Design Rationale

smith&nephew

JOURNEY◊

Bi-Cruciate Stabilized
Knee System

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Designed by nature.
Shaped by technology.

Introduction

While literature reports good outcomes for many current knee systems,[1] clinical scores do not necessarily reflect patient satisfaction.[2,3] While this dissatisfaction could be attributed to abnormal motion, such as paradoxical motion and AP instability,[4] today's active patients simply expect more out of their knee replacements than ever before. These expectations are not being met by the current generation of knee replacement designs.

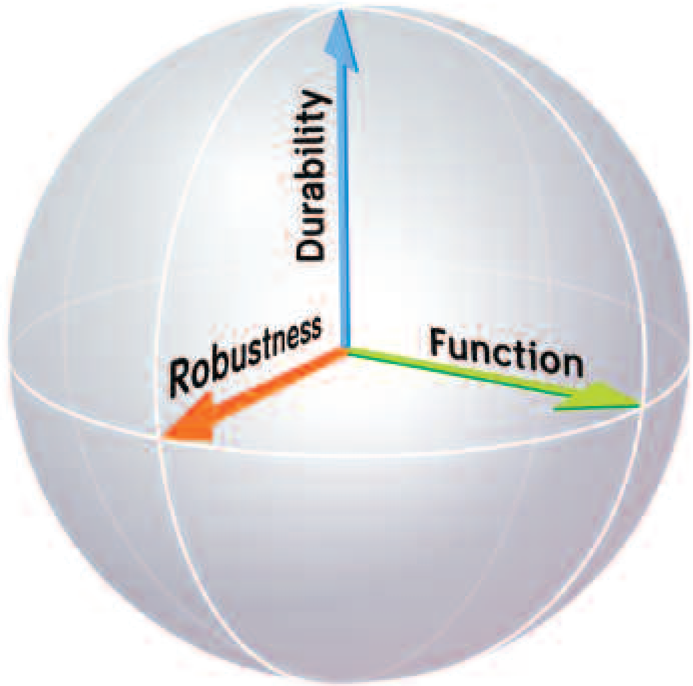
To replicate normal knee function, Smith & Nephew conducted in-depth analyses of the geometry, kinetics and kinematics of the normal knee and conventional TKA systems. These analyses created a better understanding of how the normal knee works and the limitations inherent in current knee designs. The knowledge gained through this research fueled the creation of a knee system that successfully addresses those limitations.

The JOURNEY◊ Bi-Cruciate Stabilized Knee System is the first knee system to successfully replicate PCL and ACL function, accommodate deep flexion, induce normal tibiofemoral axial rotation and provide proper patellar tracking throughout the entire range of flexion. Utilizing the latest in low-wear materials technology, OXINIUM◊ Oxidized Zirconium, the JOURNEY knee system also addresses the issues of implant longevity.

By designing a knee system that replicates normal knee function and overcomes limitations of conventional systems while maintaining excellent durability and robustness, Smith & Nephew has created a true high performance knee system that redefines success in total knee arthroplasty.

Maximizing the performance envelope

The guiding principle behind the design of the JOURNEY◊ Bi-Cruciate Stabilized Knee System was to achieve near normal function, while maintaining excellent durability and robustness. The balance that is achieved between these attributes defines the performance envelope of a knee system. Since the initial concepts for the JOURNEY knee system were developed, the ultimate goal has been to maximize this performance envelope.



What it takes to maximize the performance envelope

Function

- Stability – Replicate the natural stability inherent in the knee
- Kinematics – Maximize range of normal AP and axial motion
- Functional flexion – Provide a kinetic environment within the knee that optimizes muscle function and mechanical efficiency

Durability

- Minimize polyethylene wear
- Provide sufficient post strength
- Provide sufficient bone/cement/implant interface strength

Robustness

- System design that is insensitive to:
  - Uncontrollable environmental factors that can affect performance (implantation alignment/positioning)
  - Variability in patient-related factors (ie, anatomy, BMI, musculature, activity)

Advanced design tools and methods

Sizing and fit

To design the JOURNEY◊ knee system, statistical data from over 250 femurs and tibias was used to characterize articular shapes and resected profiles in an effort to optimize four types of fit:

- Coverage fit – coverage of resected bone
- Resection fit – resection required to attach implants to bone
- Interface fit – implant/bone interface stability
- Biomechanic fit – restoration of functional surfaces

This wealth of data showed clear dimensional and size differences between male and female anatomy that required a non-linear progression of implant dimensions throughout the size range. Bone coverage was optimized by providing asymmetric baseplates and 10 (non-scaled) femoral sizes. Bone resections were minimized by reducing distal/posterior resections and PS box volume for smaller sizes and by angling the PS box and posterior resection for all sizes. Interface fit was improved through a unique femoral ‘hooking’ implantation method that helps pressurize the cement and lock the implant to the femur. Biomechanic fit was improved by restoring the sagittal profiles, trochlear depth and joint line. The result is a system that is gender optimized for all types of fit.

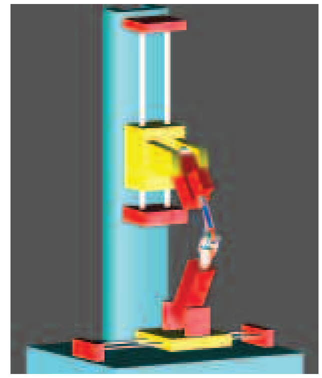


Photo courtesy of Biomechanics Research Group, Inc.

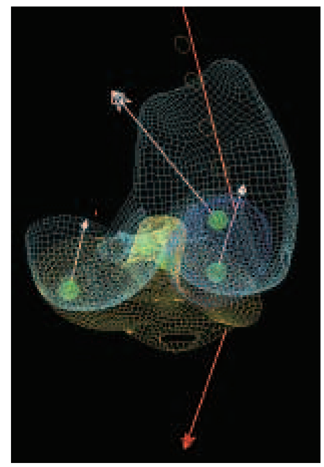
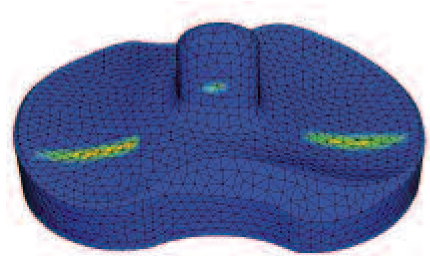


Photo courtesy of Biomechanics Research Group, Inc.

Virtual simulation

The JOURNEY knee system was designed using state-of-the-art computer simulation and optimization techniques. Parametrically controlled CAD models were virtually implanted in an advanced computer knee simulator (proprietary enhanced version of LifeMOD/KneeSIM™) and driven through multiple activities including deep knee bend and gait. Over 120 parameters for each functional activity were measured to characterize the biomechanic performance. Output from LifeMOD/KneeSIM™ was used to drive dynamic finite element analysis (FEA) simulations to characterize the stress environment. During development, the JOURNEY knee system was designed, simulated and modified over 50 times, a process that would take several years using conventional methods. The resulting optimized design is anatomically shaped, which induces a force environment that drives the desired normal motion.

Photo courtesy of Biomechanics Research Group, Inc.



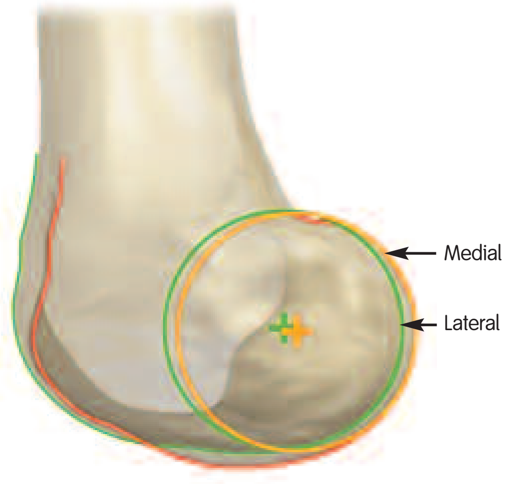
Dynamic finite element analysis

Normal knee function

Shape

Joint line

- Medial condyle more distal than lateral condyle
- 3° physiological joint line

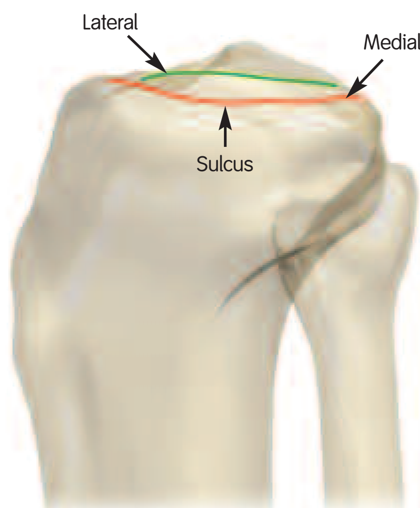


Femur

- Distal lateral condyle less round than the medial condyle
- Lateral posterior offset less than medial
- Posterior condyles circular in shape

Tibia

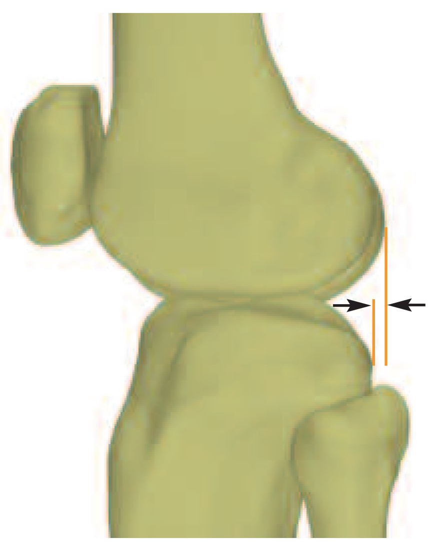
- Medial concave surface
- Medial sulcus near AP midline
- Lateral convex surface



Concave medial, convex lateral surface

AP stability

- ACL provides anterior stability and limits anterior translation of the tibia (femoral posterior translation)
- PCL provides posterior stability and limits posterior translation of the tibia (femoral anterior translation)
- Medial sulcus causes the medial posterior femoral condyle to sit nearly flush with the posterior tibia
- In this anterior position, the force environment causes femoral rollback during flexion

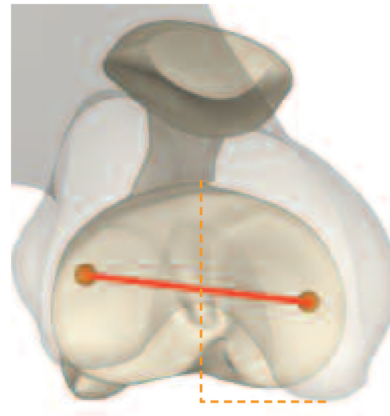


Anterior AP position

Kinematics[5]

0° – Screw-home, anterior AP position

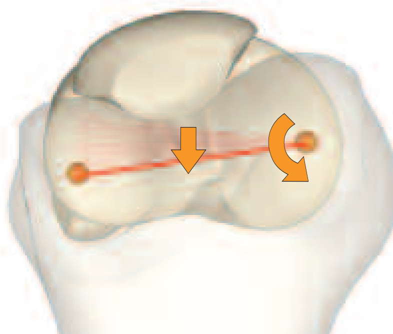
- Tibial tubercle approximately 10mm lateral to the ML midline
- Femur internally rotated 5° creating a Q-angle of 14-17°
- This is known as the screw-home position
- Sulcus of medial side and ACL cause the femur to sit nearly flush with the posterior tibia



0° – Screw-home, anterior AP position

0-90° – Rollback medial pivot

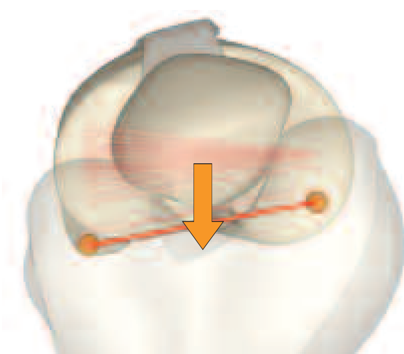
- Because of the anterior position of the femur, forces during flexion direct the femur to roll back approximately 6mm
- During flexion, the quadriceps mechanism attempts to straighten and applies external rotation torque to the femur through the patella
- Femur external axial rotation is aided by the downhill force of the convex lateral compartment
- Axial rotation continues (approximately 12°) until the quadriceps mechanism is straight and the Q-angle is minimized
- Rollback combined with femoral external axial rotation yields a medial pivot



0-90° – Rollback medial pivot

90-155° – Posterior translation

- Femur translates posteriorly about 12mm
- No additional femoral axial rotation occurs



90-155° – Posterior translation

Functional flexion

- Lateral posterior offset is less, so femoral external axial rotation and convex lateral compartment are necessary for lateral condyle to clear tibia
- Medial condyle is more anterior than the lateral condyle, therefore, large posterior translation is needed to clear tibia
- Femoral external axial rotation minimizes patellofemoral ML shear force, which optimizes quadriceps mechanism function

Conventional PS TKA function

Shape

Joint line

- Medial and lateral condyles equal thickness
- Non-physiological 0° joint line

Femoral

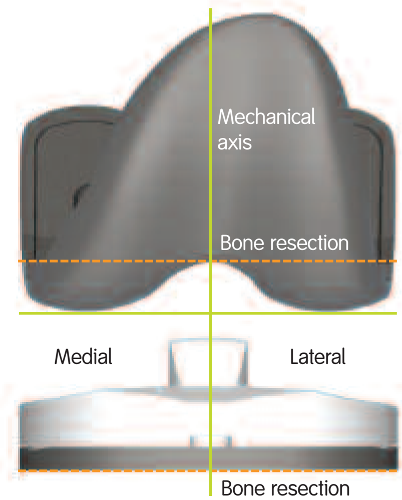
- Symmetric distal condyles identical in thickness and shape
- Symmetric posterior condyles identical in thickness and shape

Tibia

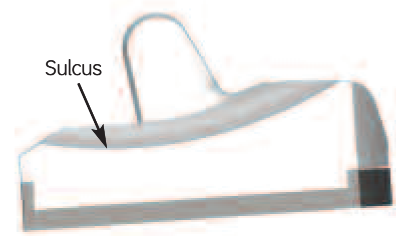
- Symmetric insert identical in thickness and shape, creating a bi-concave design
- Sulcus located in posterior 1/3 of insert
- Symmetric baseplate does not provide anatomic coverage

AP stability

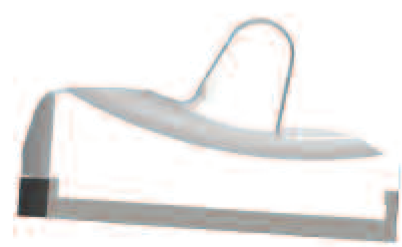
- Lack of ACL replicating feature causes anterior instability, especially in early gait
- Posterior cam provides posterior stability and limits anterior translation of the femoral component
- Insert sulcus causes the posterior femoral condyles to overhang the tibia posteriorly
- In this posterior position, the force environment causes femoral paradoxical anterior translation during flexion



0° non-physiological joint line



Concave medial



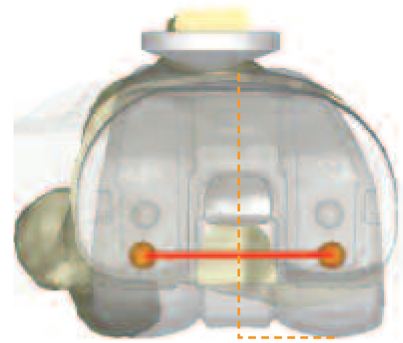
Concave lateral

Posterior overhang

Kinematics

0° – No screw-home, posterior overhang

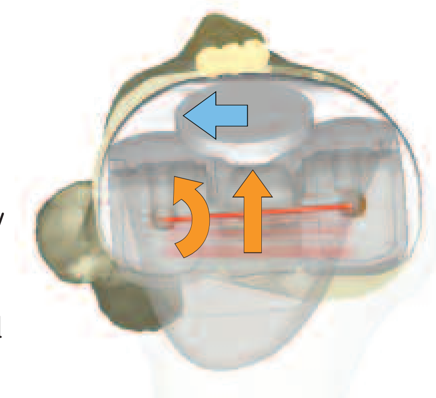
- Symmetric insert causes femoral component/femur to be directed anteriorly
- This results in no screw-home, reducing Q-angle
- Posterior sulcus and lack of an ACL cause the femur to overhang the tibia posteriorly
- This may require continuous use of the quadriceps muscle to stand, causing fatigue



0° – No screw-home, posterior overhang

0-90° – Paradoxical motion, lateral pivot

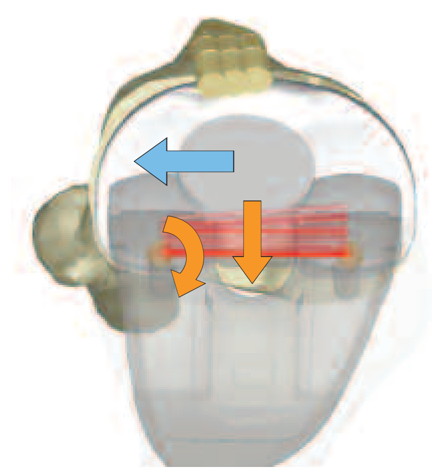
- Because of the posterior position of the femoral component, forces during flexion direct the femur to paradoxically translate anteriorly
- During flexion, the quadriceps mechanism attempts to straighten and applies external rotation torque to the femur through the patella
- Femoral external axial rotation resisted by insert bi-concave conformity
- Q-angle is not minimized, causing patellofemoral ML shear force
- Paradoxical anterior translation combined with limited femoral external axial rotation yields a lateral pivot



0-90° – Paradoxical motion, lateral pivot

90°-max flexion – Posterior translation, abnormal rotation

- Posterior cam causes femoral posterior translation
- Insert bi-concave conformity exceeds external torque applied by the quadriceps mechanism
- Femoral component abnormally rotates internally and aligns with symmetric insert
- Posterior translation combined with femoral abnormal internal rotation yields a lateral pivot
- Q-angle is increased, causing significant patellofemoral ML shear force



>90° – Posterior translation, abnormal axial rotation

Functional flexion

- Lateral posterior offset is less, so femoral internal axial rotation and concave lip of lateral insert may cause early bone impingement, limiting flexion
- Large patellofemoral ML shear force may cause anterior knee pain, which can limit functional flexion

JOURNEY◊ Bi-Cruciate Stabilized Knee System function

Shape

Joint line

- Medial condyle more distal than lateral condyle
- 3° physiological joint line created

Femoral

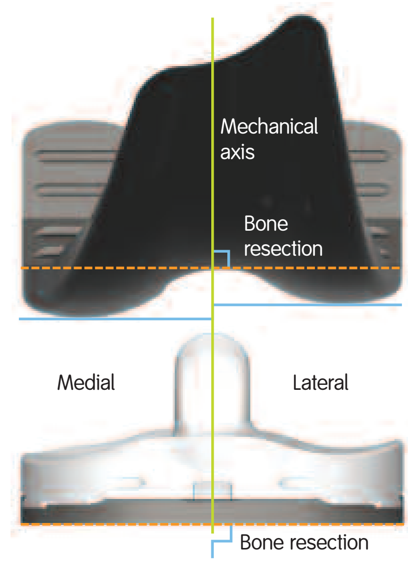
- Lateral distal condyle less thick than medial femoral condyle
- Posterior offset of medial and lateral condyles maintained
- Posterior condyles circular in shape

Tibia

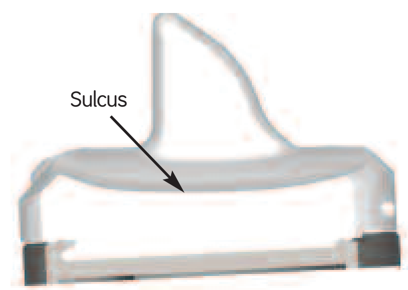
- Concave medial surface
- Medial sulcus near AP midline
- Lateral compartment thicker than the medial compartment
- Convex lateral surface in sagittal plane creates a slight posterior slope

AP stability

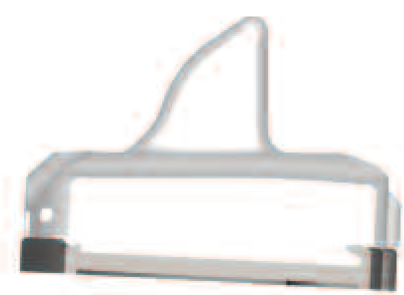
- Anterior cam provides anterior stability and limits anterior translation of the tibia (femoral posterior translation)
- Asymmetric posterior cam provides posterior stability and limits posterior translation of the tibia (femoral anterior translation)
- Bi-cruciate stabilized – anterior and posterior cam replicates ACL and PCL function
- Medial sulcus causes the medial posterior femoral condyle to sit nearly flush with the posterior tibia
- In this anterior position, the force environment causes femoral rollback during flexion



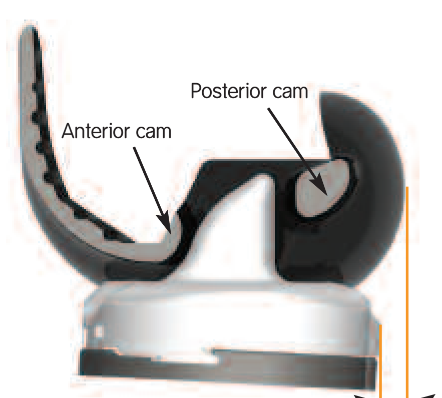
3° physiological joint line



Concave medial



Convex lateral

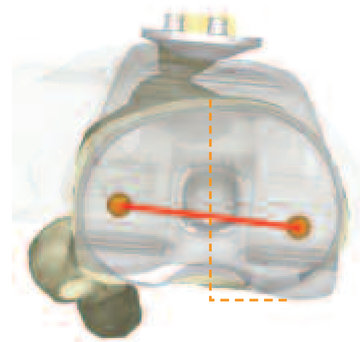


Anterior AP position

Kinematics

0° – Screw-home, anterior AP position

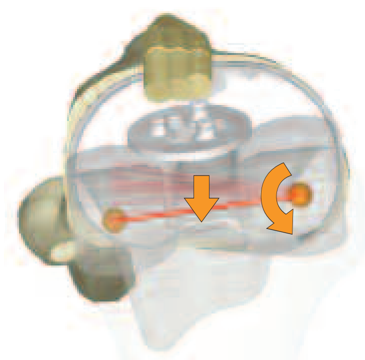
- Insert arcuate path allows for 5° of screw-home
- Sulcus of medial side causes the femur to sit nearly flush with the posterior tibia
- Normal Q-angle and AP position created in extension



0° – Screw-home, anterior AP position

0-90° – Rollback medial pivot

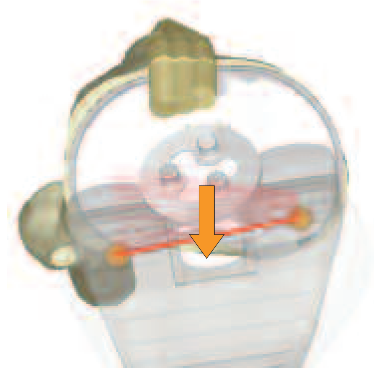
- Because of the anterior position of the femur, forces during flexion direct the femur to roll back
- During flexion, the quadriceps mechanism attempts to straighten and applies external rotation torque to the femur through the patella
- Femur external axial rotation is aided by the downhill force of the convex lateral compartment
- Rotation continues until the quadriceps mechanism is straight and the Q-angle is minimized
- Rollback combined with femoral external axial rotation yields a medial pivot



0-90° – Rollback medial pivot

90-155° – Posterior translation

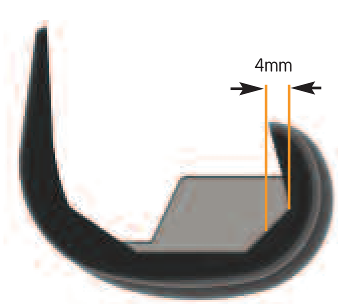
- Femur translates posteriorly
- No additional femoral axial rotation occurs



90-155° – Posterior translation

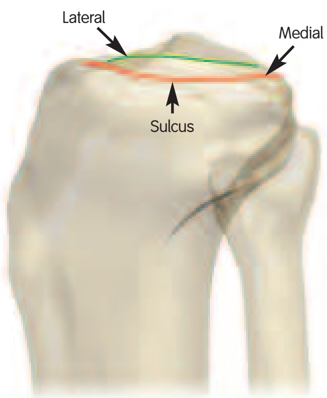
Functional flexion

- 15° flexed cut extends articular surfaces by 4mm while minimizing bone resection
- Lateral posterior offset is less, so femoral external axial rotation and convex lateral compartment are necessary for lateral condyle to clear tibia
- Medial condyle is more anterior than the lateral condyle, therefore, large posterior translation is needed to clear tibia
- Femoral external axial rotation minimizes patellofemoral ML shear force, which optimizes quadriceps mechanism function

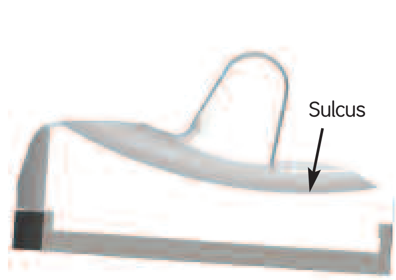


15° flexed cut extends the articular surfaces

Function summary

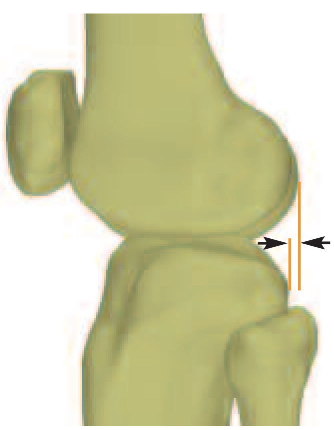


Shape – Normal knee
- Concave medial surface
- Sulcus near AP midline
- Convex lateral surface
- 3° physiological joint line



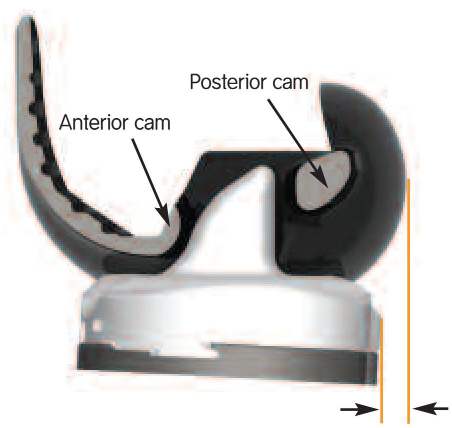
Shape – Conventional PS TKA
- Symmetric concave medial and lateral surfaces
- Sulcus located in posterior 1/3
- 0° unnatural joint line

Shape – JOURNEY° Bi-Cruciate Stabilized Knee System
- Concave medial surface
- Sulcus near AP midline
- Convex lateral surface
- 3° physiological joint line



AP stability – Normal knee
- ACL provides anterior stability
- PCL provides posterior stability
- Anterior AP position causes femoral rollback

AP stability – Conventional PS TKA
- Lack of anterior stability (ACL function)
- Posterior overhang causes femoral paradoxical anterior translation
- Anterior and mid-flexion instability



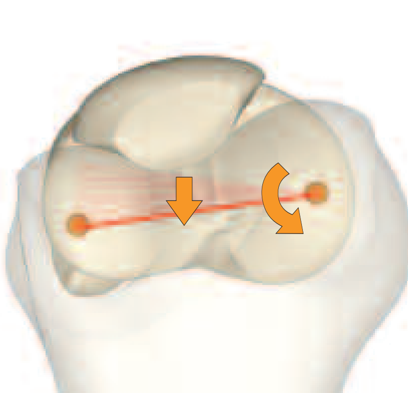
AP stability – JOURNEY Bi-Cruciate Stabilized Knee System
- Anterior cam provides anterior stability
- Anterior AP position causes rollback
- ACL function and femoral rollback provide anterior and mid-flexion stability

Conventional PS TKA function

AP stability	Ant. instability (No ACL function)	Mid-flexion instability (Paradoxical motion)	Posterior stability (Posterior cam)
Kinematics	No screw-home	Lateral pivot (Paradoxical motion and limited axial rotation)	Posterior translation (Posterior cam)
Flexion	Adequate quadriceps efficiency	Patellofemoral ML shear stresses increase	

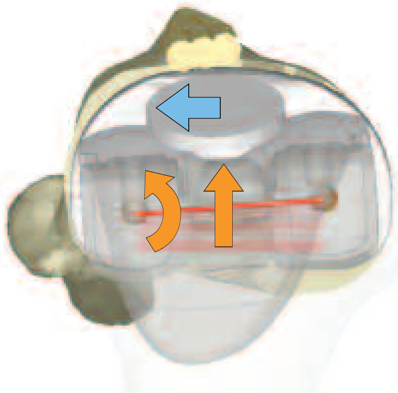
-5 0 10 20 30 40 50 60 70 80 90 100 110 120 130 140 150

Flexion



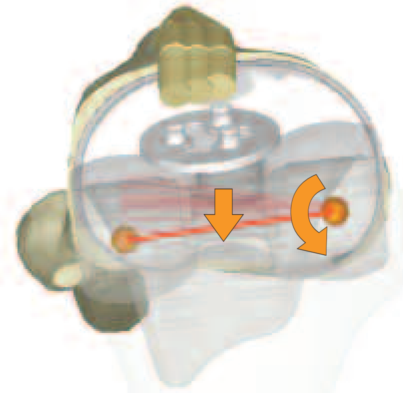
Kinematics – Normal knee

- 0° – Screw-home, anterior AP position
- 0-90° – Rollback plus femoral external axial rotation yields medial pivot
- 90-155° – Posterior femoral translation



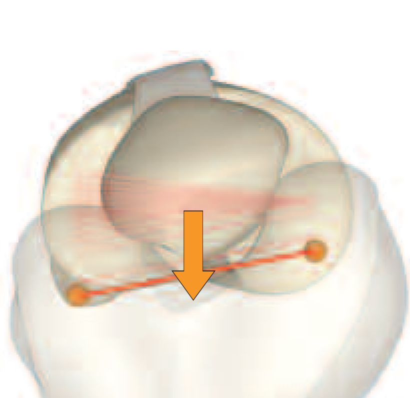
Kinematics – Conventional PS TKA

- 0° – No screw-home, posterior overhang
- 0-90° – Paradoxical motion plus limited axial rotation yields lateral pivot
- 90-155° – Abnormal femoral internal axial rotation



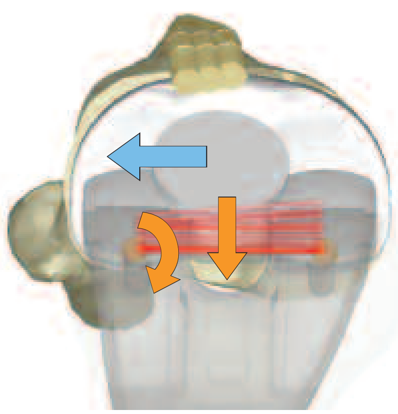
Kinematics – JOURNEY° Bi-Cruciate Stabilized Knee System

- 0° – Screw-home, anterior AP position
- 0-90° – Rollback plus femoral external axial rotation yields medial pivot
- 90-155° – Posterior femoral translation



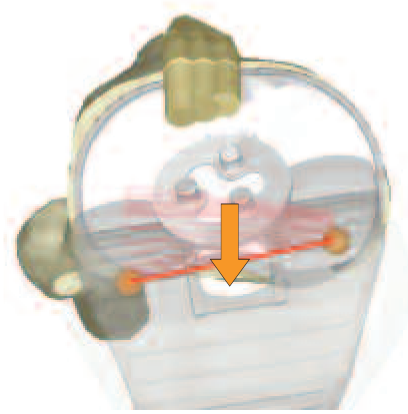
Flexion – Normal knee

- External axial rotation of femur allows lateral condyle to clear posterior tibia
- Large posterior translation allows medial condyle to clear posterior tibia
- Patellofemoral ML shear force minimized



Flexion – Conventional PS TKA

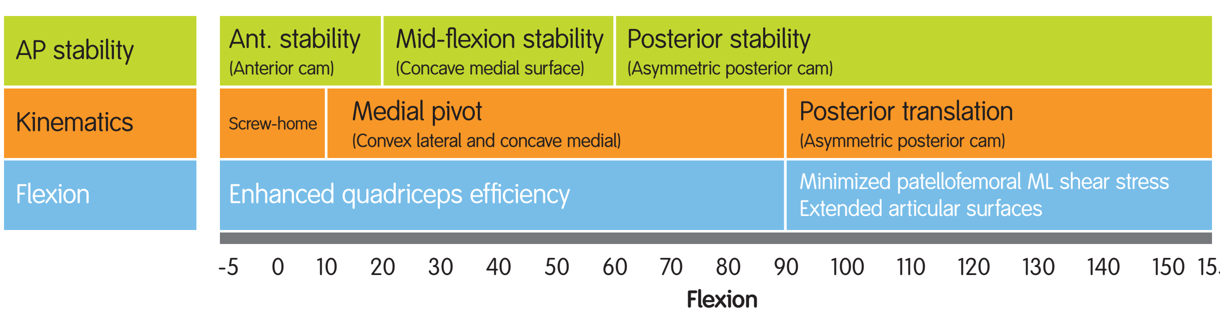
- Abnormal internal axial rotation causes early bone impingement, limiting flexion
- Internal axial rotation causes significant patellofemoral ML shear force



Flexion – JOURNEY Bi-Cruciate Stabilized Knee System

- External axial rotation of femur allows lateral condyle to clear posterior tibia
- Large posterior translation allows medial condyle to clear posterior tibia
- Patellofemoral ML shear force minimized

JOURNEY Bi-Cruciate Stabilized Knee System function



Durability

Conventional PS TKA wear

- Paradoxical motion during flexion increases the relative sliding velocity, increasing wear
- Concave lateral insert conformity increases the wear footprint (the total amount of area that the femoral traverses during the entire ROM), which increases wear

Conventional PS TKA post contact

- Unintended femoral contact with the post causes severe post stresses
- Surpassing fatigue stress can cause post breakage
- Non-rounded posts and cams can cause edge loading during femoral external axial rotation, increasing stresses on the post

Conventional PS TKA patellofemoral shear forces

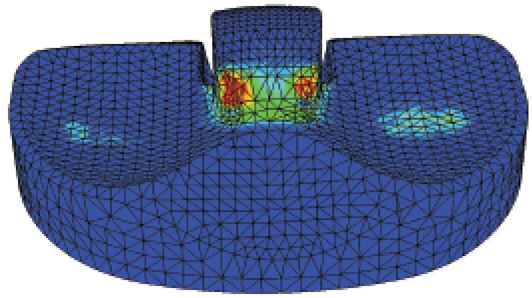
- Limited and abnormal femoral axial rotation increases patellofemoral ML shear forces
- Excessive shear force may cause anterior knee pain, premature articular wear and/or peg breakage

Conventional PS TKA materials

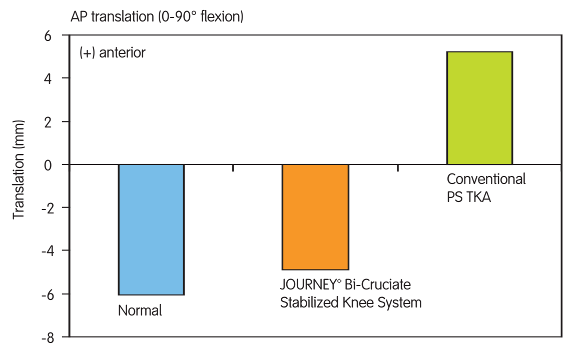
- CoCr is less scratch resistant and is less lubricious than OXINIUM◊ Oxidized Zirconium, increasing both adhesive and abrasive wear
- Non-polished baseplates produce more backside wear than polished baseplates
- Crosslinked UHMWPE can decrease mechanical properties which can increase the risk of post breakage

Conventional PS TKA locking mechanism

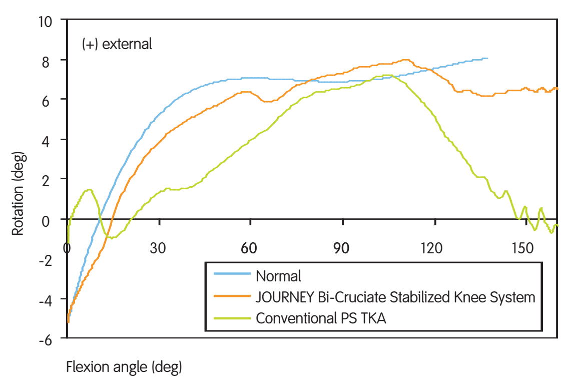
- Inferior insert/baseplate locking mechanisms require a screw or bolt augment through the insert to prevent insert disassociation



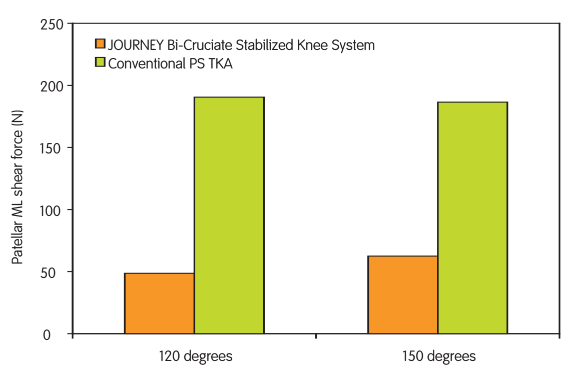
Conventional PS post edge impingement



Kinematic comparison - AP translation



Kinematic comparison - femoral axial rotation



Kinematic comparison - patellofemoral ML shear force

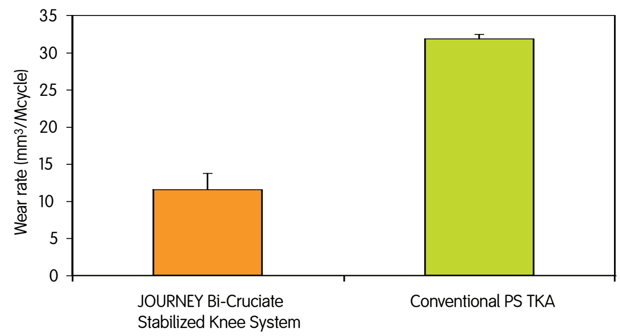
JOURNEY◊ Bi-Cruciate Stabilized Knee System wear

- Wear tested to 10 million cycles
- Predominant wear feature on the insert articular surface was burnishing
- There were no signs of fatigue wear or delamination
- Volumetric wear was less than previously published wear for conventional TKA[6,7,8]
- Medial pivot and rollback cause the lateral side to roll more and slide less
- Convex lateral insert compartment reduces wear footprint

Wear simulator

JOURNEY knee system post contact

- Large, rounded anterior cam reduces contact stresses and eliminates edge loading
- Asymmetric, rounded posterior cam maintains congruent contact during femoral axial rotation, eliminating edge loading and minimizing stress



Wear rates

JOURNEY knee system patellofemoral ML shear forces

- Femoral external axial rotation minimizes patellofemoral ML shear forces
- Risk of premature wear, peg breakage and anterior knee pain reduced

JOURNEY Bi-Cruciate Stabilized Knee System insert

JOURNEY knee system materials

- OXINIUM◊ Oxidized Zirconium reduces abrasive and adhesive wear
- Compression molded poly reduces the amount of wear and the number of particles
- ETO sterilization does not produce free radicals, which reduces the risk of oxidation and subsequent delamination
- Polished tibial baseplate reduces backside wear

JOURNEY knee system locking mechanism

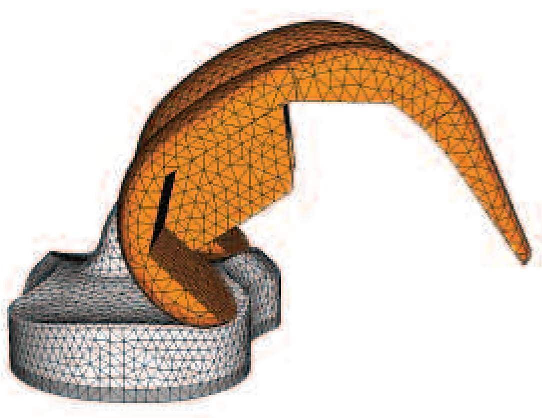
- Dovetail perimeter increased by 19%
- Strength increased by 50%
- Large dovetail interface area eliminates the need for fixation augmentation
- Deep flexion possible

JOURNEY Bi-Cruciate Stabilized Knee System baseplate

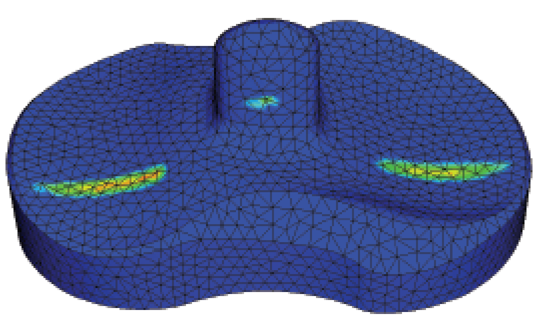
Robustness

Sensitivity analysis

- Used to determine how stress sensitive JOURNEY◊ knee system is when not implanted in optimal alignment
- Eighteen clinically relevant deviations from the optimal alignment simulated in LifeMOD/KneeSIM™
- Deep knee bend output data from the virtual simulator used as inputs for a 3D finite element analysis (FEA) model to determine the contact pressures in the UHMWPE insert
- Polyethylene insert stresses were on average within 10% of the optimal alignment



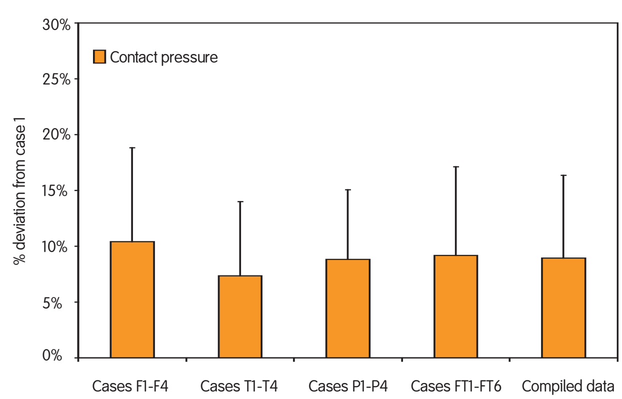
Finite element model



Dynamic finite element analysis

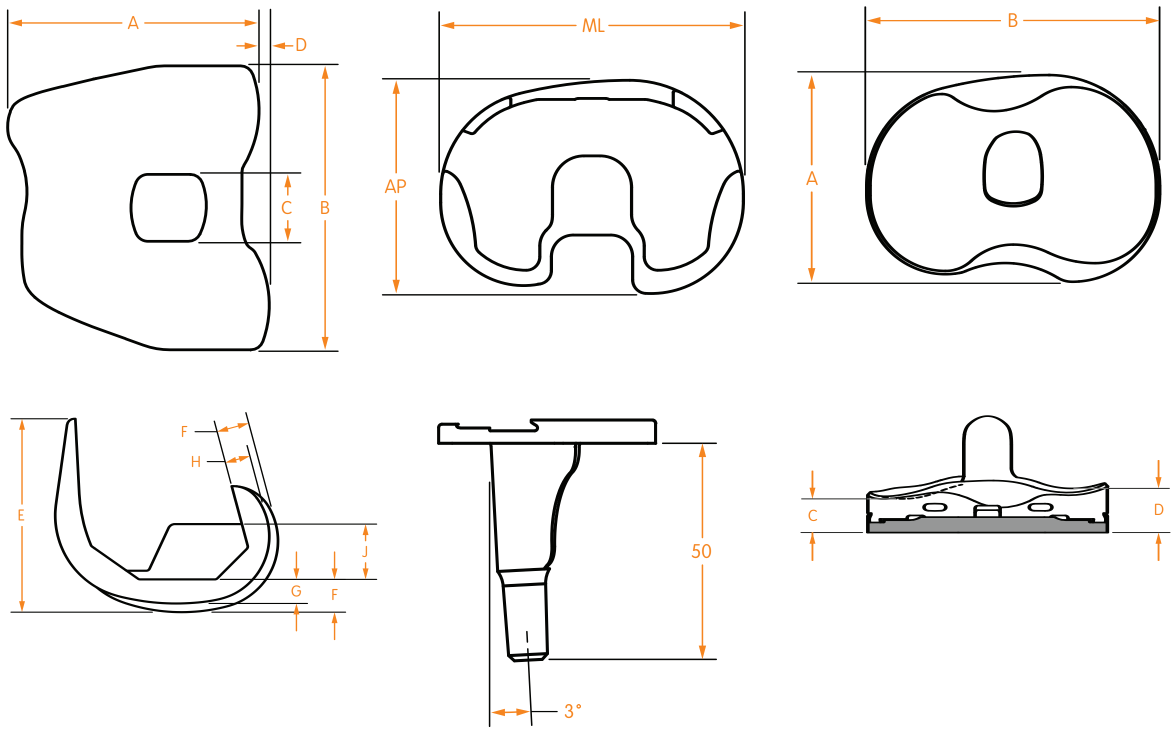
Case	Femoral	Tibial insert	Patella
1	Optimal	Optimal	Optimal
F1	3° Internal	Optimal	Optimal
F2	3° External	Optimal	Optimal
F3	4° Flexed	Optimal	Optimal
F4	LCL, MCL 5mm ant.	Optimal	Optimal
T1	Optimal	5° Internal	Optimal
T2	Optimal	5° External	Optimal
T3	Optimal	0° Posterior slope	Optimal
T4	Optimal	6° Posterior slope	Optimal
P1	Optimal	Optimal	5mm lat.
P2	Optimal	Optimal	3mm ant.
P3	Optimal	Optimal	3mm pos.
P4	Optimal	Optimal	6mm pos.
FT1	3° Varus	3° Varus	Optimal
FT2	3° Valgus	3° Valgus	Optimal
FT3	3mm Proximal	3mm Proximal	Optimal
FT4	3mm Distal	3mm Distal	Optimal
FT5	7.5° External	7.5° Internal	Optimal
FT6	6mm Proximal	6mm Proximal	Optimal

Implantation positions



FEA results

System overview



Femoral component

Size	A (Anterior posterior)	B (Medial lateral)	C (Box width)	D (Condylar offset)	E (Flange height)	F (Medial condylar thickness)	G (Distal lateral thickness)	H (Posterior lateral thickness)	J (Box height)
1	51	59	14.5	2.2	49.50	7.5	5.3	5.6	14.00
2	53	61	14.5	2.2	50.75	7.5	5.3	5.6	14.50
3	56	64	16.5	2.5	52.50	9.5	7	7.4	14.00
4	59	67	16.5	2.5	54.25	9.5	7	7.4	15.00
5	62	70	16.5	2.5	56.00	9.5	7	7.4	16.00
6	65	73	16.5	2.5	57.75	9.5	7	7.4	17.25
7	68	76	16.5	2.5	59.50	9.5	7	7.4	18.50
8	71	78	16.5	2.5	61.25	9.5	7	7.4	19.75
9	75	80	16.5	2.5	63.50	11.5	9	9.4	19.00
10	79	82	16.5	2.5	65.75	11.5	9	9.4	20.25

Tibial baseplate

Size	AP (Anterior posterior)	ML (Medial lateral)
1	42	60
2	45	64
3	48	68
4	50	71
5	52	74
6	54	77
7	56	81
8	59	85

Note: Stem sloped 3° posteriorly. Stem length is 50mm on all nonporous sizes.

Articular insert

9mm Insert	A (Anterior posterior)	B (Medial lateral)	C (Medial ** thickness)	D (Lateral ** thickness)
Size 1-2 small*	42	60	9.0	11.2
Size 3-4 small*	48	68	9.0	11.2
Size 1-2 std	42	60	9.0	11.5
Size 3-4 std	48	68	9.0	11.5
Size 5-6 std	52	74	9.0	11.5
Size 7-8 std	56	81	9.0	11.5

Minimum polyethylene thickness for a 9mm metal backed component is 6.7mm on the medial side.

*Can only be used with size 1 and 2 femorals.

**Baseplate thickness included.

Insert offering/Compatibility

	Femoral size									
	Small		Standard							
Insert size	1	2	3	4	5	6	7	8	9	10
1-2 Small*	●	●								
3-4 Small*		●								
1-2 Std			●	●						
3-4 Std			●	●	●	●				
5-6 Std				●	●	●	●	●	●	
7-8 Std						●	●	●	●	●

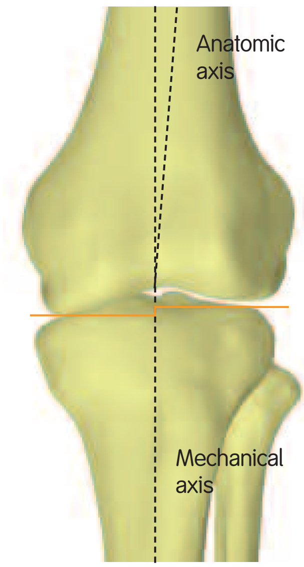
*Can only be used with size 1 and 2 femorals.
General rule = 2 down / 1 up from femoral size

Implantation

Position slightly flexed femoral component near posteriorly resected edge

Roll femoral component onto femur

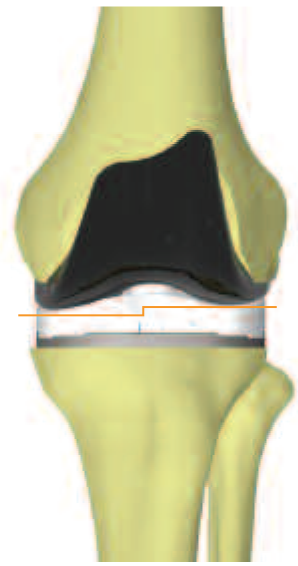
Once seated, femoral component is locked onto distal femur



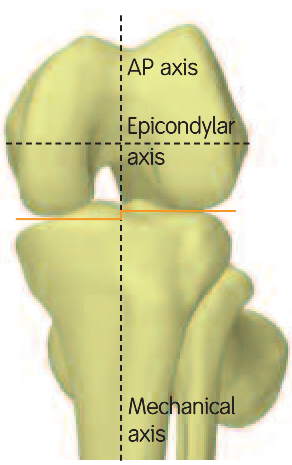
0° Flexion

Bone cuts perpendicular to mechanical axis

Femoral condyles have asymmetric thickness

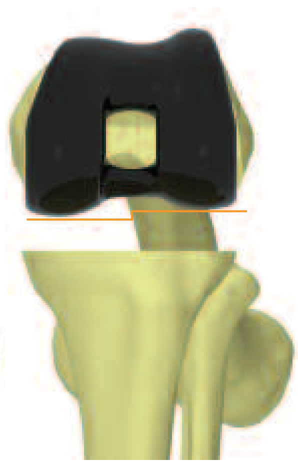


Original joint line restored



105° Flexion

Bone cuts perpendicular to mechanical and AP axes



Femoral condyles have asymmetric thickness

Original joint line restored

Summary

The JOURNEY◊ Bi-Cruciate Stabilized Knee System is the first knee system designed to truly restore normal function, because it is the first to restore normal knee AP stability, kinematics and deep flexion. Smith & Nephew has utilized new technologies to better understand normal knee kinetics and the relationship between these forces and the articular shapes of the knee. With a design based on natural anatomy, the JOURNEY Bi-Cruciate Stabilized Knee System addresses many of the problems associated with conventional systems, while maximizing durability and minimizing sensitivity to malpositioning.

The JOURNEY Bi-Cruciate Stabilized Knee System achieves a balance of function, durability and robustness that sets a new standard for total knee design.

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Printed in USA
40490401 7128-1354 03/06