ATTUNE™ KNEE SYSTEM: ATTUNE GRADIUS™ CURVE

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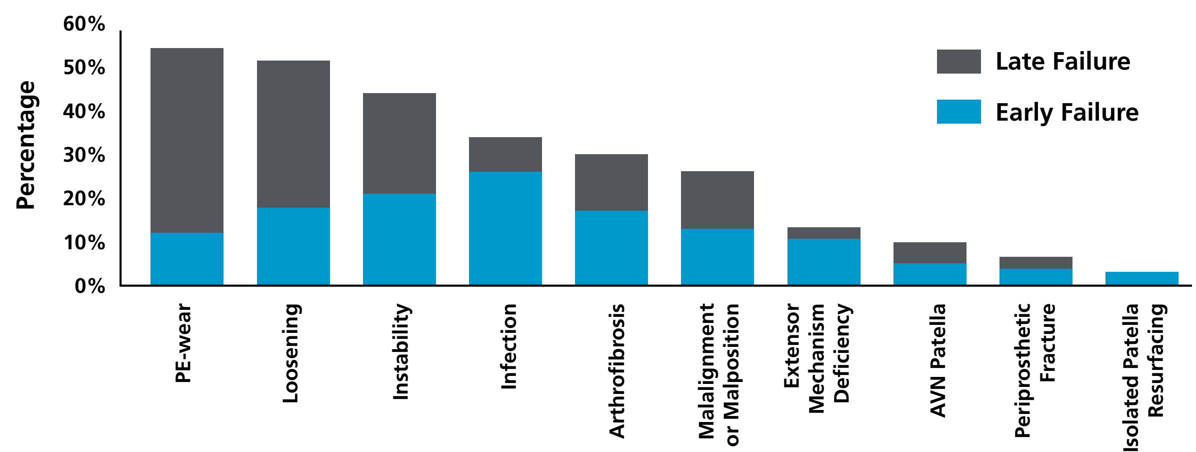
While total knee arthroplasty (TKA) has been established as a durable and effective operation, several problems continue to contribute to patient dissatisfaction. Despite the fact that many advances have been made in terms of surgical technique and implant design, in some series patient dissatisfaction has been shown to be as high as 20%.[1,2] Chief among the reasons for dissatisfaction is the persistent problem of instability. Previous publications by Fehring in 2001 and Sharkey in 2002 documented that up to 26% of revision TKA cases were being performed for instability (Fig 1).[3,4]

A review presented at the 2012 Knee Society by Dalury showed that, despite an additional 10 years of advancements in surgical technique and implant designs, 16% of revision cases were being performed for instability out of a group of 872 consecutive revision total knee replacements.[5]

Fig. 1: 2002 Sharkey, et al data showing instability being a key issue in early knee failure.[3]



The classic instability symptoms include difficulty arising from a seated position and trouble with stairs and uneven surfaces. Patients will often describe a sense of having to "get the knee under them" before they can move. While frank dislocation, particularly of a posterior stabilized (PS) designed knee is uncommon, there are, in fact, many patients who suffer from the more subtle findings of swelling, lack of confidence and pain. This is due to the muscles surrounding the knee constantly working to provide external support. The cause is often an entity known as mid-flexion instability, which is a challenge to both diagnose and treat. Mid-flexion instability is typically described as laxity in the varus-valgus plane between 30 and 60 degrees of knee flexion. It can be seen in all designs, both PS as well as cruciate retaining (CR). Treatment ranges from therapy, bracing, activity modification and occasionally surgery to a more conforming device. Obviously the preference is to attempt to prevent the instability in the initial surgery.

The cause of instability following TKA is multifactorial. A patient's pre-operative condition can certainly play a role and patients who are hyper-lax (particularly hyperextension) or who have had previous ligament injuries are at a higher risk of having post operative instability. Also, patients with significant pre-operative deformities (greater than 20 degrees and particularly valgus – Fig. 2) are at increased risk.

Fig. 2: A severe valgus knee

Additionally, surgical technique can contribute to this problem. As a result, it is critical that correct femoral component rotation, size and offset, as well as balanced and equal flexion and extension gaps, are achieved at the time of surgery. Equally important are correct alignment of the components and re-establishment of the joint line, both of which must be appropriately executed during TKA to prevent knee instability. Soft tissue balancing must be carefully performed to avoid over-release of the medial and posterior soft tissues. In addition, over-releasing or late rupture of the PCL has been shown to cause late knee instability in CR knees.[6]

A third and final critical factor in helping to reduce instability is implant design. Femoral component sizing and sagittal design as well as the contact and conformity with the tibial bearing surface have been shown to be very influential in knee function and the key driver in achieving implant stability. However, designs must be careful not to err completely on the side of conformity. It has been shown that to achieve deep flexion the normal knee rolls back, particularly on the lateral side of the joint and TKA designs are meant to achieve similar motion (Fig 3). As a result, knee designs must find a healthy balance between conformity and rotational freedom.

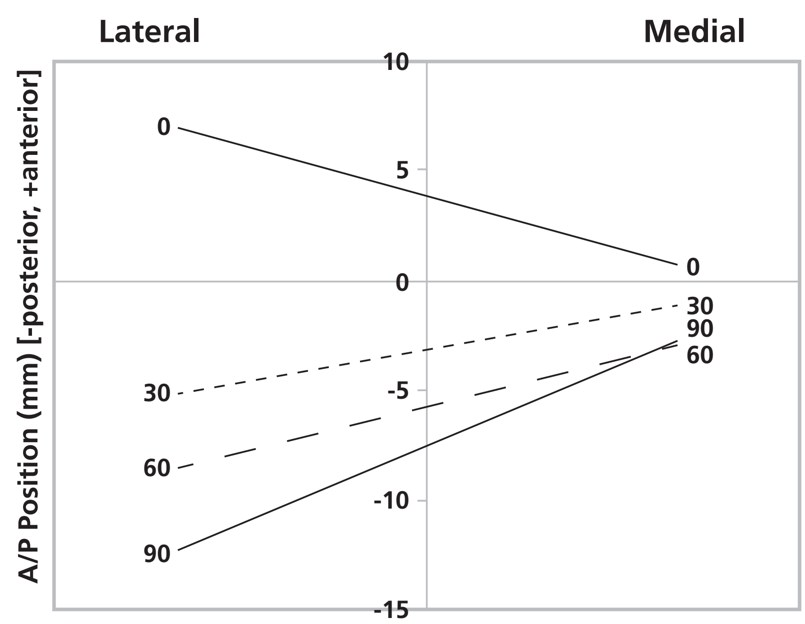


Fig. 3: Dennis, et al. data showing the average medial and lateral contact positions during a deep knee bend for the normal knee[7]

MULTI-RADIUS DESIGNS

Traditionally femoral components have used a "J Curve" to achieve this goal (Fig 4). A "J Curve," in effect, is a multi-radius design. It has been used for many years in several successful designs such as NexGen®, Kinemax®, and AGC®. This concept originated in the desire to mimic the sagittal profile of the native femur. In extension, the broad distal femoral radius is in contact with a conforming and relatively congruent tibia surface providing stability to the knee. The smaller posterior femoral radius, where the curve becomes a "J" is designed to decrease the conformity of the construct allowing the femur to roll back and rotate as the knee moves to deeper flexion.

A particular problem with these "J Curve"designs is that the knee is prone to sudden shifts during the course of knee flexion. A potential consequence of this transition area of the femoral "J Curve" is that as the knee flexes, the knee can become relatively unstable as it moves from one distinct radius to the next. Both fluoroscopic data and computer modeling have shown that as the knee flexes along this varying curve, there can be both flexion instability and paradoxical anterior sliding as opposed to the more desired consistent posterior rollback. This can occur with both PS and CR designs, although more frequently in the latter.

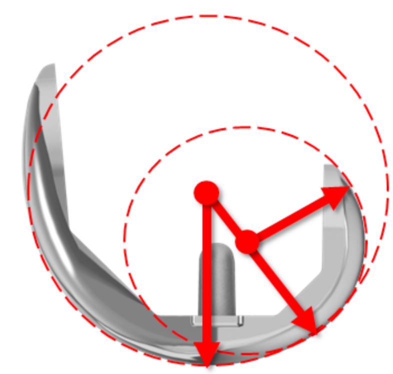


Fig. 4: Traditional knee designs feature a "J Curve" design. This femur transitions from a broad distal radius to a smaller posterior radius.

SINGLE RADIUS DESIGNS

Some other femoral designs have moved away from the traditional "J Curve" and, particularly in the case of the Triathlon® knee, have gone to a single radius concept (Fig 5). The intent of this design is to have a single radius based approximately on the transepicondylar axis. In theory this would deliver more normal soft tissue tension and stability throughout the flexion arc. A problem with this idea is that the natural shape of the femur in the sagittal plane, and the location of its soft tissue attachments, precludes the knee from being able to rotate along one axis. This single radius femoral design means that the femoral-tibial construct is more of a round on flat design and while that may increase the rotational ability of the knee joint, this may lead to relative instability in extension and paradoxical anterior sliding as the knee flexes.[8,9]

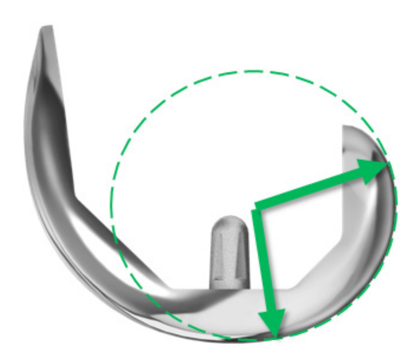


Fig. 5: Single Radius designs have the same radius of curvature from 10 to 110 degrees, but have a relative lack of conformity.

ATTUNE GRADIUS™ CURVE

The challenge with these historic designs is delivering on the goals of providing stability in high demand situations seen in early flexion, allowing rotational freedom in deeper flexion, and mitigating abrupt changes in kinematics throughout the range of motion.

A new and different approach for achieving these goals has been created and adopted in the ATTUNE™ Knee System. The concept behind the patented ATTUNE GRADIUS™ Curve (Fig 6) femoral sagittal design is that while there remains a broad distal radius for knee stability in extension and a smaller posterior radius for better knee flexion, there is a gradual, rather than an abrupt, reduction of the femoral sagittal radius between 5 and 65 degrees of knee flexion for the CR knee (Fig 7) and 5 and 70 degrees of knee flexion for the PS knee. This is achieved by multiple different radii points along the curve, which in turn reduces the sudden transition between the two radii seen in the traditional J Curve designs and is designed to prevent sudden changes in knee stability (Fig 8). The added stability imparted by this design has the potential to help improve knee kinematics. This may improve a patient's sense of confidence, particularly in situations such as stair climbing. Additionally, this design has the potential to decrease wear.

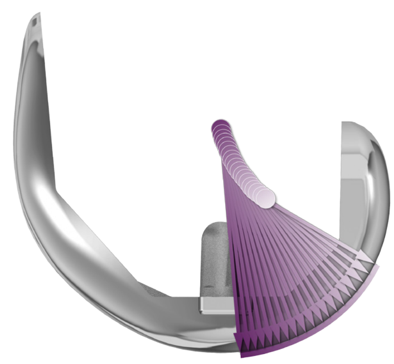


Fig. 6: ATTUNE GRADIUS Curve features a continuously changing radius of curvature that reduces the abrupt transition from distal to posterior radii.

These concepts have been thoroughly tested with both cadaveric and computational models and studies supporting these concepts have been presented at national and international forums.[10]

My personal experience with the ATTUNE Knee System has been excellent. My learning curve was very short and the ideas of appropriate soft tissue releases and removal of impinging bone are even more important when using this system because of the amount of conformity and rollback that the system provides. My clinical results have confirmed the expected excellent early motion and stability throughout the flexion arc. The knee "feels" different and more stable, particularly from 30-60 degrees, but also in maximal flexion. After at least 250 cases, I can say that I noticed increased contact and conformity as well as the outstanding kinematics that the ATTUNE Knee System was designed to deliver.

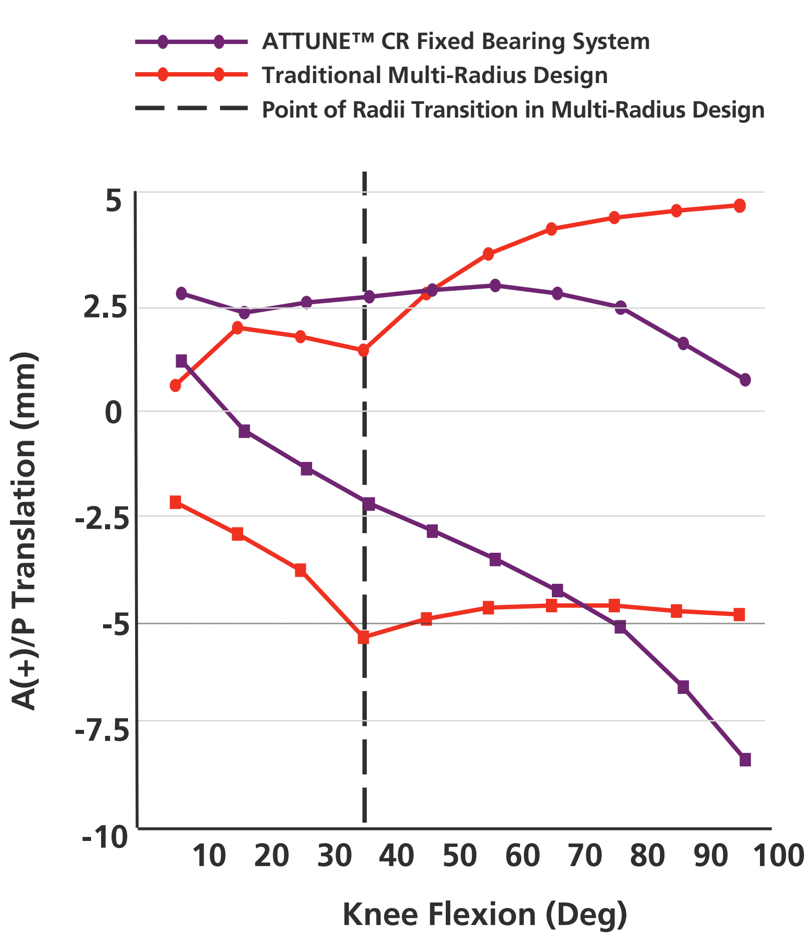


Fig. 7: An ORS study reviewing A/P translation showed the ATTUNE GRADIUS Curve did attenuate paradoxical sliding versus other fixed bearing knee designs.[9]

	0	15	30	60	90
ATTUNE CR	**0.88**	**0.83**	**0.77**	**0.66**	**0.67**
NexGen® CR	0.54	0.54	0.54	0.31	0.31
Triathlon® CR	0.38	0.22	0.22	0.22	0.22

Fig. 8: This This table shows the gradually reducing conformity of the ATTUNE GRADIUS Curve design relative to other designs in the marketplace.

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