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No difference between double-high insert and medial-pivot insert in TKA

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Abstract
Purpose To compare the clinical midterm results in ADVANCE total knee arthroplasty (TKA) with double-high (DH) insert, with same type implant with medial-pivot (MP) insert.
Method Forty ADVANCE TKAs were randomly divided into two groups, and two different design insert, DH insert, and MP insert were used in each group. At midterm, 4–5 years after surgery, Knee Society Scores (KSS), Knee Society Functional Scores (KSFS), range of motion (ROM), and UCLA activity score were assessed and reported in this study.
Results Midterm clinical results, including ROM and KSS, were comparable with both groups. KSFS and UCLA activity score were equally good between the two groups.
Conclusion The results in this study revealed equally good clinical results with these types of implants at midterm follow-up, although the significant better ROM has not achieved by using DH insert. We concluded that the selection of inserts only could not achieve the better clinical results, including ROM and activity level in this study.
Level of evidence Therapeutic studies—investigating the results of treatment, Level II.

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Keywords Total knee arthroplasty · Clinical outcome · Midterm results · Range of motion · Medial-pivot insert · Double-high insert

Introduction

Total knee arthroplasty (TKA) is a well-established procedure that generally results in a high rate of success. However, knee kinematics after TKA are quite different from normal kinematics. Although normal knee kinematics are generally recognized as medial-pivot motion, several studies have demonstrated different findings after TKA, including paradoxical anterior sliding of the femur [7, 17]. ADVANCE medial-pivot (MP) total knee arthroplasty (Wright Medical Technology, Arlington, TN) is designed to replicate medial pivoting behaviour and has been found to exhibit excellent anterior–posterior (AP) stability. This implant has a single radius of femoral curvature and a high level of conformity in the medial compartment about which it rotates. It does not roll back as in the post and cam mechanism of posterior stabilized (PS) arthroplasty. This prosthesis is more bone conserving and reported to improve the biomechanics of the patellofemoral joint [1] and generate less polyethylene wear particles than traditional PS TKA [12]. This implant has two tibial inserts with different designs, MP insert and double-high (DH) insert. The MP tibial insert has a fully conforming ball-in-socket articulation on the medial side with both anterior and posterior lips to roughly simulate the constraint provided by the anterior cruciate ligament and PCL. On the other hand, the DH tibial insert is a more recently designed tibial insert that is intended to achieve "high stability, high flexion". The design of the insert has the same anteromedial constraint geometry, and to allow posterior femoral rollback

and get a better flexion angle, the posterior lip of the DH insert is designed to be 3 mm lower than that of the MP insert, which results in a posterior slope (Fig. 1).

There have been some reports revealing good clinical results using MP inserts in ADVANCE TKA at midterm follow-up [2, 8, 11, 19]; however, as far as we can ascertain, there is nothing in the English literature that shows clinical outcomes using DH inserts nor clinical differences from MP inserts in ADVANCE TKA. The aim of the present study is to reveal midterm clinical outcomes using DH inserts for the first time and reveal the clinical utility of this insert, compared to MP inserts in ADVANCE TKA. It was hypothesized that differences in insert design only could not account for improvements in clinical benefits, such as improvements in range of motion; thus, both inserts would reveal equally good clinical outcomes in ADVANCE TKA at midterm follow-up.

Materials and methods

The study was approved by the Institutional Review Board of Hyogo Rehabilitation Centre Central Hospital, and informed consent was obtained from all patients. From May to November 2005, 40 ADVANCE TKAs were performed in varus deformity patients diagnosed with osteoarthritis. Patients with valgus deformity, severe bony defects, and rheumatoid arthritis were excluded from this study. The remaining patients were randomly divided into two groups as follows: DH group, TKA with DH insert; MP group, TKA with MP insert. In the approximately 5-year follow-up, no patients were lost in the final follow-up and a total of 20 patients in each group were included in this study (Table 1). TKA in both groups were implanted by the same senior author (N.T.) using a conventional manual technique, as explained below. Briefly, knees were exposed with a medial parapatellar arthrotomy, and bony resection was performed using the measured resection technique. The posterior cruciate ligament (PCL) was sacrificed at the beginning of the procedure. Additionally, the femoral prosthesis was set at 3° of external rotation in relation to the posterior condylar axis, separately for each patient. Clinical evaluations were performed at pre-operation, 2 months postoperatively, and final follow-up. Knee Society Clinical Rating System [9], which includes a knee score (KSS), functional score (KSFS), and range of motion (ROM), were evaluated. Patients' activity level was evaluated using University of California, Los Angeles (UCLA) activity score at pre-operation, 1 year postoperatively, and final follow-up [20]. UCLA activity score is generally agreed to be the most appropriate scale for assessment of physical activity levels in patients undergoing total joint arthroplasty [13]. In addition, complications or need for revision surgeries was recorded. These evaluations were performed by an independent observer, independent of the treatment.

Table 1 Demographic data of the double-high group and medial-pivot groups [median value (range)]

Demographic information	Double-high group ($n = 20$)	Medial-pivot group ($n = 20$)	P value
*Age (years)	72 (63–79)	71 (60–81)	(n. s.)
Gender (% male)	5	5	(n. s.)
BMI	26.0 (21.8–34.5)	27.2 (21.4–36.2)	(n. s.)
Follow-up period (months)	57 (48–62)	57 (48–61)	(n. s.)

BMI Body Mass Index

*Age at operation

n. s. not statistically significant differences between the two groups ($p \geqq 0.05$)

Anteroposterior and lateral weight-bearing digitized radiographs of the operated knee joints (a 320 mA, 0.03 s exposure at 80–100 kV, depending on soft tissue thickness) were taken at final follow-up. The progressive radiolucencies were evaluated using radiographs taken at final follow-up. Additionally, the coronal mechanical axis of the long leg at pre-operation and at final follow-up was measured using anteroposterior long leg weight-bearing radiographs. These evaluations were performed using commercially available imaging software systems (SYNAPSE; FUJIFILM, Tokyo, Japan) at least three times in each patient by two authors (K.I. and T.M.) blinded to clinical information and the averages were used in this study. The test–retest reliability of these three measurements was confirmed and found to be excellent (intraclass correlation coefficient = 0.93).

Statistical analysis

Results were analysed statistically using a statistical software package (Stat Mate III; ATMS Co., Ltd., Tokyo, Japan). The differences in the clinical results between the two groups were analysed using the non-paired Student t test. Results in the same group at different time points were analysed using the paired Student t test. Differences of $p < 0.05$ were considered statistically significant.

Results

The total number of patients enrolled in this study was 40. This number was chosen based on a previous study in our department on the minimum number of patients required to examine clinical differences, and further backed up by the power analysis for the study (alpha = 0.05; power

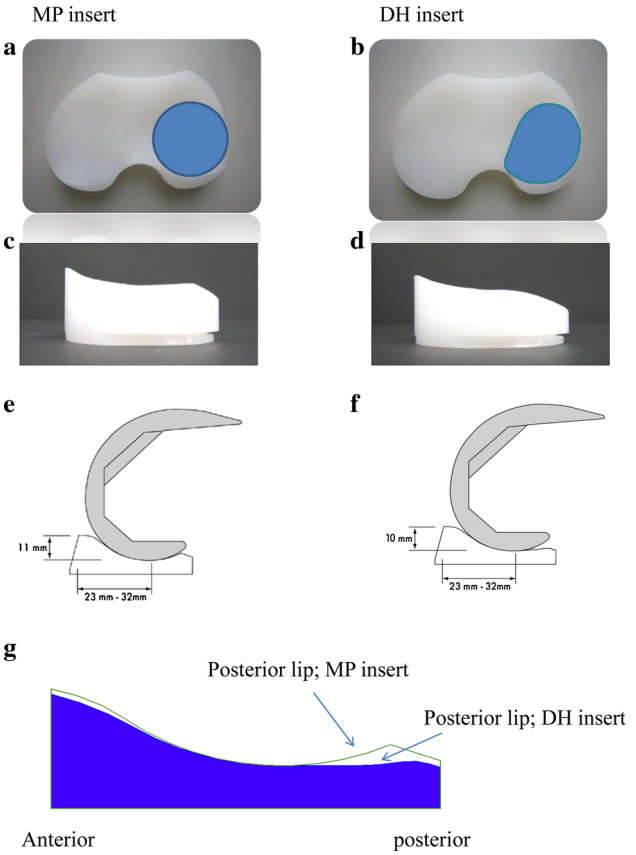

Fig. 1 Design profile of double-high and medial-pivot insert design profile of MP insert (**a**, **c**, **e**) and DH insert (**b**, **d**, **f**). Overview (**a**, **b**), sagittal images (**c**, **d**), and schematic figures (**e**, **f**) are shown. The MP tibial insert has a fully conforming ball-in-socket articulation on the medial side with both anterior and posterior lips to roughly simulate the constraint provided by the anterior cruciate ligament and PCL (**a**, **c**), meanwhile the DH *insert* is modified its shape to allow posterior femoral rollback and get a better flexion angle (**b**, **d**). MP insert contains an anterior lip that provides a vertical jump distance of 11 mm for all sizes (**e**), and the anterior lip of DH insert is 10 mm from the deepest point of the articular surface (**f**). The posterior lip of the DH insert is designed with a 3 mm lower than that of the MP insert, which resulted in a posterior slope (Medial-pivot)

level = 80 %, typical standard deviation = 20 %; difference detection = 20 %; JMP Statistical Software Version 8.0.1). No patients in either group had any complications or needed any revision surgery. KSS and KSFS in both groups were significantly improved postoperatively ($p < 0.05$). The scores at 2 months postoperatively and final follow-up were not statistically different between the two groups. In addition, there was no statistically significant difference between the two groups in pain score or stability score, including KSS. UCLA activity score revealed the activity of the patients significantly improved postoperatively ($p < 0.05$); however, there was no statistically significant difference between the two groups (Table 2). Radiographic measurement to investigate the coronal mechanical axis showed that the mechanical axis was equally improved in the two groups postoperatively (Table 3). There was no significant difference in ROM at every time point; however, early ROM recovery was observed in the MP group at 2 months postoperatively, and better flexion was found in the DH group at final follow-up (Table 4). Assessment of radiographs at final follow-up revealed no progressive radiolucencies, and there were no signs of gross migration or impending failure.

Table 2 Pre-operative and final follow-up comparisons of clinical scores [median value (range)]

	Double-high group	Medial-pivot group	*P* value
Preop. KSS (points)	36 (21–68)	34 (6–68)	(n. s.)
Post 2 months. KSS (points)	77 (54–95)	76 (47–100)	(n. s.)
Final KSS (points)	85 (53–99)	89 (63–96)	(n. s.)
Preop. KSFS (points)	45 (5–70)	40 (5–70)	(n. s.)
Post 2 months. KSFS (points)	60 (30–100)	60 (25–100)	(n. s.)
Final KSFS (points)	65 (10–95)	65 (10–100)	(n. s.)
Preop. pain score (points)	10 (0–30)	10 (0–30)	(n. s.)
Post 2 months. pain score (points)	40 (20–50)	40 (20–50)	(n. s.)
Final pain score (points)	45 (30–50)	45 (20–50)	(n. s.)
Preop. stability score (points)	23 (15–25)	23 (15–25)	(n. s.)
Post 2 months. stability score (points)	23 (15–25)	23 (15–25)	(n. s.)
Final stability score (points)	25 (23–25)	25 (23–50)	(n. s.)
Preop. UCLA activity score (points)	3 (1–8)	3 (2–8)	(n. s.)
Post 1 year UCLA activity score (points)	5 (3–8)	5 (3–8)	(n. s.)
Final UCLA activity score (points)	4 (1–8)	4 (2–8)	(n. s.)

KSS Knee Society Score, *KSFS* Knee Society Functional Score, *ROM* range of motion

n. s. not statistically significant differences between the two groups ($p \geqq 0.05$)

Table 3 Radiographic mechanical axis evaluations [median value (range)]

Angles	Double-high group	Medial-pivot group	*P* value
Pre-operation final	11 (1–20)	12 (1–21)	(n. s.)
Follow-up	1 (−1–5)	1 (−2–5)	(n. s.)

n. s. not statistically significant differences between the two groups ($p \geqq 0.05$)

Plus means varus, minus means valgus alignment

Table 4 Comparisons of range of motion [median value (range)]

	Double-high group	Medial-pivot group	*P* value
Preop. ROM (°)	110 (75–135)	110 (85–130)	(n. s.)
Post 2 months. ROM (°)	102.5 (80–125)	105 (80–125)	(n. s.)
Final ROM (°)	115 (95–130)	110 (90–130)	(n. s.)
Preop. Ext. (°)	−10 (−25–0)	−10 (−25–0)	(n. s.)
Post 2 months. Ext. (°)	−5 (−20–0)	−5 (−20–0)	(n. s.)
Final Ext. (°)	0 (−10–0)	0 (10–0)	(n. s.)
Preop. Flex (°)	120 (90–135)	120 (90–135)	(n. s.)
Post 2 months. Flex (°)	105 (35–125)	110 (90–125)	(n. s.)
Final Flex (°)	115 (100–130)	110 (90–135)	(n. s.)

n. s. not statistically significant differences between the two groups ($p \geqq 0.05$)

Discussion

The most important finding of the present study was that the differences of insert design could not provide clinical benefits at midterm follow-up in ADVANCE TKA. The patients with DH insert gained good clinical improvements; however, there was no clinically significant difference between the patients with MP insert and those with DH insert in ROM, stability, or activity level.

DH inserts were developed to improve ROM, to as much as 150°. In the ROM evaluation in this study, the DH group showed higher median and mean values of ROM; however, the differences were not statistically significant at final follow-up. Furthermore, the results at 2 months after operation suggested that the recovery of ROM postoperatively was constant and slightly faster in the MP group, thus the result of this study demonstrated different findings than the concept of the DH insert for ROM. It is suggested that the expected femoral rollback motion, which is considered to be desirable for deep knee bending [10], might not have been constantly achieved in the DH group in this study. It is also considered that one contributing factor could be the condition of the PCL. In ADVANCE medial-pivot, controversy exists as to whether the PCL should be retained or sacrificed in the presence of this constraint [4, 11, 15, 18]. Some authors opt to retain or discard the PCL during the soft tissue balancing procedure [11]. Other authors recommend complete resection of the PCL [15]. Pritchett pointed out that MP knees with PCL retained will not regain adequate flexion or function [16]. Accordingly in our institution, some cases with severe femoral lift-off and subluxation under the passive flexion manoeuver were experienced during the operation when MP inserts with PCL retained were used soon after this prosthesis was introduced. Thereafter, the PCL was routinely sacrificed in all instances of MP insert usage. For DH inserts, few discussions have focused on the retention or discarding of the PCL [14]. Omori et al. recommended in their cadaveric study that the PCL should be retained when the DH design is used and sacrificed when the MP design is used [14]. Barnes et al. [5] reported that patients implanted with DH TKA exhibited higher mean values of maximum kneeling flexion, compared to MP TKA patients; however, the differences were not statistically significant, consistent with the results of this study. They compared DH inserts with PCL retained and MP inserts with PCL sacrificed at an average of 6–9 months follow-up. However, the influence of DH insert with PCL retained remains unknown because each group contained only 9 patients in their study. In our study, it was supposed that PCL retention might lead to better ROM, via better femoro-tibial kinematics in DH inserts. A direct comparison may be needed to determine the appropriate management of the PCL in DH inserts.

Additionally, stability after DH insert was investigated. In ADVANCE TKA, although the absence of the post-cam mechanism might reduce the risk of postoperative breakage and generation of polyethylene wear particles, joint stability, especially anteroposterior stability, is largely dependent on the constrained design of the insert in the PS condition. Therefore, in the present study, it was hypothesized that the reduced lip might produce more instability in the DH insert, compared to the MP insert. However, results revealed that the stability scores included in KSS, and walking, ascending/descending stairs ability included in KSFS showed no statistically significant differences between the two groups. Generally, it is agreed that patients with TKA walk differently than normal controls [3, 6]. Even if a PS prosthesis is used, kinematics abnormalities are similar to CR prosthesis [6, 7]. Such AP instability induces difficulties for patients such as getting up from a chair, ascending/descending stairs, walking on uneven ground, and performing activities such as playing golf [6]. ADVANCE MP TKA was expected to improve such instability, and actually patients who received TKA preferred this medial-pivot prosthesis [16]. However, the results in the current study imply that the DH design improvements over the MP design did not induce additional instability for patients. One reason may be the activity level of the patients participating in this study. The UCLA activity scores in the current patients *suggested* a relatively low activity level both pre-operatively and postoperatively. A high stability demanding activity such as sports might reveal differences regarding prosthesis-dependent stability.

There are some limitations in this study. Firstly, although this study is a randomized prospective study, this study included a small population based on our previous

clinical study and power analysis, so subtle differences were not detected as significantly different. A larger population study might reveal subtle differences in clinical outcomes, such as ROM. Additionally, there was no subjective assessment; therefore, patients' satisfaction remained unknown in this study. To clarify the differences between normal conditions and postoperative conditions patient subjective assessment is required to assess whether there is a higher level of patient satisfaction after TKA, which would allow the establishment of a more refined TKA.

In summary, the authors believe study results provide useful information for surgeons to aid understanding and appropriate selection of the type of inserts in this prosthesis.

Conclusion

The clinical outcomes of DH inserts compared in this study were equally good compared to MP inserts in ADVANCE TKA at a midterm 4- to 5-year follow-up. The present results suggest that improvements of ROM cannot be expected based only on the design of the DH insert. The results also suggested that differences in insert design only could not improve clinical benefits at midterm follow-up.

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