ATTUNE® Knee System: Cruciate Sacrificing Fixed Bearing

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INTRODUCTION:

The purpose of a well functioning posterior cruciate ligament (PCL) in a native knee is to prevent the femur from translating too far anteriorly or the tibia from translating too far posteriorly. The PCL also guides posterior rollback of the femur. A surgeon who prefers to retain the posterior cruciate ligament (PCL) generally utilizes a cruciate retaining (CR) component, while a surgeon who excises the PCL generally utilizes a posterior stabilized (PS) component, replacing the PCL with a cam and spine. A subset of surgeons utilize a cruciate sacrificing (CS) procedure in which the PCL is released but is not replaced by a cam and spine. This procedure requires certain implant design considerations in order to provide the resistance for translation that is typically provided by either the PCL in a CR knee or the cam and spine in a PS knee. The ATTUNE™ Knee System CR fixed bearing (FB) insert has been designed with the surgeon who uses a CS procedure in mind, and it has been cleared by the FDA for a CS application.

HISTORICAL REVIEW OF CS KNEES

One of the historical challenges of excising the PCL has been the effect on the flexion space and anterior-posterior (A/P) stability. Numerous studies have demonstrated that once the PCL is removed the flexion space can open up by several millimeters[1, 2] and A/P translation increases.[3, 4]

To address these challenges, two distinct design approaches were considered for CS applications. The first approach was the development of a rotating platform (RP) device that incorporated a high degree of femoral to insert conformity. This device, called the Low Contact Stress Knee (LCS™ Knee System), enabled size to size insert to femur matching. To achieve this conformity, a decoupling of rotational forces was built into the design by allowing flexion and extension to occur on the top side of the insert and internal and external rotation to occur on the backside (Figure 1). The system also incorporated gap balancing instruments to help balance the increased flexion space that occurred with an excised PCL. Literature has shown that this type of design was able to attenuate anteroposterior translation when the PCL was removed.[5]

The second approach to CS applications was directed at fixed bearing (FB) knees. Due to rotation and flexion occurring on the top side of the insert, and the articular surface accommodating several sizes of femoral

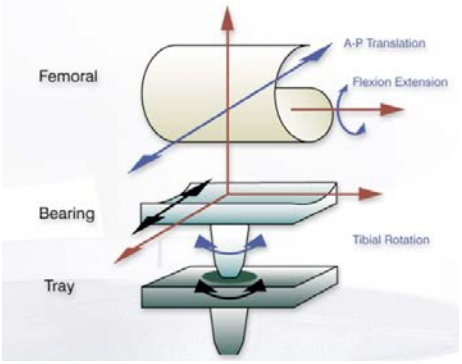

Figure 1

Figure 2

components, a different approach was taken from CS RP Knees. This new approach incorporated a uniquely designed polyethylene insert that featured a raised anterior lip (Figure 2). This was first launched within the Natural-Knee® System,[6] with the raised anterior lip acting as a ramp to provide subluxation resistance.

CURRENT DESIGN CHALLENGES WITH FIXED BEARING CS KNEES:

Based upon the success of the FB Natural-Knee® Ultracongruent insert, the industry began widely adopting a raised anterior lipped polyethylene insert for fixed bearing CS applications. Mid-term survivorship with these types of inserts has been good.[6] However, to begin addressing the 15- 20% of patients who are dissatisfied after TKA,[7] it is important to understand the limitations of these devices and how they may be improved.

The first limitation is associated with the raised anterior lip. In many cases the raised anterior lip does not attenuate A/P sliding as compared to a standard CR insert.[8] The anterior lip acts as a deterrent to subluxation. This is a result of compromises that have been accepted into current FB constructs. In these FB constructs, the tibial tray and insert sizes match and the femur is allowed to be upsized or downsized on top of the insert. As a result, FB CS inserts must be designed to accommodate articulation with a larger or smaller sized femur. This creates a compromise in femoral to insert conformity. This compromise allows for the possibility of the femoral component sliding forward rather than rolling back before it interacts with the anterior ramp of the CS polyethylene. *DePuy Synthes Joint Reconstruction* testing has shown that the sliding distance of a femoral component on a raised anterior lipped insert, is similar to a standard CR insert.[8] This demonstrates that the anterior lip is not helping patients improve their stability throughout flexion but instead acting only as a barrier to subluxation.

The second limitation of current CS FB knees is related to the sagittal curvature of the femoral component. Data has shown there is relatively no difference in the extension gap when comparing knees with and without a PCL.[1,2] However, as the knee flexes to 45 degrees and 90 degrees, the flexion gap increases significantly in PCL deficient knees (Figure 3). When reviewing most current TKA designs, there is generally a significant, sudden reduction in the femoral radius of curvature between 30 and 60 degrees. In some designs, such as Triathlon®, this transition occurs at 10 degrees.[9] This sudden decrease in the femoral radius of curvature has the potential to increase the femoral component's ability to slide forward on the polyethylene during mid-flexion,[9] especially in a PCL deficient knee where the flexion gap increases with deeper flexion.[1]

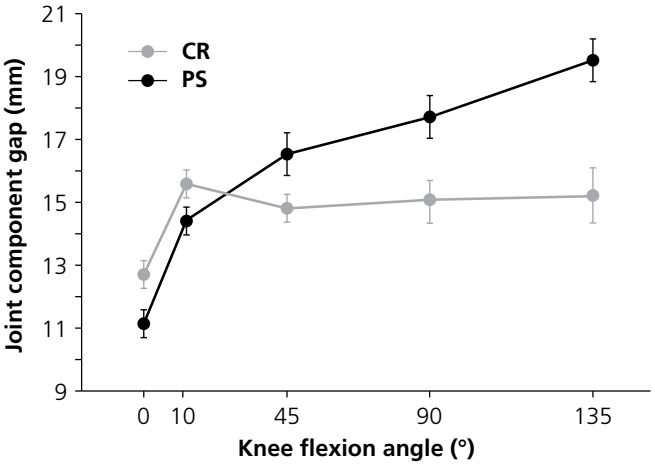

Figure 3: Graph showing the flexion space opening up in a PS knee versus a CR knee as the knee flexes

The last limitation is with regard to gap balancing. While many companies in the industry have begun providing femoral components with consistent A/P increments in between femoral sizes, there is still a need for inserts that provide fine tune options for gap balancing. In many cases tibial inserts designed for a CS application have inconsistent increments between thicknesses.

To address these challenges in FB CS knees, the ATTUNE Knee has focused on improving the following:

- Femoral to Insert Conformity for Fixed Bearing CS Applications
- Femoral Geometry for Fixed Bearing CS Applications
- Knee System Sizing and Balancing Features for CS Surgeons
- Subluxation Resistance

ATTUNE CR FEMORAL TO INSERT CONFORMITY FOR FIXED BEARING CS APPLICATIONS:

To address limitations with an insert that can accommodate several different femoral sizes, the ATTUNE System incorporates a patented fixed bearing central locking mechanism design that works across all sizes to optimize patient fit and kinematics. This design, the LOGICLOCK™ Tibial Base, allows for the insert to always match the femoral component. In a FB CS application this enables increased sagittal conformity and stability.

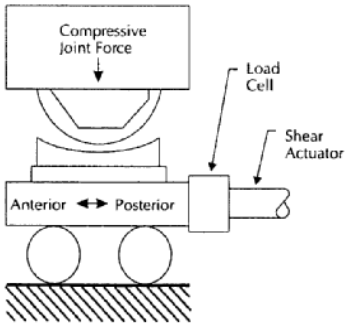

Figure 4: Depiction of in vitro A/P stability test

To demonstrate an increase in A/P stability with the ATTUNE CR versus a raised anterior lipped polyethylene construct, a test was conducted to compare the ATTUNE CR insert to the SIGMA® Knee Curved Plus (CVD+) insert (Figure 4). The SIGMA CVD+ design features a higher raised anterior lip than the ATTUNE CR insert design. The testing that was performed assessed the amount of force required to move the femoral component anteriorly and posteriorly on the tibial insert.

As shown in the graphs below (Figure 5), the ATTUNE CR insert provided similar or more resistance against anterior translation than the SIGMA CVD+ insert at different flexion angles.[8] This indicated a greater force is required to move the ATTUNE CR Femoral component anteriorly on the tibial insert.

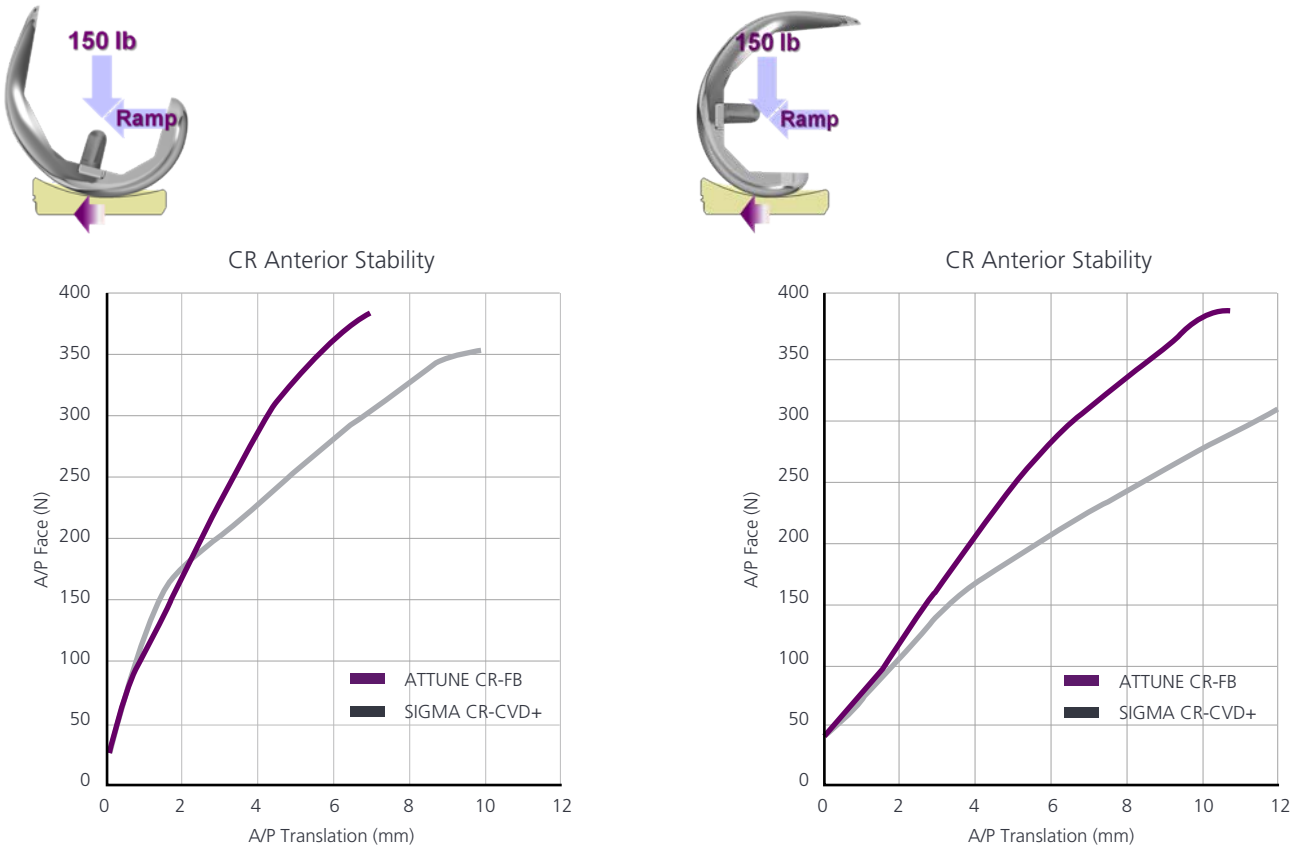

Figure 5: A/P stability of CS fixed bearing designs (ATTUNE CR and SIGMA CVD+) at 15 and 90 degrees of flexion.

ATTUNE FEMORAL GEOMETRY FOR FIXED BEARING CS APPLICATIONS:

To address the limitations associated with a reduction in the femoral radius of curvature leading to instability,[9] the ATTUNE Knee femoral components have incorporated a gradually reducing radius of curvature (ATTUNE GRADIUS™ Curve). The following data shows the gradually reducing conformity ratio of the ATTUNE CR in comparison to the SIGMA Knee, NexGen® and Triathlon® (the conformity ratio is defined as the ratio of the femoral radius to the polyethylene insert radius). The data demonstrates higher stability with the ATTUNE CR throughout the range of motion, while still providing rotational freedom in deeper flexion (Figure 6).

	0°	15°	30°	60°	90°
ATTUNE CR FB	0.88	0.83	0.77	0.66	0.67
SIGMA CR FB	0.76	0.76	0.76	0.47	0.47
NexGen® CR	0.54	0.54	0.54	0.31	0.31
Triathlon® CR	0.38	0.22	0.22	0.22	0.22

Figure 6: Sagittal conformity ratios for the ATTUNE CR Fixed Bearing, SIGMA CVD Fixed Bearing, NexGen® CR Fixed Bearing, and Triathlon® CR Fixed Bearing from 0 to 90 degrees flexion.

After the ATTUNE GRADIUS Curve, which occurs from 5 to 65 degrees in the CR knee, there is another feature which further works to the benefit of a surgeon in a CS procedure. After 65 degrees, the ATTUNE CR femoral component incorporates a "brake radius." The "brake radius" acts as a cam and spine for the CR knee. This is accomplished by slightly increasing the femoral radius of curvature from 65-105 degrees, in turn helping the knee to roll back and reduce anterior slide. This is especially important in the absence of a PCL.

To evaluate the ATTUNE CR femoral geometry, Fitzpatrick et al. (2012) analyzed the influence of implant geometry on the inherent stability, motion, and contact mechanics of the knee joint.[9] Specifically, A/P and internal-external (IE) motions of the knee in four current TKA implant designs (Triathlon® [Stryker® Orthopaedics, Mahwah, NJ], NexGen® [Zimmer®, Warsaw, IN], ATTUNE Knee System [*DePuy Synthes Joint Reconstruction*, Warsaw, IN], and SIGMA® Knee System [*DePuy Synthes Joint Reconstruction*, Warsaw, IN]) were compared. Each design was assessed for A/P stability during a step-down (high A/P shear) and rotational stability/freedom during stance-phase gait (high IE torque). The ATTUNE Knee System was shown to provide a greater degree of A/P stability than other designs in the marketplace while avoiding excessive rotational constraint. The result was a balanced level of stability and freedom that more closely matches that found in the native knee.[10]

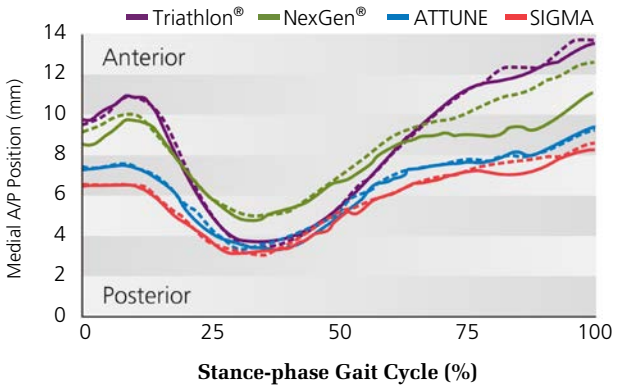

Figure 7: This graph shows the A/P movement of Triathlon®, NexGen®, the ATTUNE Knee, and SIGMA Curved throughout the stance phase of gate.
Note: The more vertical variation in a line, the greater the A/P movement

ATTUNE KNEE SYSTEM SIZING AND BALANCING FEATURES FOR CS SURGEONS:

Knee arthroplasty is considered to be a soft tissue procedure.[11,12] Balancing the flexion and extension gaps is extremely important in achieving optimal stability and motion, especially in PCL deficient knees. Significant research and development was spent on the ATTUNE System femoral and tibial insert sizing and geometry so that surgeons would be enabled to retain or sacrifice the PCL. This included working with anthropometric research experts at the University College Dublin (UCD) to take advantage of their extensive database of bone scans. This database represented a global patient population of Caucasian, Indian, Chinese, and Japanese ethnicities.[13] To accommodate a worldwide population, the ATTUNE Knee System provides a comprehensive femoral size offering including 10 standard and 4 narrow femoral sizes, in consistent 3 mm A/P increments and 1 mm insert thickness increments in the smaller thicknesses. (Figure 8). This sizing range combined with INTUITION™ Instruments and the ability to get precise implant placement (Figure 9) enable the restoration of posterior femoral offset and flexion gap balance in a CS application.

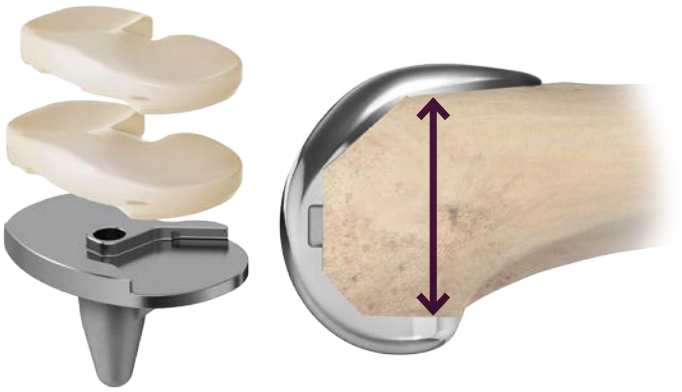

Figure 8: 1 mm insert thickness increments (left) and 3 mm femoral A/P increments (right)

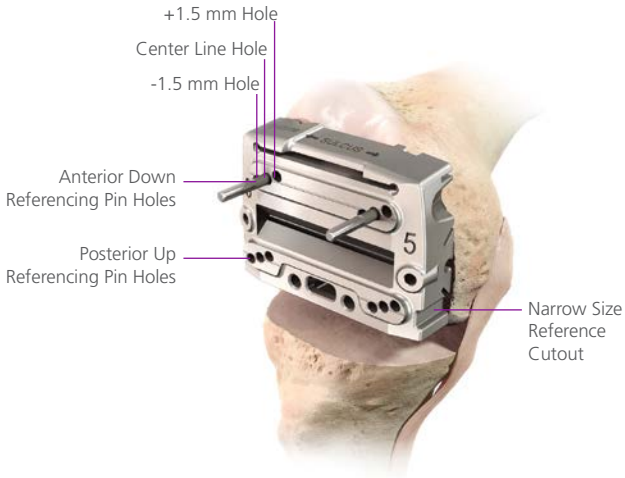

Figure 9: INTUITION™ Instruments 4-in-1 cutting block provides 1.5 mm positional shift

SUBLUXATION RESISTANCE:

The comprehensive offering of 3 mm femoral A/P increments, 1 mm insert increments, and precise gap balancing tools, works together in a CS application to provide better or equal frank subluxation resistance with ATTUNE CR vs. a raised anterior lip polyethylene construct.

For example: When looking at the SIGMA Knee, there is the opportunity to downsize the femoral component, using anterior referencing. This opens up the flexion space by 4 mm in a worst case scenario. In addition there is also an opportunity to downsize the thickness of the insert by 2.5 mm. In a worst case scenario this would create a 6.5 mm gap mismatch (4 mm femoral + 2.5 mm insert). To address this, SIGMA incorporates a CVD+ insert to prevent subluxation by providing an anterior lip height of 7.5 mm. In a worst case mismatch scenario (a downsized femur and a thinner insert) the height of the anterior lip of a CVD+ insert would still prevent dislocation from occurring: 7.5 mm Anterior lip height – 6.5 mm mismatched gap = 1 mm remaining preventing dislocation.

With ATTUNE CR, when using the same anterior referencing technique above, the largest mismatch with a CR femur that can occur is 3 mm. With the first 4 tibial insert thicknesses, the maximum polyethylene thickness mismatch that can occur is 1 mm. The worst case scenario mismatch for the ATTUNE Knee comes out to 4 mm (3 mm femoral + 1 mm insert). The ATTUNE CR insert provides an anterior lip height of 6 mm. Therefore, in a worst case mismatch scenario (a downsized femoral component and a thinner tibial insert) the height of an anterior lipped ATTUNE CR tibial insert would provide

more dislocation resistance than a SIGMA CVD+ tibial insert: 6 mm Anterior lip height – 4 mm mismatched gap = 2 mm remaining, preventing dislocation.

In the event that a thicker ATTUNE CR insert is being used, and the jump between thickness increments goes up to 2 mm, ATTUNE CR would still provide the same frank subluxation resistance as a SIGMA CVD+ tibial insert: 6 mm ATTUNE CR anterior lip height – 5 mm mismatched gap (2 mm insert + 3 mm femur) = 1 mm remaining preventing dislocation (Figure 10).

	SIGMA CVD+ (insert > 10 mm)	**ATTUNE (insert < 8 mm)**	**ATTUNE (insert > 10 mm)**
Anterior Vertical Rise	**7.5 mm**	**6.0 mm**	
Max femoral A/P size mismatch (anterior down)	4 mm*	3 mm	3 mm
Max polyethylene thickness mismatch	2.5 mm	1 mm	2 mm
Total Possible Mismatch	**6.5 mm**	**4 mm**	**5 mm**
Resistance to Frank Subluxation (Anterior Vertical Rise - Total Mismatch)	**1 mm**	**2 mm**	**1 mm**

*Utilizing SIGMA size 3-5

Figure 10: Resistance to Frank Subluxation for SIGMA CVD+ and ATTUNE CR

CONCLUSION:

While current industry CS designs are characterized by an increased anterior lip height, ATTUNE CR has been designed with the intent of helping surgeons reduce A/P instability in CS applications without compromising rotational freedom in deep flexion. Through proprietary technologies like the ATTUNE GRADIUS Curve, LOGICLOCK Tibial Base, and INTUITION Instruments, the ATTUNE Knee System provides surgeons with a CS implant that maintains optimized kinematics for improved stability and motion when the PCL is absent. All these benefits are achieved without the need for increased inventory or additional insert options.

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