresponding surfaces on the femoral component, provide the necessary rotation and softened surfaces to avoid impingement should hyperextension or varus/valgus lift off occur. The shape of the posterior surfaces of the spine are designed to successfully manage forces transferred through the spine as well as loads transmitted to the tibial fixation interface by incorporating a smaller coronal radius, resulting in a curved shape. This curvature reduces edge loading of the femoral component against the tibial spine when the knee rotates in flexion (Figure 5). This design has been proven to reduce the contact forces on the tibial spine as compared to other knee designs.[7] It also helps to diffuse the torsional forces which are transferred to the modular insert locking mechanism and the tibial fixation interface during femoral rotation.

Figure 5: Photograph demonstrating how the curved tibial spine allows freedom of rotation as knee flexion increases.

Finally, the shape of the femoral intercondylar box has been designed to conserve bone by making an 18° angled cut (Figure 6). The amount of bone resected is proportional to the femoral component size, which can be beneficial in bone conservation for smaller patients with limited bone mass (Figure 7). The volume of bone removed is therefore appropriate for specific patient size.

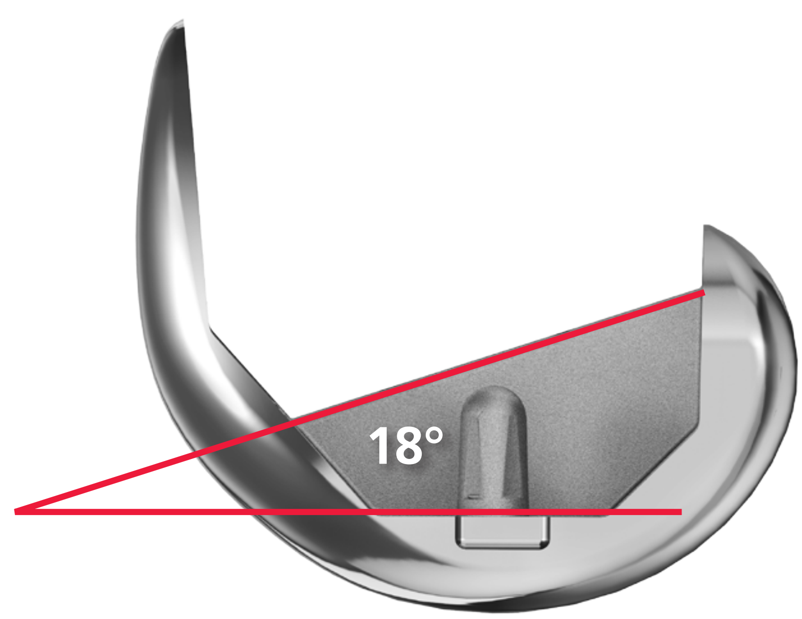

Figure 6: Sagittal view of the ATTUNE System femoral component demonstrating the angular (18°) intercondylar box which gives rise to less intercondylar bone removal.

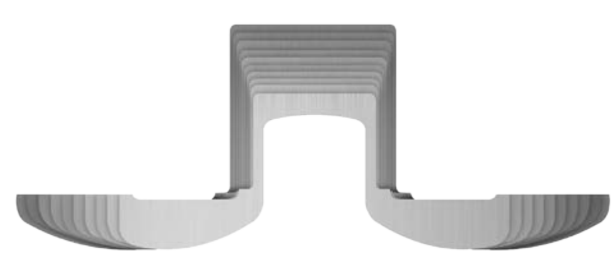

Figure 7: Diagram of the coronal cross-sectional geometry of the ATTUNE Knee femoral component demonstrating how the intercondylar box width, and subsequent intercondylar bone resection required, lessens with decreasing femoral component size.

SUMMARY

In summary, SOFCAM Contact was developed after exhaustive testing to help address challenges with PS Knees. SOFCAM was designed with the goal of creating optimized cam-spine mechanics for a wide range of patient anatomies. The final components includes improvements on the cam and spine shape, location, and intercondylar box geometry to allow for slow engagement of the femoral component with the tibial spine, providing a smooth transition from condylar control to cam/spine control. Cam and spine shape, location, and intercondylar box geometry have been designed with the goal of creating optimized cam-spine mechanics for a wide range of patient anatomies.

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