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A Step Forward to Normal Knee Kinematics with Single Radius Knee

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With the decreasing trend of average age in patients undergoing total knee arthroplasty (TKA), patients may be expecting more from their TKA than in the past. It has been reported that approximately 20% of TKA patients experience some level of dissatisfaction with their outcome after surgery.[1] Younger patients tend to have a greater need for more range of motion, longer implant stability, decreased anterior knee pain and faster rehabilitation.

Since the first TKA was performed, surgeons have been constantly improving the surgical approach along with implant and instrument design. As surgical techniques have evolved, femoral components are routinely implanted in external rotation to improve collateral ligament isometry and enhance patella tracking.

TKA implant design evolved according to the research performed on knee anatomy and kinematics. In the mid 70s, the J-Curve theory was proposed and drove the first monumental implant development in TKA. In the past, many successful implants were developed concomitantly. However, as our surgical technique has changed, it is important to make sure that our current implant designs match our scientific approach to implantation to provide TKA patients with more natural and stable knees.

With further improvement in research technology, the understanding of relative motion with regards to the tibia and femur, and the crucial role ligaments play in knee kinematics have evolved. New research approaches have led to the single axis theory to better explain the flexion/extension (F/E) motion of the knee joint. This new theory has led to the development of a knee design with a more circular sagittal profile, or the so-called Single Radius (SR) knee geometry. Previous knee designs had pronounced elliptical sagittal profiles as they were based on the Multi-Radius (MR) theory. The objective of this paper is to provide a critical analysis of the MR theory, introduce the science of a SR theory and contrast the knee designs based on each of these theories.

MR or J-Curve Theory

The MR concept was first hypothesized by Braune and Fischer et al. in 1891. They believed that the kinematics of the knee occurs about a variable F/E axis that was located in the posterior femoral condyles, and that this axis was perpendicular to the sagittal plane.[2] This theory was also proposed by several other investigators.[3-5]

To further investigate the MR theory, Frankel and Burstein et al. used a planar mathematical technique called Reuleaux Method to locate the instant canters of rotation in 1971.[6] They acquired 6-8 lateral roentgenograms of each subject's knee from full extension to 90° of flexion. The next step was to locate two reproducible femoral points on each x-ray image. The researchers then superimposed the tibial images on two sequential x-rays, for example from 0 to 15 degrees of flexion. The displacement vectors were determined for each of the two anatomic points and from them, the instant centers were calculated based on the Reuleaux method (Figure 1).

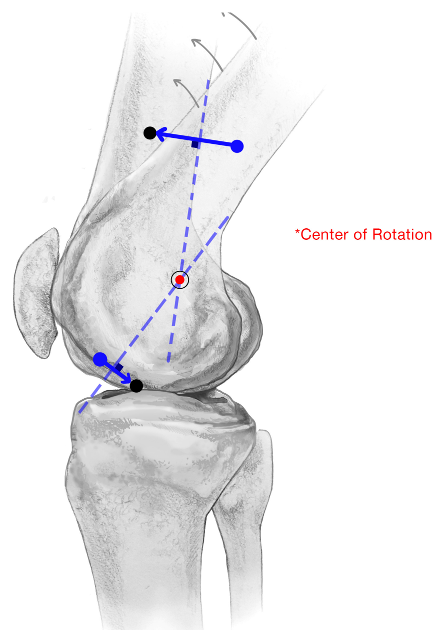

Figure 1. The Reuleaux method: The first point was determined by first drawing a line that bisects the femur, then locating the point where the line intersects with the distal femur. The second point was determined by locating a point 10 cm proximal to the first point. The Instant centers of rotation were determined by finding the intersection (the red dot) of the perpendicular bisectors of these displacement vectors (the blue arrows) of the two femoral points as the knee went into full extension in this case.

They reported that the instant centers of rotation changed throughout flexion and extension when determined in this fashion. It was postulated that the sagittal profile of the posterior femur formed a "J" shape when the instant centers of rotation were connected (Figure 2).

The methodology of the Frankel and Burstein investigation which was the basis of the MR theory has

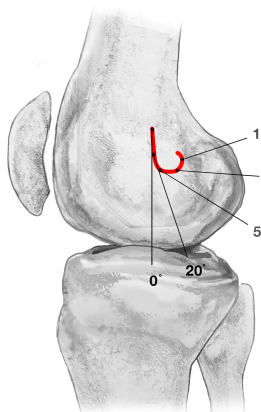

Figure 2. The connection of Instant Centers of Rotation form a "J" shape. As the flatness of a shape is proportional to the length of the radius, this would suggest that the distal condyle is markedly flatter than the posterior condyle- leading to egg shaped designs.

been criticized by several researchers.[7,8] Some of the criticisms include: 1) the method used to determine results involved x-rays rather than actual knee motion, and 2) the major flaw was the assumption that all knee motion was occurring in the plane in which the x-rays were taken. Any out of plane motion, such as the obligatory internal/external (I/E) rotation of the tibia during knee flexion, would have adversely impacted the accuracy of the center of rotation calculation.

Meanwhile, results of the other studies conducted using similar methods indicate that the center of rotation analysis is extremely sensitive to experimental design errors. Studies conducted by Blacharski[9], Siegel[10] and Smidt[11] have been criticized by Panjabi et al.[8] because improper experimental design led to inaccurate results and larger variations (95% confidence interval were calculated to be 2.84cm for Frankel Study and 6.28cm for Smidt study), which makes it difficult to draw conclusions from these studies.[7–11]

Another criticism of the Frankel/Burstein study is that they only determined two anatomic points on the femur to locate the instant centers of rotation. When studying the motion of only two points on the femur, the intersection of their perpendicular bisectors will always be a single point. It would have been instructive to have included a third anatomic point femoral point to confirm that its perpendicular bisector would have intersected at the same point.

The largest criticism of the application of the Reuleaux method for studying knee motion is the assumption that the images are capturing all of the knee motion. The accuracy of these displacement vectors used to determine the centers of rotation is adversely affected by any out of plane motion. Clearly, the knee internally and externally rotates with flexion and extension. Consequently, any conclusions based on the application of assumed planar motion to what is clearly non-planar motion need to be questioned. However, many contemporary knee designs continue to incorporate a MR design based on these questionable investigations (Figure 3).

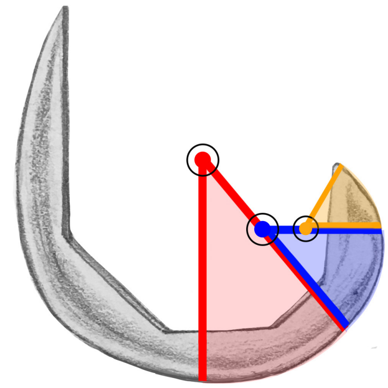

Figure 3. To mimic the changing centers of rotation and shape of the femur in sagittal plane, the MR implant typically consists of larger radii distally and smaller radii posteriorly.

Fixed Flexion Extension Axis Theory

In 1986, Hollister and Kester first reported that the motion of the knee can be described by single F/E axis using a device called the Axis Finder.[12]

The axis finder is a simple device to locate the axis of rotation of a rotating body. This mechanical device consisted of a series of metal rods connected via universal joints which permit the positioning of an axial rod to be located along the axis of rotation of two linked segments undergoing a rotation. As the motion is occurring, the axial rod's motion will describe an arc unless the axial rod is pointing along the axis of rotation for that motion under study. It can only be used if the motion under study can be modeled as having a single axis of rotation. Also, if a joint under study has more than one axis, each motion must be studied separately (i.e. the F/E axis must be studied separately than the I/E axis). The documented accuracy of the device when studying a hinge joint is within 1 mm and 1.5°.[7]

Hollister and Kester[7,12] used axis finder on both in vivo and in vitro specimens to determine the axis of rotation. To study flexion and extension in a cadaver model, the axis finder was attached to the tibia and a Steinman pin (the adjustable axial rod) that was freely locatable in the space around femur. The cadaver femurs were mounted on a specially designed frame. The tibia was passively moved from flexion to extension to locate the axis for this motion. In this study, they reported that:

- The knee has a fixed F/E axis that is in the posterior aspect of the femoral condyles.
- The location of the axis is just distal to the origins of the collateral ligaments, and slightly externally rotated with respect to the sagittal plane.
- The tibia has an independent longitudinal rotational axis that projects posteromedial from the anterior cruciate ligament (ACL) attachment on the tibia.
- The knee motion has obligatory motion in all three planes due to the offset F/E axis, like the motion in an ankle joint.

- The shape of the femur is circular when viewed down the axis. (Figure 4)

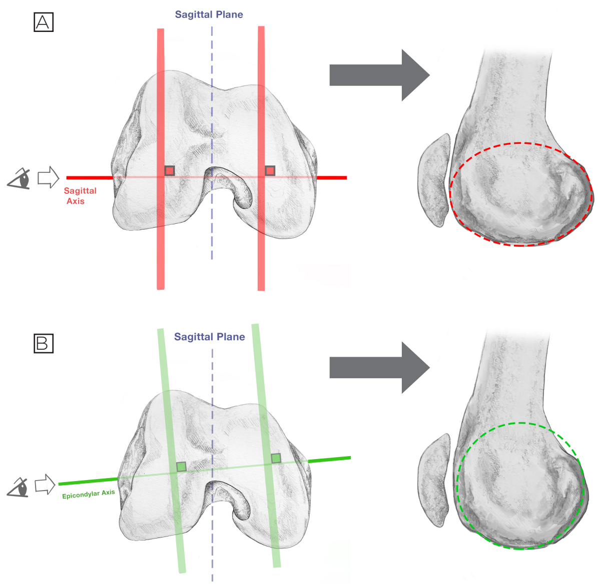

Figure 4 A&B. Figure A shows the distal end of the femur. The red line shows the sagittal plane from the MR theory. If the knee is viewed from the side along this J curve axis, the knee has an elliptical shape. In contrast, Figure B shows the SR axis which is coincident with the epicondylar axis. When the knee is viewed down this axis, the profile is circular. This circular profile of the SR knee design is indicated when the femoral bone is resected in external rotation.

This study was one of the first reports documenting the circular as opposed to elliptical femoral condylar shape.[6] In a previous study, Hollister, Kester and Cook et al. had used the axis finder and reported the condyles appeared to be circular but could not document that the circularity was present in full extension.[12] Based on the findings of the previous study, Hollister et al. further investigated the concept using the same method in 1993 and concluded that the knee axis from the previous study was valid through full extension.[7]

After these studies, additional research groups have focused on studying knee motion and the location of the functional F/E axis. In 2005, Asano et al.[13] conducted an in vivo study using computer assisted biplanar image matching technique. The objective was to test the hypothesis that the knee has a fixed F/E axis in the posterior femoral condyles and this axis coincides with the epicondylar axis. The investigation used a weight bearing squatting activity to study this hypothesis. The findings showed a fixed oblique F/E axis and its location which supported the circular contour of the femoral condyle determined in the previous study by Kester and Hollister.[7,12]

Freeman et al. further investigated the arcs of knee motion with radiographic imaging, magnetic resonance imaging (MRI) and autoptic methods, and believed that there are 3 distinct arcs of motion: hyperextension, active flexion and hyperflexion. Fundamental active flexion arc, where the everyday activities occur, ranges from ~30° to 110°. Through the active flexion arc, both femoral condyle surfaces are circular in profile.[14,15]

Churchill, Incavo, Johnson et al.[22] tested the hypothesis that all knee motion could be described in terms of rotations about two axes- a F/E axis and I/E rotational axis. They used a validated test fixture in which 15 cadaveric legs went through simulated squatting activity. The motion was captured with electronic sensors and optimal axes were calculated. The F/E axis was found to be coincident with the epicondylar axis, and the I/E rotational axis was fixed to the medial tibial plateau. During a squat, all knee motion could be described as rotation about these two fixed axes, except for an average 3.4mm in translation and 2.9°in orientation. This research strongly supported the work by Kester and Hollister.

Coughlin et al. used ten whole cadaveric knees with electromagnetic sensors and recorded the position of the patella relative to the femoral bony coordinate system, and found out that the position and motion of the patella relative to the femur was a circular shape. This indicated that the shape of the femoral contour was circular and also uncovered an important relationship between the F/E axis orientation and the arc of patellar tracking.[16]

Howell et al. studied 155 varus knees and forty-four valgus knees using MRI scans that were obtained perpendicular to the F/E axis of the femur and reported that the femoral condyles are circular when viewed down this axis.[17]

These six different research groups using different research methods produced similar results. This further underscores the accuracy of the conclusions of Kester and Hollister regarding both the circular shape of the condyles and the location of the axes of rotation.

Just as the advent of J-Curve theory brought multiple radius implants, the advent of Fixed F/E Axis theory also led to a new type of implant design - a SR design - available for surgeons and patients. In the 1990's, Mark Kester worked with Stryker Corp. and developed the first generation of SR knee implants. The designs were based on the goal of replicating the SR geometry based upon viewing the condyles along the functional F/E axis. Surgeons have evolved the way that they set femoral component in TKA. Femoral components are set in slight external rotation. This was done to improve patella femoral tracking and achieve better collateral ligament balancing by setting the component in line with functional F/E axis.[7,12,13,18-22] The design reinforces the benefit of the common surgical approach of externally rotating the femoral component by implanting a circular, not elliptical, femoral component whose geometry better matches the bone being resected when the cuts are externally rotated (Figure 5). Egg shaped implants based on the application of the Reuleaux method cannot convey this benefit.

The center of the circular shape of the SR implant (the rotational axis of the implant) is in line with the functional F/E axis. Consequently, the design of the implant is in agreement with the most common surgical procedure of TKA involving external rotation of the femoral component.[18-21] Therefore, SR implants may be more capable of reproducing normal knee kinematics after surgery, as reported by Churchill et al.[22] and Kessler et al.[23]

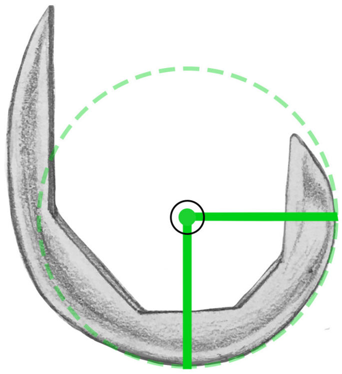

Figure 5. SR implants maintain a consistent geometry throughout the functional range of motion, this consistent geometry leads to more consistent soft tissue tension.

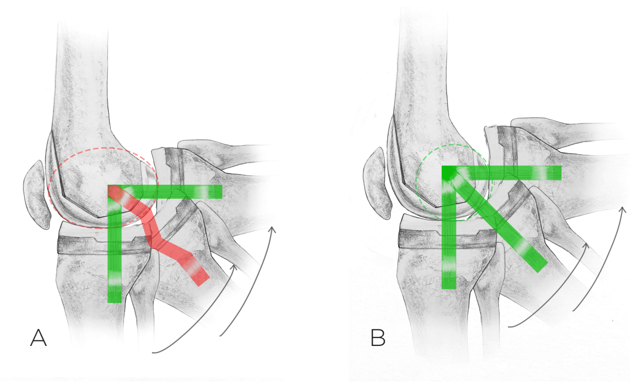

Figure 6. (A) In a MR design, when the knee flexes from the distal radii to posterior radii, the ligament tension can change- especially in mid-flexion due to the changing profile (B) Due to the constant geometry of SR implants, the ligament tension remains more isometric, providing the patient with more consistent support.

Externally rotating the femoral component, however, raises a concern if implanting a MR femoral component. It is necessary to question the clinical consequences produced by implanting an egg-shaped implant when the resected bone is circular in geometry. Multi radius implant design are not based on an externally rotated view of the femur and consequently, they may not convey the same clinical benefits when implanted in external rotation as a SR knee design.

Theoretical Advantages of Fixed Flexion Axis Theory in Implant Design

Since the first application of fixed oblique axis theory in implant design in 1996, numerous clinical studies have been conducted comparing SR and MR knee systems. These studies have demonstrated that there are several theoretical advantages of SR design, including more stable mid-flexion, larger range of motion, less anterior knee pain and faster rehabilitation.

1. Stability in Mid-Flexion

Stability in mid-flexion is of crucial importance, because it directly impacts patients' postoperative quality of life by giving them confidence in their knee while performing daily activities comfortably, or even independently.

Various authors have documented that mid-flexion stability is negatively affected when a MR knee design transitions between different radii.[24–27] Wang et al. suggested that this instability is caused because the tension of the collateral ligaments changes, resulting in more abduction motion needed to stabilize the knee joint (Figure 6 A).[26,27] Wang et al. also pointed out that it is difficult to correctly adjust the tension of the collateral ligaments throughout the range of motion due to varying radii of rotation in a MR design.[27] Clary et al. and Gomaa & Williams demonstrated that this instability can produce paradoxical anterior translation of the femur in mid-flexion, which is caused by sudden radial changes when the implant moves from the distal radius onto the posterior radius.[24,25] Wang et al. observed that the hamstrings of MR patients were co-activated in order to augment knee joint stability.[27]This co-activation was not observed in patients who received SR knees.

The consistent curvature of SR designs reduces the negative effect caused by the transition of different radii of MR designs by providing smooth articulation surface geometry through the entire range of motion (Figure 6 B). In the active flexion range, the SR geometry facilitates intraoperative ligament balancing and provides more varus/valgus stability. Removing instant radius changes eliminates sudden decreases in conformity, which helps reduce anterior shifting while providing more stability in mid-flexion in combination with ligament balancing.[23,26,27]

2. Quadriceps Muscle Efficiency

The center of rotation in SR designs is placed relatively posterior compared to MR knees (Figure 7). A greater F/E axis lengthens the quadriceps moment or lever arm, which improves the mechanical efficiency of the muscles. D'Lima et al. showed that the moment arm in SR design is approximately 1 cm longer than MR designs.[28] Due to this effect, it decreases the quadriceps muscle force needed to attain full extension and reduces joint reaction force.[28] This same effect also lead to reduced levels of anterior knee pain. In other studies:

- D'Lima et al. measured knee kinematics and quadriceps forces using 6 cadaver knees and found that the SR design had a mean 5%-20% reduction in quadriceps tension. The difference was significant at flexion angles greater than 50 degrees.[28]
- Ostermeier et al. used a device that simulates an isokinetic extension cycle of the knee. Using 12 cadaveric knees (6 physiological knees, 3 SR knees and 3 MR knees), they investigated the amount of quadriceps muscle forces needed to extend the knee. The results documented that SR knees had lower quadriceps forces needed to achieve knee extension when compared to the MR knee design tested.[29]
- Mahoney et al. observed that after 2 year follow-up of 184 knees (83 MR and 101 SR), patients with SR knee showed improved post-operative extensor mechanism function.[30]

- Wang et al.[26,27] reported that patients who received SR TKA took less time to perform sit-to-stand and stand-to-sit time perhaps due to the higher torque produced by the SR design. They also demonstrated that patients with MR knees had to increase the effort of their contralateral limb to compensate for their weak TKA limb.
- Gómez-Barrena et al. enrolled 60 patients (30 SR and 30 MR) to study postoperative rehabilitation and quadriceps efficiency. They used an Isokinetic Dynamometer to perform isokinetic evaluation, and showed that patients with SR knee had better quadriceps performance and exhibited a quicker recovery in rehabilitation.[30]

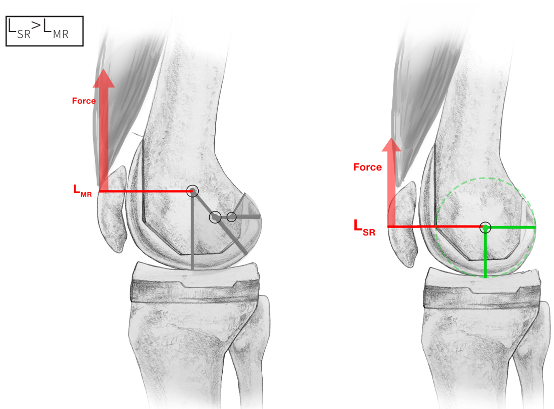

Figure 7. A SR femoral design positions the flexion-extension axis more posteriorly when compared to a MR design. This more posterior position increases the length of the patella- femoral moment arm for the SR design. The longer lever arm results in the quadriceps muscle needing to generate less force to reach needed torque levels for patients to achieve full extension. This can benefit patients as their muscles are often atrophied.

3. Anterior Knee Pain and Rehabilitation

The extended moment arm and reduced joint reaction force on the patella may lead to reduced anterior knee pain.[31,32] In the Mahoney et al. study, it was documented that patients with SR knees had less anterior knee pain compared to patients with MR knees (1%in SR knee patients and 22% in MR knee patients, p=0.001).[31] Browne et al. also demonstrated that reduced patellofemoral forces decreases contact stress between the patella and femur after TKA, which may result in decreased wear and, consequently, longer survivorship.[32] It has also been reported that improved quadriceps muscle efficiency and decreased anterior knee pain results in less effort and more comfort for SR knee patients performing daily activities, such as walking, rising from a chair, climbing stairs and using assistive walking devices, compared to MR knee patients. Thus, the implantation of SR knees can result in faster rehabilitation.[28,32]

These theoretical advantages have proven to be clinically significant by other researchers, as well.[30,33,34] Cook et al. compared 426 SR TKA patients with 133 MR TKAs with an average of 3.9 years follow-up. The SR patients had statistically significantly less anterior knee pain (p=0.021), less mid-flexion instability (P=.002), and greater extensor mechanism efficiency, as demonstrated in the patient's ability to fully extend the leg (p=0.025) and climb stairs (p=0.0001). The SR patients also demonstrated faster rehabilitation, as evidenced by improved walking (p=0.0005), improved use of assistive walking devices (p=0.0005) and higher knee society scores (p=0.002).[34]

Conclusion

There are many factors which can influence a patient's outcome, such as their expectations, surgical technique, rehabilitation, as well as implant choice and design. The SR design is an evolution of knee implants based on multiple research groups employing different scientific methods, yet still arriving at similar conclusions. Knee motion can accurately be modeled as simple rotations about a F/E axis fixed to the femur, and an I/E axis fixed to the tibia. In both the laboratory and clinical setting, the SR design has consistently demonstrated the ability to convey improved biomechanical advantages when directly compared to MR knee designs. These SR benefits include enhanced stability, better patella-femoral mechanics resulting in less anterior knee pain, which ultimately leads to improved patient rehabilitation.[24-34] Implant design is one of the central pillars of successfully treating patients who undergo TKA, and scientific evidence has shown that the SR knee design is a step forward in the goal of optimizing patient outcomes after TKA.

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Addressing the Issue of Anterior Knee Pain after Total Knee Arthroplasty

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Introduction to Anterior Knee pain

Anterior Knee Pain (AKP) is peripatellar or retro-patellar knee Pain. AKP can occur after Total Knee Arthroplasty (TKA) with or without patellar resurfacing. AKP is often indicative of patellar instability[1]. It is most pronounced when patients are performing stressful activities such as ascending/descending stairs, raising from a chair or even riding a bike[2]. Kneeling, which is an important activity for many patients, can also be a challenge to many patients due to pain, an insufficient range of motion or involvement of another joint[3–5]. It has been documented that although a majority of patients may be able to kneel postoperatively, they may benefit by including kneeling in postoperative TKA protocols[6]. Patients complaining of a stiff knee and decreased range of motion (ROM) after TKA may be experiencing patellar subluxation and AKP[2]. Depending on the root cause, treatment options may involve revision of TKA components and/or soft tissue releases[1]. The large incidence of AKP in the early history of TKA led to the redesign of the patellofemoral joint and modification of surgical techniques[7,8]. The purpose of this paper is to provide a contemporary review of AKP: its causes, prevention and treatment.

What is the incidence of AKP?

As few as 43% of TKA patients report being completely pain free[9]. Reports of the incidence of AKP vary significantly, but they generally fall in the range of 8-11% of all TKAs[10,11]. Along with aseptic loosening, instability and infection, patellar pain is a significant cause of revision knee surgery[11–13]. Alarmingly, it has been reported that up to 41.1% of AKP is due to modifiable factors, such as implant design or surgical error[14,15].

What are some of the causes of AKP?

Patient Factors such as young age, female gender and certain ethnicities can lead a higher incidence of AKP[9,16–18]. Valgus knees, patients with marked preoperative deformity, neuromuscular pathologies and obese patients are also more prone to AKP[19]. Other common patient factors include depression and increased body mass index (BMI)[20]. Interestingly, preoperative AKP does not appear to be predictive of postoperative AKP[21–25]. Muscle imbalance, particularly involving a weakened vastus medialis, can activate the vastus lateralis that can produce lateral tracking and associated AKP after TKA[10,26]. Also, weakness in the hip adductors can lead to a dynamic lateral thrust that can also produce lateral patellar tracking and AKP[10].

Surgical Technique Factors such as component malposition, can lead to AKP. The surgical placement of implant devices in internal rotation produces an increased Q angle that is linked to lateral patellar tracking, instability and AKP[27–31]. Dislocation and implant failure have been reported in cases of severe component malrotation[32]. Further, in cases of large medial soft tissue releases, if the gap balancing technique is used, there a higher chance of internally rotating the femoral component[33]. In patients with severe internal and external valgus deformities, the use of the gap balancing technique can also result in internal rotation of the femoral component. The gap balancing technique can also produce a proximal shift in the joint line that can lead to increased pressure on the patella and extensor mechanism[34]. There are several considerations in the implantation the femoral TKA component. With respect to choosing a method to gauge the amount of external rotation, the transepicondylar axis (TEA) is the most consistent landmark to use, especially when compared to the posterior condylar axis[1]. The TEA is coincident with the flexion/extension axis of the knee and is perpendicular to the weightbearing axis of the tibia[35–37]. It has been documented that using a fixed guide that references the posterior condyles can lead to femoral rotational errors of ≥3°in over 45% of TKAs[38]. The TEA is also the best guide for determining a balanced flexion space, as opposed to the posterior condyles that often leads to an inconsistent flexion gap[39]. This benefit in achieving balanced gaps was particularly evident in valgus knees due to abnormal posterior geometry[40]. Correct external rotation often lessens the need to perform soft tissues releases that have been associated with postoperative patellar complications[41–44].

Surgeons should avoid implanting femoral components that are boxy and could add thickness to the patellofemoral groove and overstuff the joint. The femoral component may benefit by being implanted in a lateralized position that can help reduce the Q angle and aid in patellar tracking. When lateralizing the femoral component, though, an important limitation is to limit any resulting overhang to ≤3 mm. Overhang exceeding 3mm has been associated with a 90% increase in the incidence of patient reported pain two years after TKA[45]. In summary, if the femoral component is poorly sized or shaped, and/or placed incorrectly in the sagittal or transverse, the result could be abnormal strain in the anterior knee soft tissues that could result in failure, AKP and reduced knee flexion[46-54].

Likewise, the orientation of the tibial component is an important surgical step. The key is to avoid internal rotation of the tibial component that can lead to lateral tracking, subluxation and AKP. Attention should be directed at not increasing the Q angle of the patellar mechanism. It is suggested to position the tibial component in line with the medial one-third of the tibial tubercle[1].

If a patellar component is used, the surgeon must be careful that the patellar resection is equal on the medial and lateral aspects. If the overall thickness is increased, this could result in lateral instability of the patellar[55]. Attention needs to be directed at the ultimate patellar thickness as constructs either too thin or too thick have been associated with an increased chance of post-operative complications[1]. A 4mm increase in patella thickness can reduce the passive ROM by 4°[48]. It is suggested to medialize the dome 1-2 mm as lateral dome placement can tense the lateral retinacular tissue and produce lateral tracking and AKP56. Lastly, the surgeon must pay attention to the patellar tracking prior to closing the wound. If the patella is not tracking satisfactorily, the surgeon should first check patella tracking after releasing the tourniquet, if it is being used. If this does not resolve the problem, then a partial or full lateral tissue release can be performed or any mispositioned implants should be addressed. Failure to achieve good patellar tracking can lead to postoperative issues, such as AKP.

Implant Design can impact outcomes. Femoral designs that are boxy or have a short trochlear groove, thick and non-anatomic anterior flange can adversely impact patellar tracking by overstuffing or can lead to patellar clunk[57-62]. Sagittal geometry, femoral sizing and tibial insert design can also impact AKP.

Anterior flange and trochlear groove

It has been documented that a deepened patellofemoral groove can help to avoid overstuffing[19,63-65]. Shallow femoral grooves or femoral components with anterior aspects that are too thick in the sagittal plane or too wide in the transverse plane should be avoided[66]. A shortened femoral groove from the proximal femur to the intercondylar notch is one of the factors that can produce patellar clunk syndrome, as evidenced by a thick fibrous nodule proximal to the patella that can be observed under arthroscopic evaluation. Clinically, patella clunk presents as a painful clunking sensation which occurs between about 30-45° of flexion[67-69]. Patellar clunk is most prevalent with posterior stabilized knee designs. Design features such as a short patellar groove, a boxy design or a design having a sharp anterior edge on the box should be avoided[67-70].

Femoral Sizing Options

An implant system that has a wide array of sizes is helpful to avoid excessive overhang that can occur when lateralizing the femoral component to reduce the Q angle to aid in satisfactory patellar tracking.

Sagittal Plane Geometry

Mahoney et. al. documented that the sagittal geometry of the femoral component can have a statistically significant impact on the incidence of AKP[71]. A group of 184 patients having two different posterior stabilized knee systems were compared. In group "J" (n=83), a standard femoral component with a traditional "J" shaped femoral component was used, while in group "S" (n=101), a single radius component was chosen. Theoretically, the single radius designs provided the patient with a longer quadriceps' moment arm (Figure 1 A,B) and hence less force should be required to extend the leg[72,73]. In this study, patients with the single radius femoral design reported significantly less AKP (15% vs 22%; p=0.001) when raising from a standard office chair. This significant decrease in AKP was reported to be attributable to the longer quadriceps lever arm of the single radius femoral component design[74]. A longer lever arm enables extension, which can decrease the overall force on the patellar thereby reducing the incidence of AKP in normal daily activities such as stair climbing or raising from a chair[75]. A recent study utilizing 220 consecutive patients also documented less AKP (p<0.05) when comparing a single radius versus a "J" or multi-radius design femoral TKA component[76].

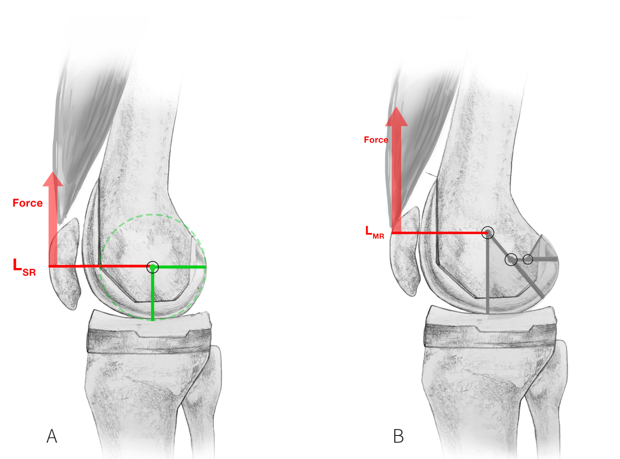

Figure 1. The Single Radius (SR) design femoral design (A) positions the flexion-extension axis more posteriorly when compared to a Multi-Radius (MR) or "J" shaped design (B). This more posterior position of the SR increases the length of the patella-femoral moment arm. The longer lever arm results in the quadriceps muscle needing to generate less force to reach needed torque levels for patients to achieve full extension. This can benefit patients as their muscles are often atrophied as well as less force needed across the patellofemoral joint which can reduce the incidence of AKP.

Insert Design

A few design features of polyethylene inserts may be important to consider when reducing the incidence of AKP. Patients may benefit by using inserts with a generous anterior relief along the anterior aspect. This relief may lessen the incidence of the extensor mechanism being stretched across the anterior insert, especially in deep flexion. In a posterior stabilized knee, the design and location of the post is important. The anterior portion of the post should be designed to avoid any rubbing against the host patella or the patellar implant. The degree of hyperextension allowed before the anterior aspect of the post impacts on the anterior aspect of the box is an important design consideration to avoid potential implant failure. Lastly, the issue of mobile versus fixed inserts can affect AKP. Although one study has reported that mobile bearing inserts may reduce the incidence of AKP[77], most studies have concluded that there are no clinical benefits for mobile bearing knees when compared to fixed bearing designs[78,79].

AKP and the choice of patellar resurfacing

In the sports medicine literature, it has been documented that patients can have severe AKP even though their patellofemoral articular cartilage appears intact and that some patients with severe cartilage damage are pain free[80]. Articular cartilage is completely free of nerve fibers[80,81]. The largest number of nerve fibers in the knee are found within the quadriceps muscle group followed by the retinacula, patellar tendon, and synovium[80,81]. There are also nerve fibers within the infrapatellar fat pad that can be subjected to overloading of impingement, which can lead to AKP[82].

Studies of TKA vary on the correlation of AKP with patellar resurfacing or retention. A meta-analysis of seven high quality studies suggested that there was no benefit in resurfacing the patella to prevent AKP[83]. The subject remains controversial with some studies demonstrating better results with resurfacing[11,24,41,84-89] while other studies documenting no benefit[23,90,91]. Patellar resurfacing has been associated with component loosening, necrosis and fracture[84,92].

There is literature support that suggest the anatomic patella may improve quadriceps function when compared to some circular implant patellar designs[93,94]. These results may be design dependent, as implant design has been documented to influence on the incidence of AKP[19,63,64]. This may be of importance when a posterior stabilized knee is used, as their revision rate is typically much higher when the patella is not resurfaced[11].

How the design of the MOBIO™ total knee can help address the issue of AKP

The MOBIO™ knee design features an anatomic and thin anterior flange, gradually deepened trochlear groove, quadriceps friendly sagittal geometry and insert that has a generous anterior relief and patella friendly tibial post.

1. Anterior Flange

The MOBIO™ knee has an anatomic 7° valgus patella track which can help maintain the Q angle, which is an important consideration in proper tracking. The patellar track is broad and open at the superior/anterior flange, which progressively forms a deep trochlear groove as the patella travels from extension to flexion (Figure 2).

Figure 2. The design of the trochlear groove and notch of the MOBIO™ TKA allows the patella to be gently funneled into the groove from full extension to 45 degrees of flexion. This funneling effect accepts various anatomic entry points for the patella. After 45 degrees, the groove deepens to reduce stress on the anterior tissues. After about 60 degrees of flexion into full flexion, the patella is accommodated in the trochlear notch area. As the patella comes from full flexion into extension, there is a gentle ramping effect at 60 degrees of flexion that allows an easy transition from the notch to the groove area of the femoral component.

The design allows the patella to be funneled gently into the groove as the knee flexes. Multiple studies have demonstrated the correlation between poor posterior stabilized femoral design and the incidence of adverse events, such as patellar clunk[57-62]. The MOBIO™ knee design has an elongated trochlear groove that supports the patella into deep flexion. As the knee extends, the deep groove of the MOBIO™ design softens the transition of the patella as it transitions in deep flexion from condylar support to trochlear groove. The MOBIO™ knee has a thin anterior flange that minimizes overstuffing, which can reduce flexion and cause AKP[1,48,55,66]. This thin anterior flange conserves bone and produces less tension in the anterior soft tissues by relaxing the extensor mechanism.

2. Trochlear Groove

A deep patellar groove, such as the groove designed into the MOBIO™ knee, has been shown to decrease the incidence of AKP and even revision with either resurfaced or unresurfaced patella[19,63-65,95]. The deep groove found on the MOBIO™ design further provides safety against lateral patellar subluxation. Internal testing of the patellofemoral constraint of the MOBIO™ knee documented an increasing resistance to lateral subluxation as the patella moved from extension to flexion. At all tested positions of flexion (15°, 45°and 90°), the force needed to sublux the MOBIO™ patella laterally was higher than anticipated physiological values reported in the literature (Figures 3-5)[96].

As the patella moves from 0° to 45° of flexion, the anterior thickness of the medial and lateral flanges grad-

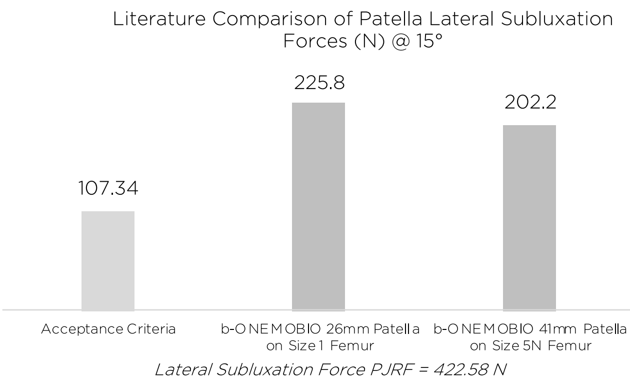

Figure 3. The resistance of the MOBIO™ TKA patellar component to frank subluxation is nearly double anticipated physiologic loads at 15 degrees of flexion. This was true for all combinations tested.

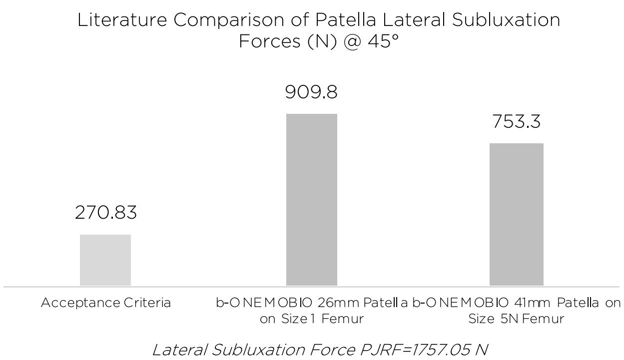

Figure 4. At 45 degrees of flexion, the MOBIO™ TKA patella offered significant resistance to lateral subluxation. The MOBIO™'s resistance to subluxation was much more than twice the levels anticipated in the patellofemoral joint.

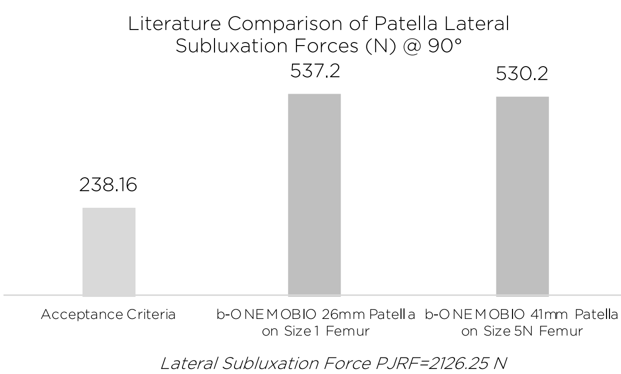

Figure 5. At 90 degrees of flexion the forces required to sublux the MOBIO™ patella were significantly higher than the patella is expected to experience anatomically. This was true for all configurations tested. This suggests that the MOBIO™ design would effectively resists lateral subluxation of the patella.

ually increase, producing a deepened trochlear groove that helps to resist patella subluxation. From 45° to 60° degrees of flexion, the funnel moves the patella contact point from the center of the groove to the medial and lateral facets of the femoral component. At 60° degrees of flexion, a deepened radius creates a boat ramp feature anterior to the intercondylar notch, or the box transition, permitting the patella to have a smooth transition into the condylar region (Figure 2). This ramp on the MOBIO™ knee can decrease the incidence of "catching" that can produce patellar clunk and AKP.

During this transition, the internal testing shows, both the lateral subluxation force and patella contact area

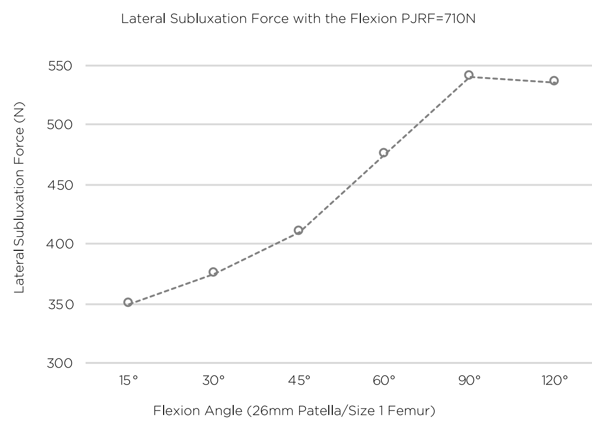

Figure 6. As the flexion angle changes from 15° to 90°, the subluxation force needed for MOBIOTM gradually increases, which restrains the patella as the flexion goes deeper.

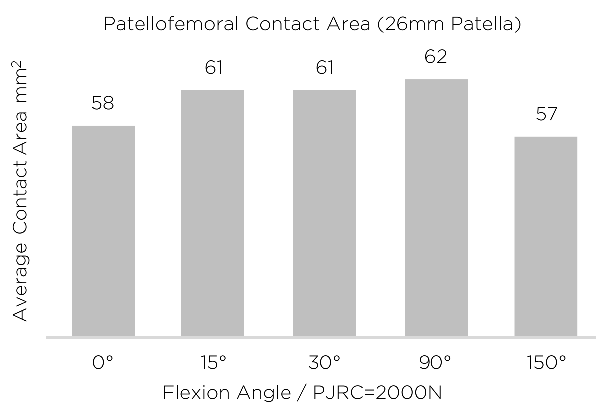

Figure 7: Patella contact area increases with the flexion angle from 0° to 90° of flexion, thus reducing the contact stress.

shows and increasing trend with the increase of the flexion angle (Figure 6 & 7).

3. Tibial Insert Geometry

The MOBIO™ tibial insert component is designed with a deepened anterior patella relief and anatomically shaped tibial post. The combination of these two features can help to prevent patellar tendon irritation during deep flexion and facilitate a deeper range of motion (Figure 8).

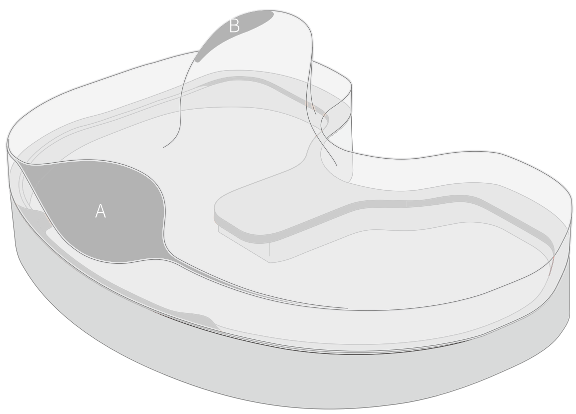

Figure 8. The MOBIO™ insert is designed with a generous anterior relief (A). This feature accommodates patellar tendon in deep flexion and reduces the chance of tense anterior soft tissues which could reduce range of motion. Also, the anterior aspect of the post (B) is chamfered to avoid impacting the posterior aspect of the patella- a feature incorporated to reduce the chance of AKP.

4. Sagittal Geometry

The MOBIO™ TKA femoral component also features a single radius sagittal profile (Figure 1A). This design feature increases the effect lever arm of the quadriceps muscle group as expressed through the femoral-patellar joint. Importantly, the increased lever arm decreases the amount of force exerted through the patella in extending the leg, which has been documented to decrease the incidence of AKP in controlled clinical studies[71–73,76].

5. Sizing Options

Importantly, to avoid overhang which can lead to AKP, the MOBIO™ knee system offers 15 sizes (each in left/right configuration) of femoral components[45]. This includes 5 narrow options that are 2-3mm more narrow than standard sizes in the medial lateral plane. While allowing for maximum lateralization possible, this type of design also allows surgeons to effectively avoid overhang on the medial and lateral sides, which has a higher incidence when operating on the small Asian female patients.

AKP diagnosis and some treatment options

The main AKP symptom is pain in the peripatellar and/or retro-patellar regions. The pain is generally described as different that the pain experienced before TKA. If the pain is persistent after TKA, surgical error needs to be considered. A complaint of perceived stiffness producing a decreased ROM and the inability to achieve full flexion may be indicative of patellar subluxation. The examination may involve palpitation of the extensor mechanism throughout the ROM as the patient indicates the painful areas. Checking the patella throughout the entire ROM can reveal areas of subluxation and even frank dislocation. Lastly, lateral tissue tightness or too much patellar freedom should be explored. Radiographic studies should include lateral and sunrise patellar views. The polyethylene thickness, the balance of the patella in the groove and the quality and quantity of the patellar resection should be evaluated. Computed tomography (CT) scans can be used to evaluate the alignment and importantly check the rotation of the TKA implants. The femoral component rotation should be checked against the transepicondylar axis, and the tibial component rotation may be checked against the tibial tubercle. If no obvious malposition or resection issues are noted, conservative treatments such as extensor mechanism strengthening, bracing or having the patient avoid painful activities can be considered. If conservative treatment fails, surgery may be considered[1].

Conclusion

Anterior Knee Pain (AKP) can be caused by several factors, such as patient demographics, surgical technique and implant design. Patient education regarding their demographic propensity to sustain complications such as AKP should be discussed with the patient prior to surgery. Surgical technique and implant choice are within the realm that the surgeon can most easily control. Appropriate placement of the components, especially with respect to internal/external rotation, is very important in avoiding AKP. Surgeons should avoid increasing the Q angle and perform any required soft tissues releases. Implant design is also a major consideration in avoiding AKP. Like the MOBIO™ knee design, implants should have an anatomic, deepened groove. The deepened groove helps to stabilize the patella against subluxation and releases tension in the soft tissues that could lead to AKP and /or reduced ROM. Femoral designs should gently gather the patella into the groove from extension and should support the patella into deep flexion, which is especially important for posterior stabilized design implants. Any abrupt geometric changes as the patellar transitions from flexion into extension should be avoided, as such transitions can produce patellar clunk. Implanting an implant that is too wide should also be avoided by choosing an implant system with a wide variety of sizes, such as the 15 sizes of MOBIO™. AKP can be a troubling scenario for the patient after TKA, but through appropriate patient education, surgical technique and implant choice, the incidence AKP can be greatly reduced.

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Cam and Post Design Considerations in Contemporary Primary Total Knee Arthroplasty

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Introduction

Posterior Stabilized (PS) total knee arthroplasty (TKA) design was first implanted by John Insall at the Hospital for Special Surgery in 1978. The original PS design evolved from the Total Condylar (TC) knee mainly to help to increase the range of motion. The PS design was a collaboration between John Insall and Al Burstein- thus the name- IB. Like the TC design, the IB design involved sacrificing both cruciate ligaments, however the IB incorporated a cam and post mechanism that was designed to contact at 70° of flexion. Once engaged the cam/post was to stabilize the sagittal motion of the femoral component on the tibia to prevent anterior translation of the femur. It was believed that this anterior translation prevented sufficient range of motion which was generally limited to no more than 90° with the TC design. While the TC was highly conforming in extension, as the knee flexed the sagittal profile of the femoral component transitioned to a smaller radius which permitted an anterior translation the femur on the tibia. As the femur moved forward with further flexion, the posterior aspect of the femur impacted against the posterior lip of the tibial insert blocking further flexion. The cam and post of the PS knee was to reduce this blocking of flexion by inducing the femur to roll posteriorly on the tibial insert as flexion increased. This rollback allowed deeper range of motion by allowing the femur to be stored behind the tibia by increasing the flexion angle.[1]

There were of course concerns with the new PS design. Would the forces involved in the cam/post loosen the implant/cement or cement/bone interface? Would the polyethylene post break or wear out? Would the cam jump over the post in extreme envelopes of motion? Would PS design really increase range of motion? How would patients tolerate the sensation of the cam and post coming into contact and driving knee motion?

Early clinical results were indeed encouraging, but not perfect. The range of motion was higher with the PS design when compared to the TC. The average flexion was close to 115°which represented a gain of nearly 25°.[1] There were few cases of aseptic loosening or post fractures. There were some cases of cam/post dislocation. This complication was attributed to surgical error in balancing the extension and the flexion gaps. If the flexion gap was larger than the extension gap and the knee is in high flexion, and subjected to a coronal force, the cam could subluxate anteriorly over the post. Activities such as crossing the legs and attempting to tie the shoes could potentially lead to a cam/post subluxation. Obesity has also been correlated to dislocation of PS knees.[2] Another observation was a low but troublesome incidence of patellar issues.[3] In particular, some patients complained of persistent anterior knee pain (AKP). This AKP is believed to be related to several factors including suboptimal rotational alignment of the femoral and the tibial components, the lack of left and right side specific femoral implants, a suboptimal patellofemoral trochlea design, and a boxy sagittal femoral component profile.[4–9] The IB nonetheless was an exciting foundation for the evolution leading to the contemporary PS designs.[10]

Many different PS designs have been introduced into clinical use over the past 4 decades. Some important PS design features include the cam/post contact angle, the allowable range of motion in flexion, the freedom of internal/external rotation, the allowed freedom for varus/valgus constraint, and the constraint against hyperextension. The contact area is important not only for the femoral tibial footprint, but also the area of contact between the cam and the post. The sagittal profile of the femoral component has been shown to have an impact on the overall range of motion, and the incidence of anterior knee pain.[11–13] The implant sizing accuracy has also been shown to have an impact on the clinical results.[14] The cam/post so called "jump height" or the distance for the cam to subluxate over the post at various flexion angles needs to be adequate for a patient's needs for activities of daily living. There have been isolated reports of PS inserts disassociating from the tibial trays.[15–17] Therefore, the bearing insert locking mechanism must be robust to withstand the load of daily activities. The purpose of this paper is to examine each of these important design parameters that may influence the clinical outcome of a PS TKA design.

Implant Design Parameters

Cam-Post Engagement Angle

The cam/post contact angle is defined as the flexion angle at which the cam and the post engage to induce femoral rollback. Classic design rationales included two ranges for the cam/post engagement angles: 1) engagement in midflexion (about 45°), and 2)engagement at higher flexion (> 60 degrees). Some of the design parameters for commercially available implant systems include: the Triathlon (Stryker) at around 45°, the Scorpio NRG (Stryker) and the Vanguard (Zimmer-Biomet) at 75-80 degrees, and the NexGen HF (Zimmer-Biomet) at 102 degrees.[18] The MOBIO™ PS TKA design (b-ONE) engages at 65° to induce optimal femoral rollback, and facilitate achieving higher range of motion.

There are potential advantages and disadvantages with both design rationales. Post wear is theorized to be reduced with the cam/post engagement at higher flexion angles. Earlier cam/post engagement can result in more impaction and potential increased wear. Late engagement may also result in a more sudden increase of contact pressure rather than a more gradual increase in the contact pressure with designs which offer earlier contact flexion angles. Later engagement can also reduce the range of motion as the femoral rollback may be adversely affected.[18]

The cam/post engagement can be altered with surgical variables such as the posterior tibial slope as well as the positioning of the femoral and tibial implants. Higher posterior tibial slope can lead to the femoral component to assume a more posterior position on the tibial insert which increases the needed flexion angle for the cam/post engagement. If the tibial insert is moved to a more anterior position, this leads to a lower angle of flexion before the cam and the post would engage. Different size pairings of the implants may also change the flexion angle needed to have effective cam/post engagement. A femoral component which is placed in flexion would increase the needed flexion angle for the cam/post engagement. The clinical outcomes therefore are not exclusively influenced by the design characteristics of an implant system.

Allowable Internal-External Rotation

Due to the femoral geometry (both in the native and in the replaced knee) and muscle pull on the tibia, there is an internal/external rotation (I/E rotation) of the tibia associated with knee flexion and extension. Apart from duplicating the screw-home mechanism, the effect of this motion is also to diminish the Q angle in flexion to decrease patellar subluxation forces in the normal knee and after TKA.[20]

Figure 1. A total arc of 30°(±15°) is present for internal/external rotation in the articulation of the MOBIO™ PS (b-ONE) knee system.

Several design principles could affect the relative I/E rotation, such as the space between the cam and the post (Figure 1). If the tolerance is too tight, impingement between the post and the box could occur leading to insufficient I/E rotation and excessive post wear[21]. It is reported that in those knee designs with relatively flat posterior post geometry, earlier post/cam impingement may occur due to external rotation early in the flexion range.[22]

Moreover, impingement and reduced I/E rotation can lead to component fixation loosening and excessive wear.[23] Thus, more I/E rotation is a desirable design characteristic in the PS TKA system. The MOBIO™ (b-ONE) PS system allows for 30° (±15°) of I/E rotation (Figure 1) which is more than adequate to meet the demands of a patient's active daily living requirements.[24]

Torque is the measurement of the required force applied over a lever arm to induce a rotation movement. The torque needed for the I/E rotation is another important design consideration. It is important when designing the femoro-tibial articulation to optimize both the conformity and the freedom of movement which are often competing objectives. If a high amount of torque is required to induce the desired rotation, the knee joint may not not be able to attain the desired pattern of motion. Early loosening of tibial implants have been reported when the articulation has produced too much resistance to motion.[23]

Testing was performed according to ASTM 2083 in order to document the resistance to internal/external rotation under axial load. This ASTM standard measures the torque needed to reach 20° of I/E rotation. However, if more the 25 n-m of torque is required, the test is discontinued and the degree of rotation is recorded. The results were very favorable for the MOBIO™ PS system (b-ONE) when compared to the 2 most popular PS TKA systems on the market currently. The torques required for the MOBIO™ PS (b-ONE) TKA to reach 20° of I/E rotation were nearly only half of the torques required for such IE rotation with designs from Zimmer Biomet™ and from Stryker™.[25] This testing data demonstrated that the MOBIO™ system (b-ONE) can rotate more freely when compared to those other knee designs. This was true at all flexion angles required by the ASTM 2083 which are at 0°, 15°, 90°and 150° of flexion. These low torque values suggest that the articular surfaces of the MOBIO™ PS system (b-ONE) would permit more anatomic motions and reduce the impact forces of the femoral box on the post during the range of motion. Furthermore, the lower torque and the less impact forces would reduce the loads upon the insert locking mechanism as well as the forces experienced at the implant/cement and at the cement/bone interfaces.

The contact area between the femur and the tibia is important to avoid polyethylene wear. Both the MOBIO™ PS and PS+ articulations (b-ONE) were tested according to the ASTM standards F2083 and F1223. The results of the testing at a variety of flexion angles and loads were comparable or better than those reported for 22 other TKA PS systems that are approved by the US Federal Drug Agency (FDA).[26]

Varus Valgus Rotation

In the coronal plane, the degree of the varus and valgus rotation is controlled not by the post/box contact, but rather by the collateral ligaments. In the coronal plane, the MOBIO™ PS insert (b-ONE) offers no resistance to varus/valgus rotation. If the surgeon determines that there is insufficient tension or balance of the collateral ligaments for optimal coronal stability, then a MOBIO™ PS+ articulation (b-ONE) may be used. The MOBIO™ PS+ insert (b-ONE) permits ±3.5° of varus/valgus rotation constraint (Figure 2). Furthermore, the MOBIO™ PS+ insert (b-ONE) permits ±5° of internal/external rotation as often the indication of insufficient coronal support is accompanied by the desire for more transverse rotational support as well.[27]

Dislocation or Jump Height

Dislocation, or the "jumping" of the femoral cam over the tibial post was a problem with the early PS designs.[2,28,29] The desired design rationale is to have the cam contact the distal aspect of the post (Figure 3). A distal contact can have three benefits: 1) it maximizes the distance between the contact patch and the proximal aspect of the post, 2) it minimizes the lever arm on the post which can increase the post longevity, and 3) the distal post is the strongest areas of the post thus reducing the risks of post breakage over time.

The main design considerations related to the jump height are: 1) the height of the post, 2) the contact point of the cam and the post, and 3) the geometry of the cam. There is limitation of the post height. If the post is too high, the anterior portion of the post could contact the cam and cause patellar tendon irritation resulting in anterior knee pain. The MOBIO™ PS insert (b-ONE) post height is designed to optimize the jump height while avoiding the risk of impingement on the extensor mechanism.

Hyper Extension

The contact area in the extreme ranges of knee motion should be large enough to avoid excessive wear or even potential fracture of the polyethylene insert-especially the post. If the femoral component box impacts the anterior aspect of the post in extension or in hyperextension when the extension gap is not ideally balanced, post fractures have been reported.[13,30-32] The MOBIO™ PS (b-ONE) box/post design characteristics allow for 10° of hyperextension before the anterior aspect of the femoral component box/trochlear notch would impinge against the anterior portion of the post (Figure 4).[27]

Post Breakage and Strength

Post breakage had been a problem in some of the early generation TKA PS designs. It is infrequent with improvements in the biomaterials and in the design characteristics of newer generations of TKAs. However, there are certain design considerations that should be discussed on the subject. Some at-risk design characteristics include: anterior impingement of the post and the box, high contact pressure due to poor post/cam geometry match, and high contact stresses caused by late cam/post engagement.[12, 17, 28-30]

An additional risk is excessive cam/post engagement could also lead to post breakage. TImpingement of the cam and the post can occur when mid-flexion stability is present. In several studies it has been reported that inconsistent sagittal femoral implant geometry could cause paradoxical anterior translation of the femur.[33,34]

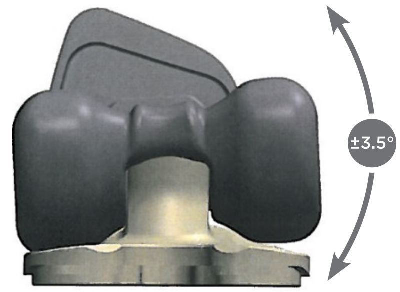

Figure 2. If coronal stability is needed, the MOBIO™ PS+ (b-ONE) insert permits ±3.5° of varus/valgus angulation.

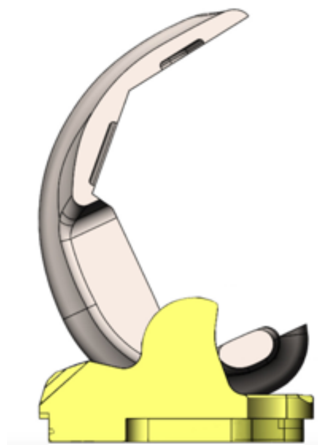

Figure 3. By designing the cam post contact point to be more distal on the tibial post, the jump height is larger which provides additional security against subluxation.

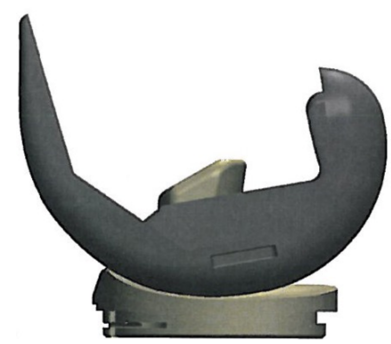

Figure 4. The MOBIO™ PS (b-ONE) knee permits up to 10°of hyperextension

This anterior shift could result in frequent impingement of the cam with the post which increases wear and, in extreme cases, break the post (Figure 5).

The stability of the PS TKA is reliant on the collateral ligament tension and stability due to the absence of both the cruciate ligaments. Indeed, one may think of the PS TKA as a collateral ligament stabilized knee. The single radius design has been shown to resist anterior motion of the femur on the tibia.[12] It has been reported that knee designs with the multi-radius sagittal geometries may be susceptible to this anterior motion of the femur on the tibia during flexion, when there is a significant change in the sagittal geometry.[13,35] In the PS TKA, in addition to potentially reducing flexion, this paradoxical anterior femoral translation could cause the cam to impact on the tibial post which may produce audible clunk. Moreover, the increased impact pressure can have deleterious effects on wear and potential post breakage. Femoral component designs with the single-radius sagittal profile such as the MOBIO™ PS system (b-ONE) is less likely to have this complication, and would simulate more normal knee kinematics.

TKA systems with the single-radius femoral component design have been reported to have two important clinical benefits. The first is a documented decrease in the incidence of anterior knee pain when compared to TKAs with the multi-radius design characteristic.[37] This difference may be because to the increased effective lever arm of the quadriceps which decreases the force needed by the quadriceps to fully extend the leg.[38,39] (Figure 5).

The tibial bearing post strength of the MOBIO™ PS design (b-ONE) has been rigorously tested.[36] The cam was loaded to post at three times the estimated physiological loads for 10 million load cycles (Figure 6). At the end of the testing, all three samples tested successfully survived this rigorous testing protocol. There were no post fractures, no insert dislocations and no significant permanent deformation of the post.

Additional Considerations

Size Options and Interchangeability

Implant systems should allow the surgeon to have intraoperative flexibility to select the implants that best matches a patient's bone morphometry. As the femur and the tibia components are sized independently, the ability to combine various size arrays is crucial. The MOBIO™ PS (b-ONE) system allows for matching variations. The femur and the tibia sizing could vary by up to 2 sizes. Most commercially available systems would allow for size matching variation of only one size. For every given femoral component size, there are potentially 5 sizes of compatible tibial trays. This allows optimization of the tray position which can avoid overhang or malrotation of the tibial component.[14]

Locking Mechanism

The design characteristics of the tibial insert locking mechanism is of critical importance. The insert must withstand the millions of load cycles during daily activities. Moreover, the mechanism must be secure to avoid micromotion that could lead to backside wear of the polyethylene, and potential failure of the edges of the insert in the tongue-in-groove geometry. Although rare, cases of disengagement of the insert from the tibial tray have been reported.[15–17] One strategy to minimize the force on the locking mechanism is to make the contact point of cam on the post distal

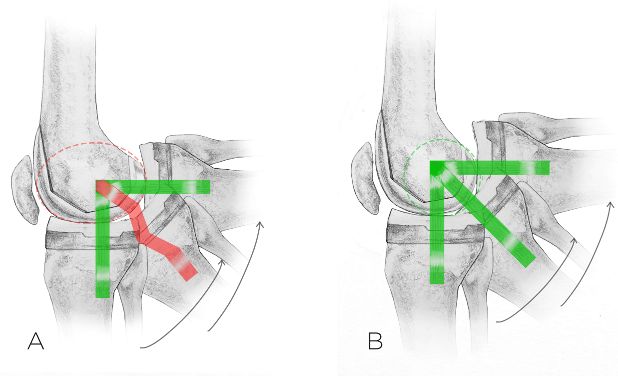

Figure 5 A&B. In a Multi-Radius knee (A), the change in sagittal geometry in midflexion can generate instability in the collateral ligaments (shown in red). By contrast, in a Single-Radius (B) knee such as MOBIO™ (b-ONE), the consistent sagittal geometry throughout flexion can produce enhance collateral ligament isometry.

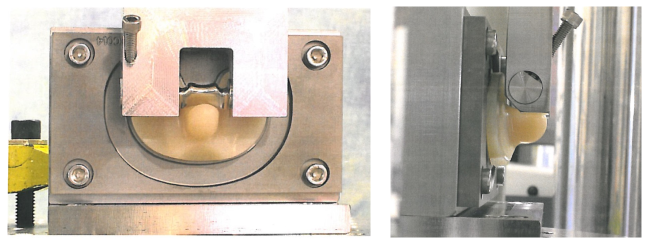

Figure 6. The fatigue loading setup for the MOBIO™ (b-ONE) PS knee. The cam cyclically loaded the post at a load that was three times anticipated physiological loading for ten million cycles.

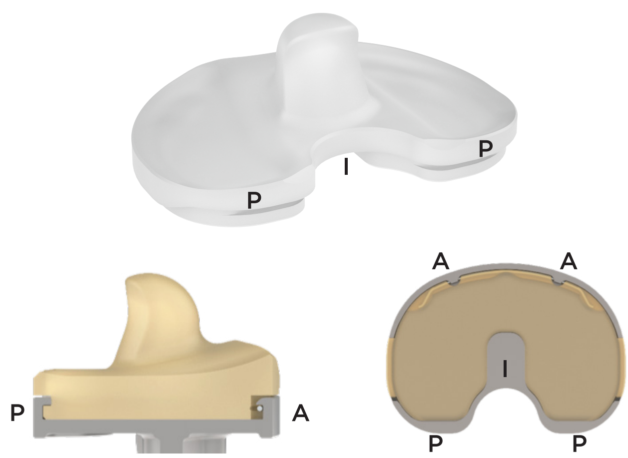

Figure 7. The locking mechanism of the MOBIO™ (b-ONE) knee. The mechanism engages posteriorly(P) with locking tabs which resists liftoff in hyperextension. Anteriorly (A), a CoCr wire on the insert engages with two metal barbs on the tray. There is also a press fit of the insert along the island (I) located anterior to the PCL cutout on the tray. These three locking strategies (A,P and I) engage to secure the insert in the sagittal and coronal planes to minimize micromotion.

on the post. Some of these design characteristics are put into the MOBIO™ PS (b-ONE) system. The contact position between the cam and the post is distal which effectively minimizes the bending force on the locking mechanism. Furthermore, the locking mechanism the MOBIO™ PS (b-ONE) insert incorporates an anterior Co-Cr locking wire which is engaged with metal locking bars within the anterior aspect of the tray which enhances the locking stability (Figure 7). To further secure the insert locking, the insert is press fit along the metallic island anterior to the PCL recess to minimize motion in the coronal plane. This combination of locking mechanism design characteristics is one the most secure and has a successful clinical history.[11,40,41]

Conclusion

In summary, the MOBIO™ PS system (b-ONE) is designed and manufactured to have clinically efficacious functions, and durable fixation and wear. The cam and the post design incorporates established biomechanical principles based on proven clinical performance. The cam/post contact occurs later in flexion and permits a large range of internal and external rotation with reduced torque to achieve the rotation. Moreover, other design features would reduce the risks of impingement during extension. The contact areas are designed to reduce polyethylene wear, but not to reduce the ability for physiological motion to occur. Additionally, the implant geometry and the articulation insert allow for the most optimal knee kinematics to meet the high demands of the daily activities. The single radius profile of the femoral component maximizes the collateral ligament stability while minimizing the paradoxical anterior femoral translation during flexion. The available sizing array matching reduces the risk of malposition and wrongful size selection of the components. The cam/post design characteristics allow for optimal freedom of range of motion and rotation, while providing excellent stability. The knee kinematics are also optimized to meet the patient demands. In conclusion, the MOBIO™ PS system (b-ONE) is designed to minimize the potentials for device failure while maximizing patient outcomes.

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