Vanguard XP
Total Knee System

Design Rationale

BIOMET
Over 1 million times per year, Biomet helps one surgeon provide personalized care to one patient.

The science and art of medical care is to provide the right solution for each individual patient. This requires clinical mastery, a human connection between the surgeon and the patient, and the right tools for each situation.

At Biomet, we strive to view our work through the eyes of one surgeon and one patient. We treat every solution we provide as if it’s meant for a family member.

Our approach to innovation creates real solutions that assist each surgeon in the delivery of durable personalized care to each patient, whether that solution requires a minimally invasive surgical technique, advanced biomaterials or a patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.
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Solution-Driven Design
Patient-Focused Design

The Vanguard XP bicruciate preserving total knee design incorporates geometry that enables the retained ACL/PCL and collateral ligaments to work harmoniously with knee joint muscles to naturally drive joint kinematics. The Vanguard XP development team recognizes the role of the ACL in maintaining optimal knee function and believes that ACL retention is a key principle for patient satisfaction. This document outlines the rationale behind the Vanguard XP Total Knee System.

*The Vanguard XP Total Knee System was designed in collaboration with the following development team:*

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Going Beyond Survivorship

Studies suggest that patient satisfaction in TKA is often suboptimal. In a 2010 study, Bourne et al. found that 19% of TKA patients were not satisfied after their surgery.¹ A similar study in 2006 reported by Noble et al. found that 14% of TKA patients were dissatisfied or very dissatisfied.² Furthermore, Parvizi et al. reported a high level of residual symptoms in young TKA patients, with one in three indicating that their joint did not feel normal and 50% had not engaged in preferred activities.³ Of particular note, when analyzing patient satisfaction, a gap was evident in the level of satisfaction between patients with a Biomet Oxford Partial Knee and those with a traditional total knee implant. Although long-term results have allowed for pain relief and functional improvements with both types of knee arthroplasty, patients have expressed more overall satisfaction with a partial knee when compared to a total knee due to a more natural “feel” of the joint.⁴

In addition, ACL resection can compromise kinematic function and lead to abnormal patterns of knee movement as the surfaces are partially decoupled by the loss of the ligament.⁵⁻⁷,¹⁴ ACL resection may explain some of the less-than-optimal patient satisfaction results seen in TKA.
When Tradition is Not Enough

While standard total knee arthroplasty (TKA) is well established and considered to be a successful solution for patients with osteoarthritis, efforts to further improve clinical outcomes continue. Each new generation of implants and instruments have been developed with similar goals: to enhance motion, extend survivorship, and facilitate a logical and efficient surgical technique. The success of TKA has traditionally been measured by the degree of pain relief, the improvement in joint function, and the extent to which the patient can engage in normal activities of daily living. However, the overall satisfaction of TKA patients does not always correlate to the level of pain relief and functional improvement.

In examining the parameters of patient satisfaction, the Vanguard XP Knee development team identified an element of contentment that was lacking in many TKA patients. This unfulfilled measure of outcomes relates to the “feel” of the joint postoperatively, and is distinct from the pain relief and restoration of motion that knee implant designs have traditionally sought to achieve. Furthermore, many patients express a desire to return to activities of daily living. In essence, Biomet perceived a need to further enhance patient satisfaction by striving to create an implant system that provides optimal functional outcomes through proprioception due to the retention of the ACL, when possible.

RECOGNIZING A GAP
Understanding Patient Satisfaction

Biomet’s 35+ year experience with the Oxford Partial Knee has provided a unique insight into the knee’s function before and after knee arthroplasty. The Vanguard XP Knee development team sought to leverage surgical technique principles from the Oxford Partial Knee as well as focus on its ligament preservation (especially preserving the ACL) design to support patient function.

A multi-center study found that Oxford Partial Knee patients were 2.7 times more satisfied with their ability to perform activities of daily living than patients receiving a traditional total knee implant. This indicates a potential link between ACL preservation and higher patient satisfaction.6–8
Moreover, one study suggested a patient preference for bicruciate preserving total knee arthroplasty. A study conducted by Dr. Pritchett in 2004 compared patients undergoing bilateral knee arthroplasty that received a standard design prosthesis on one side and a bicruciate preserving design on the other side. Among the 440 patients who were available for follow-up at seven years, there was no significant difference in postoperative range of motion, pain, knee score, or functional score. However, 89% of the patients preferred the bicruciate design over the PS design and 74% of the patients preferred the bicruciate design over the CR design, stating that the joint felt “more normal” or “more stable.” Patients also noted that the bicruciate preserving knee seemed stronger when ascending and descending stairs, and had fewer “clunks,” “pops,” or “clicks.”
Bicruciate Preserving TKA

Motivated by favorable patient satisfaction of early bicruciate preserving total knee implants, Biomet continued researching and exploring designs that demonstrated long-term survivorship and began addressing documented technical challenges of these designs. When researching bicruciate knee clinical outcomes, the Cloutier ACL/PCL preserving knee revealed bicruciate-preserving TKA could produce long-term survivorship,10 which aided in Biomet’s decision to pursue the development of a bicruciate total knee.

Though the Cloutier ACL/PCL preserving knee demonstrated a bicruciate knee with positive survivorship, many of the early designs experienced technical challenges unrelated to bicruciate ligament retention. Biomet discovered early designs presented surgical technique challenges due to limited instrumentation; lack of tray strength, excessive polyethylene wear as well as loss of fixation.11-13

Biomet, in conjunction with the development team sought to address previous bicruciate total knee design challenges when designing the Vanguard XP Knee. To address surgical technique support, the team leveraged key instrumentation for the Oxford Partial Knee and Vanguard Complete Knee System as well as focused on designing new instrumentation to allow for a reproducible technique. The team also applied Biomet’s experience in material sciences to address hurdles in tibial tray strength, polyethylene wear and loss of fixation. The technical overview of specific design changes made to the Vanguard XP Knee is revealed in subsequent pages of this design rationale.
Performance-Driven Design
The design goals of the Vanguard XP Knee are to enhance patient satisfaction while achieving optimal function and long-term survivorship. The Vanguard XP Total Knee System is a cruciate retaining design allowing healthy anterior cruciate ligaments (ACL) and healthy posterior cruciate ligaments (PCL) to be preserved while incorporating geometry to accommodate and enable the natural function of the knee’s ligaments. The ACL is an essential structure to maintain optimal knee function; thus, the Vanguard XP development team created a partially constrained knee design where ligaments and soft tissue drive knee function.

*Biomet is currently enrolling patients to measure patient satisfaction and functional long-term survivorship.
The primary focus of the Vanguard XP Knee design centers around the ACL and its essential role in knee function. Traditional total knee arthroplasty designs support only PCL retention despite the presence of an ACL at the time of surgery. One study has shown that the ACL is present in approximately 80% of total knee arthroplasty patients who have not had a history of knee trauma and ACL injury\(^\text{14}\). The Vanguard XP Knee development team believes preserving the ACL is the next progressive step needed to serve today’s diverse patient population.

**ACL-FOCUSED DESIGN**

Native Kinematic Design: Envelope of Functional Motion

Preserving the ACL and understanding its role in knee function was leveraged in the Vanguard XP Knee design. The ACL works with the PCL to close the kinematic loop and drive knee motion. Professor Tom Andriacchi’s extensive research over the years on the ACL’s role within the Envelope of Functional Motion (EFM) influenced the Vanguard XP Knee design\(^\text{15}\). The EFM is the range of secondary motions (anterior/posterior translation and internal/external rotation) that occur during knee flexion.

During active and passive motion, the knee’s soft tissues define the boundaries of the EFM. These soft tissue boundaries change based upon the angle of knee flexion, muscle activation and the activity performed (i.e. walking, stair climbing and squatting). Figures 1–3 reveal the four bar linkage and how the ACL functions during various flexion angles. The Vanguard XP Knee femoral and tibial components were designed to allow the ACL to function within the EFM.
ACL FUNCTION AND HEALTHY KNEE

Closing the Kinematic Loop

Figure 1.

ACL Tension Varies with Knee Flexion
0 Degree Flexion

Figure 2.

AP Translation of Femur Relative to Tibia
45 Degrees Flexion

Figure 3.

AP Translation of Femur Relative to Tibia
90 Degrees Flexion

Images courtesy of Prof. Tom Andriacchi’s presentation, "A Rationale for an ACL/PCL Preserving Total Knee."
The ACL plays a key role in defining the Envelope of Functional Motion at all flexion angles (Figures 4–6), and thereby is responsible for important elements of knee function, including:

**Anterior/Posterior Stability During Flexion/Extension**

The ACL serves as a primary restraint against anterior tibial translation near full extension.\(^{17}\) As the knee flexes, the ACL works in harmony with other knee ligaments and soft tissues to constrain the anterior/posterior tibia movement.

**Internal/External Rotation**

The ACL helps prevent rotation of the knee in extension. As the knee is extended, the ACL stretches and tightens thus restricting any internal tibial rotation when the knee is in full extension. Likewise, as the knee is flexed, the ACL relaxes which increases the envelope of motion.\(^ {18}\)

**Proprioception**

When the ACL is strained, receptors in the ligament provide a sense of joint position, creating a natural feel to the joint.\(^ {19}\)

**Normal Muscle Function**

Muscle function is guided by sensory response from soft tissue as it undergoes strain. This response initiates muscle contractions that help keep the knee within a dynamic Envelope of Functional Motion. In particular, the ACL is critical to joint function as the knee approaches full extension by enabling natural muscle function. Studies have shown a ruptured ACL may lead to quadriceps atrophy by creating a reflex inhibition to use, which may result in a more difficult TKA rehabilitation.\(^ {15,20}\)
KINEMATIC REQUIREMENTS OF ACL FUNCTION

Motions are Limited by Soft Tissue Constraint

Figure 4.

Walking Envelope of Functional Motion

KEY POINT:
ACL Functions as Knee Extends to Provide Anterior Stability

Envelope of Functional Motion (EFM)

Figure 5.

Stair Climbing Envelope of Functional Motion

KEY POINT:
PCL Function Roll-Back During Mid-Flexion

Figure 6.

Squatting Envelope of Functional Motion

KEY POINT:
ACL and PCL Function in Deep Flexion

Images courtesy of Prof. Tom Andriacchi’s presentation, “A Rationale for an ACL/PCL Preserving Total Knee.”16
APPLICATION: The Vanguard XP Knee Design

The Vanguard XP Knee is built on the firm foundation of the clinically proven design elements of the Vanguard Complete Knee System while incorporating new design elements necessary to function within the Envelope of Functional Motion.

Applying research done by Professor Tom Andriacchi and Dr. Jorge Galante on dynamic knee motion, the Vanguard XP Knee incorporates design elements supporting the EFM concept. The proprietary design of the anatomic/asymmetric femoral and anatomic/asymmetric articular surfaces (patent pending) are intended to optimize ACL function and allow the knee to articulate within the Envelope of Functional Motion (Figures 7–9). In developing a successful bicruciate preserving implant, every aspect of the bearing surfaces, tibial tray, femoral component, patellar component, and instrumentation was reviewed for potential performance enhancements.
GOAL FOR VANGUARD XP KNEE DESIGN =
Envelope Determined by Soft Tissue Forces, Not Articular Surface Constraint

Figure 7. **ACL Tension: Full Extension (walking)**

Figure 8. **PCL Tension: 45° Flexion (stair climbing)**

Figure 9. **ACL/PCL Tension: Deep Flexion (squatting)**

Images courtesy of Prof. Tom Andriacchi's presentation, "A Rationale for an ACL/PCL Preserving Total Knee."16
Vanguard XP Bearings

In a standard total knee prosthesis, the constraint of the bearing surfaces plays a key role in determining knee stability. With the absence of the ACL and in many instances the absence of the PCL, standard total knee designs are dependent on the constraint of the bearing/femoral interface to provide the stability of the knee. The Vanguard XP Knee design goals are to permit natural ACL function and allow the soft tissues to constrain motion, and thereby stabilize the joint within the EFM through a range of activities, such as walking and stair climbing.

Bearing Options

**XP-XP Bearings:** The XP-XP articulation is a fixed-bearing design that allows A/P translation and internal/external rotation to be controlled primarily by soft tissue. Furthermore, it produces no varus/valgus constraint, thereby allowing the soft tissue to control stability.

**Sagittal Geometry:** To help facilitate the function of the knee’s ligaments and allow the soft tissue to constrain motion more naturally, the medial and lateral articulations of the Vanguard XP design are plateau-specific. The motion of the medial compartment is independent and different from that of the lateral compartment, and is allowed by incorporating different geometries into the medial and lateral bearing surfaces. The medial bearing surface is flat with a slightly raised lip on both the anterior and posterior edges. The lateral bearing surface also has a raised lip on the anterior and posterior edges, but the flat area is longer so the overall length of the unconstrained portion of the articulation is greater. **This design allows the soft tissue to drive the A/P translation and internal/external rotation of the femoral component on the tibial bearing surface, for functional articulation.**

**Coronal Geometry:** To achieve the combination of moderate constraint, adequate congruency, and femoral/tibial component interchangeability, the Vanguard XP coronal geometry consists of moderately radiused condyles with a 1.25:1 tibial/femoral conformity.

Testing was performed to measure the resistance of the XP-XP bearing surface during M/L, A/P, and rotational movement under a load at various flexion angles. The results showed minimal resistance within the EFM with increasing resistance as the anterior and posterior bearing lips are engaged at the edges of the envelope.22 (Figures 10–12).

**XP-AS Bearings:** To accommodate surgeon preference and provide intraoperative flexibility to meet patient needs, the Vanguard XP Knee offers an XP-AS bearing design that provides an anterior stabilized option. The XP-AS articulation is for patients without an ACL along with a non-functional posterior cruciate ligament. It is a fixed-bearing design with a deep-dish contour. Without the presence of the ACL and a non-functional PCL, the XP-AS bearing provides more constraint than the XP-XP bearings. Testing was performed to measure the resistance of the XP-AS bearing surface during M/L, A/P, and rotational movement under a load at various flexion angles.22 The results were similar to those of the Vanguard AS bearing (Figures 13–15).22
Figure 10. XP Bearing – A/P Draw 15° 22
(+ Displacement = Posterior Tibial Displacement)

Figure 11. XP Bearing – ML Shear 15° 22
(+ Displacement = Medial Tibial Displacement)

Figure 12. XP Bearing – Rotary Laxity 15° 22
(+ Displacement = External Tibial Rotation)

Figure 13. AS Bearing – A/P Draw 15° 22
(+ Displacement = Posterior Tibial Displacement)

Figure 14. AS Bearing – ML Shear 15° 22
(+ Displacement = Medial Tibial Displacement)

Figure 15. AS Bearing – Rotary Laxity 15° 22
(+ Displacement = External Tibial Rotation)
Polyethylene

Polyethylene continues to be a significant factor in the long-term survivorship of total knee prostheses. The Vanguard XP tibial bearing components utilize E1 Antioxidant Infused Bearings. This polyethylene technology was developed to overcome the limitations of remelted and annealed polyethylenes.23

Choosing an oxidatively stable and strong bearing material was important to the design of the Vanguard XP Knee tibial bearings. Through the manufacturing process, E1 Antioxidant Infused Bearings are not remelted and are infused with Vitamin E resulting in oxidative stability. E1 Technology is also used due to its strength properties. Lab testing reveals E1 material has a higher ultimate tensile and yield strength than irradiated and remelted UHMWPE.24

The E1 material has undergone extensive testing, including Environmental Stress Crack testing (ESC), which mimics cyclic loading in vivo. Stress cracking from cyclic loading is a major reason for bearing breakdown. ESC testing has shown that E1 polyethylene is more oxidatively stable than sequentially crosslinked and annealed polyethylene.24

Further testing of E1 Vanguard Tibial bearings demonstrated a volumetric wear rate that was 86% less than that of conventional DCM UHMWPE.24 Also, Biomet conducted an internal wear study on a knee simulator which demonstrated that Vanguard XP tibial bearings made from E1 polyethylene had a 90% volumetric wear reduction compared to Vanguard CR bearings made from ArCom polyethylene (Figure 16).25
Figure 16.

WEAR RATE
of the Vanguard XP-XP Tibial Bearings

MT4318,
ArCom, 87/91 mm
Vanguard CR

MT6254,
E1, 87/91 mm
Vanguard XP - XP
Vanguard XP Tibial Trays

The Vanguard XP-XP tibial tray is designed to preserve both the ACL and PCL by incorporating a U-shaped design to accommodate both cruciate ligaments without impingement. Cement fixation is enhanced by two anterior pegs, and two posterior keels. A specific tibial tray has been designed for each of the bearing options; however, the bearings and tibial trays are interchangeable.

The Vanguard XP-CR tibial tray provides central tibial coverage while accommodating independent bearing surfaces. Cement fixation is enhanced by a 40 mm cruciate stem.

Sizing/Profile

Because cortical coverage may be more important for a tibial tray without a central stem, size increments became an important consideration for the Vanguard XP Knee. To address this issue, 11 symmetrical tibial tray sizes are available (63 mm–91 mm). Within the core size range (63 mm–75 mm), consistent sizing increments are 2 mm in the M/L dimension and 1.2 mm in the A/P dimension. The width of the tibial bone island is 15.9 mm (63 mm–83 mm sizes) and 18.6 mm (87 mm–91 mm sizes). The anterior tray notch width, regardless of tray size, is 2 mm wider than the tibial bone island preparation. The tray is 3 mm thick centrally, but 5 mm thick around the edge to provide additional stability for the polyethylene bearings.

Tibial Tray Strength

During development of the U-shaped bicruciate preserving tibial implant, Biomet emphasized material strength and structural integrity. To optimize strength, developers transitioned from the commonly used titanium and cast cobalt-chromium-molybdenum alloys to forged cobalt-chromium-molybdenum alloy. Rotating beam fatigue testing shows that the fatigue strength of forged CoCrMo is 1.5x the fatigue strength of cast CoCrMo and 1.9x the fatigue strength of Ti-6Al-4V (Figure 17).

Following ASTM F1800, fatigue testing to 1000N (225 lb) was performed on the 87 mm XP tray. The ASTM test protocol models a worst case scenario with one half of the tibial tray completely unsupported. All five samples remained intact after 10M cycles.
Figure 17.

ROTATING BEAM FATIGUE STRENGTH TEST

psi = pounds per square inch
Locking Mechanism

The Vanguard XP locking mechanism includes design elements from the long-established Biomet locking mechanism. In a study by Sosa et al., Biomet’s locking mechanism design was shown to be “the most stable overall, showing the lowest recorded micromotion medially, laterally, and posteriorly.” Another study, by Parks et al., concluded that the Biomet design was the most stable overall.

Continuing Biomet’s locking bar legacy, the Vanguard XP Knee uses a locking bar to compress the bearing against a posterior rail designed with a 10 degree mating slope to increase the stability of the tibial construct. The intent is to minimize micromotion and subsequent backside wear. Micromotion testing showed less than 100 microns of A/P and M/L motion before and after simulated use. The strength of the locking mechanism was also shown to be ample in testing using the worst-case combination of the smallest tibial component and the thickest, most constrained bearing surface.

Tibial Tray Fixation

The Vanguard XP tibial tray has two anterior pegs and two posterior keels for added fixation. Similar designs with 4 pegs have long term follow-up that have shown to provide excellent long-term fixation. Testing was performed to determine if the tibial bone/implant fixation surfaces are adequate to withstand simulated use. The trays were cemented into 4th-generation composite sawbones. A knee simulator was then used to apply varied loads in an A/P “rocking” motion to test “worst case” motion. After 550,000 cycles, the samples remained well-fixed with no visible disruption of the fixation interface as long as there was posterior cortical support.
Vanguard XP Femoral Components

The Vanguard XP Knee femoral component maintains several design elements from the Vanguard CR Knee, including the patellofemoral geometry. The funneling trochlear groove helps balance patellar capture during flexion with the need for less patellar constraint in extension. Furthermore, the patella track has a 7° valgus angulation to support patellar tracking. This valgus angulation has been shown to reduce patellar shear stresses.33

New Key Design Features

New design features were also incorporated into the Vanguard XP femoral component to accommodate and support the integrity and function of the ACL. In the sagittal profile, the posterior condyles are 1.4–2.3 mm shorter than the Vanguard Knee (prorated by femoral size) to allow for increased flexion without edge loading on the tip of the condyles. In addition, the lateral distal condyle has a larger transition radius, facilitating increased rollback on the lateral side to support natural rotation of the joint.

Sizing/Profile

The Vanguard XP Complete Knee System offers twelve femoral sizes specifically designed for optimal bone coverage in all patient populations. Femoral A/P sizes increase by an average of 2.2 mm and M/L sizes by 2.4 mm. A narrow anterior flange with rounded corners helps to reduce the likelihood of femoral overhang. The posterior condyle length increases proportionally to reduce the possibility of implant overhang in smaller femurs and the potential for undersizing the posterior condyles in larger femurs.

The effort to optimize coverage of the posterior condyles was driven by the need to achieve high flexion. The geometry of the posterior condyles carried over from the Vanguard Knee System has also been optimized to provide larger contact areas in deep flexion to more effectively dissipate forces on the bearing.34

Patella

The Vanguard XP Knee utilizes the standard Vanguard Series A patella, which is available as a single-peg patella and a three-peg patella. All are available in standard thicknesses as well as a low profile which is approximately 1.5 mm thinner than the standard patella.
“A partial knee is not half of a total knee—there are different rules. In the same vein, the Vanguard XP Knee is not a total knee that keeps the ACL—different principles apply.”

Dr. Craig Della Valle
**Instrumentation and Surgical Technique**

To meet the unique demands of bicruciate preserving TKA, it was also necessary to develop new instrumentation that would help ensure an efficient and reproducible surgical technique. Leveraging the design elements of the Vanguard Premier and Oxford Microplasty instruments, the Vanguard XP Total Knee System delivers a comprehensive instrumentation platform to accurately size and position implants to accommodate the patient’s anatomy.

In doing so, consideration was given to the key principles of the surgical technique, including exposure, respecting the joint line, tibial slope, tibial tray rotation, M/L tibial tray position, resection level, posterior bone coverage, and cementing technique. The development team has created a very innovative and practical instrumentation platform to allow all surgeons the freedom to preserve their patient’s soft tissues, while maintaining an OR experience that is reproducible and comparable to standard total knee surgeries.
Answering the Question...

One of the common questions posed to the design team during the limited launch phase of the project was, when reviewing the designs of the past, “What makes the Vanguard XP Knee design different than preceding bicruciate preserving knee designs?” In other words, what have you learned and incorporated into the design of the Vanguard XP Knee?

As detailed in this design rationale, there are three fundamental elements that were incorporated into the Vanguard XP Total Knee system that the design team believe to be enhancements on older designs. In summary those elements are:

- **A better understanding of the role of the ACL and incorporation of the Envelope of Functional Motion**

- **Advances in material sciences allowing for articulation, design freedom and component integrity**

- **Extensive surgical technique experience from partial knee arthroplasty aided the development of a reproducible bicruciate preserving total knee surgical technique**
REFERENCES


4. Study by researchers at Washington University in St. Louis, Missouri, US. Portions of study funded by Biomet. Determined based on adjusted odds ratio calculation.


The Vanguard XP Knee is indicated for pain and disability due to osteoarthritis, rheumatoid or traumatic arthritis, and correction of varus, valgus, or arthrodesis, or failure of previous joint replacement procedure. Potential risks of knee replacement surgery include, but are not limited to, loosening, dislocation, bone or implant fracture, wear, and infection, any of which can require additional surgery.

In the United States (US), the Oxford Partial Knee is intended for use in individuals with osteoarthritis or avascular necrosis limited to the medial compartment of the knee and is intended to be implanted with bone cement; it is not indicated for use in the lateral compartment or patients with ligament deficiency. Various countries outside of the US offer Oxford partial knees intended for lateral use and indicated for cementless application; these devices are not available for sale in the US. Please check your local product clearances.

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