SIGMA® HIGH PERFORMANCE PARTIAL KNEE

Patello-Femoral Joint (PFJ) Trochlea Implant Freehand Surgical Technique
INTRODUCTION

The SIGMA® High Performance Partial Knee trochlea implant is intended to be less constrained than earlier generations, and designed to reduce wear, to reduce the shear forces acting on the patella throughout the normal range of motion and to reduce the risk of loosening. The patella component is the same component used for the P.F.C.® SIGMA® Total Knee Replacement. However, the SIGMA HP Partial Knee trochlea component is not identical to the trochlea from the SIGMA Knee femoral components. It is narrower and more bone conserving and is redesigned for independent implantation. In addition, it allows the component to be either inset or onset into the trochlea and decreases the overhang impingement that has been associated with post-operative anterior knee pain. As this design closely replicates the normal anatomy, soft tissue balancing is important. Appreciation of the role of the medial and lateral patello-femoral ligaments in balancing the patella is emphasized. All efforts are made to reproduce normal patellar tracking with this anatomic design.
Pre-operative Planning

In addition to the instruments and trial implants supplied with the SIGMA High Performance Partial Knee, the following instruments are recommended to complete a patello-femoral replacement:

- High-speed hand piece with burr
- Orthopaedic rasp
- Power drill
- Pulsatile lavage unit to prepare the cancellous bone for the trochlear component
- Bone cement

The supplied instruments do not include patellar resection instruments, which are needed to complete the entire patello-femoral replacement.

Approach and Exposure

Pre-operative:

The knee should be classified pre-operatively from the list below to allow optimal surgical treatment:

Isolated patello-femoral (PF) degenerative joint disease (DJD) with normal anatomy

Isolated patello-femoral arthritis with no history of instability. These patients will typically have normal anatomy that can best be treated with an inset rather than an onset trochlear component. The patellar resurfacing may be of the surgeon’s preference. The patient may be counseled that the failure mode will often be through tibio-femoral (TF) degeneration. In addition, patients should be advised that if intra-operatively there is more TF degeneration than expected, they could be treated with bicompartamental or Total Knee Arthroplasty (TKA).

Isolated PF DJD with PF dysplasia

Dysplasia and isolated patello-femoral arthritis without a history of instability. These patients will have trochlear morphology typically best treated with an onset trochlear technique. They often have associated patella alta, which needs to be rechecked and treated as indicated. These patients typically do not have significant TF compartment degeneration.

Isolated PF DJD with history of instability

Isolated patello-femoral arthritis with a current or remote history of instability. These patients may have normal to severely dysplastic PF compartments with considerations as above. However, they present additional challenges. The most common history is one of dislocations in their youth followed by a period of no dislocations and finally a presentation of pain and arthritis. They may have had multiple surgeries including chondroplasty, tibial tuberosity osteotomy and medial soft tissue tightening and lateral release. Thus, there may be medial as well as lateral instability. Once the arthritic PF compartment is replaced with low friction components, old instability patterns may reappear in the post-operative setting if not addressed intra-operatively.
Isolated patello-femoral arthritis with a history of trauma

This category is historically included in discussions of PF degenerative joint disease treatment. However, post-traumatic problems may include instability from the trauma, or post-traumatic changes with or without a fracture. Those with post-traumatic arthritis after a fracture may have an enlarged irregularly shaped patella with bone incongruities that require special attention to positioning the patella component and managing the soft tissue scarring and ligament imbalances. The post-traumatic patients with arthritis, but without a fracture, may have had chondrocyte death from the impact and subsequent premature patellar degenerative changes. These patients appear to have a good long-term prognosis with reduced risk of TF compartment changes. Those with a history of post-traumatic instability would be assessed as noted above in the instability section.

Examination

After classification of the PF compartment by X-ray, it is important to review the specifics of the pre-operative examination:

1. Patellar Tracking: Should be observed while actively flexing and extending the knee when sitting and/or loaded against resistance or squatting if not too painful.

2. Patellar Displacement: Medial and lateral displacement of the patella may be observed from a central trochlear position. Excessive medial and lateral patholaxity may be noted and considered for intra-operative treatment.

3. Patellar Tilt: Inability to lift the lateral facet of the patella to neutral while the knee is in 20 degrees of flexion may be considered a fixed tilt.

Skin Incision:

The skin incision should be midline and long enough to obtain adequate exposure.
**Deep Soft Tissue Approach:**

The knee may be entered by a medial or lateral parapatellar arthrotomy. With a medial approach, the medial patello-femoral ligament (MPFL) can be shortened (tightened) at closure. The capsular incision should begin at the superior border of the patella and should extend distally along the medial border of the patella and patella tendon. A proximal extension of the incision is advised when first starting to use the procedure or if the patient is obese. It is important not to harm the uninvolved articular cartilage and the meniscus.

Alternatively, the deep approach may be made laterally if the patient does not have MPFL patholaxity, and the primary soft tissue pathology has excessive lateral tightness associated with patellar tilt. This may be through a standard lateral parapatellar incision or the less widely known lateral lengthening approach. This lateral approach allows for direct treatment of patellar tilt and avoids possibly weakening the Vastus Medialis Oblique (VMO).

Once the joint is exposed, make a final assessment of the extent of arthritic damage in all three compartments and the suitability of the joint for this procedure. If the TF compartments have chondrosis, various treatment options must be considered based on the extent and site of the involvement. These options include: proceed with patello-femoral arthroplasty, and transfer an osteochondral plug from the patella to a small focal defect; add a TF unicompartmental component; or proceed to total knee replacement. This illustrates the importance of pre-operative planning and the patient informed consent process.

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**Trochlear Component Preparation**

1. To appreciate the true bony architecture, remove all osteophytes from the intercondylar notch and from the lateral and medial ridges of the trochlea. Select the proper implant size using the Transparent Trial so that the distal tip sits 2-3 mm above the apex of the intracondylar notch roof and the width does not exceed local anatomy. The superior border of the trial will lie just above the superior articular surface of the trochlea. The Transparent Trial has the same shape and size as the final component, but does not have pegs or the cement pocket geometry of the final component.

2. Mark the outline of the Transparent Trial on the cartilage and bone of the trochlea using a sterile marking pen or applicator dipped in methylene blue.

3. Use a burr and/or rasp to remove cartilage and bone within the outline. Check the cavity with the Transparent Trial often to ensure proper fit and alignment. Do this until the trial fits into the trochlear cavity as desired. The goal is to set the distal tip flush with surrounding cartilage and be flush to slightly recessed laterally.

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*Transparent Trial*
Preparation of Peg Holes

After the Transparent Trial fits properly in the trochlea cavity, drill the peg holes.

1. Impact the Metal Trial into the prepared area noting there are proximal spikes for stability. Ensure that the trial does not deviate from the planned position during seating. Recheck for flushness with the end of an osteotome.

2. Assemble the Drill Guide onto the Metal Trial (C) by inserting the Lock Rod (A) through the center hole of the Drill Guide (B) and screwing it into the center hole of the trial. Be sure to position the Drill Guide correctly for “left” or “right” components.

3. When the assembly is complete, use the Peg Drill (D) to drill the first hole.
Preparation of Peg Holes (continued)

4. After the first hole is drilled, insert a Stabilizing Pin (E) into that hole.

5. Drill the second hole and insert a second Stabilizing Pin. Drill the third hole and remove the Drill Guide, leaving the Metal Trial in place.
**Patella Preparation**

Prepare the patellar bone for the SIGMA Dome Patella using the technique as described in the SIGMA Fixed Reference Surgical Technique (0612-87-510). Alternately, the SIGMA Inset Patella may be used by following the technique described in the PFC SIGMA Knee System: Inset Patella (SIG-086).

Do not cement the final patella component at this time.

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**Trial Assessment**

With the patellar and trochlear trials in place, move the knee through range of motion and assure:

1. Smooth transition of patella from trochlea into the notch.
2. Smooth entrance of the patella into the trochlear component on extension.
3. With proximal traction on the quadriceps tendon, the patella component should be engaged on the trochlear component in the fullest extension possible for the knee.
4. No abrupt medial or lateral movements occur.
5. Assess for tilt (will also need attention during closure).
6. Assess medial and lateral displacement (in certain advanced cases this may require temporary suturing and final tuning after the components are cemented).

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**Trochlea Implantation**

Drill any area of eburnated bone to improve cementation. Clear the bone of debris, blood and fat. Apply cement to the posterior surface of the trochlear prosthesis and also apply cement packed with finger pressure to the prepared bone. Impact the component into the prepared cavity using the impactor. Pay special attention to the alignment of the three pegs into the three fixation holes.
**Patella Implantation**

The patellar cut surface is thoroughly cleansed with pulsatile lavage. Apply cement to the cut surface and implant, then insert the component. The Patellar Clamp is designed to fully seat and stabilize the implant as the cement polymerizes. Center the silicon O-ring over the articular surface of the implant and the metal backing plate against the anterior cortex, avoiding skin entrapment. When snug, close the handles and hold by the ratchet until polymerization is complete. Remove all extruded cement with a curette. Release the clamp by unlocking the locking switch and squeezing the handle together.

After the cement is cured, the patella is reduced and the patella implant tracking is re-evaluated. An unrestricted range of motion and proper patella tracking should be evident.

**Closure**

Common in many knees, the post-operative composite patello-femoral thickness is greater than pre-operatively (bone and cartilage loss have been restored with metal and plastic) even though the components are technically not too thick (true overstuffing). The new composite PF thickness relatively “stuffs the soft tissue envelope” that the knee has acquired over time. With flexion, soft tissue lengths change with the lateral side becoming tighter and the medial side more lax. In other words, even with a technically correct thickness, the new thicker composite will apply tension in the lateral soft tissues causing tilt during flexion. The typical required external rotation of a TKR to balance flexion/extension gaps is not always desired for a PFA (as the tibia was obviously not cut into relative valgus—the reason for TKR external rotation). Thus, it will be more common to have lateral tightness in flexion with a PFA than a TKR and therefore lateral release, lateral subperiosteal recession or lateral lengthening will be necessary more often after PFA than TKR. Closely monitor mid-term post-operative axial radiographs to observe for this phenomenon.
Important
This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Intended Use
The SIGMA High Performance Partial Knee System is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Indications
The SIGMA High Performance Partial Knee is indicated for single or multi-compartmental knee replacement in skeletally mature individuals with osteoarthritis, post-traumatic arthritis of the tibio-femoral and/or patello-femoral articular surfaces or a history of gout or pseudogout. All components are intended for CEMENTED USE ONLY.

Contraindications
The use of the SIGMA High Performance Partial Knee is contraindicated in:
- Skeletal immaturity
- Active inflammatory arthritis
- Severe soft tissue instability or unreconstructed deformity, including unstable or unreconstructable collateral and/or cruciate ligaments
- Non-physiologic or uncorrectable axial alignment
- Compromised quadriceps or hamstrings mechanisms
- Overt infection of the knee joint, i.e., osteomyelitis, pyogenic infection
- Loss of musculature or neuromuscular compromise leading to loss of function in the involved knee
- Lesions of the supporting bone structures (i.e., aneurysmal or simple bone cysts, giant cell tumors or any malignant tumor)
- Uncorrected patella baja is a contraindication for the trochlear component
- A patellar bone that is unsuitable for accepting the patellar component is a contraindication for use of this component.

Warnings and Precautions
Warning: High demand patients may require ligamentous reconstruction.
The following conditions tend to adversely affect knee replacement implants: excessive patient weight, active sports participation, manual labor, high levels of patient activity, likelihood of falls, alcohol or drug addiction, poor bone stock, metabolic disorders or systemic pharmacological treatments leading to progressive deterioration of solid bone, infections, severe deformities, tumors of the supporting bone structures, allergic reactions to implant materials, tissue reactions to implant corrosion or implant wear debris, disabilities of other joints and patients with paraplegia, cerebral palsy or Parkinson’s Disease.

The implantation of the unicompartmental components will not in themselves guarantee a high level of post-operative flexion. The degree of post-operative flexion is multi-factorial. These factors include, but are not limited to, surgical technique, patient build, post-operative flexion and age.

Adverse Events
The following are the most frequent adverse events after knee arthroplasty: early or late loosening, bending, cracking, fracture, deformation, or wear of one or more of the prosthetic components, early or late infection, pain, dislocation, subluxation, flexion contracture, decreased range of motion, or lengthening or shortening of the leg, excessive wear of the polyethylene components, fractures of the tibia or femur, cardiovascular disorders and thromboembolic disease, tissue reactions, osteolysis, myositis ossificans, possible peroneal nerve palsy, hematoma, delayed wound healing or wound dehiscence, varus-valgus deformity, subsidence associated with tibial components, inadequate range of motion due to improper selection or positioning of components, impingement and/or periarticular calcification, periarticular calcification or ossification, with or without impediment to joint mobility, patellar fracture as a result of excess tension or inadvertent intra-operative weakening, and aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy.

Limited Warranty and Disclaimer:
DePuy Synthes Companies products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.