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Positive clinical outcomes at 10 Years with the universal femoral component in total knee arthroplasty

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ABSTRACT

We evaluated a unique implant system that included a universal femoral component (UFC) design and instrumentation that would accommodate the UFC on both the left and right femur. There was a commitment to test two hypotheses: firstly, that the results of this 10-year follow-up study maintained patient outcomes compared to the initial 6-year follow-up assessment and secondly that this unique Q-angle design maintained patella tracking over the 10-year period. The results of the 10-year follow-up period determined that the two hypotheses were supported with the Knee Society Score (KSS) data and continued to support the use of this UFC.

1. Introduction

It is common for a surgeon to examine a different total knee design in hopes of improving efficiency and patient outcomes in their practice. This single surgeon study examined a universal femoral component (UFC) design with a thinner anterior flange to prevent overstuffing of the patella-femoral component and to ensure adequate patellar tracking (Fig. 1). The goal was also to maintain range of motion due to the deeper trochlear groove with a wider Q-angle. This was to ensure patellofemoral tracking over a wide spectrum of anatomic variations. It had previously been reported that improved patellar alignment and tracking led to improved patient satisfaction and maintenance of range of motion.[1]

Asymmetric femoral components were first introduced by the Porous-Coated Anatomic knee arthroplasty (PCA, Howmedica, Rutherford, NJ) and generally consisted of a raised flange of the lateral condyle and an anatomic trochlea, thought to reduce patellar subluxation and more closely mimic the native anatomy of the distal femur.[2] While more modern designs have gravitated towards using asymmetric components, there has been little data to suggest its superiority over a symmetric design.[3] Some investigators reported no differences in patellar tracking.[4] Utilizing a UFC component with surgical instruments that worked on both left and right knees had the added benefit of simplified surgical technique, reduced turnover times, and improved efficiency by eliminating the need for left and right femoral components.[5]

The UFC used in this study aimed to improve on earlier designs like the Apollo Universal Femoral Component, originally developed by Dr. Larry Dorr (Zimmer Biomet, Warsaw, IN).[6] The UFC in this investigation introduced a thinner anterior flange to prevent overstuffing of the patellofemoral component, which was intended for increased range of motion. Additionally, there was a deeper "V-shaped" symmetric groove with a $\pm 9^\circ$ double Q-angle to allow for bilateral implantation and reduced maltracking of the patella, whether it was resurfaced or not (Fig. 1). The implant system in this investigation was inspired by the success of the Total Condylar Knee (Johnson & Johnson), which was introduced in the 1970s and demonstrated excellent survivorship and long-term results.[7]

This unique UFC design allowed two hypotheses to be studied—the first hypothesis was that the Knee Society Scores would be improved compared to preoperative scores and maintained over a 10-year period. The second hypothesis was that the unique Q-angle design of this femoral component maintained patellar tracking over the 10-year period.

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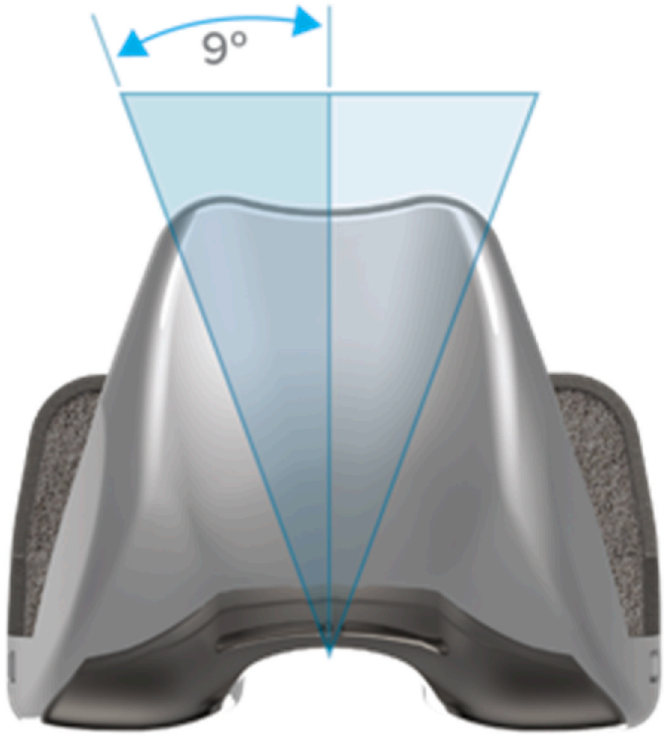

Fig. 1. Image depicting the double-wide 9° Q-angle of the Universal Femoral Component. This image was provided with the permission of TJO.

2. Methods

2.1. Surgical procedure

The TJO Klassic® Knee (Total Joint Orthopedics Inc., Salt Lake City, Utah) used in this study was a cemented cobalt-chrome UFC combined with a modular, keeled, stemless titanium tibial baseplate. An ultra-congruent cruciate-sacrificing bearing was used. A pneumatic tourniquet was insufflated to 300 mmHg in all patients and let down during the cement curation. A standard median parapatellar or subvastus approach was used based on patient habitus, as well as patellar resurfacing based on a modified Outerbridge scoring system.[8] If patellas had Outerbridge grade III or greater lesions they were resurfaced. After the thickness of the patella was measured a freehand cut of the patella was performed using measured resection technique to replace the cut amount with a 7 mm thick all-polyethylene 3-pegged sombrero patellar component. Then the patellar component was centered and cemented over the patients' median sagittal ridge.[9] Lateral facetectomy was routinely performed in addition to some inside-out lateral retinacular release.[10] The femur was prepared by resecting 10 mm of distal femur (9 mm measured bone-cut + 1 mm kerf of the saw blade), which was replaced with a femoral component that was 10 mm thick at its distal end. In a similar fashion for the tibia, an 8 mm bone-cut was replaced with a tibial component that was 2 mm thicker than the resected bone cut. This accounted for 2 mm of increased laxity after sacrificing the PCL. Tibial cuts matched the patient's native slope minus 2° to tighten the flexion gap after PCL resection. This cut allowed for greater load carrying capacity and stiffness of the resected tibial surface.[11] Various polyethylene liners were trialed before selecting a component that demonstrated appropriate stability to varus and valgus stress in flexion and extension.

2.2. Data collection & review

This study expands upon the previously reported 6-year data of the same patient cohort, focusing the results on patients with exclusively 10-year follow-up.[10] At the 10-year follow-up mark, data on 107 patients (122 knees) was available for review after accounting for 23 patients that had died or declined participation in the study. All data was collected independent of the implanting surgeon. The data was collected via retrospective chart review on patients who underwent surgery using the UFC from January to December 2014. Hip-knee-ankle angle measurements, patellar tilt, and patellar shift were based on x-ray measurements taken from the most recent clinical follow-up. Demographics, range of motion measurements, and preoperative and postoperative Knee Society Scores were collected and reviewed (Table 1, Fig. 2). Tukey's HSD statistical test was used to determine statistical significance of data.

3. Results

In total, there were 107 patients and 122 knees that met the inclusion criteria. Mean age was 66.3 ± 8.3 years. There was an even distribution of men and women patients (49.5 % men, 50.5 % women). Average BMI was 32.8 ± 7.0 kg/m^2. In total 89 (73 %) patients had their patella resurfaced due to Outerbridge grade III or greater changes; patellar resurfacing was not indicated in 33 (27 %) of knees (Table 1).

Long-standing weight-bearing x-rays measured hip-knee-ankle angle (HKA). Based on the most recent radiographs at clinical follow-up, data demonstrated preoperative and postoperative valgus of 7.8° ± 5.8° and 3.9° ± 2.4° (n = 39), respectively, and preoperative and postoperative varus of 3.3° ± 2.3° and 1.4° ± 1.7° (n = 56), respectively (Table 1).

Exclusively in patients with 10-year follow-up, there were 6 (4.9 %) manipulations under anesthesia (MUA), 5 (4.1 %) polyethylene exchanges for ligamentous laxity, 1 (0.1 %) infection, and 1 (0.1 %) case of aseptic loosening requiring revision. Revision surgery (excluding MUA) was performed in 7 (5.7 %) of the cohort. Mean time to failure requiring reoperation was 55.0 ± 45.1 months (Table 2). Compared to the 6-year data, the 10-year data demonstrated no further complications aside from two polyethylene liner exchanges for ligamentous laxity, as well as one native patella resurfacing due to progression of arthritis.

Clinical score, a subsection of the KSS, at preoperative and 10-year time points was found to be 63.0 ± 14.5 and 94.5 ± 9.5 ($p < 0.001$), respectively, with a maximum of 100 points. Similarly for functional scores, 55.3 ± 18.8 preoperatively versus 90.3 ± 13.2 at 10-years ($p < 0.001$). Combining clinical and functional scores for a maximum of 200 points revealed a significant improvement in KSS of 116.4 ± 33.5 (preoperative) versus 184.8 ± 19.4 (10-years postoperative) ($p < 0.001$) (Fig. 2). Total KSS did not significantly differ in patients that had their patella resurfaced versus not ($p=0.39$): preoperative score of resurfaced patellas was 117.8 ± 35.7 versus a non-resurfaced score of 113.8 ± 26.3 ($p = 0.57$); 10-year postoperative resurfaced score was 186.2 ± 16.3 versus a non-resurfaced score of 182.6 ± 24.9 ($p = 0.38$). Average patellar tilt was 2.8 ± 3.7° and average patellar shift was 0.06 ± 0.07 mm. Additionally, patellar tilt greater or less than the mean of 2.8° and patellar shift greater or less than the mean of 0.06 mm did not

Table 1
Description of patient demographics at 10 years. Average preoperative varus and valgus deformities were measured by using long-standing weight-bearing x-rays (HKA). There were no issues with patellar maltracking in this study.

Variable	Value
Number of patients	107
Number of knees	122
Age (years) at time of surgery – mean ± SD	66.3 ± 8.3
Gender (men/women)	53/54
Body Mass Index (kg/m^2) ± SD	32.8 ± 7.0
Patella Resurfaced – n (%)	89 (73)
HKA (Degrees ± SD (Range))	
Preoperative valgus (n = 39)	7.8 ± 5.8 (1–24)
Postoperative valgus	3.9 ± 2.4 (1–9)
Preoperative varus (n = 56)	3.3 ± 2.3 (0–9)
Postoperative varus	1.4 ± 1.7 (0–6)

Fig. 2. Knee society scores show significant improvement, which were sustained at the 6 and 10-year postoperative time points ($p < 0.0001$). There was no statistical difference between scores at 6 and 10-years ($p = 0.99$).

Table 2
Complication rate comparing the 6 and 10-year postoperative time points. There was not a significant difference in the rate of all cause revision (excluding MUA) between the 6 and 10-year follow-up cohorts ($p = 0.28$).

Reoperations — n (%)	6-year (n = 131)	10-year (n = 107)
Manipulation under anesthesia	6 (4.0)	5 (4.1)
Poly exchange for instability	3 (5.0)	5 (4.1)
Quad tendon tear	2 (1.3)	0 (0)
Patella fracture	1 (0.7)	0 (0)
Aseptic loosening of the femur	1 (0.7)	0 (0)
Aseptic loosening of the tibia	0 (0)	1 (0.1)
Wound dehiscence	1 (0.7)	0 (0)
Infection	2 (1.3)	1 (0.1)
All cause revision excluding MUA	10 (7.6)	7 (5.7)

appear to result in significant differences in KSS (p=*00.28*) or range of motion (p=*0.32*).

Range of motion preoperatively was found to be 1.2° ± 1.5° (extension) – 116.1° ± 6.7° (flexion), and at 10-year follow-up was 0.4° ± 1.0° (extension) – 119.9° ± 6.4° (flexion). No significant differences were found in flexion (p=*0.16*) or extension (p=*0.13*) at these time points.

4. Discussion

The evidence from this research supported the hypothesis tested that the modern UFC would provide good clinical and functional results at 10-year follow-up compared to contemporary asymmetrical designs.[12,13] The use of this UFC in total knee arthroplasty presents various advantages that could appeal to surgeons including reduced turnover and setup times, instrument clutter, and sterilization costs.[14,15] However, early designs faced criticism, particularly concerning potential complications such as the risk of patellar maltracking, poor knee flexion, or non-anatomic femoral rollback.[16,17] One radiographic study found that the design of this implant allowed for axial rotation and femoral rollback comparable to that found in the native knee, although less in magnitude.[18] This study found no measured issues with patellar maltracking, even in high-risk patients with preoperative valgus alignment of >20°.[19] With this UFC design, one study also found normal axial rotational patterns and similar femoral rollback compared to reports of asymmetric designs.[20] This outcome was likely due to specific features of the implant's design, including a deeper trochlear groove, an extended 9° double Q-angle, and a more slender anterior flange, which together may have contributed to better patellar alignment and tracking. These results were supported by a biomechanical study which showed that asymmetry did not improve patellar tracking in a similar implant system.[21]

The complications observed in this study were well within the known rate of occurrence after total knee arthroplasty. The data supports that none of the complications observed were directly attributed to the implant design or surgical placement. From follow-up years 6–10, there were two revisions for polyethylene exchange due to ligamentous laxity as well as one patellar resurfacing. There were no issues with patellar maltracking or instability. The patellar tilts and patellar shifts measured at the 10-year mark were comparable to those observed in asymmetric designs.[22] At the 10-year mark, the rate of knee manipulation under anesthesia (MUA) was 4.9 % and polyethylene exchange due to instability was 4.1 %, which was consistent with figures reported in the literature.[23,24] Other complications included infection (0.1 %) and aseptic loosening (0.1 %), which were also within an acceptable range (source).[25,26]

While excellent outcomes were demonstrated and the stated hypotheses were supported, they do only represent the results of a single surgeon practicing kinematic alignment and measured resection. It may be difficult to extrapolate data in this investigation onto surgeons who differ in their surgical technique. Additionally, ultra-congruent polyethylene bearings were used in this study and results may differ for different bearing types. A multi-center study with a larger pool of patients and multiple surgeons should be examined to further investigate this UFC design. Finally, the fact that no differences in KSS or range of motion were found in knees with resurfaced versus non-resurfaced patellas offers a need to further investigate the criteria for patella resurfacing when performing total knee arthroplasty.

5. Conclusion

The Universal Femoral Component demonstrated excellent Knee Society Scores at the 10-year follow-up period with minimal complications in this study. Additionally, there were benefits of the UFC that made it attractive for the implanting surgeon. The complication rates were comparable to asymmetric designs. The two hypotheses were supported. Excellent implant survivorship and clinical outcomes were appreciated at the 10-year follow-up point in a cohort of patients who underwent total knee arthroplasty using the universal femoral design.

CRediT authorship contribution statement

Alexander Nielsen: Data curation, Formal analysis, Investigation, Visualization, Validation, Writing – original draft. **Jesua Law:** Data curation, Investigation, Visualization, Validation, Writing – original draft. **Lauren Homolka:** Data curation, Investigation, Validation, Writing – original draft. **D. Alex Forrester:** Data curation, Investigation, Visualization. **Aaron Hofmann:** Conceptualization, Methodology, Supervision, Validation, Writing – review & editing.

Consent

General Consent for Research was received from received from the Patient's within this cohort.

Ethical statement

This research was conducted in accordance with the code of ethics of the World Medical Association.

Funding statement

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