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Patients undergoing total knee arthroplasty using a contemporary patella-friendly implant are unaware of any differences due to patellar resurfacing

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Abstract

Purpose Anterior knee pain after total knee arthroplasty (TKA) is often unexplained, spurring ongoing debates on the need for patellar resurfacing. It was hypothesized that a contemporary patella-friendly implant would restore patellofemoral kinematics more physiologically than outdated implants and that there would be no perceived or clinically demonstrable differences due to resurfacing of patella (RP).

Methods This prospective bilateral randomized study was undertaken in 49 patients scheduled for the same-day bilateral TKAs. One knee was subjected at random to RP while withholding RP on the opposing side (non-RP). A recently approved single-radius femoral prosthesis featuring a deep, elongate trochlear groove with lateral tilt and a high lateral flange was implanted bilaterally in all patients. Mean follow-up duration was 5 years. Group comparisons were based on patient-reported outcomes [anterior knee pain, Forgotten Joint Score (FJS), and side preference], physician-rated results [Feller patellofemoral (PF) score], radiographic patellar position, patella-related complications, and need for reoperation.

Results There were no differences in midterm rates of anterior knee pain (RP 8%; non-RP 4%; n.s.), FJS (all n.s.), or side preference (RP 47%; non-RP 45%; n.s.), nor did the groups differ by Feller PF score (all n.s.) or radiographic patellar position (all n.s.). No secondary resurfacings of non-RP or RP revisions were required.

Conclusions Patients were incapable of distinguishing whether RP was done, casting doubt on its benefits. Surgeons may thus forego RP during TKA when using contemporary patella-friendly TKA implants.

Level of evidence Therapeutic study, Level I.

Keywords Osteoarthritis · Patella · Patellar resurfacing · Patella-friendly design · Total knee replacement

Introduction

The etiology of anterior knee pain (AKP) after total knee arthroplasty (TKA) is often elusive, fueling debates on the need for patellar resurfacing [1, 5, 8, 23]. Many surgeons are committed to routine resurfacing of the patella (RP) based on evidentiary claims that AKP and rates of reoperation are thereby reduced [20, 21]. In some instances, RP is done only as warranted by the intraoperative status of patellofemoral (PF) cartilage, thus avoiding unnecessary resurfacing and its related risks [12]. However, the intraoperative state of PF cartilage bears no strong association with symptoms [2, 9, 24], and

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newly developed AKP may occur following RP. In addition, a substantial proportion of patients subjected to secondary resurfacing experience no relief from AKP [2, 18, 28]. It is also likely that rates of reoperation in patients who forego RP are artificially high, given that secondary resurfacing is their only remedial surgical option [20]. Ultimately, some surgeons choose not to perform RP during TKA procedures. Although it is erroneous to attribute all AKP after TKAs to patellar management, such contradictory evidence makes it difficult to establish the best practices.

Design and position of prosthetic componentry are important factors in postoperative AKP and increasingly have prompted attempts to replicate human anatomy [25, 26, 29]. Most of the currently available implants incorporate "patella-friendly" concepts to optimize patellar tracking, thus improving kinematics and lowering PF contact pressure. These designs typically include deepening and elongation of intercondylar notch, a laterally oriented trochlear groove, and a high lateral flange [15, 16, 20]. A single-radius femoral component is also known to benefit PF joint by reducing joint reaction force [20]. In theory, such modifications should have merit whether or not RP is performed. However, this remains unproven and the current available data are conflicting. Therefore, a comparison between knees that underwent different patellar management in a single patient might be the best method of assessing the difference between RP and non-RP. However, results of several earlier randomized bilateral trials are supportive of RP [6, 19, 28], whereas others have shown no difference [2, 4, 11, 27]. In addition, most of the implants under investigation in the previous studies were developed 30 years ago, and the assessment tools applied were either ill-suited or lacked the sensitivity to detect subtle PF changes [2, 4, 6, 11, 19, 27, 28]. Hence, the impact of contemporary patella-friendly implants on postoperative patient perceptions remains uncertain.

The aim of this prospective bilateral randomized study of patients undergoing the same-day bilateral TKAs was to determine whether RP can be distinguished by prosthetic recipients, while also comparing midterm clinical outcomes and rates of complications. The hypotheses of this study were the following: contemporary patella-friendly implants would restore patellar kinematics more physiologically than outdated implants, there would be no perceived or clinically demonstrable differences between RP and non-RP when evaluated by recently developed validated outcome tools that assess the awareness of a prosthetic knee and PF function, and rates of reoperation would be similar.

Materials and methods

Between December 2012 and August 2013, a total of 55 patients were scheduled for the same-day bilateral TKAs. Upon approval by our institutional review board, one knee in each patient was randomly selected for RP, while foregoing RP on the opposite (non-RP) side. Eligibility criteria included age < 75 years, American Society of Anesthesiologists (ASA) score of 1 or 2, and authorization for same-day bilateral TKA. Patients with a diagnosis other than primary osteoarthritis, who declined to participate in this trial, or who failed to provide informed consent were excluded. Six of the fifty-five enrollees were subsequently excluded (one with rheumatoid arthritis, one with post-traumatic arthritis, and four patients who declined to participate) leaving forty-nine subjects. A computer-generated randomization table, divided into blocks of four and six, was used for random designation of patient knees as RP or non-RP. A scrub nurse, uninvolved in recruiting patients for this trial, revealed allocation at start of surgery. During the entire study period, all medical records and radiographs of patients were recorded electronically at our hospital database and only authorized healthcare providers of this study were allowed to access. Neither the patients nor the investigator (one of the authors) collecting clinical data prospectively was aware of knee assignments until all final analyses were completed. Ultimately, 49 patients (98 knees) in 48 women and one man were assessed (Fig. 1). Mean age was 70 years (standard deviation 5.8 years), and mean body mass index (BMI) was 27.4 kg/m^2 (standard deviation 4.9 kg/m^2). There were no differences in preoperative clinical conditions, including range of motion (ROM) and intraoperative grading of patellar articular surface by Outerbridge scale [17], Knee Society scores, Western Ontario McMaster University Osteoarthritis Index (WOMAC), and Feller PF scoring (PFS) [7] (Table 1). Final outcome adjudications were completed in February 2018. The mean follow-up period was 5 years (range 4.6–5.3 years). The study protocol was registered at ClinicalTrials.gov (NCT02683460).

All operations were performed by a single surgeon (one of the authors) in standard fashion. A posterior-stabilized knee system (Lospa; Corentec Co, Ltd., Seoul, Korea) developed in 2010 was implanted in all patients. Its single-radius femoral component incorporates cutting-edge patella-friendly design concepts with dome-type all-polyethylene (PE) patellar constituents, including lateral orientation of the trochlear groove, a high lateral flange, and a deeper and longer intercondylar notch than its competitors [Vanguard (Zimmer Biomet, Warsaw, IN, USA) and Triathlon (Stryker Orthopaedics, Mahwah, NJ, USA)] (Fig. 2). A subvastus approach was taken, using cement

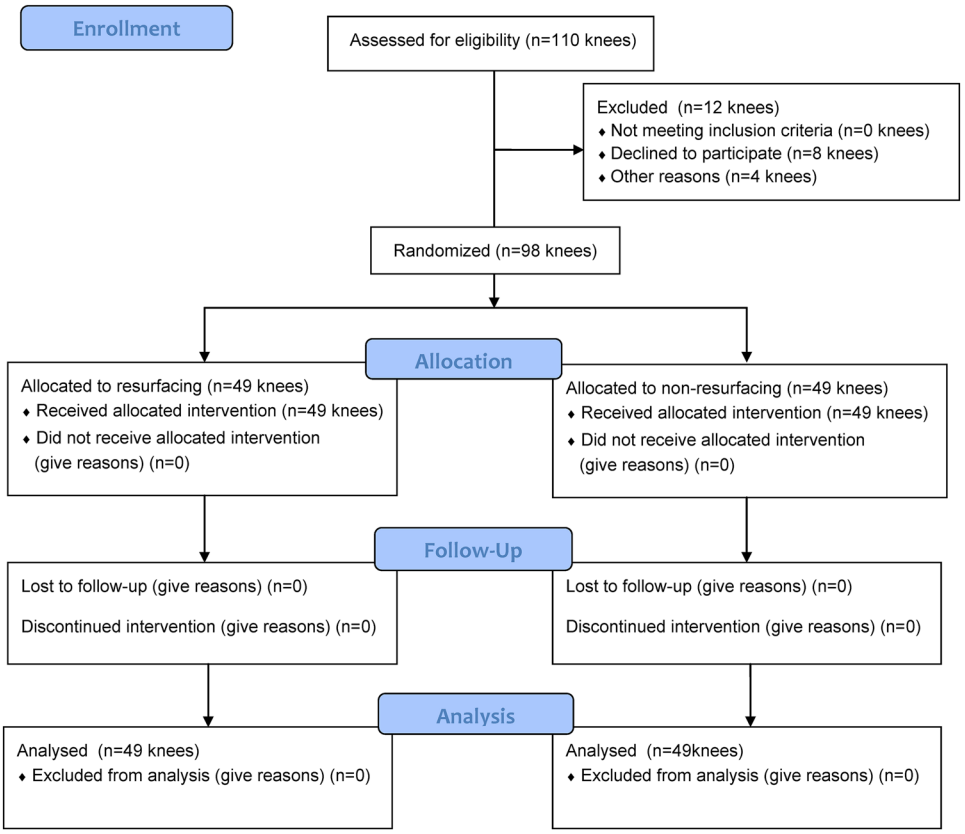

Fig. 1 Schematic of study design

fixation for all components in every instance. The patella was either resurfaced or not, as designated by the random allocation. Patellar thickness was obtained so that patellar PE thickness could replicate preoperative dimensions. All patients received the general anesthesia and a multimodal perioperative management protocol. Beginning at postoperative day 1, patients were encouraged to ambulate using a walker and engage in increasingly strenuous range of motion (ROM) exercises while in bed. Patients were then monitored with follow-up visits at 6 weeks, 3 months, 6 months, and 1 year, with yearly visits thereafter.

The primary study endpoint was prevalence of AKP, with secondary endpoints of Forgotten Joint Score (FJS) [3], side preference, Feller PFS, and radiographic assessment of patellar position, in addition to rates of patella-related complications and reoperation at minimum 4 year follow-up. Rates of AKP, FJS, and side preference were recorded to assess patient awareness of between-knee differences. A blinded investigator (one of the authors) recorded any existing AKP and estimated its severity by visual analog scale (VAS), ranging from 0 (no pain) to 10 (worst imaginable pain). AKP was characterized as continued, newly developed, subsided, or absent postoperatively. The FJS is a 12-item patient questionnaire used to gauge artificial joint awareness during daily activities. Patients selected one of five scored responses (never, 0 points; almost never, 1 point; seldom, 2 points; sometimes, 3 points; mostly, 4 points) to a series of related questions. Side preferences expressed by patients were recorded preoperatively and at last follow-up visits. To compare midterm clinical outcomes, Feller PFSs and radiographic data on patellar position were analyzed, as well as rates of patella-related complications and reoperation. A blinded investigator (one of the authors) elicited Feller PFSs at each visit and evaluated for any patellar crepitus or clunk. Likewise, reoperation for any reason was recorded.

Radiographic imaging was performed under fluoroscopic guidance at every follow-up visit and stored in Digital Imaging and Communications in Medicine format, utilizing ruler and protractor functions of Picture Archiving and Communication System software (M-View; Marotech, Seoul, Korea) for measuring purposes. Patellar position was examined in weight-bearing anterior–posterior, lateral, and Merchant views of the knee flexed at 45°, determining patellar tilt, patellar displacement, and Insall–Salvati ratio as previously described [10]. In addition, patella-to-groove distance which was defined as the span from patellar surface to the nadir of trochlear groove was measured comparing postoperative PF articulation of RP and non-RP subsets in sagittal plane. Using a template of the femoral component, PF center and trochlear groove configuration were estimated. By drawing a line from PF center to patellar surface (passing through

Table 1 Patient demographics and preoperative characteristics

Demographic data ($n=49$)			
Age (years)			70 (5.7)
Gender (female)[a]			48 (98%)
Weight (kg)			63.5 (9.9)
Height (cm)			152.7 (9.7)
BMI (kg/m^2)			27.4 (4.9)
	Resurfacing ($n=49$)	Non-resurfacing ($n=49$)	p value
Preoperative parameter			
Range of motion (°)	122.3 (10.3)	121.5 (11.3)	n.s
Flexion contracture	5.7 (6.4)	6.0 (6.4)	n.s
Further flexion	128.0 (6.6)	127.5 (7.3)	n.s
Outerbridge grading [17][a] of patellar articular cartilage			n.s
1	11 (22)	11 (22)	
2	15 (31)	19 (39)	
3	19 (39)	15 (31)	
4	4 (8)	4 (8)	
Knee Society Scores			
Pain	24.2 (11.3)	24.7 (12.2)	n.s
Function	69.9 (19.4)	68.3 (22.1)	n.s
Total	94.7 (28.6)	94.3 (30.1)	n.s
WOMAC			
Pain	28.7 (8.9)	29.2 (8.5)	n.s
Stiffness	10.0 (4.7)	11.2 (4.9)	n.s
Function	102.1 (27.9)	106.2 (25.6)	n.s
Total	141.0 (38.5)	146.6 (36.0)	n.s
Feller PF score [7]			
Anterior knee pain	7.2 (5.9)	6.7 (5.9)	n.s
Quadriceps strength	3.9 (1.2)	3.9 (1.1)	n.s
Ability to rise from chair	2.0 (1.2)	2.0 (1.3)	n.s
Stair climbing	2.6 (0.8)	2.7 (0.8)	n.s
Total	15.5 (7.1)	15.2 (7.5)	n.s

Data are presented as mean (standard deviation)

BMI body mass index, *WOMAC* Western Ontario McMaster University Osteoarthritis Index, *PF* patellofemoral, *n.s* not significant

[a]Data are presented as the numbers (percentage)

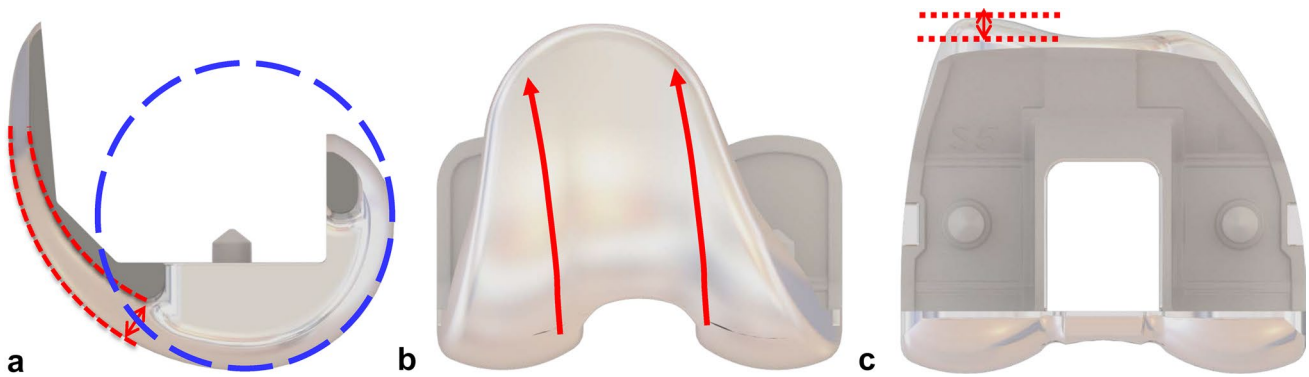

Fig. 2 Knee system (Lospa; Corentec Co, Ltd., Seoul, Korea) incorporating patella-friendly design concepts: **a** a single-radius femoral component with deepest and lengthiest trochlear groove; **b** laterally tilted trochlear groove; **c** high lateral flange

mid-patella), the distance from patellar surface to the greatest depth of trochlear groove was measured (Fig. 3). Within a 2-week interval, all radiographic measurements were generated in duplicate by two independent sources (both authors), using average values for analysis. All measurements were rounded to one decimal place. Intra- and inter-observer reliabilities of each measurement were expressed as intraclass correlation coefficients (ICCs). Intra- and inter-observer reliabilities for all radiographic measurements were considered acceptable, ranging from 0.84 to 0.99 and 0.81 to 0.99, respectively. This study was approved by the institutional review board of Seoul St. Mary's Hospital, The Catholic University of Korea (KC12OISI0512).

Statistical analysis

Primary and secondary endpoints in RP and non-RP subsets were compared. Continuous variables, namely ROM, Knee Society clinical ratings, WOMAC, Feller PFS, AKP pain VAS, FJS, and radiographic data, were analyzed using Student's *t* test or the Wilcoxon rank-sum test. Chi-square or Fisher's exact tests were used to determine differences in categorical variables, namely intraoperative Outerbridge patellar articular cartilage grade, prevalence of AKP, side preference, and rates of patella-related complications and reoperation. All computations relied on standard software (SPSS v21.0 for Windows; IBM Corp, Armonk, NY, USA), setting statistical significance at $p < 0.05$.

A priori power analysis based on the results of a recent randomized bilateral study was performed to determine the necessary sample size needed for sufficient statistical power [19]. Using the two-sided hypothesis test at an alpha level of 0.05 and a power of 80%, it was found that 45 knees in each group were required to detect a 60% reduction in incidence of AKP. A 60% reduction in the incidence of ACP was considered clinically meaningful as recent randomized bilateral trials reported that the difference in incidence of AKP between RP and non-RP groups was 57–66% [19, 28].

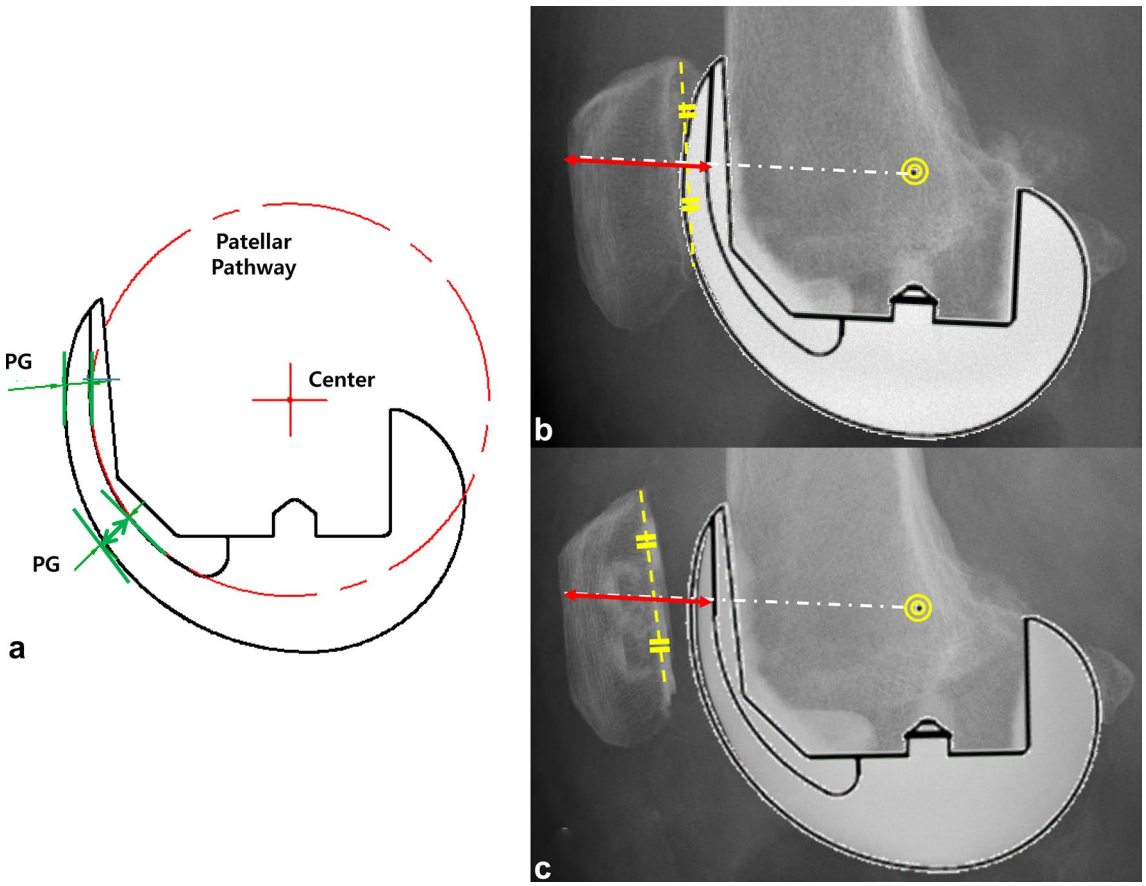

Fig. 3 Patella-to-groove distance determinations in **b** non-RP and **c** RP subsets: an implant template (**a**) incorporating PF center and femoral contours (trochlear groove based on femoral component dimensions) is overlain on postoperative lateral radiographs. A line is then drawn from PF center (once located) to patellar surface, passing through mid-patella, and the distance between patellar surface and the nadir of trochlear groove is measured, shown as red arrow-headed lines in **b, c**

Results

Patient perceptions failed to distinguish between knees (RP versus non-RP) in terms of AKP and changes in prevalence of AKP during the 5 years of postoperative monitoring were similar in both knees (Table 2). In addition, preoperative AKP, as well as persistence of AKP, showed substantial alleviation following TKA regardless of whether or not resurfacing was done. Newly developed AKP was limited to one knee only after RP. Otherwise, there were no between-group differences in awareness of prosthetic knees during daily activities or leisure recreation based on FJS (Table 2). Moreover, patellar management had no-effect patient-side preference. Although 16 patients of 49 (33%) deviated from their side of preference at preoperative baseline, there were no differences in midterm-side preference (Table 3).

Table 2 Patient-reported midterm outcomes of bilateral TKAs

	Resurfacing ($n=49$)	Non-resurfacing (n=49)	p value
Anterior knee pain[a]			
Preoperative baseline	28 (57)	30 (61)	n.s
Postoperative year 5			
Continued pain	3 (6)	2 (4)	n.s
Newly developed pain	1 (2)	0 (0)	
Pain subsided	25 (51)	28 (57)	
No pain since preoperative	20 (41)	19 (39)	
Pain VAS[b]	1.1 (1.0)	1.2 (1.3)	n.s
Forgotten Joint Score [3][b]			
Are you aware of your artificial knee when…			
1. In bed at night	0.9 (1.2)	1.0 (1.2)	n.s
2. Sitting on a chair for > 1 h?	0.8 (1.0)	0.9 (1.1)	n.s
3. Walking for > 15 min?	1.0 (1.0)	1.0 (1.0)	n.s
4. Taking a bath/shower?	0.9 (1.0)	0.8 (1.0)	n.s
5. Traveling in a car?	0.9 (1.1)	0.9 (1.1)	n.s
6. Climbing stairs?	1.2 (1.2)	1.1 (1.3)	n.s
7. Walking on uneven ground?	1.2 (1.3)	1.1 (1.3)	n.s
8. Standing up from a low-sitting position?	1.5 (1.2)	1.5 (1.2)	n.s
9. Standing for long periods of time?	0.9 (1.0)	0.9 (1.2)	n.s
10. Doing housework or gardening?	1.0 (1.0)	1.0 (1.0)	n.s
11. Walking or hiking?	0.9 (1.0)	1.1 (1.1)	n.s
12. Participating in a favorite sport?	1.0 (1.2)	1.0 (1.1)	n.s
Total	12.3 (10.4)	12.5 (10.6)	n.s

TKA total knee arthroplasty, *n.s* not significant

[a]Data are presented as numbers of patients (percentage)

[b]Data are presented as mean

Table 3 Patient-side preference at preoperative baseline and postoperative year 5

Side preference	Preoperative baseline ($n=49$)					
	Side	Assigned to RP	Same	Assigned to non-RP	Total	p value
Postoperative year 5 ($n=49$)	RP	15 (31)	2 (4)	6 (12)	23 (47)	n.s
	Same	0 (0)	3 (6)	1 (2)	4 (8)	
	Non-RP	7 (14)	0 (0)	15 (31)	22 (45)	
	Total	22 (45)	5 (10)	22 (45)	49 (100)	
	Significance	n.s				

Data are presented as numbers of patients (percentage)

RP resurfacing patella, *n.s* not significant

At midterm follow-up assessment, Feller PF scores improved in both groups, showing similarities in all the items (Table 4). In addition, all measurements indicated that patellar position/status in radiographs were independent of patellar management. There were no between-group differences in patellar-to-groove distance, Insall–Salvati ratio, or patellar tilt and displacement. Ultimately, patella-related complications and reoperation rates were unaffected by RP. Proportionate detection of crepitus did not differ significantly, and no revisions of patellar resurfacing or secondary resurfacing procedures were needed.

Discussion

The most important finding of this study was that patients who underwent same-day bilateral TKA using contemporary patella-friendly implant were generally unaware of any differences due to patellar resurfacing. Although patients undergoing same-day bilateral TKAs seem optimally suited for resurfacing comparisons, the previous trials of this sort have culminated in equivocal results [2, 4, 6, 8, 11, 19, 27, 28]. However, the devices used in most of these prior studies were outdated (developed in the 1980s), and the diagnostic tools applied were not particularly sound [23].

Table 4 Clinically determined midterm outcomes of bilateral TKAs

	Resurfacing ($n=49$)	Non-resurfacing ($n=49$)	p value
Feller PF score [7]			
Anterior knee pain	13.5 (2.8)	14.1 (1.8)	n.s
Quadriceps strength	4.4 (0.9)	4.4 (1.0)	n.s
Ability to rise from chair	4.1 (1.0)	4.1 (0.9)	n.s
Stair climbing	4.1 (1.1)	4.0 (1.2)	n.s
Total	26.2 (3.3)	26.9 (3.0)	n.s
Radiographic patellar position			
Anterior–posterior position			
Patella-to-groove distance	23.9 (2.8)	24.0 (2.8)	n.s
Superior–inferior position			
Insall–Salvati ratio [10]	1.0 (0.2)	1.0 (0.2)	n.s
Medio-lateral position			
Patellar tilt (°)	9.6 (3.9)	9.9 (4.0)	n.s
Displacement (mm)	3.3 (1.4)	3.5 (1.4)	n.s
Patellar-related complication[a]			
Crepitus	9 (18)	13 (27)	n. s
Clunk	0	0	-
Reoperation	0	0	-

Data are presented as means (standard deviation)

TKA total knee arthroplasty, *n.s* not significant

[a]Data are presented as numbers of patients (percentage)

The present-study findings were decisive, demonstrating that patients who undergo bilateral TKAs are incapable of subjectively distinguishing a resurfaced patella from one that is not. Midterm assessment of AKP, side preference, and FJS determinants proved comparable, regardless of patellar management posture, and these results support similar studies citing no differences in patient-reported outcomes (i.e., AKP, satisfaction, and side preference) after bilateral TKAs [2, 4, 11, 27]. On the other hand, some researchers still report superior results after TKA through resurfacing [6, 19, 28], which is somewhat mystifying.

In this study, whether or not patients could differentiate between prosthetic knees was ascertained by determining the FJS of each knee, prior to exploring the possible relationship between postoperative AKP and patellar management. Despite a clear lack of awareness, AKP and side preference shifted in a substantial proportion of patients during midterm follow-up monitoring. Thus, postoperative AKP may be unrelated to prosthetic PF articulation, rendering the results of secondary resurfacing unpredictable. Better, more sensitive measures of prosthetic PF joint outcomes are needed to avoid unnecessary secondary resurfacing and more accurately depict the relation between AKP and PF functional performance.

Nevertheless, comparable functional performance and radiographic positioning of the patella are obtainable by a contemporary patella-friendly implant, regardless of the patellar management strategy. Midterm Feller PFSs in RP and non-RP subsets improved considerably and are supported by various studies recording significant functional gains such as walking, stair climbing and ability to rise from a chair with and without RP [8, 20, 21]. In all the planes of postoperative radiographic assessment, patellar positioning was similar for the two groups. It, therefore, appears that this implant's femoral component provides excellent PF tracking and improved functional performance across the board, thus obviating the need for patellar resurfacing as objective physician-assessed clinical findings and radiologic outcomes attest.

Rates of patella-related complications and reoperation were unaffected by patellar management. There were no resurfacing-related complications and no secondary resurfacing in non-RP group. In addition, crepitus was detected comparably in both groups. The present-study results are in agreement with some counterpart studies reporting similarities in group reoperation rates [2, 4, 11, 27], but conflict with other studies reporting higher reoperation rate in non-RP group due to more AKP [19, 28]. Given the elusive nature of postoperative AKP, alleviation of postoperative AKP through resurfacing is not guaranteed [2, 18, 20]. The results of this study, together with those previous studies, suggest

that surgeons should exercise caution in decisions to perform secondary resurfacing. Further long-term follow-up studies are critical to ascertain whether group-wise increases in complication and reoperation rates will materialize as time goes by.

This study has acknowledged limitations, the most obvious being its confinement to Korean patients, nearly all of whom were women. For unknown reasons, this female predominance is well documented in the Korean population [13, 14]. Because women are deemed more accepting of RP results, this gender imbalance must be considered when extrapolating these findings elsewhere [22]. Second, the more frequent squatting and kneeling inherent in Korean daily routines and lifestyle may not be widely generalizable, despite the valuable input provided on high-flexion patellar performance. Third, only patients < 75 years old with ASA scores of 1 or 2 were eligible for the same-day bilateral TKA [13], with osteoarthritis stipulated as the sole diagnosis to avoid confounding factors. These constraints must also be considered before any broader generalizations are made. Fourth, partially ineffective blinding to treatment assignment may have influenced the outcomes. However, we believe that the blinding of the group assignment was maintained, because all medical records and radiographs were recoded electronically and only authorized healthcare providers of this study were allowed to access the database. Fifth, memory effect might affect the measurements of radiographic outcomes, because they were measured twice within a 2-week interval. Sixth, although all patients visited at midterm follow-up ranging from 4.6 to 5.3 years, we could not demonstrate changing patterns of AKP or patellofemoral functional performance during the 5-year period, because interim follow-ups were quite inconsistent among patients. Seventh, the exclusive use of subvastus approach likewise may negate any applicability to other surgical techniques, although a number of studies have suggested that tactical impacts of TKA are limited only to the early postoperative period [14]. Eighth, we did not perform patellar denervation which might reduce AKP in non-RP group [1, 5]. Further bilateral randomized trial is needed to ascertain whether patient undergoing same-day bilateral TKA would perceive differences due to patellar denervation. Finally, this study has largely focused on pertinent aspects of a patella-friendly implant and installed a relative newcomer (Lospa Knee System; Corentec) to the commercial market.

Despite these limitations, this study provides valuable information on patient perceptions of patellar management and PF functional performance following TKA using a contemporary implant incorporating cutting-edge patella-friendly design concepts. The results of this study showed that patients were unaware of any differences between RP and non-RP, and that there were no between-group differences in midterm clinical outcomes. Surgeons should recognize these findings and should be cautious when establishing their strategy for patellar management, especially for secondary resurfacing.

Conclusion

Patients who underwent the same-day bilateral TKA using a contemporary patella-friendly implant were unaware of differences due to RP and similar midterm clinical outcomes were achieved without increasing the risk of reoperation, regardless of patellar resurfacing. Surgeons may thus forego patellar resurfacing under these circumstances.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no competing interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of Institutional Review Board of our hospitals and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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