SIGMA™ HP Partial Knee

Technical Monograph

Johnson&Johnson
MedTech

Historical review

Unicompartmental knee arthroplasty (UKA) is a successful treatment for symptomatic end-stage osteoarthritis (OA) of the knee. UKA has multiple advantages over total knee arthroplasty (TKA), including reduced intraoperative blood loss, decreased risk of transfusion, and faster recovery. In addition, compared with TKA, UKA is associated with superior patient-reported clinical and functional outcomes, as well as shorter hospital stays, lower readmission rates, and fewer postoperative complications, such as thromboembolism, infection, stroke, and myocardial infarction.[1] Because of these benefits, UKA (also called partial knee replacement) has been used to treat joint disease for over 50 years.[2]

Patient indications for UKA are based on substantial unicompartmental osteoarthritis/osteonecrosis symptoms with bone-on-bone contact, functionally intact anterior cruciate ligament (ACL) and medial collateral ligament (MCL), and full-thickness cartilage in the unaffected compartment. Some contraindications should be adhered to such as active infection, inflammatory disease, ligamentous instability, uncorrectable varus deformity, absence of the ACL, history of High Tibial Osteotomy (HTO), and severe wear of the lateral facet of the patellofemoral (PF) joint with bone loss and grooving.[3]

Since the SIGMA HP Partial Knee System became available in 2008, surgeons have implanted nearly 130,000 in patients worldwide needing a UKA.[4]*

The SIGMA HP Partial Knee has demonstrated significantly better 15-year survivorship compared to the unicondylar knee class.[5†]

*This data was tabulated May 2025 for worldwide sales/utilization from the time of product launch for the SIGMA™ HP Partial Knee System.

† CRR:10.9% (95% CI: 9.3%, 12.7%) vs. class CRR:14.1% (95% CI: 13.8%, 14.4%)

Considerations

The SIGMA™ HP Partial Knee System is a high flex fixed bearing (FB) unicompartmental knee implant system, designed to provide solutions to treat degenerative joint disease in one compartment of the knee joint.[6,7] This system allows the surgeon to replace only the affected compartment, leaving the healthy bone, cartilage and ligaments intact.[6,7] Since UKA is a conservative procedure, future intervention can be considered in response to later disease progression, including the possibility of revision to TKA.

Because the ACL and PCL can be retained with this system, the normal kinematics required for most daily living activities are preserved.[6,7] For these reasons, UKA is well matched to patients who desire to retain an active lifestyle.

Design parameters

Materials

The femoral component and tibial tray of SIGMA™ HP Partial Knee are manufactured from a surgical grade of cobalt chromium molybdenum (CoCrMo) alloy. The femoral component is manufactured from cast CoCrMo to ASTM F75-23 standards, making its content of nickel less than 0.5% by weight.[9-10] The tibial base component is manufactured from wrought CoCrMo to ASTM F1537-20 standards.[11]

All SIGMA HP Partial Knee insert components are manufactured from a moderately cross-linked GUR 1020 Ultra High Molecular Weight Polyethylene (UHMWPE) polyethylene.[12,13,14]

The polyethylene material used for XLK is irradiated to 5 Mrads in order to cross-link the material to enhance wear resistance.[12,13]

Therefore, the SIGMA HP Partial Knee insert would be expected to have stronger mechanical integrity, as compared to implants irradiated at higher Mrad doses.[14-17]

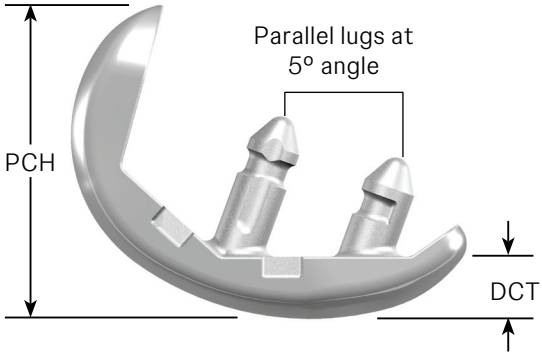
The XLK Polyethylene is remelted, eliminating free radicals to make the insert oxidatively stable both in air-permeable packaging (used for sterilization) and when exposed to oxygen after being removed from packaging.[12-15,18]

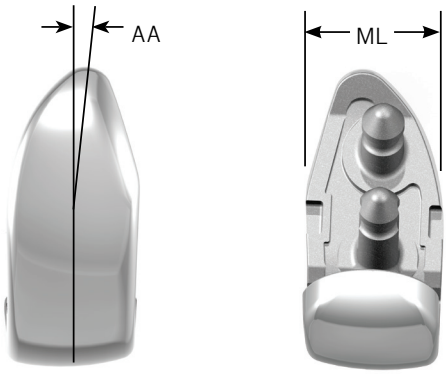
Material Attribute	XLK Property[12-15,18]
Base Resin	GUR 1020
Irradiation/Wear Resistance	5 Mrads
Free Radical Mitigation	Remelted
Sterilization	Gas Plasma (no additional free radicals)

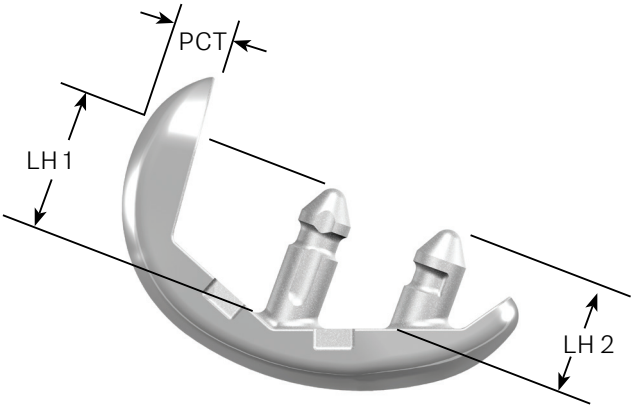
Femoral Component

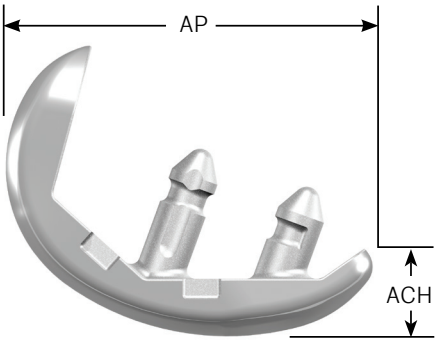
The SIGMA HP Partial Knee System offers six (6) femoral implant sizes (see table). The femoral component is asymmetric, with right and left variants for each size. Because of this feature, the system allows for utilization for either medial or lateral condyle replacements.[8,19]

Sizing was developed on the basis of anthropomorphic data.[19]









AP = Anterior-Posterior
ML = Medial-Lateral
LH = Lug Height
DCT = Distal Condyle Thickness
PCT = Posterior Condyle Thickness
PCH = Posterior Condyle Height
ACH = Anterior Condyle Height
AA = Articulation Angle

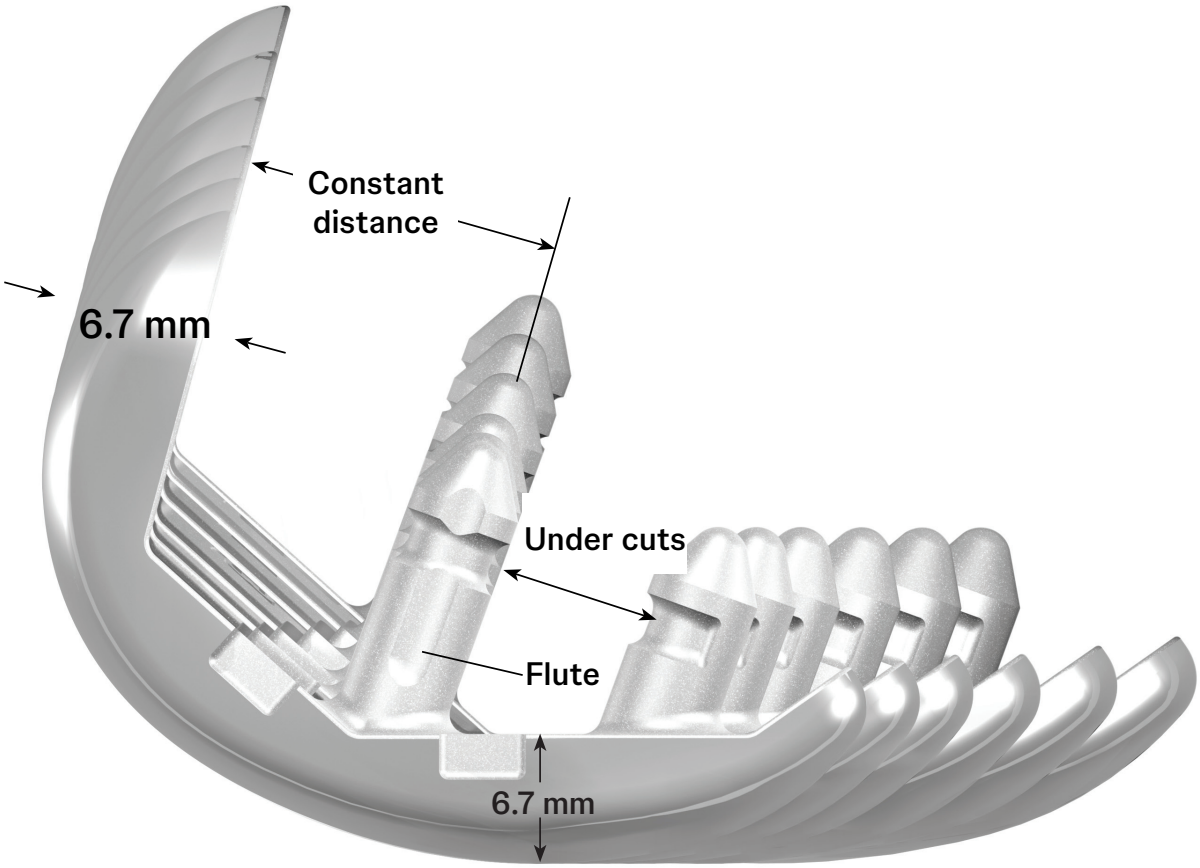
Fem Implant	AP (mm)	ML (mm)	LH 1 (mm)	LH 2 (mm)	DCT (mm)	PCT (mm)	PCH (mm)	ACH (mm)	AA (°)
Size 1	42.6	18.4	16.0	11.3	6.7	6.7	33.8	10.2	11.0
Size 2	45.1	19.4	16.5	11.3	6.7	6.7	35.5	10.5	11.0
Size 3	47.5	20.5	17.0	11.3	6.7	6.7	37.2	10.8	11.0
Size 4	50.4	22.2	18.0	11.3	6.7	6.7	39.7	10.9	11.0
Size 5	54.0	23.7	19.0	11.3	6.7	6.7	42.0	11.3	11.0
Size 6	57.5	25.2	20.0	11.3	6.7	6.7	44.4	11.8	11.0

* The parallel lugs/pegs are position at a 5° angle.

The Femoral component in the SIGMA™ HP Partial Knee System has a constant distal and posterior condylar thickness across the size range (6.7 mm), allowing the ability to choose implant size after the distal cut and independent of gap balancing.[8,19]

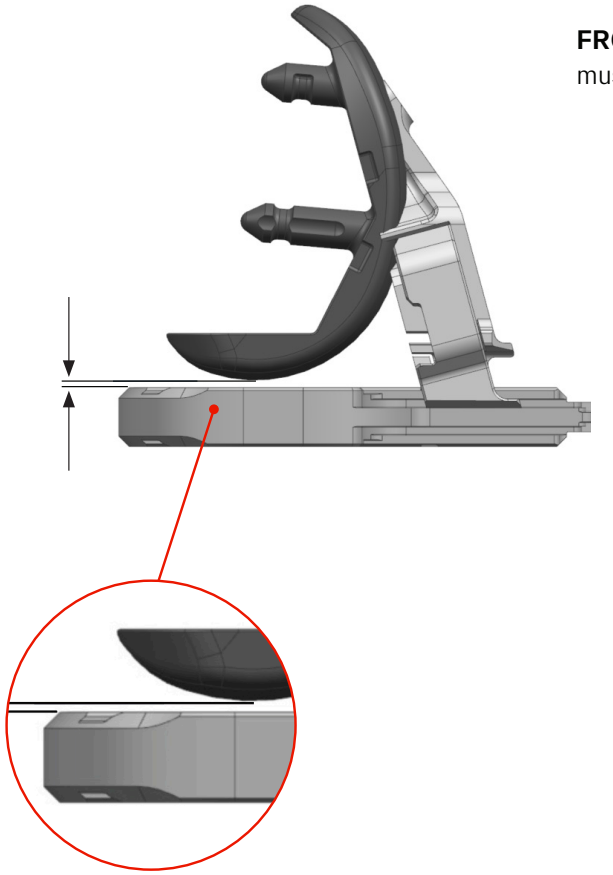
The constant distance between the posterior cut and posterior lug, supports upsizing and downsizing after trialling.[8,19-21]

The central lug has an undercut and a flute.[20-21]



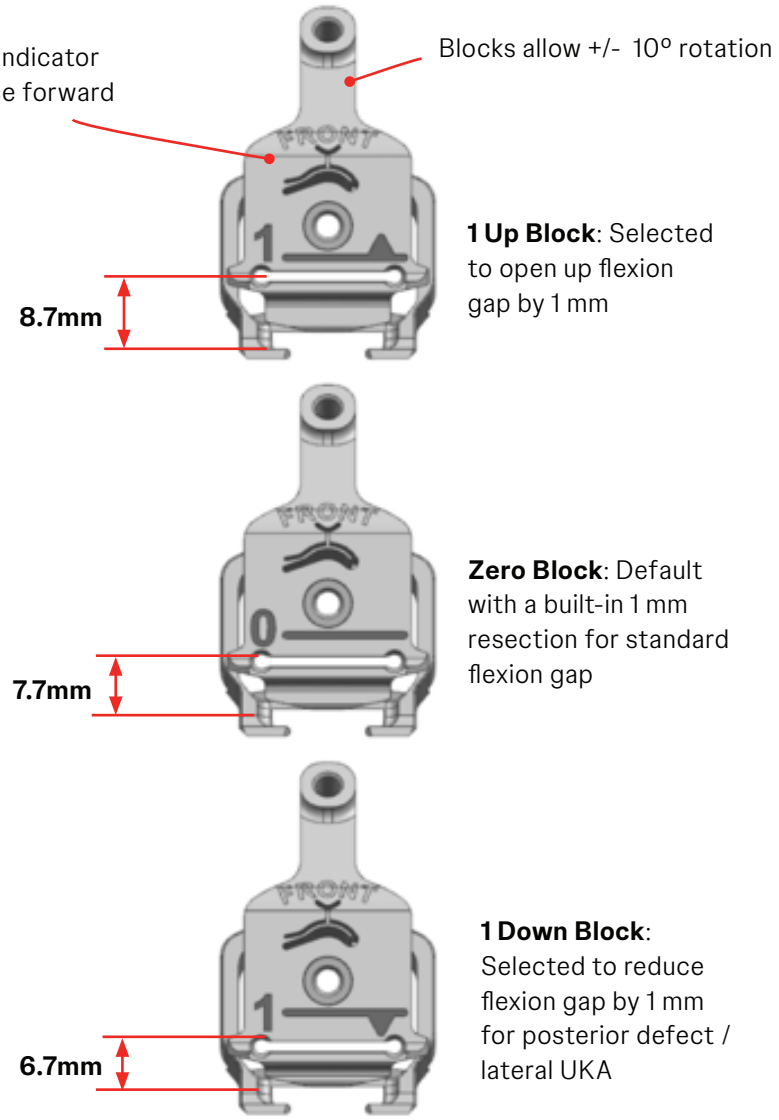
In UKA procedures, a tight flexion gap can occur, potentially requiring further surgical intervention of the posterior condyles. The SIGMA HP Partial Knee System includes INTUITION™ Instruments that offer dedicated Posterior Cutting Blocks, designed to assist with flexion gap balancing.[8]

These blocks allow you to up-size or down-size for managing the flexion gap.[8]



The Posterior Cutting Guide has 1mm additional resection by default. The system provides an option to set the posterior resection for an additional 1mm or be reduced by 1mm.

Posterior Cutting Guide Options



Tibial components

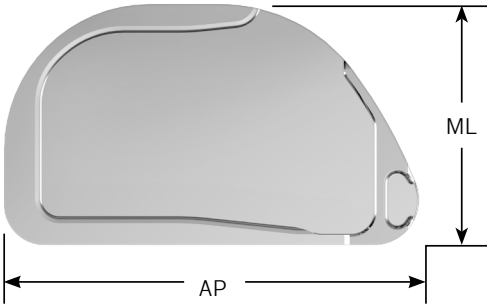
The SIGMA HP Partial Knee tibial implant and polyethylene insert component are available in six (6) sizes (see table).[8,20,22,23]

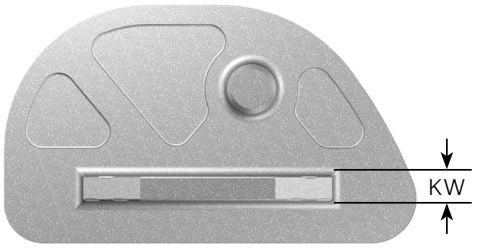
Each size poly insert comes in 5 Insert Thicknesses (IT), growing in 1mm increments from 5.4 to 9.4 mm.[8,20,23] The tibial Composite Thickness (CT) is the constant 2 mm Tray Thickness (TT) plus the Insert Thickness (IT) selected. The Construct (poly) Size (CS) offered in sizes 7-11, represents the Composite Thickness (CT) rounded down to the whole number.[8,20]

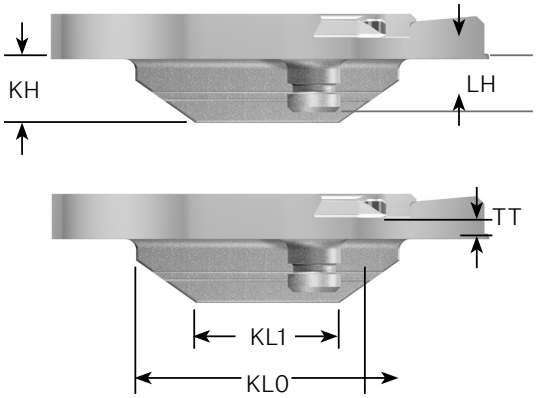
Select either the Left Medial/Right Lateral (LM/RL) or the Right Medial/Left Lateral (RM/LL) of the desired size in the SIGMA HP Partial Knee System.[8]

In the SIGMA HP Partial Knee System, the Left Medial/Right Lateral (LM/RL) tibial tray-insert is only compatible with LM/RL femoral component. Likewise, the Right Medial/Left Lateral (RM/LL) tibial tray-insert is only compatible with RM/LL femoral component.[8]

The shape of the tibial implant was designed to fit the patient through 3D shape analysis of a database of CT scans.[20,24]







AP = Anterior-Posterior
ML = Medial-Lateral
LH = Lug Height
KH = Keel Height
KW = Keel Width

KL(O) = Keel Length - Outer
KL(I) = Keel Length - Inner
TT = Tray Thickness
IT = Insert Thickness
CT = Composite Thickness
CS = Construct (Poly) Size

Tib Implant	AP (mm)	ML (mm)	LH (mm)	KH (mm)	KL(O) (mm)	KL(I) (mm)	TT (mm)	KW (mm)
Size 1	41.5	24	5	6	25	13.6	2	2.5
Size 2	44.5	26	5	6	27	15.6	2	2.5
Size 3	47.5	28	5	6	30	18.6	2	2.5
Size 4	50.5	30	5	6	33	21.6	2	2.5
Size 5	53.5	32	5	6	35	23.6	2	2.5
Size 6	56.5	34	5	6	38	26.6	2	2.5

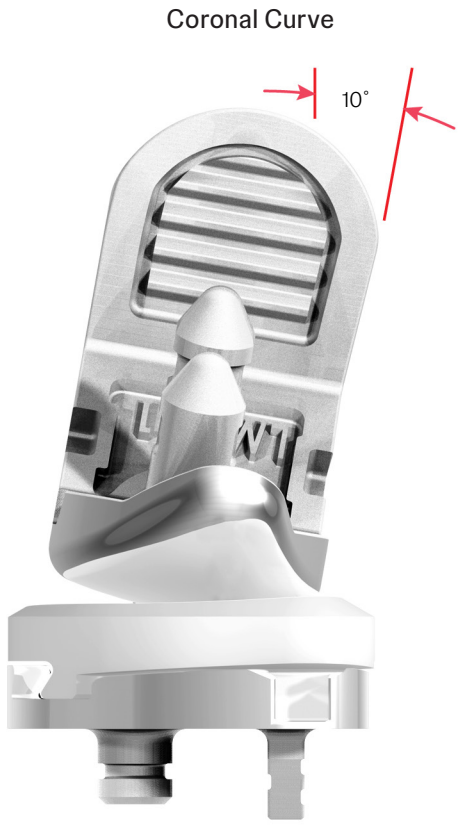
Poly Size*	TT (mm)	IT (mm)	CT (mm)	CS** (mm)
7	2	5.4	7.4	7
8	2	6.4	8.4	8
9	2	7.4	9.4	9
10	2	8.4	10.4	10
11	2	9.4	11.4	11

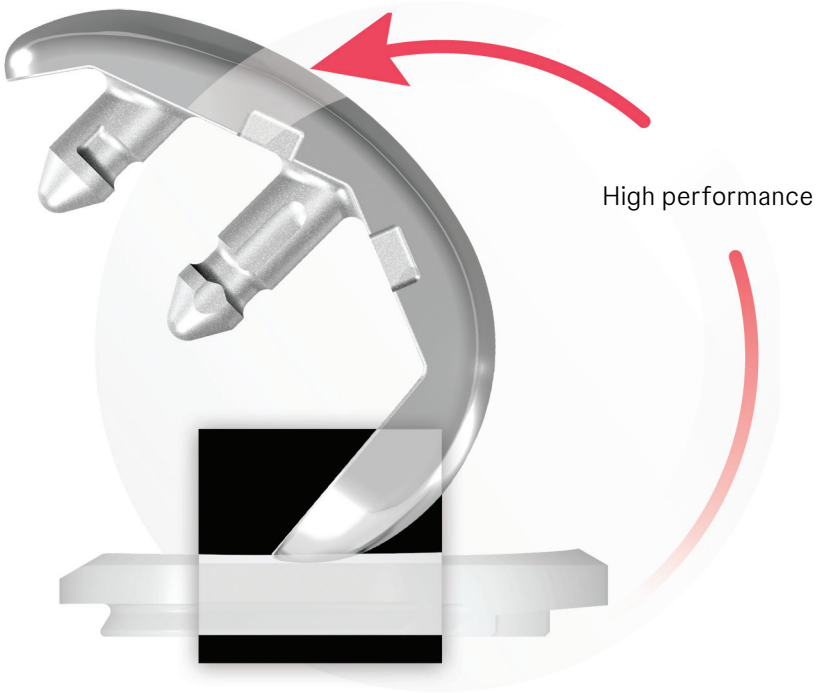
*Each Poly Size is available for each of the Tibial Component sizes 1-6.
**Note: The Construct Size (CS) or Poly Size is the Composite Thickness (CT) rounded down to the next whole number.

Articulation

The SIGMA HP Partial Knee femoral component incorporates a unique transition edge in the coronal profile to allow the femoral component to articulate with the tibial component in up to 10° of off-parallel alignment.[8,19]

The 10° coronal curve design in the SIGMA HP Partial Knee allows a large posterior condyle radius for contact in deep flexion, the reason the system is called HP for High Performance.[8,19] This is one of the reasons the SIGMA HP Partial has been so successful clinically for over 15 years.[5†]





† CRR:10.9% (95% CI: 9.3%, 12.7%) vs. class CRR:14.1% (95% CI: 13.8%, 14.4%)

Performance characteristics

Polyethylene wear

The wear rates of a knee implant are often attributed to the wear resistance of the polyethylene, the polished CoCr tray, and the locking mechanism between the polyethylene insert and the tibial tray.[25]

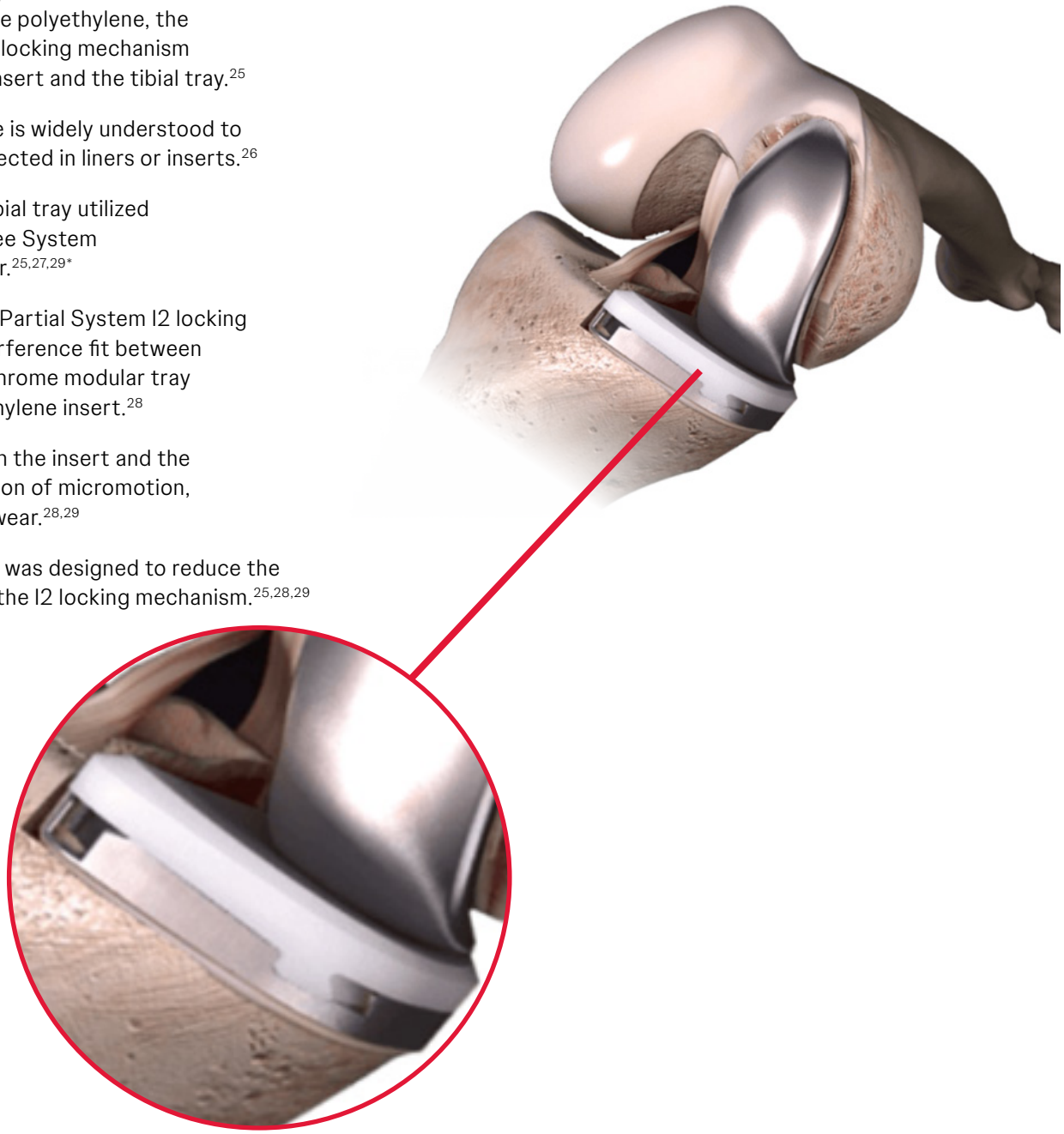
Crosslinking of polyethylene is widely understood to decrease the poly wear expected in liners or inserts.[26]

The highly polished CoCr tibial tray utilized in the SIGMA HP Partial Knee System contributes to reduced wear.[25,27,29*]

Additionally, the SIGMA HP Partial System I2 locking mechanism features an interference fit between the highly polished cobalt chrome modular tray and the cross-linked polyethylene insert.[28]

The less movement between the insert and the tray, the greater the reduction of micromotion, and backside polyethylene wear.[28,29]

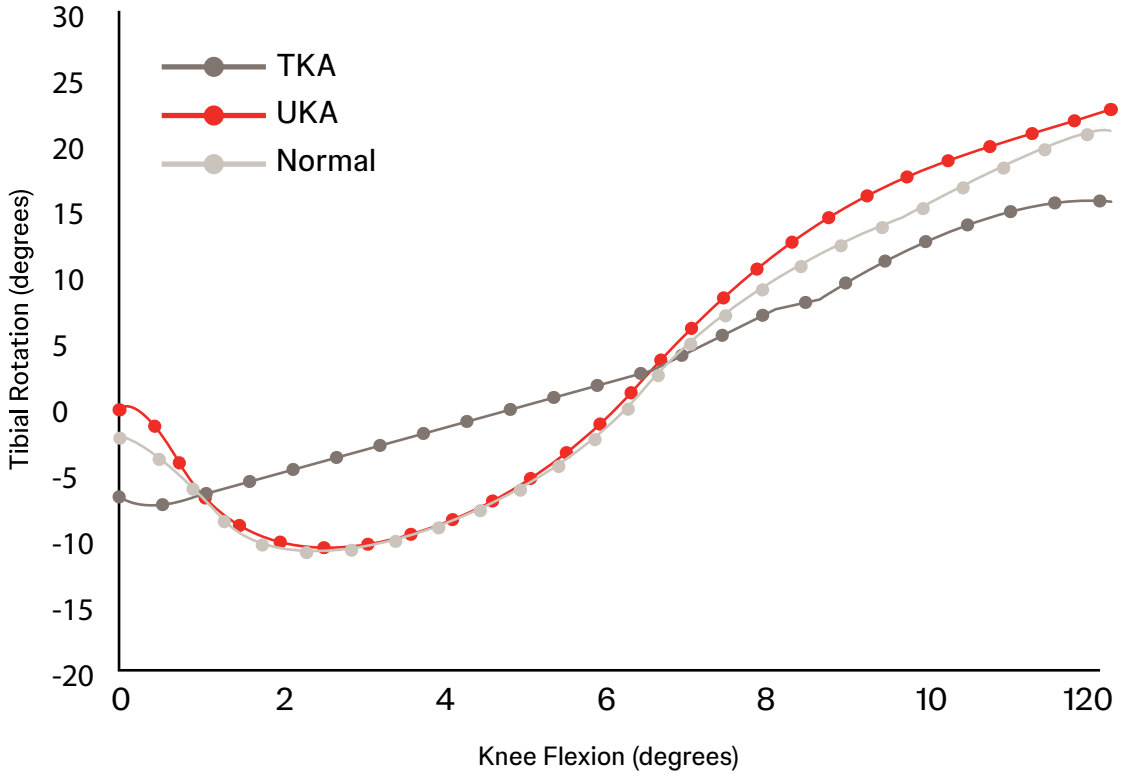
The SIGMA HP Partial Knee was designed to reduce the amount of micromotion via the I2 locking mechanism.[25,28,29]



*As compared to rough titanium trays

Normal Knee Function

A cadaver study conducted by Patil et al. compared knee kinematics after both unicompartmental (UKA) and tricompartmental (TKA) replacements to normal knee kinematics. No significant difference was found for tibial axial rotation between UKA patients and normal knee patients. This study showed that UKA does not diminish normal knee kinematics and, therefore, may benefit patient rehabilitation, extensor function, implant survivorship, and wear.[7*t]



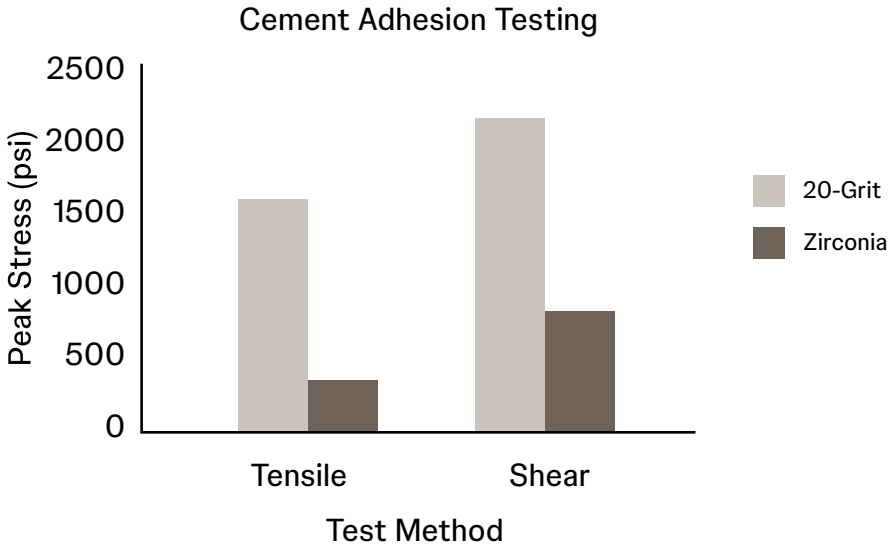
Reproduced from: Patil S, Colwell C Jr, D'Lima D. Can Normal Knee Kinematics Be Restored with Unicompartmental Knee Replacement? J Bone Joint Surg (AM), 87,332-338, February 2005.

* Pre-clinical test data/results may not necessarily be indicative of human clinical performance (or outcomes).

t (p-value=0.0001)

Fixation Performance

The cement fixation surfaces of the SIGMA HP Partial Knee femoral component are roughened with a 20-grit aluminum oxide blast process. This creates a stronger bond (greater tensile and shear strength) between the implant and the cement.[30*] In fact, the shear strength of the cement-implant bond with the 20-grit aluminum oxide blast surface is +250% greater than that with a zirconia blast surface.[30]



*As compared to zirconia blasting

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