

Does a High-Flexion Design Affect Early Outcome of Medial Unicondylar Knee Arthroplasty?

Clinical Comparison at 2 Years

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Abstract: Recently, implant companies have sought to target a more active segment of the population with high-flex implants. Our aim was to compare a successful medial UKA implant with its newer high-flex version. Sixty-one patients (nonflex, 33; high-flex [HF], 28) were prospectively followed after medial UKA with a minimum of 2-year follow-up. Patients were evaluated using Short Form 12, Western Ontario and McMaster Osteoarthritis (WOMAC), Knee Society Scores, and range of motion (ROM). The HF group exhibited significantly higher WOMAC Physical Function scores at 3-month follow-up and higher WOMAC Pain and SF-12 Mental Component scores at 2-year follow-up; all other comparisons were not statistically different, including ROM. The HF cohort had significantly higher improvements in Knee Society Function and Knee score at 1- and 2-year follow-up, respectively; all other comparisons yielded no significant differences in mean improvement from baseline, including ROM or survivorship.

Keywords: unicondylar knee arthroplasty, high flex, fixed bearing.

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The surgical management of isolated medial compartment osteoarthritis (OA) of the knee with unicondylar knee arthroplasty (UKA) has been controversial since its arrival in the 1950s [1-4]. Proponents of UKA tout that it maintains the general kinematics and proprioception of a natural knee [5,6]. In addition, there have been reports of faster recovery, better range of motion (ROM), and more successful return to activities of daily living compared with TKA [7-11]. Advances in surgical technique along with changes made in the original implants have allowed surgeons to better preserve the native knee and improve outcomes [12-15]. A critical

contribution to the recent success of medial UKA has been strict patient selection criteria [16].

Recently, many implant companies have introduced “high-flex” knee implants to entice surgeons to market this technology to their younger, more active patients. Many of these improvements have been adapted to implants that have had positive survivorship results in the short- to medium-term follow-up period [12,14,15,17-19]. Manufacturer claims include that the high-flex modification offers increased ROM, more tibial coverage, and more sizing options for a more accurate component fit. In vivo kinematic studies have had trouble confirming the theoretical benefits of high-flex UKA and its potential translation into improved clinical outcome [5,20]. To date, there have been no studies that compare the clinical outcome of such a modification on UKA implants. This investigation reports the outcomes of a traditional fixed-bearing UKA implant, the Miller-Galante (MG; Zimmer, Inc, Warsaw, Ind), and the newer designed implant that allows for high flexion, the Zimmer Unicondylar Knee (ZUK; Zimmer, Inc).

Materials and Methods

Study data were collected prospectively, in conjunction with the Center for Hip and Knee Replacement Joint

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Registry, under institutional review board approval, starting in April 2001. Patients eligible for study inclusion were a consecutive series of patients undergoing medial UKA between April 2001 and April 2008 with properly obtained informed consent. Patients completed baseline questionnaires including the Short Form 12 (SF-12), Western Ontario and McMaster Osteoarthritis (WOMAC) index, and Knee Society Scores. All patients had implantation of a UKA implant with no evidence of advanced OA in the patellofemoral or lateral component joint, adequate motion, and stability as described by the criteria set forth by Kozinn et al [16] and minimal coronal plane deformity. All surgeries were performed by 1 of 2 fellowship-trained arthroplasty surgeons via a medial arthrotomy. The rehabilitation protocols were identical for all patients postoperatively, including early mobilization/full weight-bearing and discharge to home on postoperative day 2 or 3, with a visiting physical therapist, followed by 6 weeks of outpatient physical therapy for ROM and strengthening.

Postoperative survey completion and ROM measurements occurred at 3 months and 1 and 2 years with follow-up radiographs to assess for implant migration, loosening, or malalignment. The implant made and its model, confirmed intraoperatively, also were recorded, later delineating the 2 study groups: MG and ZUK fixed-bearing cohorts in a nonrandomized, prospective fashion. Additional data collection included age at time of surgery, sex, body mass index (BMI), operative side, operative time (skin-to-skin), length of stay (LOS), and any perioperative or postoperative complications that may have arisen.

All data collected were performed by third-party personnel in conjunction with the Center for Hip and Knee Replacement Joint Registry protocol and stored in Patient Analysis and Tracking System (Axis Clinical Software, Portland, Ore). Statistical analysis included categorical analysis with Fisher exact test and nominal data analysis with 2-way, unpaired Student *t* test. Nonparametric data were compared via Kruskal-Wallis 1-way analysis of variance (ANOVA). Nonparametric and continuous-data group comparison was performed via a multivariate analysis of covariance (MANCOVA), allowing for control of confounding variables, including age, BMI, and sex. Nonparametric continuous and MANCOVA analyses were performed using SPSS 18.0 (SPSS: An IBM Company, Somers, NY). Kaplan-Meier survivorship analysis and cohort comparison were performed using GraphPad 4.0 (GraphPad Software Inc, La Jolla, Calif). Power analysis calculations were performed via the Decision Support Systems Researcher's Toolkit (Decision Support Systems, LP, Fort Worth, Tex).

Results

Sixty-one consecutive patients (64 knees) underwent medial UKA, with 33 patients (34 knees) in the MG

cohort and 28 patients (30 knees) in the ZUK cohort. No statistical differences were noted between the 2 groups' mean age (66.7 ± 8.5 years vs 67.9 ± 9.9 years; *P*, nonsignificant), mean polyethylene size (8.3 ± 0.9 mm vs 8.4 ± 0.8 mm; *P*, nonsignificant), LOS (3.7 ± 1.4 vs 3.3 ± 1.1 days; *P*, nonsignificant), and number of revisions (2 vs 3; *P*, nonsignificant; Table 1). Demographic data differences noted significantly more women (73% vs 43%, *P* = .02) and higher mean BMI (32.4 ± 4.6 kg/m² vs 29.5 ± 5.7 kg/m²) in the MG group (Table 1).

Analyzing the MG and ZUK cohorts, individually, Kruskal-Wallis 1-way ANOVA analysis (95% confidence interval [CI]) yielded significant improvements from baseline in all of the instrument scores and mean ROM, except for the SF-12 mental component score in the MG group (Table 2).

Using MANCOVA, controlling for age, BMI, and sex, comparisons between the MG and ZUK cohorts yielded several significant differences. At baseline, the MG group exhibited significantly higher SF-12 Mental Component scores (50.82 ± 10.5 vs 48.01 ± 9.4 , *P* = .003), WOMAC Physical Function scores (50.9 ± 17.8 vs 46.5 ± 22.1 , *P* = .03), and mean ROM ($114.9 \pm 10.8^\circ$ vs $110.9 \pm 13.3^\circ$, *P* = .003; Table 2).

At 3-month follow-up, controlling for age, BMI, and sex via MANCOVA, the ZUK cohort exhibited higher means in several outcome measures, including the SF-12 Physical Component score (39.15 ± 8.8 vs 44.09 ± 8.6 , *P* = .035), WOMAC Pain score (73.8 ± 20.2 vs 82.8 ± 16.0 , *P* = .007), WOMAC Physical Function score (70.6 ± 19.3 vs 82.4 ± 19.7 , *P* < .0001), and the Knee Society Function score (66.0 ± 20.5 vs 78.0 ± 18.1 , *P* = .022; Table 2). At 3 months, however, the MG cohort maintained significantly higher SF-12 Mental Component scores (53.97 ± 8.5 vs 53.19 ± 7.8 , *P* = .001) and mean ROM ($121.9 \pm 9.7^\circ$ vs $118.3 \pm 11.3^\circ$, *P* < .0001; Table 2).

At 1-year follow-up, significant differences seemed to plateau. No significant differences between the cohorts were noted, except for a significantly higher Knee Society Knee score in the MG cohort (86.3 ± 12.2 vs

Table 1. MG vs ZUK Demographic Data Comparison

	MG	ZUK	<i>P</i>
Age (y), mean $\pm$ SD	33 (34) 66.7 ± 8.5	28 (30) 67.9 ± 9.9	.61
Sex			.02*
Male (%)	9 (27)	16 (57)	
Female (%)	24 (73)	12 (43)	
BMI (kg/m ²), mean $\pm$ SD	32.4 ± 4.6	29.5 ± 5.7	.03†
Poly width (mm), mean $\pm$ SD	8.3 ± 0.9	8.4 ± 0.8	NS
LOS (days), mean $\pm$ SD	3.7 ± 1.4	3.3 ± 1.1	NS
Revisions (%)	1 (2.9)	3 (10)	NS

NS indicates not significant.

* *P* < .05, Fisher exact test (2-tailed).

† *P* < .05, unpaired *t* test (2-tailed).

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