Early Clinical and Radiological outcomes of the New Anatomic Knee System : Minimum 3-year Follow-up.

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Abstract

Background: For total knee arthroplasty (TKA), implant design and proper coverage are important for achieving patient satisfaction. An asymmetrical anatomic implant (Persona® knee system, Zimmer Biomet, Warsaw, Indiana) enables accurate coverage and minimal bone cutting. This study aimed to analyze the clinical and radiological outcomes of TKA using an asymmetrical anatomic implant over a minimum 3-year follow-up.

Methods: The medical records of 94 patients who underwent 132 TKAs using the Persona® knee system, between April 2015 and January 2016 were reviewed. Pre- and post-operative clinical outcomes (assessed using the International Knee Documentation Committee (IKDC), Western Ontario and McMaster Universities Arthritis Index (WOMAC), and Knee Injury and Osteoarthritis Outcome Score (KOOS) scores, and range of motion (ROM) were reviewed. The mechanical hip-knee-ankle (HKA) axis, component overhang and underhang and presence of a radiolucent line (RLL) were evaluated. Liner thickness were also reviewed.

Results: At 3-year follow-up, the mean ROM improved from 108.4° to 130.3°. The mean IKDC subjective, WOMAC and global KOOS score significantly improved from 29.2 to 70.3, from 64.2 to 11.5, and from 66.6 to 21.7, respectively ($p<0.0001$). The mean mechanical HKA axis indicated the correction of the malalignment (from 9.2° varus to 0.3° varus, $p<0.001$). The incidence rates of >3-mm bone-to-implant size mismatch were 6.8% and 8.3% for the femoral and tibial components, respectively. RLL was found in seven cases, but they were small (>2 mm) and did not progress. In 36.3% of the knees, the additional liner thickness (11 or 13mm) was used. No case of implant loosening or early failure related to the implant design occurred.

Conclusion: TKA using the Persona® knee system improved all the clinical knee scores and ROM without signs of early failure. This knee system also provides more implant size options than the conventional TKA systems and facilitates ligament balancing.

Introduction

Total knee arthroplasty (TKA) is one of the treatments of choice for patients with end-stage osteoarthritis (OA) and one of the most successful procedures in the field of orthopedic surgery [1]. While surgeons and patients can expect excellent implant survivorship with many of the currently available TKA systems, patients satisfaction with the new knees is not always achieved [2–6]. Moreover, patients are becoming more demanding and informed, and they expect to return to their previous level of activity with a natural-feeling knee with normal function [2, 6]. The factors that determine patient satisfaction, and knee function after TKA are surgical technique, implant design, alignment, postoperative rehabilitation exercise, and patient life style modification [7–9].

Internal rotation of tibial or femoral components has been linked to poor clinical outcomes [10, 11]. It has also been reported to be a major cause of pain and functional problem after TKA [11–13]. Therefore,

ensuring proper rotation of the components is key to a successful TKA surgery. However, focusing only on the ideal rotational alignment may compromise the other surgical objectives, including component overhang and bony coverage [13].

Various studies that compared the anthropometry of the knees of Asian and Western European patients have revealed that Asian knees not only are smaller in size but also has a significantly different tibial aspect ratio (ratio of the mediolateral dimension to the anteroposterior dimension) [14, 15]. As most knee designs are based on the anthropometric data of Western European patients, bone-to-implant size mismatch occurs frequently in Asian patients. Generally, concerns were raised that overhang and underhang could induce pain from the irritation of soft tissues and lead to implant subsidence and failure, respectively [16]. Therefore, an implant design that would ensure a more accurate rotational position of the implant and proper coverage regardless of patient ethnic background is needed.

The asymmetrical anatomic implant used in this study (Persona® knee system, Zimmer Biomet, Warsaw, Indiana) has undergone several design changes to reduce the problems usually associated with the conventional TKA implants. First, on the basis of the global bone atlas, they have changed to many implant sizes for various bone sizes, regardless of race. Second, the medioposterior area of the tibial component is asymmetrical in shape and slightly longer than the lateral measurements, giving it a more anatomical shape [14, 17–19]. Hence, it can facilitate proper rotation with unprecedented surface coverage [13–15, 20]. Third, the femoral components are of two types, standard and narrow. This update can prevent overhang or underhang of the component [18]. The liners of the Persona system are available in 1-mm increments range from 10 to 14 mm (i.e., 10,11,12,13,14mm), which are useful for achieving accurate ligament balance.

Some of the advantages have been mentioned earlier; however, implant instability and loosening may occur owing to a short stem length or the short and narrow keel design of the tibia. Moreover, whether a high level of knee flexion can be achieved with less cutting of the posterior femur bone than with the previous conventional model (NexGen-LPS-Flex® system (Zimmer Biomet, Warsaw, Indiana) remains to be elucidated [21]. To the best of our knowledge, only a few studies have reported short-term outcomes and no study has used this implant system in Asian knees [22, 23]. Therefore, the primary aim of our study was to evaluate the clinical outcomes of the Persona® knee system including whether it could achieve a higher level of knee flexion. Our secondary aim was to determine whether implant-related early failure or early implant loosening occurs by using radiography. Finally, we aimed to determine whether the incidence of overhang and underhang can be reduced with the Persona® knee system.

Materials And Methods

1) Patient selection

The medical records of 102 patients who underwent 143 TKAs using the anatomic Persona® knee system between April 2015 and January 2016 were retrospectively reviewed. Ethical board approval was

obtained from the Inha University Hospital Institutional Review Board (approval number: INHAUH 2018-08-026). Among the patients, eight patients (11 TKAs) were excluded from the study, including two who lived in a foreign country, three who lived in rural areas, one who was diagnosed as having an infected TKA and underwent a second-stage revision surgery at 1.6 years after the first surgery, and two who expired from unrelated causes (lung cancer, and liver cirrhosis, respectively). After the exclusion criteria were applied, 94 patients (132 TKAs) were included in the study. The indications for surgery included degenerative arthritis in 126 knees, rheumatoid arthritis in three knees, and spontaneous osteonecrosis in three knees. The mean subject age was 69.5 (range, 51 – 84 years) at the time of surgery, and the mean follow-up duration was 3.1 (range, 3 - 3.5 years). The study consisted of 14 male (18 knees) and 80 female patients (114 knees).

2) Surgical treatment and postoperative management

All the knees received TKA surgery using the Persona knee system® prosthesis, which has a fixed bearing as a posterior stabilized (PS) type. Full-length weight-bearing radiographs that showed the hip, knee, and ankle joints were obtained preoperatively. The angle of the femoral and tibial cuts and the desired position of entry were all planned preoperatively. All the surgeries were performed by one experienced surgeon who used the same technique for each procedure. A 12 to 13.5cm anterior midline skin incision was made, and a capsular incision was performed using a medial parapatellar approach in all the cases. Distal femurs were resected using an intramedullary guide with a valgus angle of 5°, 6°, or 7°, one of which was chosen on the basis of the difference between the anatomical and mechanical axis from the preoperative standing long leg antero-posterior (AP) view. Posterior femoral osteophytes were removed as much as possible. The femoral component was placed in 3° to 5° of external rotation to the posterior condyles, and this was checked using the transepicondylar axis and Whiteside line. By using an extramedullary tibial guide, approximately 10 mm of tibial bone was resected to obtain a surface perpendicular to the shaft of the tibia in the coronal plane, with a 3° to 5° posterior slope in the sagittal plane depending on the characteristics of each patient. Considering the 5° slope of the tibial plate design itself of the PS type Persona knee system® and manufacturer guide, the slope of the tibia was set to 3° when the preoperative tibial slope was within 12°. In case of a preoperative tibial slope of >12°, the slope of the tibia was set to 5° [24].

Stability and alignment were assessed using the trial components, and the varus-valgus balance of the soft tissues was emphasized in both flexion and extension with resection of the posterior cruciate ligament. The tibial component position was determined using the Akagi line and anterior border of the tibia.

Bone-to-component size mismatch (overhang or underhang) of the femoral component was measured medially and laterally at the cut surfaces (anterior, distal, and posterior cuts). The tibial component was measured at medial and lateral cut surfaces (anterior, middle, and posterior) [25]. It was measured from the bone margin to the implant border of each cut surface using a scale. If the overhang or underhang

was measured in multiple areas, the largest value was set as the size mismatch value [26–28]. Considering a 1-mm measurement error, minor overhang was defined as a measured distance of 1 to 3mm; and major overhang, as a measured distance of >3 mm between the implant and the resected bone edge in any zone. By contrast, minor underhang was defined as 1 to 3 mm, and major underhang was defined as smaller by > 3 mm. Measurements within 1 mm of overhang or underhang were considered to indicate proper coverage [18, 29]. The degrees of overhang and underhang were compared with those in a previous cases study that used the NexGen-LPS-Flex® system (Zimmer Biomet, Warsaw, Indiana) [30].

Patellar resurfacing was performed in 29 of the 132 knees because a broad cartilage defect was present (International Cartilage Repair Society grade 3 or 4) on the patellar articular surface. If patellar resurfacing was not performed, patelloplasty was carried out. This consisted of electrocautery of the patellar rim to provide partial denervation, peripatellar synovectomy, and removal of osteophyte. The femoral, tibial, and patellar prosthesis components were fixed with cement.

On the first or second postoperative day (within 48 hours), the Hemovac drain was removed, and continuous passive motion exercises were started. At the same time, the patients began active knee motion by walking with crutches or a walker. Two weeks after surgery, the stitches were removed and patients were discharged with a walker

3) Clinical and radiological outcome

Clinical assessments

All patients received clinical follow-up, and standing AP and lateral view radiographs were taken at postoperative weeks 2 and 6; at postoperative months 3, 6, and 12; and then annually thereafter. Clinical scores including the Global Knee Injury and Osteoarthritis Outcome Score (KOOS), Internal Knee Documentation Committee (IKDC) subjective form, Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores, and pre and postoperative ranges of motion (ROM) were recorded. Maximum flexion was measured before surgery and during outpatient clinic follow-up by using a manual goniometer with the arms aligned along the long lateral axes of the femur and tibia. Flexion contracture was similarly measured and reported. ROM was calculated by subtracting flexion contracture from the maximum flexion. The liner thickness used was reviewed. Any complications related to TKA were also reviewed.

Radiological assessments

Radiological assessments were performed at the same time as the clinical assessments using by AP radiography in a standing position (except for the supine position radiography which was taken immediately after surgery) and lateral view using the radiological evaluation system of the Knee Society [31, 32]. The degree of malalignment was measured using the mechanical tibiofemoral axis (same as hip-

knee-ankle (HKA) axis). Radiolucent lines (RLLs) were defined as the radiolucent intervals (measured in millimeters) between the cement and the bone [33] and were categorized as physiological and pathological lines. A non-progressive <2-mm-thick RLL was defined as a physiological RLL. In addition, a physiological RLL was usually surrounded by a sclerotic margin and not considered loosening. However, a pathological RLL was >2 mm thick and had a poorly defined progression [30]. The position of the zones was used to describe the location of the radiolucencies followed by the Knee Society total knee replacement radiological assessment of the radiolucent lines [31, 32]. It was related to aseptic implant loosening [30, 34].

4) Statistical analyses

Continuous variables were described as mean, standard deviation (SD), and range values. A paired t-test was used to compare the differences in clinical and radiological outcomes, which were repeatedly measured in pre- and post-operative treatments. The chi-square and Fisher's exact tests were used to compare the prevalence rates of overhang and underhang with those when previous implants were used. A p value of <0.05 was considered statistically significant. Statistical analyses were performed using SPSS software (ver. 18.0; SPSS, Inc., Chicago, IL, USA).

Results

Clinical results

The pre-operative mean flexion contracture, maximum flexion, and ROM were 7.5° (range: 0 to 25°), 115.9° (90 to 145°), and 108.4° (70 to 145°), respectively At a mean 3.1 years of follow-up, the mean flexion contracture was 1.2° (0 to 10°); mean maximum flexion angle was 131.5° (105 to 150°); and mean ROM was 130.3° (105 to 150°). At the final follow-up, the mean IKDC subjective score increased from 29.2 (SD 13.2) to 70.3 (SD 6.6); the mean WOMAC score improved from 64.2 (SD 12.1) to 11.5 (SD 4.5); and the mean global KOOS score improved from 66.6 (SD 11.7) to 21.7 (SD 5.8). All these changes were noted to be significantly improved ($p<0.0001$) (Figs 1 and 2).

When comparing the ratio of pathologic to proper coverage, the tibial component showed a significantly lower incidence of size mismatch than did the previous conventional implant ($p = 0.03$). However, no significant difference was found in the femoral component ($p = 0.19$) (Table 1). A total of 48 cases used liners of 11mm and 13 mm thick, which was 36.3% of the total knees (Fig 3). Of the 132 TKAs, 81 (61.3%) required ligament release procedure, including the fine needle pie crust technique [35].

Table 1
Comparison of bone-to-component size mismatch compared with the conventional implant.

	Persona ® (n=132)	NexGen LPS-Flex ® (n=122)	P-value
Femoral component Overhang > 3 mm	6	10	
Overhang 1-3 mm	18	23	
Proper coverage*(within 1 mm)*	99	81	
Underhang 1-3 mm	8	4	
Underhang > 3 mm	3	4	
Pathologic	9	14	*0.19*
Tibia component Overhang > 3 mm	0	1	
Overhang 1-3 mm	10	9	
Proper coverage*(within 1 mm)*	70	42	
Underhang 1-3 mm	41	50	
Underhang > 3 mm	11	20	
Pathologic	11	21	*0.03*

Radiological results

In all of the study subjects, the mean preoperative mechanical HKA axis was 9.2° varus (SD 7.6) and 0.3° varus (SD 2.3) at the final follow-up, which indicated that the malalignments were corrected ($p < 0.001$, Fig 4). However, to reduce the error due to the sum of the varus / valgus values, the absolute value was compared. The preoperative mean absolute value of malalignment was 9.61° (SD 4.96). At the final follow-up, the mean absolute value of alignment was 0.58° (SD 0.45) which means that it is within an acceptable range.

On the basis of the lateral radiographs, seven (5.3%) of the 132 cases had RLL. Five of the RLL cases were less than 1mm and the other two cases were 1 and 1.3 mm. However, the radiograph obtained 3-years after surgery, no increase in RLL size, component displacement, or aseptic loosening. Moreover, six cases of RLL were observed on the femoral component, five on anterior surface zones 1 and 2 and one on posterior surface zone 4. One case of RLL was found on the tibial component, which was observed at zones 1 and 2 on the AP radiograph and at zone 1 on the lateral radiograph (Fig 5). None of the patients had pain associated with RLL.

Complications.

One knee developed a moderate degree of hematoma at three days after surgery. Needle aspiration was performed and compression dressing was applied. Five days after the procedure, the hematoma was resolved. One male patient was diagnosed as infection TKA at 19 months after primary TKA. He underwent second stage revision surgery for infection TKA, no signs of recurring infection were observed in 12 months follow-up period. No other complications such as periprosthetic fracture or loosening occurred during the 3.1 years follow-up periods.

Discussion

In this study, the primary aim was to evaluate the clinical outcomes of TKA using the Persona® knee system, including whether it could achieve a high level of knee flexion. TKA using the Persona® knee system can improve clinical knee scores and ROM. Patients in this study also had a mean of 131.5° of knee flexion with this new knee system. These results were similar to those of our previous study (mean ROM: 131.76°) [30] and another 3-year follow-up study (Kim et al. mean maximum flexion: 135°) [36] that used the NexGen LPS-Flex® system. The secondary aim was to determine with radiography the occurrence of early implant failure or loosening. No evidence of early implant failure or loosening was found after the procedure during the mean 3-year follow-up. No other complications or problems related to the new implant were observed. The third aim was to evaluate whether the incidence of overhang and underhang can be reduced with the use of the Persona® knee system. In the results of this study, the incidence of bone-to-implant size mismatches at the tibia was reduced as compared with that with the NexGen LPS-Flex® system [30].

General concerns that are still controversial are that component overhang could induce pain from the irritation of soft tissues and underhang could lead to subsidence and failure. In this study, the incidence rates of severe overhang and underhang (>3 mm) were decreased with the Persona® knee system as compared with NexGen LPS-Flex®, which could be important in improving clinical outcomes. However, several studies reported that clinical outcomes related to size mismatch are different at least 3-years after surgery [15, 28, 29, 37]. In the present study, only the incidence rates of overhang and underhang were confirmed. To evaluate the differences in clinical implication with conventional implants, further study is needed about the clinical correlation of bone-to-implant size mismatch and pain location.

The size mismatch of the tibial component decreased significantly. This is considered to be an effect of the anatomically asymmetric tibia design [14]. Hartel et al. [38] reported that the anatomic tibial component design offer superior component coverage as compared with the non-anatomic designs. For accurate rotation of the tibial component, the medial compartment showed a tendency to underhang when a symmetrical design was used [13, 17, 38]. Mismatches in the medial compartment size and anterior radius lead to malrotation of the tibial tray to maximize coverage or make a compromise with posteromedial coverage to maintain proper rotation. By contrast, the anatomic design reflects all three areas of asymmetry (anteroposterior, boxiness [39], and anterior radius) in the resected tibia. The

anatomic design can more accurately guide the rotational position of the tibial tray by matching the medial and lateral anterior radii of the component with those of the resected tibia surface [13].

The thickness of the liner used is difficult to statistically evaluate because of the lack of an object for direct comparison with it. However, the added liner thickness of 11 or 13 mm was used in 36.3% of all cases, which provides more options for surgery. Additional procedures (e.g., ligament balancing and additional bone cutting) can be omitted, thereby reducing surgery time. Limited liner thickness options compromise the ideal balance and stability. Therefore, through various of insert thickness, proper ligament balance, which can help improve longevity, can be obtained more easily and accurately [40, 41].

This study has several limitations. First, this study was a retrospective study with no clear comparison group. The most appropriate group with which to compare short-term results would be a group of patients who underwent TKA with conventional implants. However, most short-term follow-up results from TKA using conventional implants are also good and this will not help to determine the possible early failure of a newly developed device. Second, the follow-up period was short. The mean follow-up period of 3.1 years may not be meaningful because many reports have good results only after a long follow-up period [1, 42]. Regardless, identifying potential early failure or device-specific problems with new implants is still valuable. Third, to ensure that the accuracy of the tibial component rotation improved, all patients should undergo a post-operative computed tomography scan; however, this was not performed in this study.

Conclusions

TKA using the Persona® knee system improved the bone-to-implant size mismatch of the tibia component as compared with the conventional implant (NexGen-LPS-Flex® system), without any indications of significant early failure at the 3-year follow-up. However, no significant difference was found in the femoral component. The Persona® knee system also facilitated ligament balancing with additional liner thickness options (11 and, 13mm). Nevertheless, we cannot conclude that clinical outcomes are better than those obtained with the conventional TKA implants. To demonstrate the superiority of the Persona® TKA prosthesis, randomized comparative studies with longer follow-up periods are necessary.

List Of Abbreviations

TKA: Total knee arthroplasty; OA: Osteoarthritis; PS: Posterior stabilized; KOOS: Knee Injury and Osteoarthritis Outcome Score; IKDC: International Knee Documentation Committee; WOMAC: Western Ontario and McMaster Universities Arthritis Index; ROM: Range of motion; AP: Anteroposterior; HKA: Hip-knee-ankle; RLL: Radiolucent line.

Declarations

Ethics approval and consent to participate

Ethical board approval was obtained from the INHA University Hospital Institutional Review Boards **(Approval number: INHAUH 2018-08-026).** This retrospective study received exemption from obtaining informed consent by the Institutional Review Board of Inha University Hospital.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the present study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors’ contributions

DJR performed the interpretation of data and drafting of manuscript. YSJ had substantial contributions to conception and design. BKS and YN were responsible for acquisition and analysis of data and performed the statistical analysis. SJP had been involved in revising the manuscript critically. MKK is an experienced knee surgeon who designed this study. All authors have read and approved the final manuscript.

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Figures

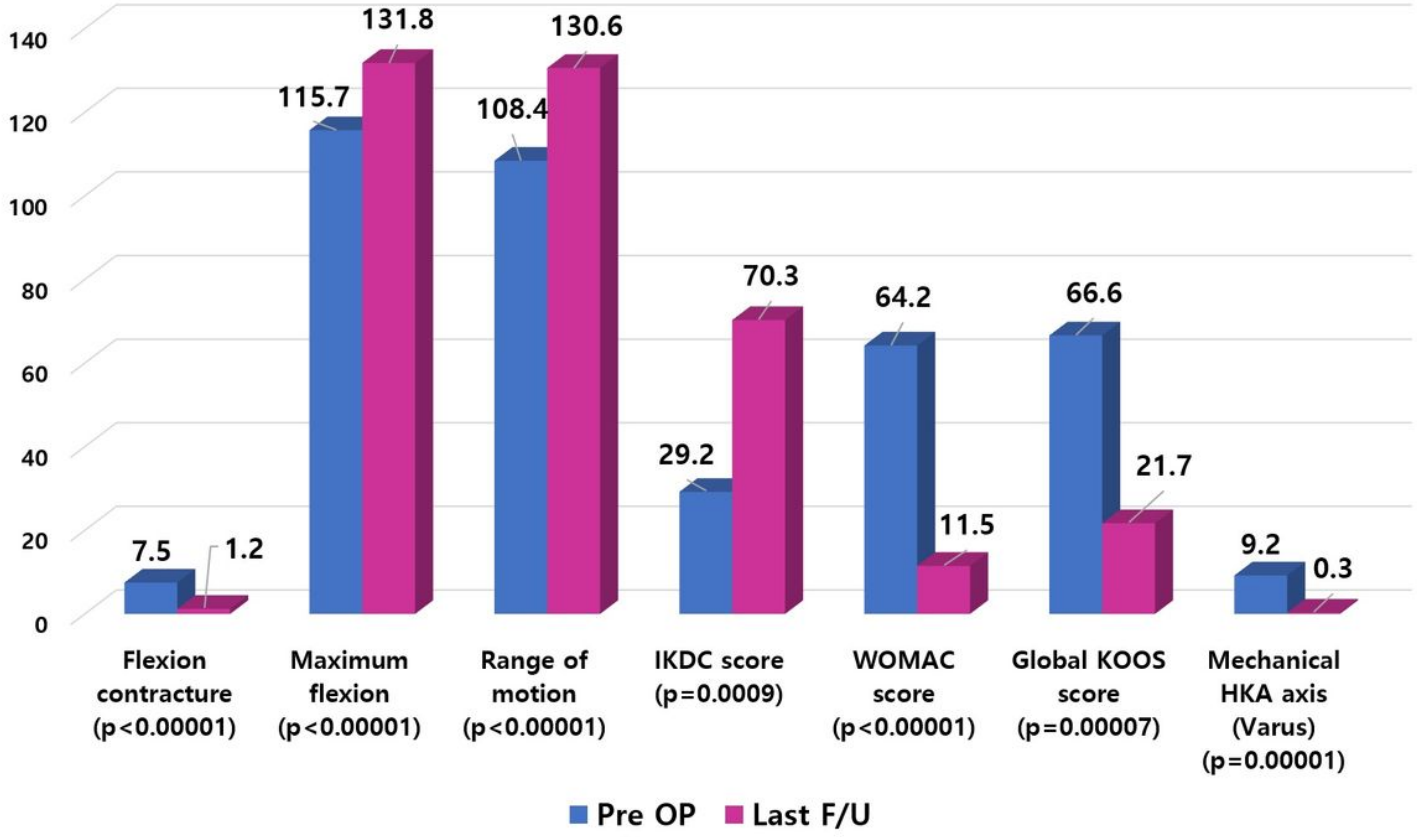

Figure 1

Changes in the preoperative and final follow-up values.

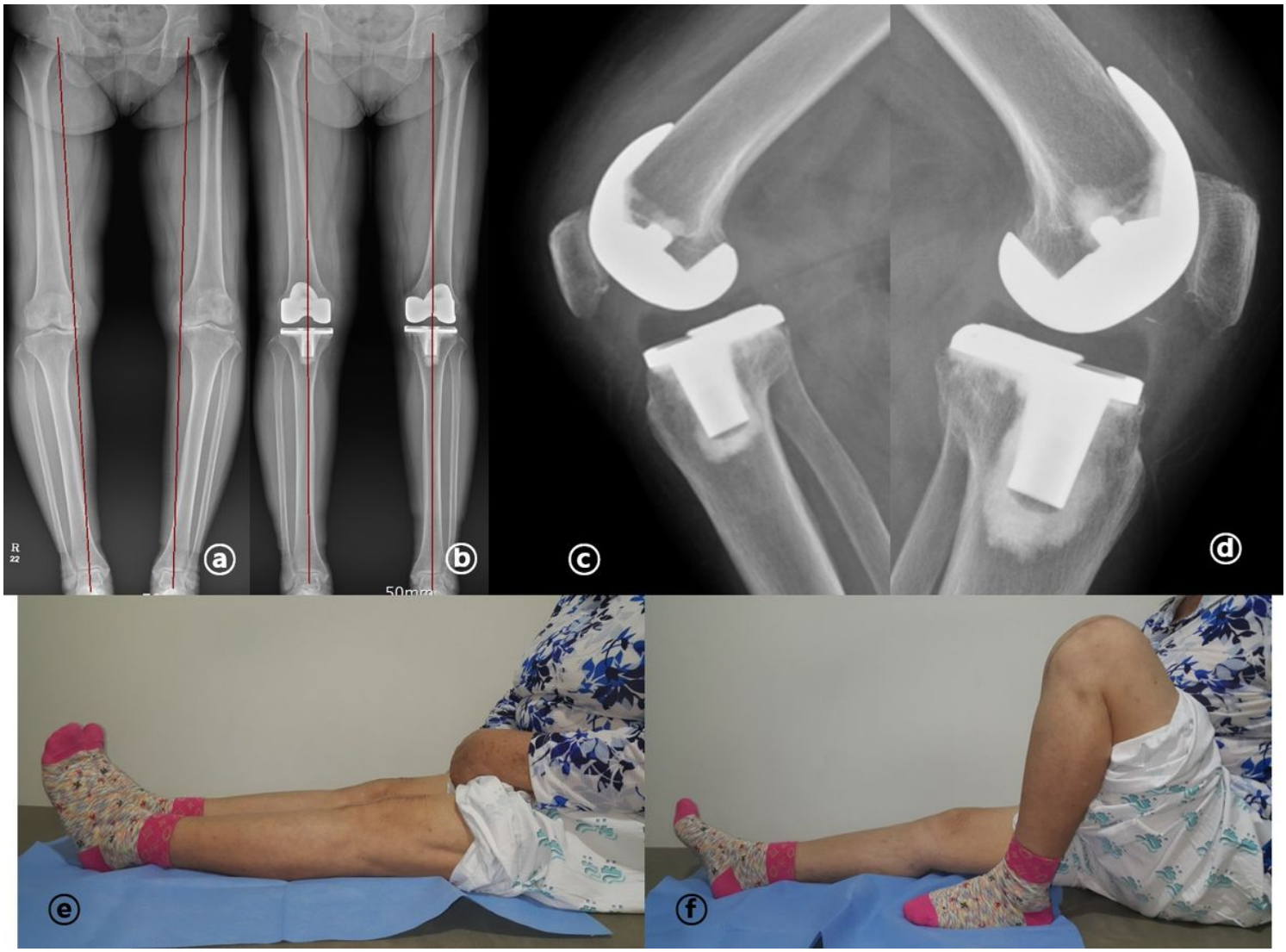

Figure 2

A 68-year-old female with osteoarthritis in both knees underwent total knee arthroplasty using the Persona® knee system. □ Preoperative knee standing radiograph of the low extremity long view (hip-knee-ankle (HKA) angle right: varus 12.4°, left: varus 16.2°). □ At 3-year follow-up, post-operative knee standing lower extremity long view (HKA angle right: varus 0.4°, left: varus 0.1°). □, □ At 3-year follow-up knee AP, lateral views show no loosening or other implant failures. □, □ The patient could perform ROM exercise from 0° to 145° without pain at the 3-year follow-up.

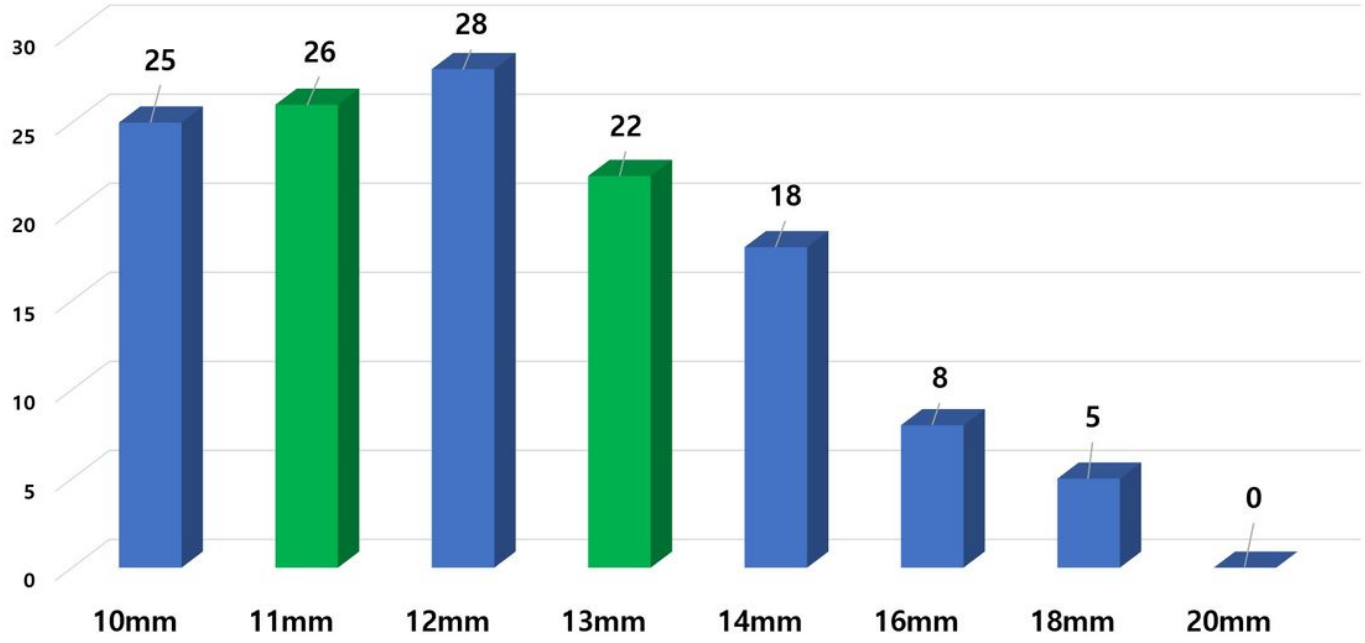

Figure 3

The liner thickness used during primary total knee arthroplasty with the Persona® knee system.

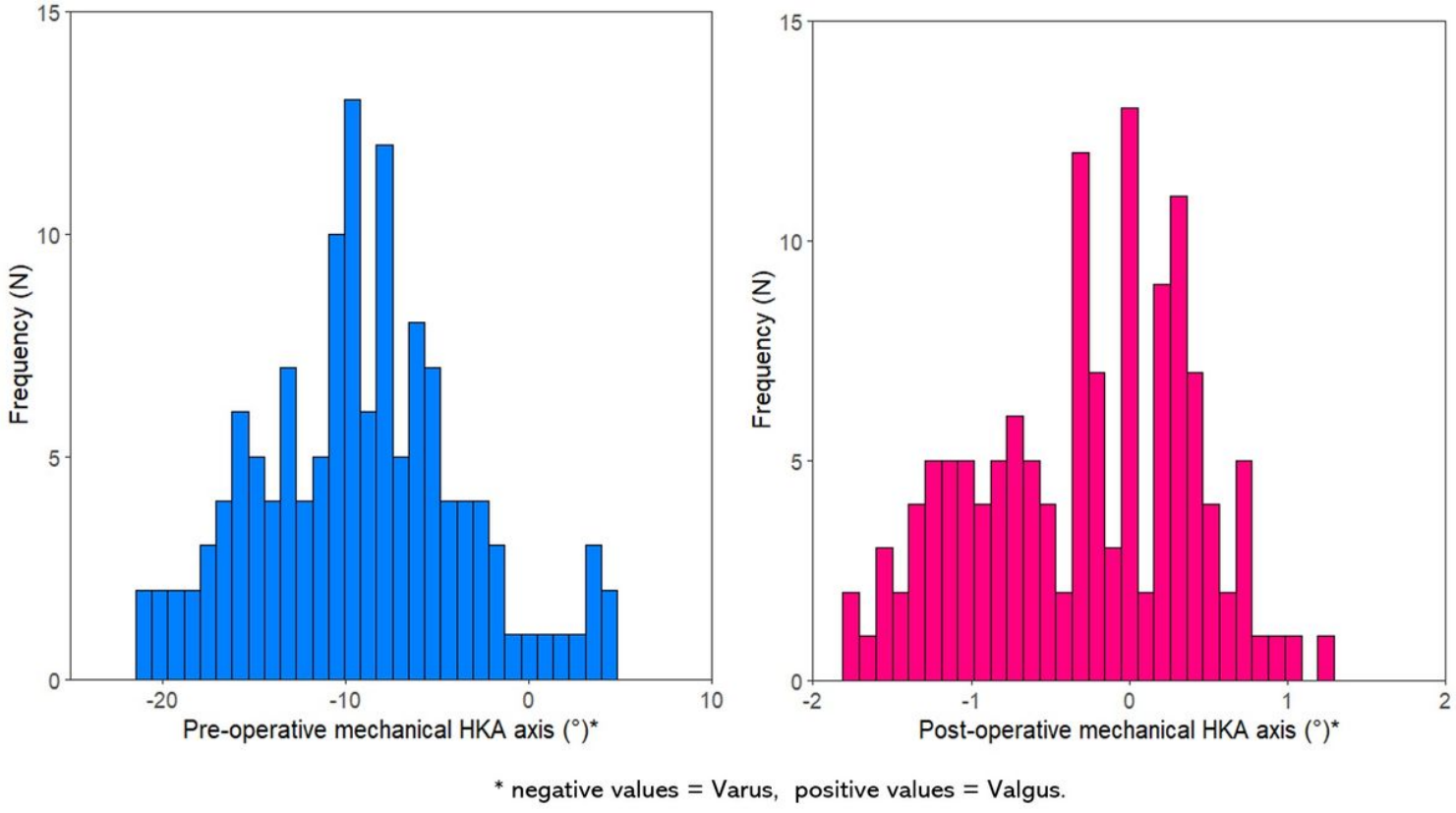

Figure 4

Distribution of pre-operative (left, blue color) and post-operative (right, red color) mechanical HKA axis measurements. Negative values are varus and positive values are valgus.

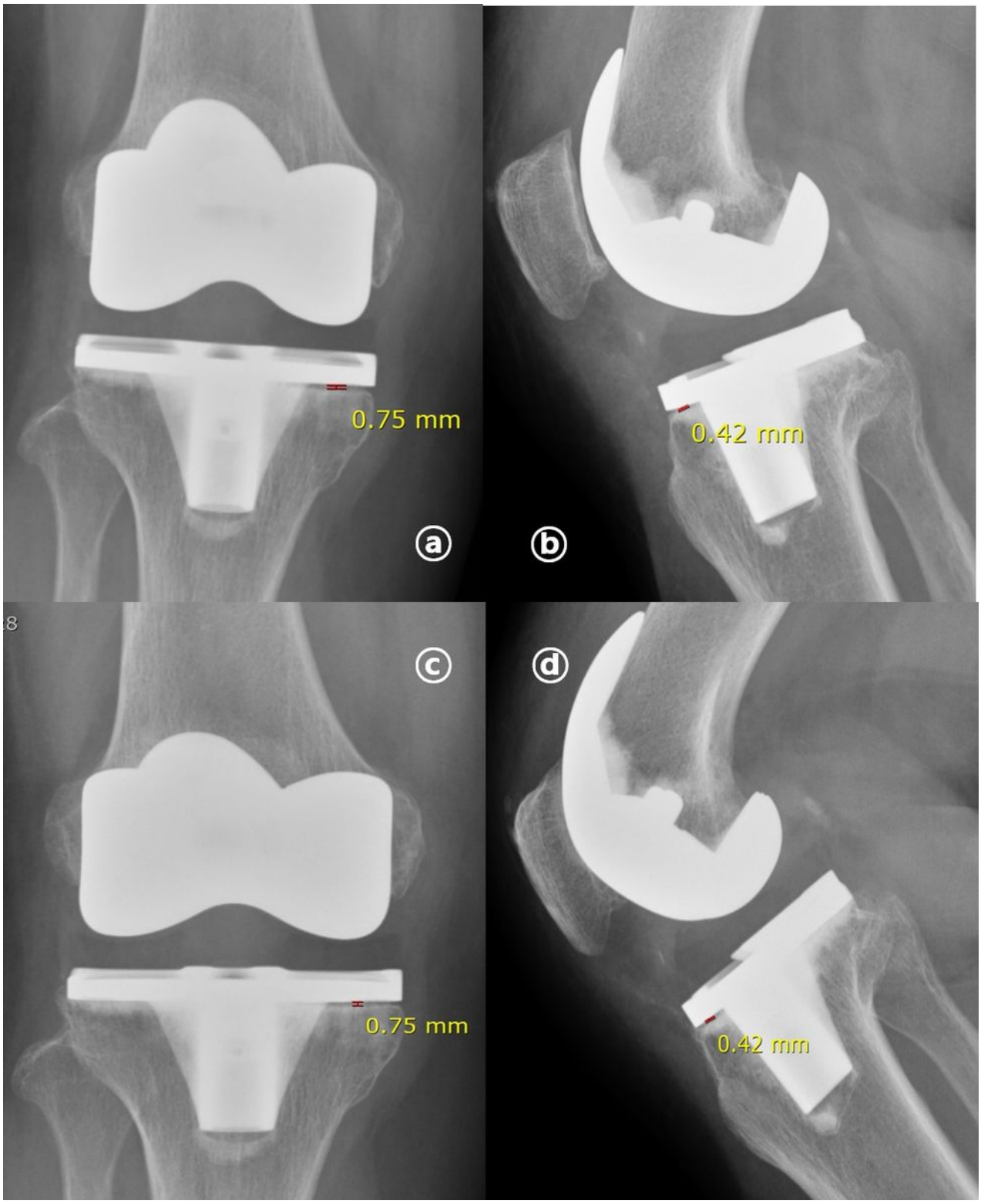

Figure 5

Right anteroposterior and lateral knee radiograph of a 72-year-old female patient showing a radiolucent line at zones 1 and 2 (AP view) and zone 1 (lateral view) of the tibial component (□, □) at 6-month follow-up. There is no widening of the radiolucency line at the 3-year follow-up (□, □).