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Difference in patient-reported outcomes of various patellar component designs in total knee arthroplasty: A randomized clinical study

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Abstract

Purpose: This study investigated the clinical effects of different patellar components without being affected by the femoral component design in total knee arthritis (TKA) for patients with knee osteoarthritis (OA). Methods: In total, 48 patients with OA who met the criteria of the American College of Rheumatology for OA were enrolled and randomly assigned in a 1:1 ratio to two groups according to the usage of patellar component design for TKA (medialized dome type [dome group] or medialized anatomic type [anatomic group]). To evaluate the clinical outcomes for TKA, knee range of motion (ROM), pain intensity of 0–100 mm visual analog scale (pain VAS), and the Japanese Knee Osteoarthritis Measure (JKOM) score were obtained at baseline and year 1. Results: The difference in knee ROM, pain VAS, or total JKOM score at year 1 was not significant between the dome and anatomic groups (p = 0.398, 0.733 and 0.536, respectively). Moreover, similar results were obtained for changes in knee ROM, pain VAS, or total JKOM scores from baseline. In both groups, the pain VAS and total JKOM scores were significantly improved at year 1. Conclusion: Both dome and anatomic groups in TKA are significantly effective for pain and function using the JKOM score. However, their efficacy did not differ, according to the JKOM score. Results of this study are rare information focusing on the patellar component design and provide one of the insights into the TKA clinical management.

Keywords

osteoarthritis, patellar component design, patient-reported outcome, total knee arthroplasty

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Introduction

Total knee arthroplasty (TKA) is a commonly performed orthopedic procedure for osteoarthritis (OA), rheumatoid arthritis, and osteonecrosis and is an established procedure that can effectively reduce pain and improve function and quality of life.¹,² Patellar resurfacing in TKA has reduced pain and improved function. Conversely, patellar resurfacing in TKA has some complications such as persistent pain, avascular necrosis, and patellar clunk.³-⁷ Patellar complications were caused by various factors such as femoral component rotation and groove, tibial component rotation, and soft-tissue balance. Moreover, patellofemoral tracking is also important. Conversely, femoral component grooves have various depth and valgus. Patellar component designs are classified into dome, offset dome, modified dome, and anatomic types. The same femoral component design is required to identify the effects of patellar

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component design. Moreover, different designs of the patellar component have been shown to affect patellofemoral kinematics.8–11

We hypothesized that clinical results are different for patellar component designs however, clinical results evaluated using various patellar component designs are insufficient. The ATTUNE® Total Knee Posterior Stabilized System® (DePuy Synthes, United States) has two patellar component designs such as offset dome and offset anatomic types. Therefore, the effect of patellar component design was investigated using the ATTUNE® Total Knee Posterior Stabilized System®. Thereby, this study clarifies clinical effects of different patellar components without affecting the femoral component design of TKA.

Methods

Patients

A total of 48 patients with OA who underwent TKA in our hospital between June 2017 and September 2018 were enrolled in analysis of this study (Figure 1). The inclusion criteria for this study included patients who were able to walk and fulfilled the criteria of the American College of Rheumatology for knee OA at the medial femorotibial joint.12 All patients had radiographic OA with Kellgren–Lawrence grade 3 and 4 evaluated by anteroposterior X-rays in standing position.13 The exclusion criteria included patients with bilateral TKA or joint arthroplasty in the hip and/or ankle joint.

Patients were randomized in a 1:1 ratio at the clinical research center of the authors’ affiliated institution into two groups according to the usage of patellar component design used for TKA (medialized dome type [dome group] or medialized anatomic type [anatomic group]).

Accordingly, this study was conducted following the principles of the Declaration of Helsinki. Informed consent was obtained from all patients. This research has been approved by the Institutional Review Board of the authors’ affiliated institutions.

Surgical technique

A standard TKA was performed using the ATTUNE® Total Knee Posterior Stabilized System® cemented and fixed-bearing. All TKAs were performed by a single surgeon in a single hospital. The surgical approach was the medial parapatellar approach. Distal femoral resection uses anatomic landmarks and plane X-rays to match the degree of normal femoral external rotation. For anterior and posterior femoral resections, the degrees of external rotation of the femoral component were determined using the posterior condylar axis and trans-epicondylar axis through the pre-operative magnetic resonance imaging (MRI). For proximal tibial resection, the posterolateral and medial tibial plateaus were used as landmarks. Tibial rotation was determined by inserting an implant to ensure a midline tibial articulation. A vernier caliper was used to measure the required cutting thickness of the patella in order to maintain its thickness after cutting. The usual amount of bone resection was equal to the thickness of the patellar component used. Then, the patellar thickness was measured again using a vernier caliper after cutting. The patellar component was the randomly used selected design.

Rehabilitation protocol

All patients underwent a physiotherapy rehabilitation protocol, including gait training of full weight bearing, range of motion training, strength training of lower extremity (e.g., quadriceps and hamstrings), and mobility exercise on day 1 post-operatively with physical therapists.

Clinical outcome assessments

To evaluate the clinical outcome for TKA, knee range of motion (ROM), pain intensity of 0–100 mm using the visual analog scale (pain VAS), valgus angle of the femoral component, external rotation of the femoral component, and the Japanese Knee Osteoarthritis Measure (JKOM) score were measured.

The JKOM score is a patient-reported outcome comprising 25 questions (0–4) in four subcategories: pain and stiffness (0–32), condition in daily life (0–40), general activities (0–20), and health conditions (0–8), with maximum score of 100 points.14 The lower JKOM score indicates a better knee condition. The knee ROM, pain VAS, and JKOM score were measured at baseline and year 1.

Patellar stability assessments

The internal rotation angle was measured on frontal view X-rays with knee in extension (baseline) and 30°, 60°, 90°, and 120° of knee flexion. The flexion angle is measured on lateral view X-rays with the knee in extension (baseline) and 30°, 60°, 90°, and 120° of knee flexion. The flexion angle is the angle between the cutting surface of the patella and anterior cutting surface of the femur. Lateral tilt was
measured on skyline view X-rays in 30° (baseline) of knee flexion and with 60°, 90°, and 120° of knee flexion. The assessments of patellar stability were used to change from baseline.10,11

### Table 1. Comparison between the dome and anatomic groups in demographic and clinical characteristics at baseline.

| Variable                              | Dome group (n = 24) | Anatomic group (n = 24) | p-Value |
|---------------------------------------|---------------------|-------------------------|---------|
| Age, years                            |                     |                         | 0.457   |
| Mean (SD)                             | 73.0 (8.8)          | 74.3 (9.9)              |         |
| Median (Q1, Q3)                       | 72 (63.75,75)       | 77 (68.80)              |         |
| Sex, female, n (%)                    | 23 (95.8)           | 22 (91.7)               | 1.000   |
| BMI                                   |                     |                         | 0.427   |
| Mean (SD)                             | 28.1 (5.5)          | 27.1 (5.5)              |         |
| Median (Q1, Q3)                       | 28 (24.5, 30.7)     | 25.2 (23.5, 30.1)       |         |
| K/L grade, 3/4, n                     | 18/6                | 17/7                    | 1.000   |
| Valgus angle of the femoral component |                     |                         | 0.802   |
| Mean (SD)                             | 6.2 (0.6)           | 6.3 (0.6)               |         |
| Median (Q1, Q3)                       | 6.1 (5.9, 6.4)      | 6.2 (5.9, 6.8)          |         |
| External rotation of the femoral component |                   |                         | 0.915   |
| Mean (SD)                             | 4.2 (0.8)           | 4.2 (0.8)               |         |
| Median (Q1, Q3)                       | 4.1 (3.5, 4.8)      | 4.2 (3.6, 4.7)          |         |
| Knee range of motion                  |                     |                         | 0.268   |
| Mean (SD)                             | 116.1 (17.9)        | 111.5 (16.5)            |         |
| Median (Q1, Q3)                       | 122.5 (105, 130)    | 112.5 (100, 121.25)     |         |
| Pain VAS                              |                     |                         | 0.942   |
| Mean (SD)                             | 61.1 (27.0)         | 61.6 (26.3)             |         |
| Median (Q1, Q3)                       | 69.5 (39.75, 82.75) | 62.5 (39.75, 84.25)     |         |
| JKOM score: total                     |                     |                         | 0.710   |
| Mean (SD)                             | 44.6 (21.6)         | 42.7 (23.0)             |         |
| Median (Q1, Q3)                       | 45.5 (30.5, 57.5)   | 35.5 (27.75, 52.75)     |         |
| JKOM score: pain and stiffness        |                     |                         | 0.726   |
| Mean (SD)                             | 13.8 (7.6)          | 14.8 (8.2)              |         |
| Median (Q1, Q3)                       | 13.5 (7.75, 19.5)   | 13 (9, 19.5)            |         |
| JKOM score: condition in daily life    |                     |                         | 0.515   |
| Mean (SD)                             | 17.0 (9.6)          | 15.4 (10.1)             |         |
| Median (Q1, Q3)                       | 15.5 (9.5, 23.25)   | 13.5 (8, 19.25)         |         |
| JKOM score: general activities        |                     |                         | 0.756   |
| Mean (SD)                             | 9.5 (6.0)           | 8.9 (5.8)               |         |
| Median (Q1, Q3)                       | 8.5 (4.5, 14)       | 7 (4.75, 12.25)         |         |
| JKOM score: health conditions         |                     |                         | 0.233   |
| Mean (SD)                             | 4.4 (2.1)           | 3.7 (2.0)               |         |
| Median (Q1, Q3)                       | 5 (2.75, 6)         | 3 (2.5)                 |         |

SD: standard deviation; Q1: 25th percentile; Q3: 75th percentile; BMI: body mass index; K/L: Kellgren–Lawrence; VAS: visual analog scale; JKOM: Japanese Knee Osteoarthritis Measure.

Statistical analysis

Mann–Whitney U test and Fisher’s exact test were used for between-group comparisons of patient demographics and clinical characteristics at baseline and year 1 of the following variables: age; sex; body mass index; K/L grade; valgus angle of the femoral component, external rotation of the femoral component, knee ROM; pain VAS; total, pain and stiffness, condition in daily life, general activities, and health conditions JKOM score. A paired t-test was used to compare pain VAS, total, pain and stiffness, condition in daily life, general activities, and health conditions JKOM scores were compared between baseline and year 1 for both groups. All statistical analyses were performed using the R Statistical Package software, version 3.3.2 (http://www.r-project.org/).

Results

Participants

The baseline characteristics of the dome and anatomic groups are summarized in Table 1. Moreover, according to the univariate analysis comparison between dome and anatomic groups, between-group differences in any variables were not significant at baseline.

Patient-reported outcomes

No significant difference in knee ROM, pain VAS, or total JKOM score was observed at year 1 between the dome and
anatomic groups ($p = 0.398, 0.733, \text{ and } 0.536$, respectively). Moreover, similar results were obtained for knee ROM, pain VAS, or total, pain and stiffness, condition in daily life, general activities, and health conditions of JKOM score changes from baseline (Table 2).

In the dome group, rates of improvement in knee ROM, pain VAS, and total JKOM score at year 1 than those of baseline were $70.8\%$, $9.8\%$, and $83.3\%$, respectively. In the anatomic group, rates of improvement in knee ROM, pain VAS, and total JKOM score at year 1 than those of baseline were $87.5\%$, $79.2\%$, and $79.2\%$, respectively. Pain VAS and total JKOM score were decreased in the dome and anatomic groups compared with those at baseline by $-39.7 \pm 15.2$ and $-40.7 \pm 25.8$ (pain VAS) and $-20.1 \pm 21.8$ and $-16.3 \pm 22.8$ (total JKOM score), respectively. In both groups, the pain VAS and total, pain and stiffness, condition in daily life, general activities, and health conditions of JKOM scores were significantly improved at year 1. However, two questions of the JKOM score (Have you been using a walking stick recently? and Have you gone to an event or to a department store during the last one month?) were not improved.

### Table 2. Comparison between the dome and anatomic groups in clinical results at year 1.

| Variable                                      | Dome group   | Anatomic group | p-Value |
|-----------------------------------------------|--------------|----------------|---------|
| Knee range of motion                          |              |                |         |
| Mean (SD)                                     | 126.5 (9.5)  | 123.5 (11.6)   | 0.398   |
| Median (Q1, Q3)                               | 125 (120, 131.25) | 122.5 (115, 130) |         |
| Pain VAS                                      |              |                |         |
| Mean (SD)                                     | 21.5 (24.7)  | 20.9 (20.3)    | 0.733   |
| Median (Q1, Q3)                               | 12 (3, 30.75) | 14 (6.75, 34)  |         |
| JKOM score: total                             |              |                | 0.536   |
| Mean (SD)                                     | 24.5 (15.2)  | 26.5 (14.5)    |         |
| Median (Q1, Q3)                               | 20.5 (13.75, 31.5) | 26.5 (15.75, 36.25) |         |
| JKOM score: pain and stiffness                |              |                | 0.267   |
| Mean (SD)                                     | 6.9 (5.1)    | 7.8 (4.5)      |         |
| Median (Q1, Q3)                               | 6.5 (3.75, 8) | 8 (4.75, 10.25) |         |
| JKOM score: condition in daily life           |              |                | 0.788   |
| Mean (SD)                                     | 9.5 (6.4)    | 10.0 (6.4)     |         |
| Median (Q1, Q3)                               | 8 (5.75, 13.5) | 9 (5.75, 15)   |         |
| JKOM score: general activities                |              |                | 0.966   |
| Mean (SD)                                     | 5.3 (5.1)    | 6.0 (4.3)      |         |
| Median (Q1, Q3)                               | 4 (2.7)      | 6 (3.75, 8.25) |         |
| JKOM score: health conditions                 |              |                | 0.089   |
| Mean (SD)                                     | 2.7 (1.6)    | 2.7 (1.5)      |         |
| Median (Q1, Q3)                               | 2.5 (1.75, 3.25) | 2.5 (1.75, 4) |         |
| Change of baseline in knee range of motion    |              |                | 0.560   |
| Mean (SD)                                     | 10.4 (16.9)  | 12.1 (12.7)    |         |
| Median (Q1, Q3)                               | 12.5 (1.25, 20) | 5 (5, 21.25)  |         |
| Change of baseline in pain VAS                |              |                | 0.959   |
| Mean (SD)                                     | -39.7 (15.2) | -40.7 (25.8)   |         |
| Median (Q1, Q3)                               | -38.2 (-73, -18.25) | -38.5 (-76.5, -9.5) |         |
| Change of baseline in JKOM score: total       |              |                | 0.464   |
| Mean (SD)                                     | -20.1 (21.8) | -16.3 (22.8)   |         |
| Median (Q1, Q3)                               | -16 (-35, -3.75) | -7 (-26.75, -1.75) |         |
| Change of baseline in JKOM score: pain and stiffness | |                  | 0.959   |
| Mean (SD)                                     | -6.9 (7.3)   | -7.0 (7.5)     |         |
| Median (Q1, Q3)                               | -4.5 (-13.25, -1) | -5 (-12.25, -0.75) |         |
| Change of baseline in JKOM score: condition in daily life | |                  | 0.311   |
| Mean (SD)                                     | -7.5 (9.5)   | -5.4 (9.2)     |         |
| Median (Q1, Q3)                               | -5.5 (-11, -0.75) | -2.5 (-8.75, 0) |         |
| Change of baseline in JKOM score: general activities | |                  | 0.180   |
| Mean (SD)                                     | -4.1 (5.7)   | -2.8 (6.2)     |         |
| Median (Q1, Q3)                               | -3 (-7.5, -0.75) | -0.5 (-5, 0)  |         |
| Change of baseline in JKOM score: health conditions | |                  | 0.356   |
| Mean (SD)                                     | -1.7 (2.4)   | -1.0 (2.1)     |         |
| Median (Q1, Q3)                               | -1 (-3.25, 0) | 0 (-1.25, 0)  |         |

SD: standard deviation; Q1: 25th percentile; Q3: 75th percentile; BMI: body mass index; K/L: Kellgren–Lawrence; VAS: visual analog scale; JKOM: Japanese Knee Osteoarthritis Measure.
Patellar stability

Changes from baseline in the internal rotation angle of the dome and anatomic types were 2.8 ± 2.2° and 3.5 ± 2.8° at 30° of knee flexion (p = 0.483), 3.9 ± 3.1° and 3.0 ± 3.2° at 60° of the knee flexion (p = 0.444), 5.7 ± 3.9° and 4.4 ± 4.6° at 90° of knee flexion (p = 0.086), and 6.3 ± 4.9° and 5.2 ± 5.3° at 120° of knee flexion (p = 0.344), respectively. Changes from baseline in the flexion angle of the dome and anatomic types were 19.3 ± 10.6° and 19.3 ± 9.6° at 30° of knee flexion (p = 0.854), 32.6 ± 12.2° and 32.7 ± 13.6° at 60° of knee flexion (p = 0.954), 47.2 ± 18.1° and 42.4 ± 16.0° at 90° of knee flexion (p = 0.476), and 60.8 ± 18.7° and 55.6 ± 20.1° at 120° of knee flexion (p = 0.313), respectively. The changes from baseline in the lateral tilt of the dome and anatomic types were 4.4 ± 6.0° and 2.0 ± 2.3° at 60° of knee flexion (p = 0.421), 7.1 ± 9.9° and 3.1 ± 4.1° at 90° of knee flexion (p = 0.274), and 6.8 ± 10.1° and 3.7 ± 3.4° at 120° of knee flexion (p = 0.701), respectively.

Discussion

This study investigated the clinical effects of different patellar component designs in TKA. This study showed no difference in patient-reported outcomes of various patellar component designs at year 1 after TKA. The dome type provides a conforming lateral facet and is an unforgiving bone interface.15,16 Although each design has different features, this study revealed that there was no difference in clinical outcomes between dome type and anatomic type. We believe that no difference in patellar stability between the dome and anatomic groups may have affected the results of this study.

In vitro, comparison of quadriceps forces between dome and anatomic types had almost no difference. Moreover, in patellar geometry cohorts, the function score of the Knee Society Scores were nearly the same between the dome and anatomic types.10 The TKA improved the knee function using each patellar component. These results were similar with that of the present study. The clinical outcome assessment in this study was performed using the JKOM score of patient-reported outcome measures. A patient-reported outcome measure can identify a health condition such as pain or function without effects from the physician. Hence, these results are useful for understanding patients for their physician. In a previous report, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain score, physical and mental component summary in Short Form 36, and EuroQol 5-domain instrument quality of life (QOL) tool of another patient-reported outcome measures were significantly improved for TKA.2 In this study, pain, function, and QOL using the JKOM score were significantly improved. On the contrary, use of a walking stick in condition in daily life and times of going to an event or department store in general activities were not improved in both groups. The rates of score 4 with regard to the use of a walking stick in dome and anatomic groups were 41.7% and 33.3%, respectively. In other words, several patients were always using stick before TKA. Similarly, the mean score on questions regarding to going to an event or department store in dome and anatomic groups were 45.8% and 29.2%, respectively. Therefore, both questions at baseline were worse in many patients. Moreover, the rate of bilateral knee OA in Japanese people was 68.4%.17 We believe that these no improvements in two questions are preoperative condition and contralateral knee OA.

This study has some limitations that should be acknowledged. First, the degrees of external rotation in the femoral component were determined using a preoperative MRI. The degrees of external rotation in the femoral component are known to be 3° relative to the posterior condylar axis.18 These results may be different if the external rotation of the femoral component is determined differently such as computed tomography. Second, this study showed that the thickness of patellar bone cut was determined considering to the preoperative patellar thickness. Therefore, the anterior femoral offset was not considered. However, in a previous report, the anterior femoral offset had no effect in the Knee Society pain score, WOMAC score, and Knee Injury and Osteoarthritis Outcome Score.19,20 Hence, the method of cutting the patellar bone in this study is believed to have a little effect on the outcomes of this study. Third, results of this study were 1 year after TKA, and results of the early phase have not been examined. In the early phase, differences may be observed between the two groups. A future prospective study is required to clarify the effects of the early phase.

In conclusion, both dome and anatomic groups in TKA are significantly effective for pain and function management using the JKOM score. However, their efficacy did not differ, according to the JKOM score. The effect on long-term results should also be observed. We believe that the results of this study are rare information focusing on the patellar component design and provide insights into the clinical management for TKA.

Declaration of conflicting interests

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