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THE PERSONALIZED KNEE

THE SHAPE MATTERS STORY

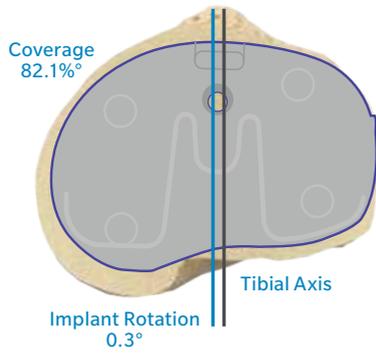


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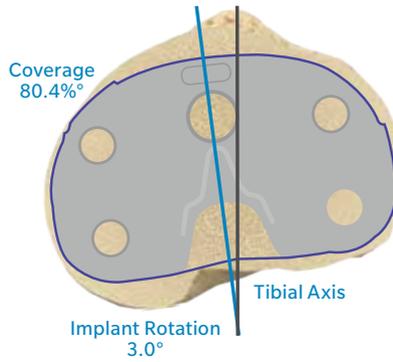
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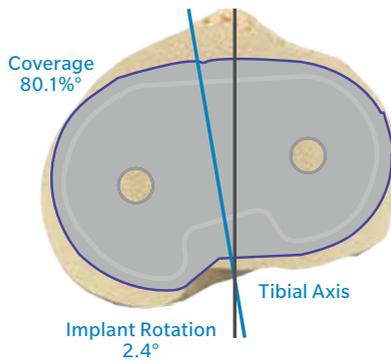
Anatomic



Symmetric



Asymmetric



The dissatisfied patient: Today's challenge in primary TKR

Total knee replacement (TKR) is a highly effective orthopaedic procedure, and a large national joint registry has found 10-year implant survival for modern systems to exceed 90 percent.¹ Despite good implant longevity, a substantial proportion of patients are not satisfied with their TKR outcome.² Bourne *et al.* reported this number to be as high as 19 percent (1 in 5 patients) following primary TKR, and suggested that satisfaction with post-TKR pain relief and function (ability to perform specific ADLs) ranged from just 72 to 86 percent and 70 to 84 percent, respectively.³ Elsewhere in the literature, the incidence of stiffness (poor motion) varies between 1.3 and 13.2 percent,⁴ while anterior knee pain is more common, with an incidence of 10 percent to 20 percent, regardless of whether or not the patella has been resurfaced.⁵

Tibial component mal-rotation: The major cause of postoperative dissatisfaction?

An increasing number of studies have been published that focus on the causes of post-TKR complications such as pain and stiffness. From these studies,^{4,5,6} it has become apparent that rotational mal-alignment of the femoral and tibial components are major causes of these complications.

Rotational mal-alignment, more specifically internal rotation of the tibial component, is now understood to play a dominant role in the pathogenesis of postoperative pain. In a CT analysis conducted by Nicoll, *et al.*, tibial component rotational mal-alignment was compared in two groups of patients - one with and one without pain.⁶ They estimated that at least 4.6 percent of all TKRs in the study had been implanted with internal rotation errors. Importantly, Nicoll, *et al.* reported that in the painful group, 17 out of 39 tibial components (43.6 percent), were internally rotated by more than nine degrees, while no tibial component in the pain-free group was internally rotated more than nine degrees. Interestingly, Nicoll, *et al.* also noted that the incidence of excessive internal rotation errors of the tibial component was more than twice that of excessive internal rotation errors of the femoral component. Furthermore, the magnitude of these errors was much greater than observed for the femoral component.

Nicoll's findings support a previous CT study conducted by Barrack, *et al.*,⁵ who also identified internal rotation of the tibial component as a cause of pain after TKR. Barrack, *et al.* found 12 out of 14 tibiae in patients presenting with postoperative pain to be internally rotated, with a mean internal tibial component rotation of 6.2 degrees. In the control group, patients without postoperative complaints, there were six internally rotated tibial components. In this group the mean internal tibial component rotation was just 0.4 degrees.

As well as pain, internal rotation of the tibial component has also been associated with postoperative stiffness of the knee joint. Bedard, *et al.* analysed CT scans of 34 patients who were revised for stiffness, and found the tibial component from the primary procedure to be internally rotated in as many as 33 cases (97.1 percent), with an average of 13.7 degrees pathological internal rotation.⁴ Again, the incidence and magnitude of femoral internal rotation errors were lower than that observed for tibial internal rotation errors. Together these results may suggest that internal tibial rotation errors have a more deleterious effect on pain and stiffness post-TKR than internal femoral rotation errors.

Why does mal-rotation of the tibial component cause postoperative complications?

During stair climbing, a recent study found a significant correlation between the rotational alignment of the tibia, the movement between the femoral and tibial implants, and the bone rotation relationship angle.⁷ These rotational mismatches affected the subsequent rotational kinematics during flexion. The designed allowance for rotational mismatch within the fixed bearing (~12 degrees) did not fully compensate for the rotational mal-alignment of the tibial component during weight bearing. As previously documented, tibial rotational alignment was particularly susceptible to error.⁸ These errors should be avoided when using a fixed bearing to prevent a rotational mismatch between both the components and the bones. The authors concluded that the rotational alignment of the tibial component is an important factor in post-TKR joint kinematics, which could influence both patient function and patient satisfaction.

Bedard, *et al.* suggested a possible mechanism whereby internal tibial component rotation would influence tibiofemoral kinematics.⁴ It relates to the position of the posterolateral corner of the internally rotated tibial component, which is shifted anteriorly. Given that posterior translation of the femoral condyle on the tibia with flexion occurs maximally in the lateral compartment, this anterior shift of the posterolateral corner of the tibial component will limit posterolateral femoral condyle rollback and thus flexion.

Tibial component internal rotation also increases the quadriceps angle (Q-angle), the angle between the quadriceps muscles and the patella tendon. As a consequence, the force vector on the quadriceps muscles is changed.⁵ The abnormal stress on the patella and surrounding soft tissue could help explain the anterior knee pain and other complications associated with internally rotated tibial trays. Internal rotation in posterior stabilized knee designs has additionally been shown to cause significant stress on the polyethylene post. Stress in polyethylene components is closely related to polyethylene failure.⁸

What causes tibial component mal-rotation?

Mal-rotation may occur during implantation of a symmetrical tibial component when an (apparently) appropriately sized implant overhangs posterolaterally. This overhang can be explained by differences between the shape of the prosthetic component and the resection plane.⁶ Overhang of the tibial component may cause painful impingement of the soft tissues.^{9,10} In attempting to avoid overhang the surgeon may compromise the alignment or size of the component. Compromising on coverage by reducing the size (downsizing) may potentially lead to component subsidence and loosening due to a lack of cortical support.¹⁰ Alternatively, the surgeon may internally rotate the tibial component to obtain better coverage of the cut tibial surface, while avoiding overhang.^{6,11} By doing so, the surgeon solves one problem but simultaneously creates another one.¹¹

Our Solution: The Persona Anatomic Tibial Tray

One of the Persona Knee design objectives was to more closely match the unique needs of individual patients. The increased range of sizes, smaller size increments, and anatomically shaped tibial tray are all intended to improve implant fit to patients. To date, five studies support the design rationale of the Persona Anatomic Tibial Tray.^{10,12-15}

With the use of MRI images for 100 knees obtained from a patient specific instrumentation planning process, Stulberg, *et al.* compared anatomic (Persona CR), symmetric (NexGen[®] CR), and asymmetric (Natural-Knee[®] II) tibial tray designs.¹² Using specially designed preoperative planning software, the researchers investigated which tibial tray design achieved the best coverage. The authors noted that the Persona Knee achieved statistically significantly higher tibial surface coverage (82.1 percent) than either the NexGen (80.4 percent) or the Natural-Knee II (80.1 percent) components. It was suggested, however, that this difference may not be clinically relevant. Nevertheless, when researchers simulated various degrees of tibial tray rotation in order to achieve maximal tibial coverage, they found that the Persona Tibia required significantly less deviation from neutral alignment (0.3 degrees) than the NexGen (3.0 degrees) or the Natural-Knee II (2.4 degrees)¹² tibias - a finding which is likely to be of clinical relevance. Finally, the researchers forced the tibial tray into a neutral rotation and assessed the impact on tibial coverage. They found that tibial coverage in neutral tibial rotation was highest for the Persona Knee (80.8 percent), versus 76.3 percent and 75.8 percent in the NexGen Knee and Natural-Knee II components, respectively.

Dai, *et al.* compared six contemporary tibial component designs in terms of tibial coverage and rotational accuracy.¹⁰ Digital surface models were obtained from CT scans of 479 tibias (Asian, n = 316; Caucasian, n = 163). The anatomically designed Persona Knee (Zimmer Biomet) was compared with the asymmetrically designed Natural-Knee II (Zimmer Biomet), and the symmetrically designed Vanguard (Zimmer Biomet), Triathlon (Stryker), Sigma (DePuy Synthes), and NexGen (Zimmer Biomet) Knees.

As in the previous study, Dai, *et al.* assessed the impact of establishing neutral rotation on tibial coverage. They also investigated the effect of maximizing tibial coverage on implant rotation, as well as component downsizing to prevent tibial overhang. The researchers observed the highest average coverage of 92 percent in the Persona Knee, compared to the other designs, which ranged from 85–87 percent. Importantly, the Persona Tibia provided a good fit in all ethnicities, compared with the symmetric designs, where a suitable component fit could not be achieved in a small percentage (one to five percent) of Asian bones. Critically, the researchers found that maximizing coverage of non-anatomic designs required more than 10 degrees of internal rotation in 30 percent of the bones, while 2–11 percent of the bones required downsizing of the tibial tray by two or more sizes. This was in contrast to the anatomic design, where just three percent of bones required a single downsize due to mal-rotation of 10 degrees or less. Finally, as in the study from Stulberg, *et al.*, the researchers forced the tibial tray into a neutral rotation and assessed the impact on tibial coverage. In the non-anatomic designs, enforcing proper alignment significantly compromised coverage by a mean of four to six percent, as well as compromised posteromedial cortical support. In the Persona Knee the decrease in coverage was marginal - less than 0.5 percent - and it did not compromise posteromedial cortical support.^{10,12}

In another study, Jin, *et al.* looked at tibial coverage for knee prostheses, specifically in Asian populations.¹³ The researchers investigated numerous tibial prostheses for tibial medial plateau fit and coverage in Korean patients. The four most common implants were used: NexGen LPS-Flex (Zimmer Biomet), Vega PS (B-Braun), Attune PS (DePuy), and Persona PS (Zimmer Biomet). The study's purpose was to understand how much the Persona Tibia's anatomical design improved coverage versus the other three symmetric designs when all implants were set to proper rotation. Persona implants had maximum optimal fit in both the medial/posterior (M/P) and medial/lateral (M/L) dimensions, 48 percent and 42 percent respectively. This was shown to be statically significant. The symmetrical tibia implants had significant numbers of absolute underhang: M/P (62 percent to 78 percent) and M/L (24 percent to 34 percent). Tibial coverage of all symmetrical implants was statistically similar for the M/P and M/L dimensions.

The authors concluded that the anatomical tibia design improves coverage in the M/P dimension compared to the symmetrical tibia designs. It specifically states, “The anatomical tibial design had significant improvement for posteromedial coverage compared to symmetrical designs.”

Mizu-uchi, *et al.* also reviewed tibial rotation and coverage in Japanese patients.¹⁴ The authors argued that Asian patients tend to require smaller component sizes and they wanted to study the conflict between rotation and coverage in these smaller-statured patients. Two different shapes of tibia baseplates were used in the study: an anatomical shape (70 knees) and a symmetrical shape (67 knees). The anatomic tibia group showed ideal rotational alignment in 81.4 percent of patients, while the symmetric tibia group showed an ideal rotational alignment in only 46.3 percent of patients. The result was statistically significant. The authors concluded that the anatomic tibia might be the reason behind this reduction of unintended internal rotation of the tibia baseplate. As a result, the rotational alignment compromise was reduced with coverage on the cutting surface for Japanese patients in TKR when an anatomical shaped tibia baseplate was used.

Finally, Indelli, *et al.* studied the relationship between tibia design and rotational alignment landmarks.¹⁵ All patients were available at two year follow-up. The symmetric tibial design demonstrated a statistically significant increase in postoperative anterior knee pain (9 percent versus 3.4 percent) and inferior average ROM (112 degrees versus 122 degrees) compared to the anatomic tibial design. These findings from the researchers further emphasize the benefit of the anatomic tibial shape of the Persona Tibia for the total knee arthroplasty patients.

The main talking points

Postoperative complications such as pain and stiffness are current and significant issues in the field of TKR. Optimal tibial coverage and correct rotational alignment of the tibial component are prerequisites for good clinical outcome.¹⁻¹⁵

The studies above^{10,12-15} concluded that, due to the anatomic shape of the implant, the Persona Knee provided the highest and most consistent tibial coverage. The Persona Tibia also required less downsizing, offered better posteromedial cortical support, and was most compatible across the multi-ethnic dataset studied. These studies have shown that the Persona Tibia more closely matches the size and shape of the resected tibia, and so may help reduce the incidence of tibial mal-rotation and both tibial over and underhang. These factors may reduce the risk of patellofemoral complications, soft tissue irritation, and posteromedial tibial subsidence, and should help surgeons to address the issue of postoperative pain and stiffness in primary TKR!

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