

Gender Solutions® Patello-Femoral Joint System

Design Rationale



Gender Solutions Patello-Femoral Joint



The Gender Solutions PFJ System provides implants to address the anatomical differences among men and women with a reproducible instrumentation platform, simplifying PFA¹. This design rationale lays out the distinct features of the Zimmer Biomet product and highlights the intended benefits for surgeons and their patients.

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Why Patello-Femoral Replacement?

Total knee arthroplasty (TKA) is routinely used in treating isolated patello-femoral disease, however, anterior knee pain continues in up to 19% of TKA patients².

Patello-femoral arthroplasty (PFA) is a form of partial knee replacement and shares the same benefits. Some of these benefits are:

- Preserving more healthy bone*³ (**Figure 1**)
- Better functionality and more natural motion³
- Faster recovery and shorter hospital stay⁴
- Fewer and less severe complications^{5,6}

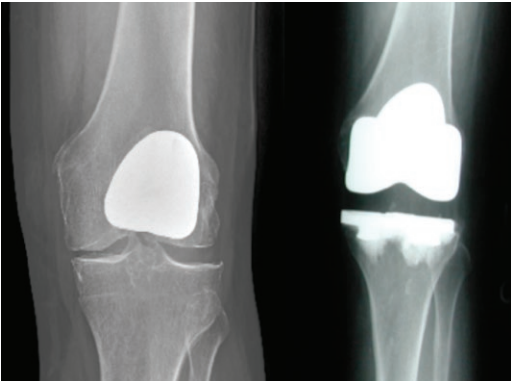


Figure 1

Specific advantages of PFA over TKA are:

- PFA is associated with shorter post-operative rehabilitation²
- PFA has better knee kinematics in the sagittal plane because of the preservation of the tibiofemoral articulation, menisci, ACL and other supporting ligaments²
- PFA patients showed better functionality, less blood loss and greater return to activity⁷

Shortcomings of Early Designs

History of PFJ Systems

Survivorship of PFA in registries around the world has been low compared to TKA⁸. This is due to multiple factors, including shortcomings in the trochlear component design, lower threshold of revision for PFA compared to TKA and more demanding technique with free hand instrumentation.

Historical Trochlear Component Design

There are multiple design features of the trochlear component that impact the success of PFA. Historically, trochlear component designs had:

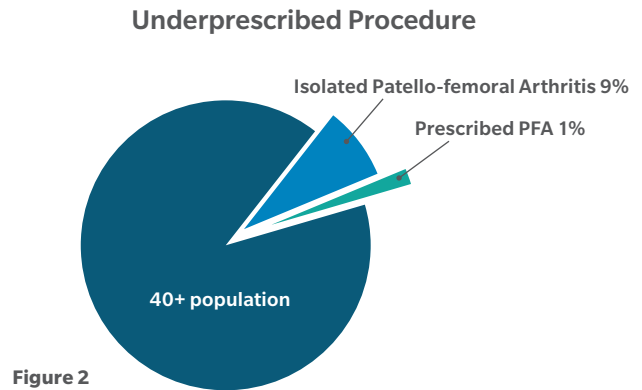
- An abrupt sagittal radius of curvature caused the component to sit proud, which led to patellar snapping, clunking and maltracking¹
- Too much variability in width of early trochlear components could cause patellar catching in narrow designs and overhang/soft tissue irritation in broad designs¹
- Limited proximal extension of component predisposed to patella catching and subluxing⁹
- Deep, constraining trochlear grooves predisposed to patella maltracking¹

Zimmer Biomet designed the Gender Solutions PFJ aiming to address the shortcomings of historical designs.

Patient Demographic

Nearly 9% of the 40+ population has isolated patello-femoral disease, but currently less than 1% of patients are receiving patello-femoral joint replacement (**Figure 2**)²

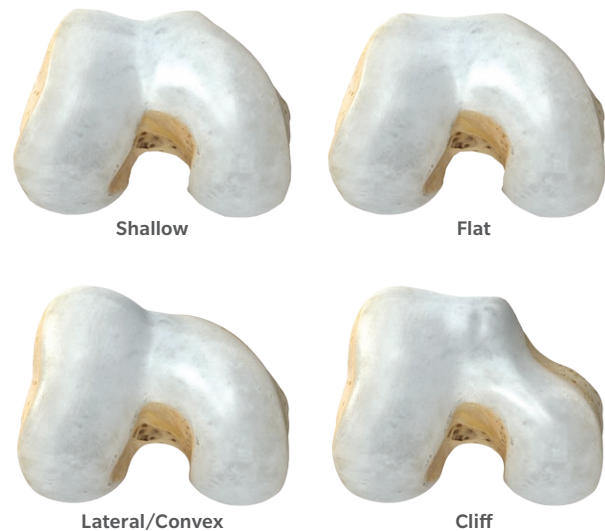
- Nearly 1 in 4 women with OA have isolated patello-femoral disease¹⁰
- Women account for over 77% of patello-femoral arthroplasties in the Australian Joint Registry¹¹



Patient Selection

The first requirement for a successful patello-femoral arthroplasty is to accurately select the patient. One or more of the following indications should be present:

- Isolated patello-femoral arthritis
 - Medial/lateral overload
 - Cartilage degeneration from normal wear
- Trochlear dysplasia (**Figure 3**)
 - Trochlear dysplasia and patellar maltracking are present in 78% of patients with isolated patello-femoral arthritis¹²
 - PFA is the most effective treatment for dysplasia⁹
- History of instability
- History of trauma or patella fracture
- Intact ligament structure
 - Includes intact meniscus
- Patient has not responded to conservative treatment



Pre-Operative X-rays

Pre-operative clinical evaluation and radiographs are an important part of patient selection. The required x-rays to determine if a patient is a candidate for PFA are:

- Weight bearing A/P
 - Preservation of the tibio-femoral compartments (**Figure 4**)
- Tangential (sunrise) at 30 degrees (**Figure 5**)
- Lateral weight bearing (**Figure 6**)
 - Assess the patella position for patella alta or patella baja

Bi-Compartmental Arthroplasty

The highest failure mode for PFA is progression of osteoarthritis to other compartments¹³

Bicompartmental knee arthroplasty (BKA) is a viable solution for many patients where the trochlear component after PFA is well-fixed and functioning, but there is progression of disease to either the medial or lateral compartments. Early clinical results have shown excellent pain relief, knee function and restoration of appropriate knee alignment with BKA¹⁴. Compared with TKA:

- The forgotten knee score is better in BKA patients¹⁵
- BKA was associated with greater comfort during everyday activities and better functional outcomes¹⁵
- Patients with BKA recover strength and are able to ambulate independently more quickly¹⁴
- Function and biomechanics are superior¹⁶

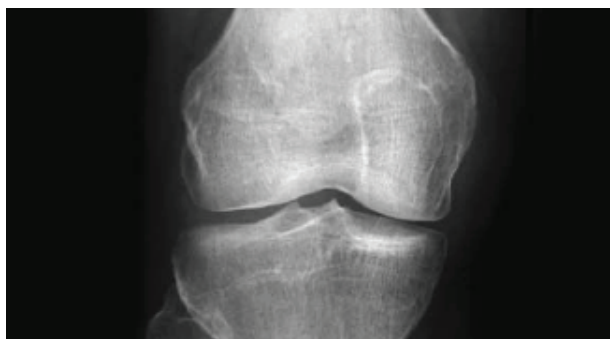


Figure 4
Weight bearing A/P x-ray demonstrating patello-femoral osteoarthritis

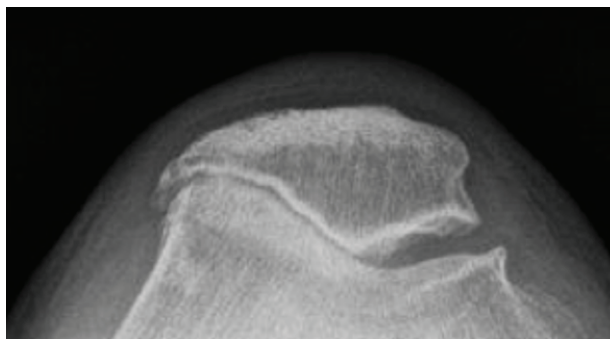


Figure 5
Tangential x-ray demonstrating patello-femoral osteoarthritis



Figure 6
Weight bearing lateral x-ray showing narrowing of the PF joint space

Unmet Gender Need

Zimmer Biomet was the first orthopedic company to recognize that when it comes to knees, men and women are different. The difference is less about the size and more about the shape of the femur.

- Data from over 800 CT scanned knees¹⁷ shows that women have a significantly shorter lateral and medial condyle height than men^{18, 19} (**Figure 7**)
 - When replacing the anterior resection with a trochlear component, the potential exists for overstuffing with a thicker flange
- Patellar maltracking is a concern, particularly for females²⁰. Women have a statistically significant higher Q-angle (**Figure 8**) than men which can lead to poor tracking, subluxation and dislocation of the patella²¹⁻¹⁴
- Females are more likely to have an abnormally high patella, called patella alta, which can lead to patella instability²⁵

These clinical differences in men and women led to a need for different design features of trochlear implants for women and men, a need not addressed by other implants on the market.

Male Resection		Difference		Female Resection	
		Lateral	Medial		
10.9mm	6.4mm	0.8mm	1.3mm	10.1mm	5.1mm



Figure 7

Difference in shape of male and female femur.

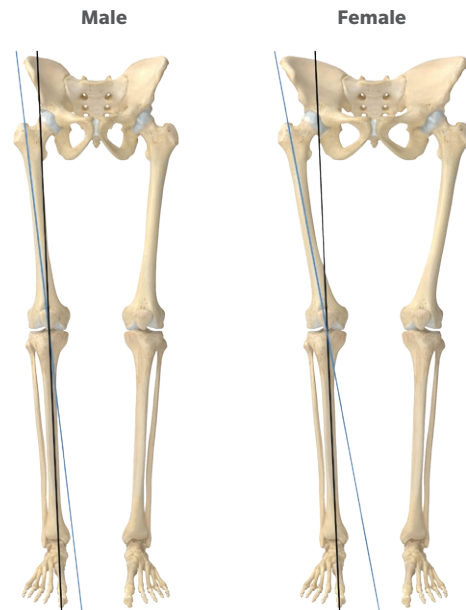


Figure 8

Difference in Q-angle between males and females

“Historically we have shaped the patients to fit the implants. Now we have implants shaped to fit the patients.”²⁶

Robert E. Booth, Jr., M.D

Zimmer Biomet Implant Design⁴

The Gender Solutions PFJ System brings unique design elements which provide a solution for the unmet gender need and correct the shortcomings of historical designs.

Gender Solutions

Increased Trochlear Groove Angle

To accommodate a relatively high Q-angle typically found in women, the trochlear groove angle is increased in all but the largest size (**Figures 9 and 10**).

This design feature helps with¹:

- Optimized patellar tracking
- Reduction of preoperative patellar subluxation
- Minimizing the need of lateral release
- Valgus orientation of femoral component

In a recent study featuring the Gender Solutions PFJ it was noted that **“This enhanced tracking angle has proven particularly useful in female patients, who account for approximately two-thirds of PFA recipients and who often have an increased Q-angle, dysplasia and patellar subluxation preoperatively...”**¹⁶

Modified Anterior Flange

A thinner anterior flange aims to address the need that women have shorter medial and lateral condyle height than men and helps avoid overstuffing the joint and soft tissue irritation (**Figure 11**).

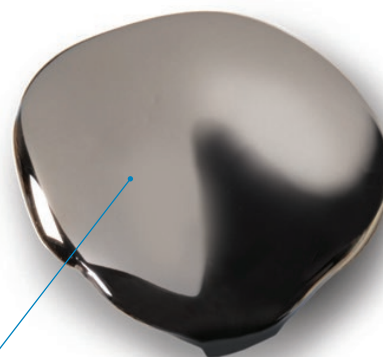


Figure 9
Trochlea Groove Angle

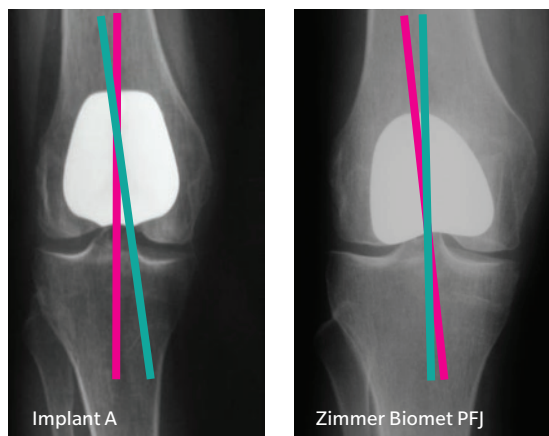


Figure 10
Enhanced tracking angle
Teal line = anatomic axis
Magenta line = trochlear groove angle



Figure 11

Zimmer Biomet Implant Design

Solution to Shortcomings of Early Designs

Increased Proximal Extension

The proximal extension of the trochlear component is increased so that patella remains in contact with trochlear prosthesis throughout entire range of extension¹.

Refined Transition Point

The transition point between the anterior trochlear flange and the intercondylar portion of the component (**Figure 12**) has been refined, designed to result in:

- Enhanced engagement of patella as the knee proceeds into flexion
- Patella contact with the trochlear component as long as possible before it begins to articulate on the weight-bearing surfaces of femoral condyles

Precise Sagittal Radius of Curvature

The sagittal radius of curvature fits accurately with the distal femoral radius of curvature that have been studied through bone scans and encountered clinically¹.

Shortened Intercondylar Region

The intercondylar portion has been shortened compared to other designs help reduce interference with soft tissues¹. It also sits flush with the bone aiming to avoid impingement of the patellar component as it moves onto the trochlear implant in extension.



Figure 12

Mediolateral Width

The system features five sizes, which vary in all dimensions, but primarily in mediolateral width. The widths increase 4-5mm increments between sizes. The range of widths should limit mediolateral component overhang and subsequent soft tissue crepitus observed with other designs¹.

Improved Onlay Design

The implant is an onlay design that uses a flush anterior cut tangential with the anterior femoral cortex to help recreate the trochlear groove. By recreating the groove, the design is ideal for patients with trochlear dysplasia, which is present in 78% of patients with isolated patello-femoral arthritis¹².

Zimmer Biomet Instrumentation

The Gender Solutions PFJ is designed for precision. Being the the first fully instrumented system on the market¹, the highly accurate instrumentation creates a reproducible surgical technique⁸. The PFJ instrumentation has been described as low profile, accurate and conducive to less invasive surgical techniques¹.

Enhanced Anterior Cut Guide

The intramedullary anterior cut guide with telescoping boom is designed to:

- Produce accurate flexion/extension of the component by referencing the IM canal
- Set external rotation by referencing your preference of the AP axis or the transepicondylar axis
- Produce flush anterior cut by referencing the anterior cortex of the femur (**Figure 13 and 14**)

Patented Guided Milling System (Figure 15)

The unique feature of Gender Solutions PFJ instrumentation is based on the proprietary guided milling system. The benefits are:

- Eliminating challenges and errors presented in free hand techniques
- Reproducible surgical technique
- Replicates the exact geometry and size of the final implant

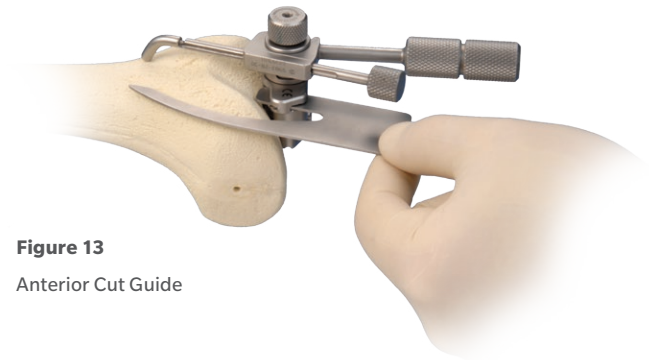


Figure 13
Anterior Cut Guide

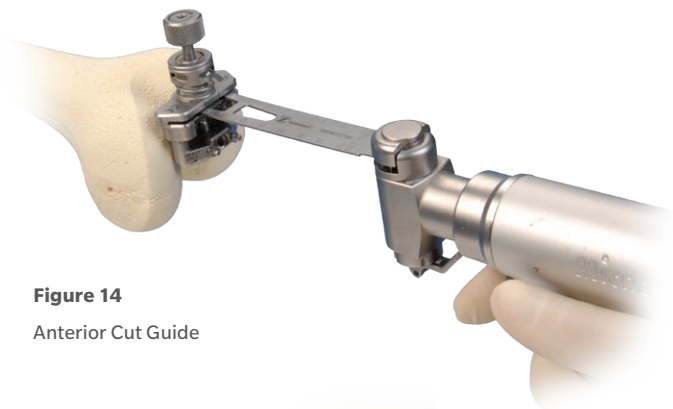


Figure 14
Anterior Cut Guide

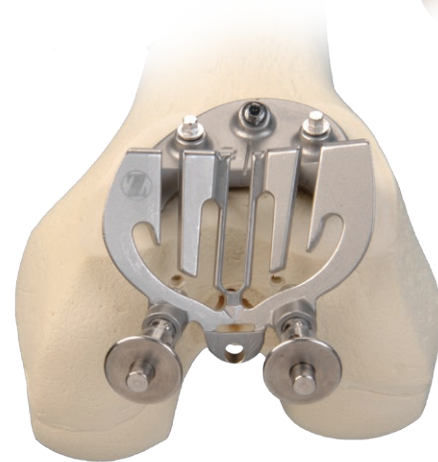


Figure 15
Guided Milling System

“Zimmer Biomet Gender Solutions has dramatically simplified the procedure and ensures anatomic mating of the implant to the articular surfaces of the transition zone. The milling system provides an effective means for addressing condylar variability and depth control which is lacking in other freehand systems.”¹

Clinical Results

Although historically revision rate has been higher for PFA compared to TKA because of implant design, and demanding technique⁸, there are promising results of the Gender Solutions PFJ and PFA in general.

Gender Solutions PFJ Clinical Results

- From a recent study at an average of 4.9 years, excluding traumatic injuries and MUA, 96% of patients needed no further surgery²⁷
 - One patient was converted to a TKA and one patient had a staged bicompartmental arthroplasty due to progression of disease
 - Patients had significantly improved range of motion and KSS and Function scores²⁷
- At 3 years in the NJR for England and Wales, the Gender Solutions PFJ has the lowest revision rate; lower than Stryker Avon, Sigma HP and Smith and Nephew Journey PFJ⁸

PFA Clinical Results

- In a long-term follow up series by Koojiman et al, at a mean of 15.6 years (range of 10-21 years), 25% of patients required secondary surgeries for progressive tibiofemoral arthritis⁹
 - These patients had more natural kinematics and the benefits of a partial knee for a number of years before being revised to total knees
- In a multi-centre study of 79 knees, 84% of patients with a patello-femoral replacement had good to excellent results with 90% functioning without pain in daily activities¹³
- Complication rate of 4% with current implant designs, compared with a 17% complication rate with first-generation designs⁹



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