ATTUNE™ Knee Rotating Platform Benefits and Registry Results

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Abstract

Rotating platform design utilized in ATTUNE™ RP Knee allows increased implant conformity and contact area without dramatically increasing stresses on the polyethylene or fixation interface. Studies of rotating platform technology have shown substantially lower polyethylene wear,[10,11] reduced torque and cortical strain on the proximal tibia,[6] and the rotational freedom assists in maintaining alignment of both the patellofemoral and femorotibial articulations throughout knee flexion. These factors are even more important in a constrained setting such as revision TKA, where use of porous coated surfaces like sleeves have helped address loosening.[22] The use of such sleeves with rotating platform in revision settings have demonstrated survivorship >98% at 5 years with similar survivorship out to 10 years.[30] This is likely due in part to the fact that RP demonstrates significantly less torque at the tibiofemoral articulation in both flexion and extension and less relative micromotion compared to FB.[31,32] These factors make RP a great option for surgeons, especially in cases where there is need for more constraint. When analyzing ATTUNE RP Knee in both The National Joint Replacement Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) and Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), it is performing significantly better than class in revision rates, hazard ratios, and PROMs.[34,35]

Introduction

Early historical failure of total knee arthroplasty (TKA) was frequently secondary to aseptic loosening, often associated with malalignment, instability, or use of excessively constrained prosthetic components. With improved surgical instrumentation, operative techniques (ligamentous balancing, better alignment, etc.) and use of lower conformity prosthetic devices, loosening rates have been minimized. Less conforming TKA designs result in a reduced polyethylene contact area which historically led to accelerated wear and periprosthetic osteolysis.[1] Excellent 10-to-15-year outcomes of TKA[2-4] encouraged many surgeons to perform TKA on younger patients who have increased activity requirements and longevity expectations approaching three decades or more. To meet these demands, future TKA design must improve functional performance, reduce articular bearing surface wear while maintaining excellent long-term fixation.

Rotating Platform TKA Advantages

Rotating Platform (RP) TKA designs allow increased implant conformity and contact area without dramatically increasing stresses transmitted to the polyethylene material or fixation interface. Polyethylene bearing mobility minimizes transfer of torsional stresses to the fixation interface that have been associated with failure of fixed bearing TKA implants. A study compared cadaveric proximal tibial strains in fixed bearing (FB) and RP TKA designs, finding 33% less compressive and 68-73% less torsional strains with RP TKA.[5] Another analysis compared the mechanical response of the tibia to femoral component rotation in composite tibia specimens implanted with primary and revision FB or RP components.[6] Using digital image correlation mapping, the authors found that FB designs exerted 13.8x greater torque and 69% greater cortical strain on the proximal tibia than RP designs. This is supported by excellent long-term primary RP TKA results which report revision rates for aseptic loosening to be as low as 0% up to 15 years.[7]

Fluoroscopic analyses have demonstrated the increased sagittal plane conformity in RP TKA reduces paradoxical anterior femoral translation.[8] The increased coronal plane conformity typically present in RP TKA increases contact area and lessens contact stresses that occur if femoral condylar lift-off occurs.[9] Numerous reports demonstrate substantially lower polyethylene wear.[10,11,12] McEwen et al.[10] noted over a four-fold reduction in knee simulator wear of a RP TKA vs. a FB design with identical femoral component geometry. A report of over 300 retrieved components (94 RP and 218 FB) showed that RP inserts had a lower ($p=0.03$) wear rate than the fixed bearing inserts (0.04 vs 0.07 mm/year).[11] Wear rates decreased in the RP cohort with time and the damaged appearance did not correlate with actual wear (loss of material).[12] The anti-oxidant polyethylene (AOX) utilized in the ATTUNE Knee system is designed to lessen wear magnitudes even further.

In vivo fluoroscopic kinematic studies have demonstrated that the bearing-tibial tray mobility is maintained out to at least 10 years postoperatively.[13] These reports demonstrate the rotating platform bearing rotates with the femoral component, independent of rotation of the firmly fixed tibial tray, reducing stresses transmitted to the fixation interface and allowing self-alignment of the polyethylene bearing with the femoral component. Advantages of self-alignment is maintenance of large centrally located surface polyethylene contact areas, improved patellar tracking, and reduced stresses transmitted to posterior cruciate substituting tibial posts. In FB TKA, if substantial internal rotation of the tibial component relative to the femoral component is present, the tibial tubercle is lateralized, enhancing the risk of patellar subluxation. A report of 1,318 FB and RP TKAs found nearly a 3-fold reduction in lateral release rates in the MB TKA cohort.[14] A rotating platform design permits greater self-correction of component rotational malalignment, allowing better centralization of the extensor mechanism. A retrieval analysis of FB PS TKA polyethylene bearings found 40% of the post surface area was worn or deformed at the time of retrieval.[15] An in vivo fluoroscopic evaluation of cam-post mechanics of FB and RP PS TKA demonstrated that cam-post engagement was located more centrally on the stabilizing post in rotating platform designs versus more eccentric cam-post contact in FB designs[16], explaining the asymmetric post wear often observed in retrievals of posterior stabilized FB TKAs. Symmetric cam-post engagement is more imperative in revision TKA cases in which more implant constraint is often required.

In summary, the rotational freedom provided in mobile bearing TKA assists in maintaining alignment of both the patellofemoral and femorotibial articulations throughout knee flexion. Self-alignment via polyethylene bearing rotation improves kinematics, lessens polyethylene surface and fixation stresses, and minimizes eccentric stabilizing post impingement, increasing the potential for enhanced implant longevity.

Rotating Platform Implant Design

It is critical to understand that all mobile bearing TKAs are not the same. Various design iterations have been created. In vivo fluoroscopic kinematic analyses of mobile bearing (MB) TKA have demonstrated variable magnitudes of sagittal plane translation, axial rotation, femoral condylar lift-off, and knee range of motion.[8,17] The most widely utilized design with best long-term results has been the classic rotating platform (RP). Most RP designs use a flat tibial tray-polyethylene countersurface that allows freedom of the polyethylene insert to rotate around a central polyethylene post on a highly polished, cobalt chromium surface with very low surface roughness. Other RP designs have the pivot point anteriorly positioned in the sagittal plane. As previously discussed, kinematic studies[13] have shown that most axial rotation in RP designs with good sagittal and coronal plane stability occurs at the interface between the inferior aspect of the polyethylene bearing and the top of the tibial tray as the polyethylene bearing "follows" the rotation of the femoral component. This creates favorable contact mechanics and lower wear. A fluoroscopic analysis of this different RP design found that the femoral component experienced more axial rotation than the mobile polyethylene bearing, suggesting the femoral component was sliding on top of the bearing. They theorized this could be due to limited articular surface conformity and an anteriorized pivot point of rotation in the design tested.[18]

Other mobile bearing implants allow both sagittal plane translation as well as rotation often by having a mushroom shaped metal prominence in the central aspect of the tibial tray. The undersurface of the polyethylene bearing has a longitudinal cut-out. The bearing is snapped onto the metal prominence. This mechanism allows anterior-posterior (AP) bearing sliding as well as rotation. Additional metal "bumpers" at the periphery of the tray are present to limit the magnitudes of both AP translation and rotation. An in vivo kinematic analysis of an implant with these design parameters showed it did not duplicate normal kinematic patterns, variable motion patterns among patients, and less AP translation than that observed for FB PCL-retaining TKAs.[18] Another design utilized in the early years of MB TKA consisted of separate medial and lateral meniscal bearings that move in curved sagittal plane tracts in the tibial tray. A meta-analysis comparing 15-year survivorship of the classic RP design was 96.4% vs 86.5% with the meniscal bearing implant.[19] Lastly, hinged TKA implants routinely incorporate mobile bearing technology to lessen both fixation and polyethylene insert stresses. As with primary MB TKA, wide variations in hinge mechanisms, kinematic patterns, amount of bone resection, and clinical results exist among hinged TKA implants.

In summary, many differing designs of MB TKA have been created exhibit differing kinematic patterns, postoperative function, and likely, long-term survivorship.

Rotating Platform in the Revision Setting:

TKA is one of the most cost-effective procedures. Revision TKA is also cost effective and volumes of both these procedures are on the rise.[20] When considering revision TKA, loosening and instability remain two of the most common causes of failure occurring up to 31% and 19% respectively.[21] Improvements in fixation with the use of porous coated surfaces like sleeves have helped address loosening after revision TKA.[22] Fixed bearing

prosthesis can produce high torque at the bone-implant interfaces which may predispose to loosening especially in the setting of central metaphyseal bone loss.

By decoupling the forces generated by rotation between the femur and tibia throughout the flexion arc, less force was placed on the bone-implant interface. This allowed for greater articular congruity with decreased polyethylene contact stresses which is the opposite of what traditionally happened with a fixed bearing design. For implants with more constraint like those in revision TKA the rotating platform design reduces articular sided wear and potential damage to the post as the poly self-adjusts to accommodate changes in rotation from extension to flexion as well as for potential malalignment.

In revision TKA one cannot discount the importance of soft tissue balancing to avoid potential instability. In addition to this, insert to femoral conformity and constraint of the varus/valgus post are crucial to balancing the knee. The tibiofemoral bearing articular surface is the primary mechanism providing coronal plane stability more so than the post-box contact and the collateral ligaments.[23] When looking specifically at the conformity ratio of the femoral and poly articulation with the ATTUNE Revision RP TKA system this is maximized to allow for improved stability in the revision setting (Table 1).

Similarly, when considering internal and external rotation of the femoral component on the tibia articulation, the rotating platform in the revision setting allows for significantly more rotation with added constraint. With the ability to rotate the tibial baseplate within a sleeve and the poly to rotate on the baseplate, ATTUNE Revision gives surgeons the opportunity to maximize boney coverage and the potential for osseous integration which can minimize risk of loosening all while maintaining a conforming tibiofemoral articulation (Diagram 1).

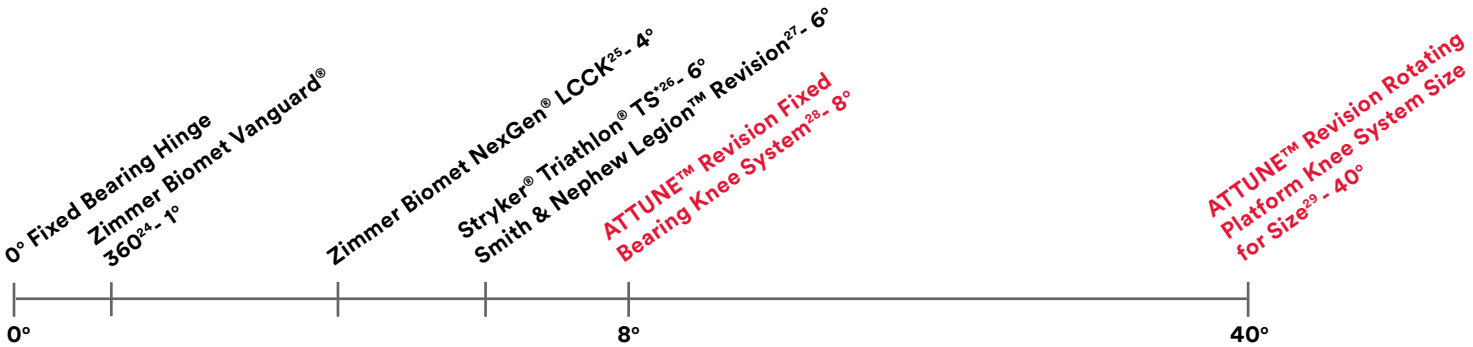
In the revision setting the use of a rotating platform with a sleeve demonstrates survivorship > 98% at 5 years with similar survivorship out to 10 years.[30] This is likely due to the biomechanical advantage the rotating platform demonstrates in regard to the torsional moment applied to the proximal tibia. The rotating platform demonstrates significantly less torque at the tibiofemoral articulation in both flexion and extension compared to a fixed bearing design.[31] Higher levels of micromotion in revision constructs have been shown during biomechanical testing during joint loading, but a rotating platform design demonstrates less relative micromotion between the tibial tray and surrounding bone during joint loading compared to a fixed bearing device.[32] A combination of the diminished torque and less micromotion at the bone-implant interface both likely contribute to the improved survivorship of the rotating platform design in combination with a sleeve in the revision setting. This coupled with the potential for challenges in gap and ligamentous balancing during revision surgery can allow for the use of a more constrained implant with diminished stress with the RP design.

Table 1: Rotating Platform Conformity Ratios

	0°	30°	60°	90°	120°
ATTUNE Revision Femoral Component with Revision RP Insert	0.99	0.81	0.66	0.45	0.38
ATTUNE Revision Femoral Component with PS RP Insert	0.99	0.81	0.66	0.45	0.38
SIGMA™ TC3 Femoral Component with TC3 RP Insert	0.99	0.99	0.61	0.61	0.61
SIGMA TC3 Femoral Component with PS RP Insert	0.99	0.99	0.61	0.61	0.61
ATTUNE PS Femoral Component with PS RP Insert	0.99	0.81	0.66	0.45	0.38

The Revision Femoral Component is designed to enhance conformity and kinematics with the tibial insert at various degrees of motion. A ratio of 1 indicates full tibio-femoral conformity/stability, a ratio of 0 indicates no tibio-femoral conformity/stability.

Diagram 1: Total Internal/External Rotation with Varus/Valgus Constraint



ATTUNE Revision Rotating Platform System currently offers more rotational freedom than the comparator systems while providing varus/valgus constraint. (V/V Constraint Provided: Zimmer Biomet Vanguard® 360: 1°, ATTUNE RP Revision: 1.25°, Zimmer Biomet NexGen® LCCK: 1.25°, Stryker® Triathlon® TS: 2.0°, S&N Legion™ Revision: 2.0°)

Surgical technique in rotating platform total knee arthroplasty

There is much debate over the definition of a "well-balanced" total knee. The surgical technique chosen to achieve this goal varies among surgeons and generally falls into one of the three broad philosophies of measured resection, gap balance, and kinematic alignment. A surgeon may choose to use a rotating platform bearing for the advantages discussed above, but surgical technique is critical to realizing these benefits without introducing bearing "spin out", a complication unique to rotating platform bearings. The use of gap balancing techniques greatly reduces the incidence of spin out. Diamond et al's review of 8,373 consecutive primary total knee arthroplasties showed a decrease in the incidence of spin out from 0.58% to 0.2% when a gap balancing technique was adopted.[33]

The surgical technique must achieve gaps that are near equal medially and laterally throughout the range of motion, especially in flexion. A gap balance technique is preferred to more predictably achieve this outcome. The combination of a symmetric flexion/extension gap, proper joint line, and the more anatomic femoral radius of curvature seen in ATTUNE Gradius™ makes for a more stable knee throughout the range of motion. A surgeon can still employ an alternative alignment strategy in extension to reduce the need for non-anatomic soft tissue releases, but femoral rotation should be parallel to the tibial cut with the medial and lateral ligamentous complexes tensioned nearly equally. The medial and lateral side should differ by no more than two mm. Anatomic landmarks for femoral rotation can be considered but should not be the priority. If the surgeon is uncomfortable with planned rotation that is too far off their preferred anatomic landmark, two options are available. The surgeon can elect to switch to a fixed bearing option or capitalize on the advantages of the rotating platform discussed in the revision setting by going to a more constrained polyethylene.

When choosing cases to start using a rotating platform bearing, a surgeon should first consider the advantages already discussed. If a surgeon has a total knee in which he/she anticipates the need for more constraint, rotating platform is the perfect option. Revisions and complex post traumatic primaries are great opportunities for utilizing rotating platform technology. As the surgeon becomes more comfortable with gap balancing techniques, the indications can expand to all total knee arthroplasty cases. After all, if a rotating platform is preferred for the most complex cases, why would it not be advantageous in all cases?

Registry Analysis

Analysis population

Product specific data for primary cemented rotating platform (RP) total knee procedures using ATTUNE Knee implants by DePuy Synthes was analyzed via a bespoke report supplied from The National Joint Replacement Registry for England, Wales, Northern Ireland and the Isle of Man (NJR), and an Automated Industry Report (AIR) from Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR).

Statistical analysis

In the NJR bespoke report, class is set as all cemented fixed bearing knees. For the AOANJRR AIR class is set as all other total knees.

NJR and AOANJRR reports both supplied yearly cumulative percent revision estimates as well as hazard ratios of ATTUNE RP Knee versus the associated comparator over the time period available. Additionally, the NJR report supplied summaries of patient reported outcomes. Both registries consider the removal or addition of any component to be a revision, and subjects are censored based on the date of data extraction if they have not experienced a revision.

Results

Table 2 summarizes the many measurements from both the bespoke NJR and AOANJRR AIR that provide evidence that ATTUNE RP Knee is performing better than the associated class of knees.[34,35]

Table 3 summarizes the cumulative revision rate from the requested NJR bespoke report for all primary cemented ATTUNE RP Knee subjects. Overall, subjects with any ATTUNE RP Knee tibial components had significantly lower cumulative revision rate at 3, 5, and 7 years than class as well as a significantly lower hazard ratio for the entire period.[34]

The AOANJRR AIR summarizes the results from primary TKA subjects implanted with any ATTUNE RP tibial component. Overall, subjects with any ATTUNE RP tibial component had significantly lower cumulative percent revision at 2, 4, 6, and 8 years (See references for corresponding table).[35] Figure 1 Cumulative Percent Revision of Primary Total Knee Replacement by Model (All Diagnoses) shows that the ATTUNE RP Knee had a significantly lower hazard ratio for the entire period.[35] Early ATTUNE Revision RP results in AOANJRR have also shown significantly lower hazard ratio compared to revision class.[36]

Table 2: Registry Findings Summary

Significiantly Better Than Class In All Categories			
	ATTUNE RP Knee	**Clinical Result**	**Class**
UK NJR Bespoke Report[34]	Cumulative Revision Rate (3 Years)	1.0% (95% CI: 0.8, 1.3)	1.4% (1.4 - 1.4)
	Cumulative Revision Rate (5 Years)	1.4% (95% CI: 1.1, 1.7)	2.0% (2.0 - 2.0)
	Cumulative Revision Rate (7 Years)	1.8% (95% CI: 1.3, 2.3)	2.5% (2.4 - 2.5)
	Cumulative Revision Rate-Hazard Ratio	0.71 (p=0.003)	-
	Oxford Knee Score - (6 Months)	37.1 (95% CI: 36.7, 37.5)	35.5 (35.4, 35.5)
	EQ-5D Index -(6 Months)	0.768 (95% CI: 0.756, 0.779)	0.739 (0.738, 0.740)
	Patient Success - (6 Months)	88.70% (p=0.014*)	85.95%
	Patient Satisfaction - (6 Months)	92.15% (p<0.001*)	89.93%
AOANJRR[35]	Cumulative Percent Revision (2 Years)	1.6% (95% CI: 1.4, 1.8)	1.9% (1.9, 1.9)
	Cumulative Percent Revision (4 Years)	2.5% (95% CI: 2.3, 2.8)	3.0% (2.9, 3.0)
	Cumulative Percent Revision (6 Years)	3.1% (95% CI: 2.7, 3.4)	3.7% (3.6, 3.7)
	Cumulative Percent Revision (8 Years)	3.3% (95% CI: 2.9, 3.8)	4.3% (4.2, 4.3)
	Cumulative Percent Revision-Hazard Ratio	0.82 (p<0.001)	-

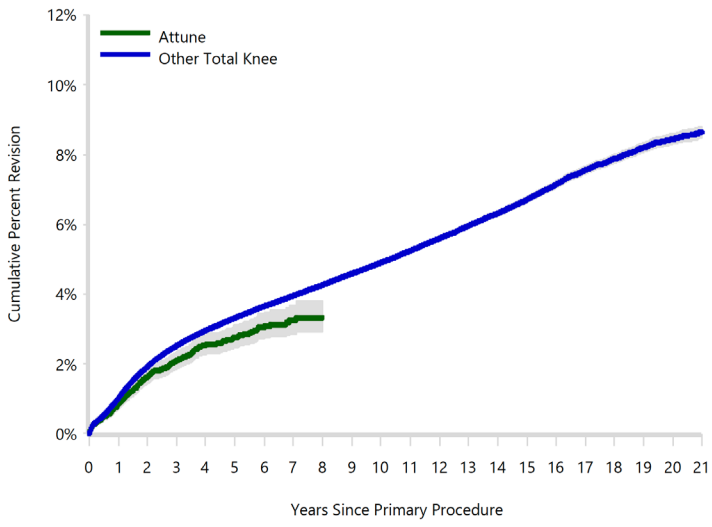
* Chi Squared p-value.

Table 3: UK NJR Cumulative Revision Rate Summary[34]

		Cumulative Percent Revision (95% CI : N at risk)			
	Implanted	**1 Year**	**3 Year**	**5 Year**	**7 Year**
All Attune Cemented RP Primary Knees	7250	0.3% (0.2, 0.4 : 5568)	1.0% (0.8, 1.3 : 3874)	1.4% (1.1, 1.7 : 2162)	1.8% (1.3, 2.3 : 811)
All Other Cemented FB Primary Knees	1152844	0.4% (0.4, 0.4)	1.4% (1.4, 1.4)	2.0% (2.0, 2.0)	2.5% (2.4, 2.5)

The following figure is from the AOANJRR.

Figure 1: Cumulative Percent Revision of Primary Total Knee Replacement by Model (All Diagnoses)[35]



HR - adjusted for age and gender

Attune vs Other Total Knee

Entire Period: HR=0.82 (0.74, 0.91),p<0.001

Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Attune	16130	13889	11622	9075	6348	4401	2577	1372	400	0	0
Other Total Knee	866723	804517	736558	672591	607333	543234	480976	421129	364243	311582	263120
Number at Risk	**11 Yrs**	**12 Yrs**	**13 Yrs**	**14 Yrs**	**15 Yrs**	**16 Yrs**	**17 Yrs**	**18 Yrs**	**19 Yrs**	**20 Yrs**	**21 Yrs**
Attune	0	0	0	0	0	0	0	0	0	0	0
Other Total Knee	218994	178683	143379	113456	87269	65717	47890	33085	21373	12198	5363

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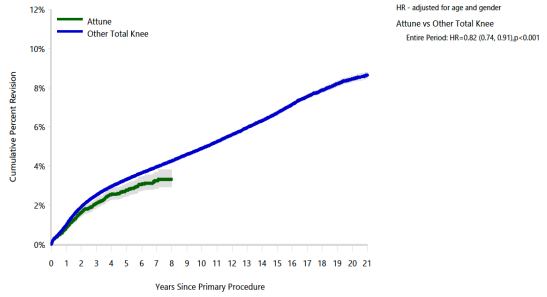
Table 10: Revision Rates of Primary Total Knee Replacement by Model (All Diagnoses)

Model	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Attune	343	16130	57795	0.59 (0.53, 0.66)
Other Total Knee	35700	866723	6577272	0.54 (0.54, 0.55)
TOTAL	36043	882853	6635067	0.54 (0.54, 0.55)

Figure 1: Cumulative Percent Revision of Primary Total Knee Replacement by Model (All Diagnoses)

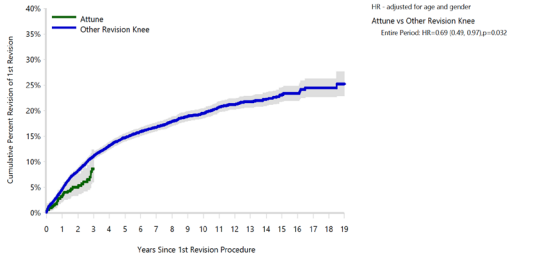


Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Attune	16130	13889	11622	9075	6348	4401	2577	1372	400	0	0
Other Total Knee	866723	804517	736558	672591	607333	543234	480976	421129	364243	311582	263120
Number at Risk	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Attune	0	0	0	0	0	0	0	0	0	0	0
Other Total Knee	218994	178683	143379	113456	87269	65717	47890	33085	21373	12198	5363

Table 11: Yearly Cumulative Percent Revision of Primary Total Knee Replacement by Model (All Diagnoses)

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Attune	0.8 (0.7, 1.0)	1.6 (1.4, 1.8)	2.1 (1.9, 2.3)	2.5 (2.3, 2.8)	2.8 (2.5, 3.1)	3.1 (2.7, 3.4)	3.3 (2.9, 3.7)
Other Total Knee	1.0 (1.0, 1.0)	1.9 (1.9, 1.9)	2.5 (2.5, 2.6)	3.0 (2.9, 3.0)	3.3 (3.3, 3.4)	3.7 (3.6, 3.7)	4.0 (3.9, 4.0)
CPR	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs
Attune	3.3 (2.9, 3.8)						
Other Total Knee	4.3 (4.2, 4.3)	4.6 (4.5, 4.6)	4.9 (4.8, 5.0)	5.2 (5.2, 5.3)	5.6 (5.5, 5.7)	6.0 (5.9, 6.0)	6.3 (6.2, 6.4)
CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Attune							
Other Total Knee	6.7 (6.6, 6.8)	7.1 (7.1, 7.2)	7.6 (7.4, 7.7)	7.9 (7.8, 8.0)	8.2 (8.1, 8.3)	8.5 (8.3, 8.6)	8.6 (8.5, 8.8)

Figure 1: Cumulative Percent Revision of 1st Revision of Primary Total Knee Replacement by Model (Excluding 1st Revision for Infection)



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Attune	633	489	304	151	21	0	0	0	0	0	0
Other Revision Knee	10517	9439	8344	7389	6457	5552	4758	4021	3337	2704	2161
Number at Risk	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Attune	0	0	0	0	0	0	0	0	0	0	0
Other Revision Knee	1681	1231	897	668	475	319	192	132	68	23	5

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