



Persona[®] Partial Knee

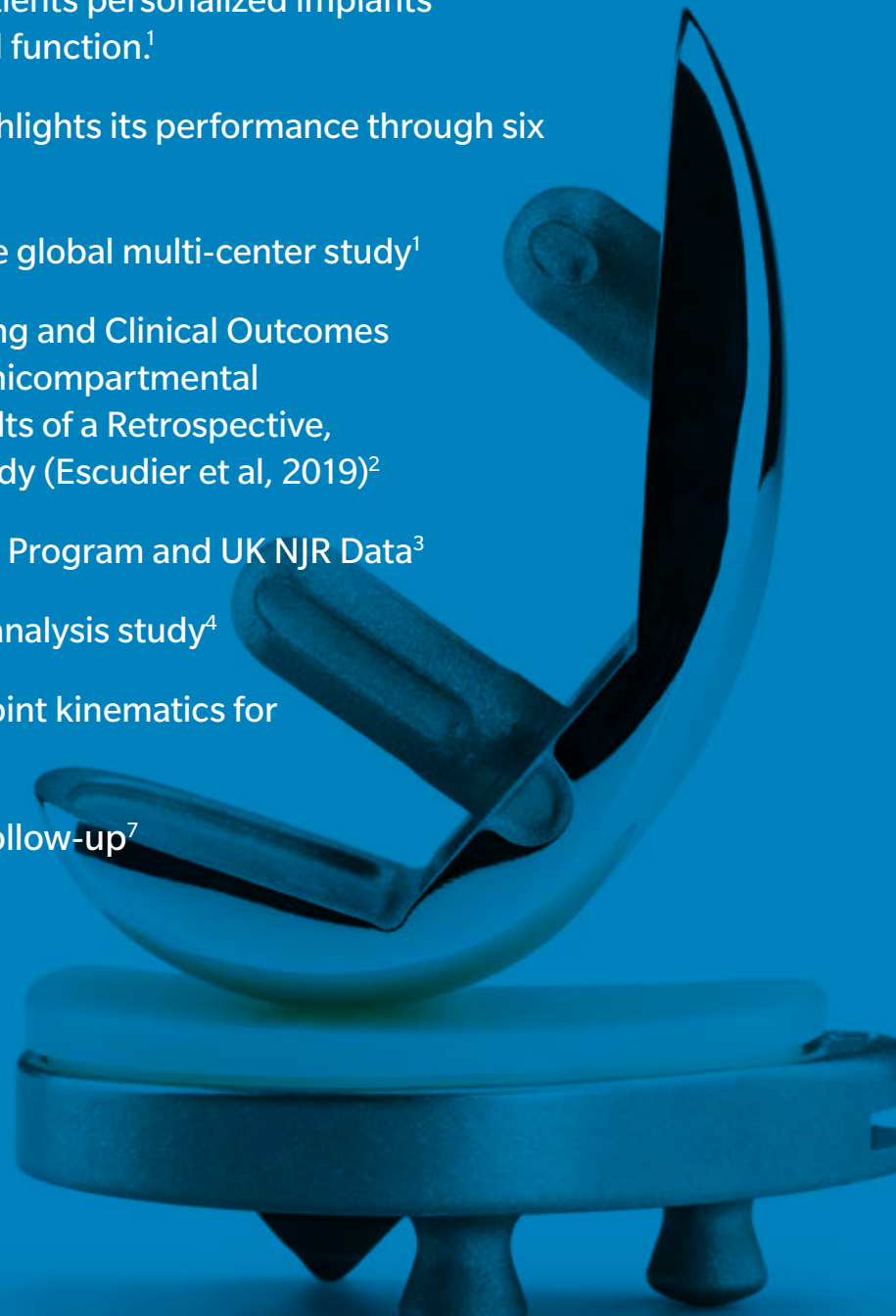
Clinical Summary

PERSONA[®] PARTIAL KNEE CLINICAL SUMMARY

The Persona Partial Knee exhibits good short-term clinical performance, providing patients personalized implants designed for optimal fit and function.¹

The following summary highlights its performance through six research engagements:

1. The Persona Partial Knee global multi-center study¹
2. Better Implant Positioning and Clinical Outcomes With a Morphometric Unicompartamental Knee Arthroplasty. Results of a Retrospective, Matched-Controlled Study (Escudier et al, 2019)²
3. The Beyond Compliance Program and UK NJR Data³
4. ZiBRA™ tibial coverage analysis study⁴
5. Robotic assessment of joint kinematics for Persona Partial Knee⁵
6. RSA data with 2 years follow-up⁷



PERSONA PARTIAL KNEE GLOBAL MULTI-CENTER STUDY¹

The objective of this ongoing study is to determine implant survivorship and clinical performance for Persona Partial Knee. 746 Persona Partial Knees were implanted at 29 sites in 11 countries. 494 have completed the 2 year follow up, with the mean follow up of the whole cohort being 1.7 years.

Results

- **97.84% survivorship** at 3 years
- 11 revisions
 - o 3 infections
 - o 2 due to an allergic reaction to nickel
 - o 1 tibial and bearing replacement for an aseptic loosening
 - o 1 unexplained pain, revised at a non-study hospital
 - o 1 bearing exchange
 - o 1 recurring bloody effusions
 - o 1 patellofemoral arthritis
 - o 1 severe pain and osteolysis in the tibia
- **97.1%** of patients **satisfied or very satisfied** with the results of surgery
- **96%** of patients were satisfied or very satisfied with the results of surgery for **improving pain**

Escudier *et al* (2019)²

This study analyzed the implementation and design of the **Persona Partial Knee compartment-specific tibial tray** to determine if the anatomic nature of the design could improve the implant positioning and patient outcomes in comparison to the ZUK **non compartment-specific tibial tray**.

Results

- Persona Partial patients scored significantly higher in the KOOS SF (Knee injury and Osteoarthritis Outcome Score) and the KSS (Knee Society Clinical Rating System) and the pain component clinical outcome score. KOOS SF (16.9 ± 6.1 vs 22.5 ± 11.8 ; $P < .003$), Global KSS (188.6 ± 6.6 vs 175.2 ± 31.7 ; $P < .01$). This demonstrates higher functionalities with Persona Partial compared to ZUK.
- **ZUK exhibited significantly more medial overhang** of greater than 3 mm

Table 1

Product	Posterior Overhang Greater than 3 mm	Medial Overhang Greater than 3 mm
Persona Partial	0%	0%
ZUK	22%	35%
<i>P-Value</i>	.0015	<.0001

- o The improvement in maximal flexion of the knee was significantly higher in the overhang <3mm subgroup compared to the overhang >3mm subgroup
- o Chau *et al.* showed that patients with significant medial overhang of greater than 3mm have an increased risk of worse knee and pain scores postoperatively at 5 years⁶

The Beyond Compliance Program*³

The Persona Partial Knee is enrolled into the Beyond Compliance Program.

Beyond Compliance is a joint effort between manufacturers such as Zimmer Biomet, implanting surgeons and the Beyond Compliance Advisory Group to support the safe and stepwise introduction of new implants to the market.

Results

- At a max of 2.4 years (mean 0.8 years):
 - o 1,468 Persona Partial Knee procedures performed
 - o 2 revisions reported for aseptic tibial loosening
 - Survivorship of 99.9%
 - The risk of a potential revision with Persona Partial is 4 times lower than with all other PKRs in the UK

ZIBRA TIBIAL COVERAGE ANALYSIS STUDY⁴

The Persona Partial Knee was designed to fit anatomically to the medial compartment by using a large database of CT scanned cadaveric bones (ZiBRA) and assessing partial knee resection levels, placement and rotation on those bones. This study was conducted assessing tibial coverage, component underhang and overhang between ZUK and Persona Partial Knee.

The Persona Partial Knee significantly decreases tibial overhang compared to previous designs²; reducing the risk of clinically relevant overhang, which can lead to severely compromised patient outcomes³.

Results

- The Persona Partial Knee shape results in **2 mm less underhang posteriorly and 1 mm less overhang medially** compared to ZUK (Table 2 and Figure 1)
- Average **plateau coverage is 2% greater** for Persona Partial Knee than ZUK, due to expanded size range, and improved profile shape (Table 2)

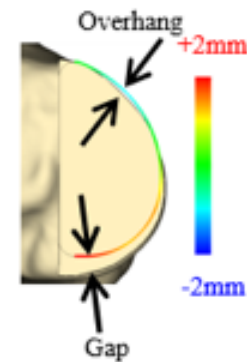


Figure 1: Example of Average Overhang and Underhang between ZUK and Persona Partial Knee

Table 2: Coverage, Underhang and Overhang Comparison

Ethnicity	Caucasian		Japanese	
	ZUK	Persona Partial Knee	ZUK	Persona Partial Knee
Coverage [%]	87.8 ± 5.0 ^{**+}	90.5 ± 4.4 ⁺	89.0 ± 5.0 ^{**+}	90.8 ± 4.4 ^{**+}
Underhang [mm]	5.6 ± 2.4 ^{**+}	3.5 ± 1.6 ⁺	5.1 ± 2.1 ^{**+}	3.7 ± 1.7 ^{**+}
Overhang [mm]	1.6 ± 1.0 ^{**+}	0.6 ± 0.5 ⁺	2.0 ± 1.2 ^{**+}	1.1 ± 1.0 ^{**+}

* Latest products participating in Beyond Compliance can be found at www.beyondcompliance.org.uk

** Statistically significant difference between ethnicities

+ Statistically significant difference between ZUK and Persona Partial Knee designs

Robotic Assessment of Joint Kinematics⁵

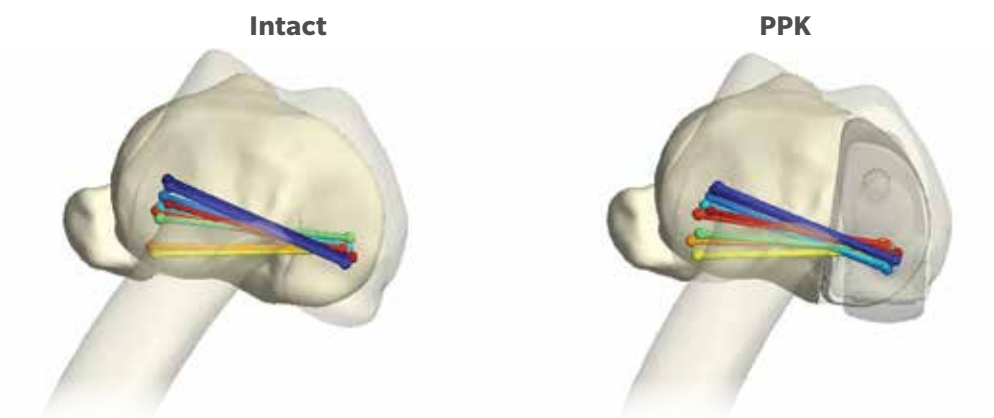
The KUKA robot specifically used for cadaveric kinematic testing compared two cohorts of knees:

1. Functionally intact, normal knees
2. Knees with Persona Partial Knee implanted
3. The two cohorts were compared looking at laxity, gait, stair descent and lunging functional activities.

Findings

- The function of a knee with the Persona Partial Knee (Figure 2) closely resembles the intact knee kinematics and resembles an intact knee more closely than a total knee replacement in all categories.

Figure 2: Stair decent patterns between an intact knee and the same knee with Persona Partial Knee implanted



Radiostereometric Study (RSA) with 2 years of follow-up⁷

A prospective cohort study of 27 Persona Partial Knees were followed-up at 6 weeks, 6 months, 1 year, and 2 years. The authors studied the migration of the femoral and tibial components and also recorded PROMs data for the cohort.

The authors reported the following results at a mean of 2 years:

- Mean translation of the femoral component: 0.14, 0.06, and 0.06mm along the x-, y-, and z-axis respectively.
- Mean rotation of the femoral component: 0.16, -0.05, and 0.17 degrees around the axes.
- Mean translation of the tibial component: 0.08, -0.18, 0.001mm along the x-, y-, and z-axis
- Mean rotation of the tibial component: 0.45, 0.1, -0.57 degrees around the axes

The authors concluded that “the Persona Partial Knee shows low migration of both the femur and tibial component and good clinical results at 2 years follow-up”.

References

1. Persona® Partial Knee Clinical Outcomes Study ANNUAL REPORT K.CR.I.G.16.16. Internal data on file at Zimmer Biomet. Sept 2019.
2. Escudier J-C, Jacquet C, Flecher X, Parratte S, Ollivier M, Argenson J-N. Ph.D. Better Implant Positioning and Clinical Outcomes with a Morphometric Unicompartmental Knee Arthroplasty. Results of a Retrospective Matched-Controlled Study. *The Journal of Arthroplasty* (2019), doi: <https://doi.org/10.1016/j.arth.2019.07.031>.
3. www.beyondcompliance.org.uk
4. Bischoff JE, Argenson J-N, Della Valle CJ, Thienpont E. Morphologic Assessment of Tibial Tray Design in Partial Knee Arthroplasty. ORS [submitted]. New Orleans, LA 2018.
5. KUKA Robotic Kinematic Assessment. Internal Data On File at Zimmer Biomet. 2017. Laboratory testing is not necessarily indicative of clinical performance.
6. Chau, et al. Tibial component overhang following unicompartmental knee replacement-Does it matter? *The Knee*, 16 (2009) 310-313
7. Early Migration in unicompartmental knee arthroplasty with the Persona Partial Knee: a radiostereometric study at 2 years of followup. *International RSA*

The Zimmer® Unicompartmental Knee is now marketed by Zimmer Biomet outside of the US, European Union, and Japan. This knee is marketed by Smith & Nephew in the US as the ZUK Unicompartmental Knee; and by Lima Corporate in the European Union and Japan as the Physica ZUK.

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