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Isolated Polyethylene Insert Exchange for Instability after Total Knee Arthroplasty: Comparable Survival Rates and Range of Motion and Improved Clinical Scores Regardless of Hyperextension

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Background: Isolated polyethylene insert exchange (IPIE) has not been established as a treatment option for hyperextension instability after primary total knee arthroplasty (TKA). The purpose of the study was to evaluate the survival rate and clinical outcomes of IPIE for the treatment of instability with or without hyperextension after TKA.

Methods: This study retrospectively reviewed 46 patients who underwent IPIE for symptomatic prosthetic knee instability by dividing them into 2 groups based on the presence of hyperextension (without for group I and with for group IH). Patient demographics, clinical scores, radiographic data, range of motion (ROM), and surgical information were collected. Clinical failure was defined as a subsequent surgery following IPIE for any reason. The survival rate of IPIE and differences in demographics, clinical scores, and ROM were compared.

Results: There were 46 patients (91% were women) with an average age of 70.1 years and a mean follow-up of 44.8 months. The average time between primary TKA and IPIE surgery was 6.5 ± 4.2 years, and during IPIE, 2 out of the 8 cruciate-retaining inserts were converted to "deep-dish" ultracongruent inserts while the insert thickness increased from 11.9 ± 1.8 mm to 17.1 ± 3.1 mm. After IPIE surgery, a significantly thicker tibial insert was used in the group with hyperextension (15.39 ± 2.4 mm for group I, 18.3 ± 2.9 mm for group IH; $p < 0.001$ by independent t-test), and no significant differences were observed in the ROM and clinical scores before and after IPIE between the 2 groups. The overall survival rate for IPIE was 83% at 5 years and 57% at 10 years, and there were no statistically significant differences between the groups using the Cox proportional hazards regression model.

Conclusions: IPIE demonstrated an overall survival rate of 83% at 5 years with no difference in the recurrence of instability regardless of hyperextension. This study highlighted the effectiveness of using thicker inserts to resolve instability without significant differences in the ROM or clinical scores between the groups, suggesting its potential as a decision-making reference for surgeons.

Keywords: *Joint instability, Polyethylene, Reoperation, Hyperextension, Isolated polyethylene insert exchange*

Tibiofemoral instability is a common cause of patient dissatisfaction and early failure after total knee arthroplasty (TKA).[1-4] Instability can be broadly classified into categories such as flexion instability, extension instability, genu recurvatum, and global instability.[5,6] Management strategies for each type of instability depend on the severity of the presenting instability and the combination of issues present.

Since the 1980s, the evolution of modular TKA components allowed for intraoperative adjustments during

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primary surgery. It has also presented an option of an isolated polyethylene insert exchange (IPIE) during revision TKA in patients with well-fixed and aligned components.[7] This simple option is attractive as it reduces surgical time and complexity, conserves bone stock, and potentially expedites rehabilitation in comparison to a full revision of all components.[8] Except for prosthetic joint infection, IPIE has been undertaken for polyethylene wear, stiffness, and instability. Despite early unfavorable reports regarding IPIE for the above indications,[7,9,10] recent investigations have shown more favorable results in selected patients.[11-13] However, consistent results have not yet been reported regarding the outcomes of IPIE for instability, and research specifically addressing hyperextension remains notably limited.[14,15] Previous investigators recommended component revision as the preferred treatment for instability due to poor outcomes and high failure rates associated with IPIE.[3,7,10,13] Modern implant systems that permit an increase in insert constraint to enhance the success rate of IPIE have recently been utilized.[12] Nevertheless, this solution is not expected to be effective in cases of hyperextension. Genu recurvatum, also known as hyperextension instability, is a rare condition identified in only 0.5 % to 2.4% of patients undergoing TKA and results from a variety of causes.[2,3,16] To our knowledge, IPIE has not been described as a treatment option for hyperextension instability following primary TKA.

The purpose of this study was to evaluate the outcomes of selective IPIE for the treatment of instability with or without hyperextension after primary TKA. The outcomes of interest included implant survivorship, causes of failure, and clinical scores. This study hypothesized that there was no difference in clinical score and survival rate regardless of the presence or absence of hypertension.

METHODS

Patient Selection

After receiving approval from the Institutional Review Board of Seoul National University Hospital (IRB No. H-2303-095-1412), a retrospective review of prospectively collected data, including surgical records and radiographs, was conducted for 788 patients who underwent revision surgeries after TKA between January 2001 and January 2021. The IRB exempted the need for informed consent due to the retrospective nature of this study. The revision TKAs were performed by 3 experienced adult reconstruction surgeons (DHR, MCL, and HSH) at a single tertiary referral hospital. Of the 788 patients, 119 (15%) underwent IPIE after excluding 470 patients who had at least 1 implant revision of the femur, tibia, or patella components and 199 patients who had implant removal and cement spacer insertion due to infection. Among the 119 patients, 69 patients who underwent debridement and implant retention along with polyethylene insert exchange due to infection and 4 patients who had polyethylene insert exchange due to polyethylene wear were further excluded. A total of 46 patients who underwent IPIE for symptomatic prosthetic knee instability were finally included in the analysis. These patients were further divided into 2 groups for comparative analysis (Fig. 1): instability without hyperextension (18 patients, group I) and instability with hyperextension (28 patients, group IH). Hyperextension was defined as any extension measured over 5° using a goniometer during the postoperative follow-up. The 46 patients had an average age of 70.1 years (range, 40–86 years) and a mean follow-up of 44.8 months (range, 12–182 months), and 91% (42/46) were female.

The requirements for IPIE included well-fixed and

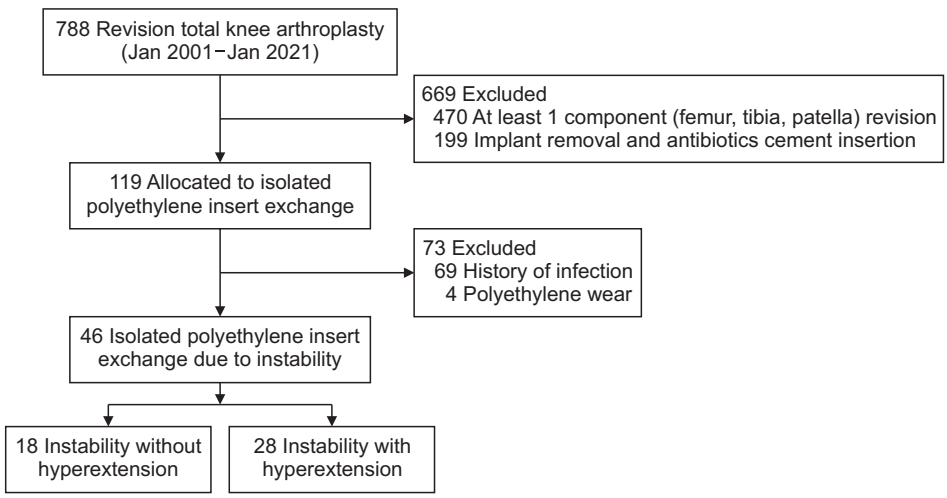

Fig. 1. Study flowchart.

well-aligned implants, with balance achievable during revision surgery. Before IPIE, component fixation was examined using radiographs and computed tomography and confirmed through intraoperative meticulous assessment. Preoperative medial-lateral stability was assessed with the patient in a supine position and the knee in extension and dynamically in an arc of flexion, while applying manual varus and valgus stress. Anteroposterior stability was assessed with the knee in extension and at 90° of flexion.

Indications for IPIE included mild global varus-valgus laxity in both flexion and extension gaps, with or without hyperextension, and anteroposterior instability attributed to posterior cruciate ligament incompetence when more constrained inserts were available. Extreme varus-valgus instability or flexion instability that could not be balanced to an acceptable level (1–3 mm) intraoperatively were considered contraindications for IPIE. Additionally, patients with hyperextension exceeding 10° were also considered contraindications for IPIE. If necessary, additional soft-tissue rebalancing or synovectomy was performed, and a thicker or more constrained polyethylene insert was implanted. However, a slight flexion contracture (< 5°) with the trial insert reduction was allowed.[17,18] Various modular polyethylene inserts were used, depending on the type of instability pattern present and the available inserts to match the existing implant.

Data Collection

Electronic medical records and institutional patient database were retrospectively reviewed to collect patient demographics, clinical scores, radiographic data, range of motion (ROM) data, surgical and prosthesis data, and information regarding any subsequent reoperations. Clinical assessments were performed before the IPIE surgery and during each annual follow-up visit by a blinded clinical researcher. However, since some primary TKAs were performed outside the hospital, pre- and postoperative TKA data were analyzed from 8 patients in group I and 18 patients in group IH. The pre- and postoperative IPIE data were collected from all patients.

The clinical scores included the Knee Society Knee Score (KSKS), Knee Society Functional Score (KSFS), and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). For radiographic evaluation, patients underwent weight-bearing long-leg radiographs, and knee x-rays were used to assess the hip-knee-ankle angle (HKAA), joint line convergence angle (JLCA), posterior tibial slope, posterior condylar offset, modified Insall-Salvati ratio, and Blackburne-Peel ratio (BPR). All radiographic parameters were evaluated by 2 authors (BSC and DHR). The intrarater and interrater reliabilities were evaluated with re-measurements performed 1 month after the initial measurement, yielding interobserver intraclass correlation coefficients (ICCs) of 0.91 or higher ($p < 0.001$) and intraobserver ICCs of 0.95 for all angles. ROM was measured with a goniometer. Operative data included the thickness and mobility of the insert, prosthesis constraint, and soft-tissue balancing techniques used. Constraint was classified as cruciate-retaining (CR), ultracongruent, posterior-stabilized (PS), and varus/valgus constrained. Clinical failure was defined as a subsequent operation following the initial IPIE for any reason.

Statistical Analysis

Data were summarized and included mean and range for continuous variables, and count and percentage for categorical variables. The presence of a normal distribution in the continuous variables was tested using the Shapiro-Wilk test. An independent *t*-test or Mann-Whitney *U*-test was used to analyze parametric data, and the Fisher exact test or chi-square test was used to compare the categorical data. The paired *t*-test was employed to compare clinical scores between pre-IPIE and the last follow-up. A Kaplan-Meier analysis was used to determine the survivorship of the index polyethylene exchange, with failure defined as reoperation involving polyethylene exchange or component revision for any reason. Potential factors associated with failure re-revision were examined using Cox proportional hazards regression models and reported with hazard ratios and 95% confidence intervals. All statistical tests were 2-sided and *p*-values less than 0.05 were considered statistically significant. Statistical analysis was performed using IBM SPSS Statistics version 26 (IBM Corp.).

RESULTS

Primary TKA and IPIE Data

A summary of the primary TKA and IPIE are presented in Table 1. The majority of the patients were female (91%), and the primary TKA prosthesis design predominantly utilized multi-radius (91%) and PS (78%) inserts. The average time between primary TKA and IPIE surgery was 6.5 ± 4.2 years. During the IPIE surgery, 2 of the 8 CR patients were converted to "deep-dish" ultracongruent inserts in patients with posterior cruciate ligament insufficiency. Furthermore, the insert thickness increased from 11.9 ± 1.8 mm in primary TKA to 17.1 ± 3.1 mm after IPIE.

Table 1. Summary of Primary TKA and Isolated Polyethylene Insert Exchange

Variable	Primary TKA (n = 46)	IPIE (n = 46)
Age at surgery (yr)	63.8 ± 7.1	70.1 ± 7.8
Female	42 (91)	
Time from TKA to IPIE (yr)	6.5 ± 4.2	
Primary TKA at outside hospital	20 (44)	
Femur multi-radius design	42 (91)	
Fixed-bearing insert	32 (70)	
Constraint of insert		
CR	8 (18)	6 (14)
UC	0	2 (4)
PS	36 (78)	36 (78)
VVC	2 (4)	2 (4)
Insert thickness (mm)	11.9 ± 1.8	17.1 ± 3.1

Values are presented as mean ± standard deviation or number (%).
TKA: total knee arthroplasty, IPIE: isolated polyethylene insert exchange, CR: cruciate-retaining, UC: ultracongruent, PS: posterior-stabilized, VVC: varus-valgus constraint.

Comparison between the Instability with or without Hyperextension Groups

Demographic and surgical data of both groups are presented in Table 2, with no significant differences observed in demographic data between the groups. After IPIE surgery, a statistically significantly thicker tibial insert was used in group IH (15.39 ± 2.4 mm for group I, 18.3 ± 2.9 mm for group IH; $p < 0.001$). Perioperative radiographic values are compared in Table 3. In group IH, the HKAA was more varus (174.0 ± 9.5 for group I, 163.9 ± 6.2 for group IH; $p = 0.006$), and the JLCA was more varus before primary TKA (4.5 ± 6.1 for group I, 9.7 ± 4.4 for group IH; $p = 0.022$). The BPR was smaller before primary TKA (0.7 ± 0.1 for group I, 0.6 ± 0.2 for group IH; $p = 0.027$).

Perioperative ROM data are presented in Table 4. Although there was hyperextension in group IH before IPIE surgery, there was no statistically significant difference in flexion contracture and further flexion after IPIE ($p = 0.096$ and $p = 0.734$, respectively). There were no significant differences between the groups in Knee Society scores and WOMAC (Fig. 2). All clinical scores showed statistically significant improvements between the 2 groups at both pre-IPIE and last follow-up time points ($p = 0.001$ for KSKS, $p = 0.004$ for KSFS, and $p = 0.049$ for WOMAC).

Table 2. Demographic and Surgical Data of the Instability with or without Hyperextension Groups

Variable	Group I (n = 18)	Group IH (n = 28)	*p*-value
Age at IPIE (yr)	70.9 ± 9.8	69.5 ± 6.4	0.572
Duration of follow-up (mo)	55.1 ± 52.6	38.3 ± 2.97	0.173
Female	15 (83)	27 (96)	0.124
Involved side of knee (right)	8 (44)	12 (43)	0.916
Body mass index (kg/m^2)	25.8 ± 3.0	27.1 ± 2.5	0.102
Time from TKA to IPIE (mo)	90.7 ± 87.0	69.8 ± 57.0	0.376
Surgery at outside hospital	10 (56)	10 (36)	0.185
Femur multi-radius design	17 (94)	25 (89)	0.545
Fixed-bearing insert	12 (67)	20 (71)	0.732
Constraint of insert			0.330
CR	4 (22)	2 (7)	
UC	0	2 (7)	
PS	13 (72)	23 (82)	
VVC	1 (6)	1 (4)	
Pre-IPIE insert thickness (mm)	11.4 ± 1.5	12.1 ± 1.9	0.172
Post-IPIE insert thickness (mm)	15.3 ± 2.4	18.3 ± 2.9	< 0.001*
Medial soft-tissue release at IPIE			0.675
Minimal	16 (89)	23 (82)	
Superficial MCL release	2 (11)	4 (14)	
Posteromedial capsule release	0	1 (4)	

Values are presented as mean ± standard deviation or number (%).
Group I: instability without hyperextension, Group IH: instability with hyperextension, IPIE: isolated polyethylene insert exchange, TKA: total knee arthroplasty, CR: cruciate-retaining, UC: ultracongruent, PS: posterior-stabilized, VVC: varus-valgus constraint, MCL: medial collateral ligament.
*Statistically significant.

Survival Rates and Causes of Failure in IPIE

The overall survival rate for IPIE was 83% at 5 years and 57% at 10 years (Fig. 3A). In group I, the 5-year survival rate was 83%, and the reasons for failure were instability without hyperextension in 2 cases and loosening in 1 case. In group IH, the 5-year survival rate was 93%, and the reasons for failure were infection in 1 case and instability without hyperextension in 1 case (Fig. 3B). In the Cox regression model, no statistically significant difference in survival rates was observed between the groups with or without hyperextension ($p = 0.657$), and no other factors were found to be associated with the survival rate.

Table 3. Comparison of Radiographic Variables between the Instability with or without Hyperextension Groups

Variable	Group I (n = 18)	Group IH (n = 28)	*p*-value
Anatomical axis angle (°)			
Pre-TKA*	174.0 ± 9.5	163.9 ± 6.2	0.006‡
Pre-IPIE†	178.4 ± 3.6	178.1 ± 4.3	0.812
Post-IPIE†	179.0 ± 3.9	178.9 ± 3.0	0.940
Joint line convergence angle (°)			
Pre-TKA	Varus 4.5 ± 6.1	Varus 9.7 ± 4.4	0.022‡
Pre-IPIE	Varus 1.1 ± 2.2	Varus 0.8 ± 2.4	0.677
Post-IPIE	Varus 0.7 ± 1.4	Varus 0.4 ± 1.2	0.362
Posterior tibial slope (°)			
Pre-TKA	8.9 ± 3.6	11.8 ± 5.7	0.179
Pre-IPIE	5.3 ± 2.7	4.5 ± 3.0	0.386
Posterior condylar offset (°)			
Pre-TKA	30.8 ± 4.0	34.4 ± 4.0	0.035‡
Pre-IPIE	30.9 ± 5.2	31.4 ± 3.9	0.697
Insall-Salvati ratio			
Pre-TKA	1.03 ± 0.20	0.97 ± 0.16	0.328
Pre-IPIE	1.04 ± 0.20	1.07 ± 0.20	0.704
Post-IPIE	1.03 ± 0.20	1.05 ± 0.22	0.866
Blackburne -Peel ratio			
Pre-TKA	0.73 ± 0.09	0.58 ± 0.18	0.027‡
Pre-IPIE	0.53 ± 0.16	0.50 ± 0.26	0.640
Post-IPIE	0.37 ± 0.13	0.33 ± 0.27	0.578

Values are presented as mean ± standard deviation.
Group I: instability without hyperextension, Group IH: instability with hyperextension, TKA: total knee arthroplasty, IPIE: isolated polyethylene insert exchange.
*Excluding patients operated on at outside hospitals, 8 patients were included in group I and 18 patients in group IH for analysis. †A total of 18 patients were included in group I, and 18 patients in group IH for the analysis. ‡Statistically significant.

Table 4. Comparison of Range of Motion between the Instability with or without Hyperextension Groups

Variable	Group I (n = 18)	Group IH (n = 28)	*p*-value
Pre-TKA*			
Flexion contracture (°)	10.6 ± 11.8	7.8 ± 7.5	0.463
Further flexion (°)	126.4 ± 14.9	121.4 ± 30.9	0.686
Pre-IPIE†			
Flexion contracture (°)	0.8 ± 1.9	–7.1 ± 2.5	< 0.001‡
Further flexion (°)	126.7 ± 11.4	124.8 ± 23.8	0.761
Last follow-up†			
Flexion contracture (°)	0.9 ± 2.7	–0.3 ± 0.9	0.096
Further flexion (°)	125.9 ± 13.1	123.7 ± 23.3	0.734

Values are presented as mean ± standard deviation.
Group I: instability without hyperextension, Group IH: instability with hyperextension, TKA: total knee arthroplasty, IPIE: isolated polyethylene insert exchange.
*Excluding patients operated on at outside hospitals, 8 patients were included in group I and 18 patients in group IH for analysis. †A total of 18 patients were included in group I, and 18 patients in group IH for the analysis. ‡Statistically significant.

DISCUSSION

The most important findings of the present study are as follows: (1) the overall survival rate for IPIE was 83% at 5 years, with no statistically significant differences in survival rates between patients with or without hyperextension (the 5-year survival rate was 83% for group I and 93% for group IH), (2) the causes for subsequent operations after IPIE in 5 patients (5/46, 11%) were instability without hyperextension in 3 patients, loosening in 1 patient, and infection in 1 patient, (3) although thicker inserts were used in group IH, there were no significant differences in the ROM between the 2 groups, and (4) no significant differences were observed between the groups in terms of Knee Society scores and WOMAC.

Data from the Australian National Registry demonstrated that revision of both femoral and tibial components resulted in a lower rate of second revision for instability, compared to changing the insert alone.[19] The failure rate for IPIE performed for aseptic reasons was 13%, which is comparable to reoperation rates following revision TKA in general.[20] However, when instability was involved, the failure rate of IPIEs increased to 30%, resulting in a higher rate of failure.[13] In cases of additional surgery after IPIE due to instability, a high rate of second revision was observed, with recurrent instability being the most common cause.[2,3,21] Prior research has suggested that outcomes regarding pain and instability could be unpredictable even when IPIE was performed with selective indications for instability.[15] Green et al.[14] showed that the survival rate of IPIE reached as high as 90% when specific indications were applied. However, existing studies addressing hyperextension are notably scarce. In the present study, despite

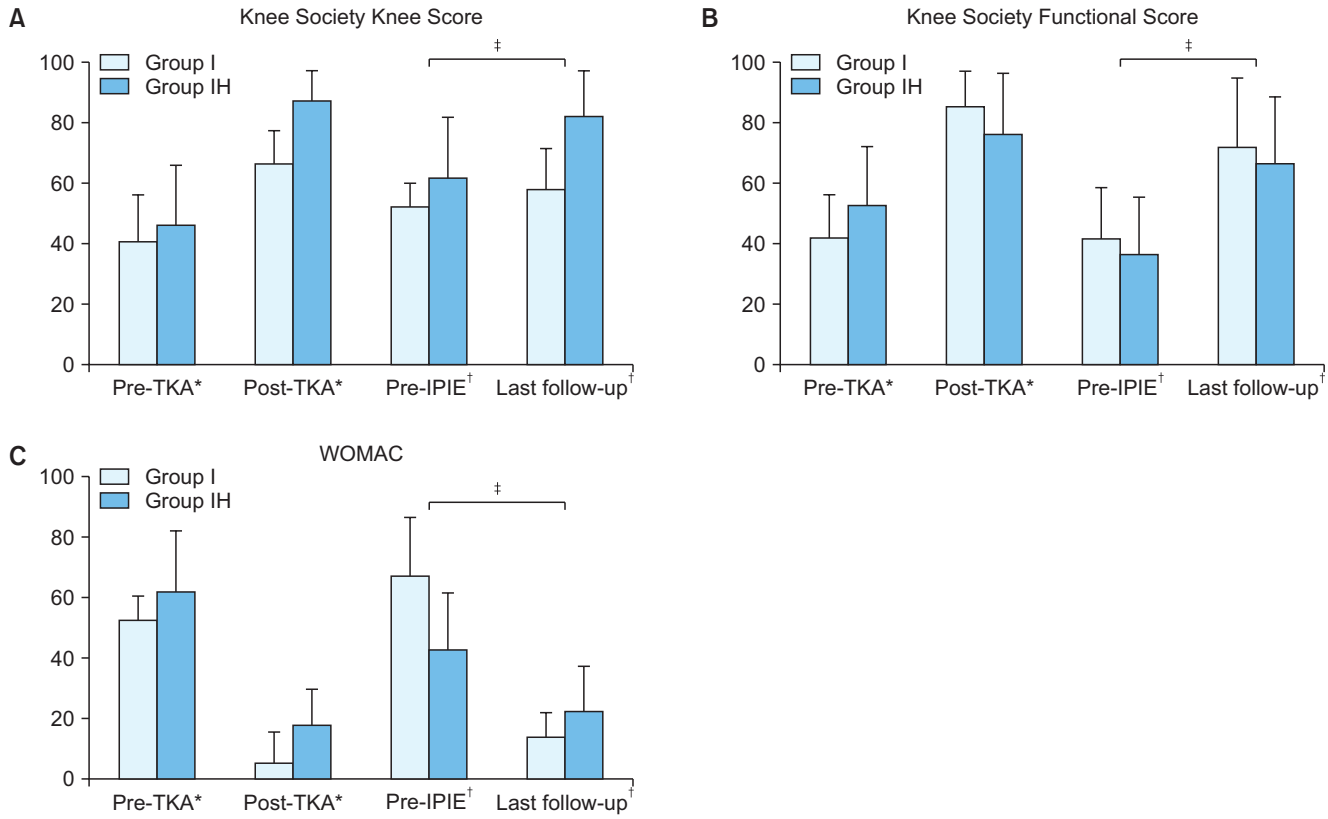

Fig. 2. Comparison of clinical scores between instability without hyperextension (group I) and with hyperextension (group IH) before and after surgery. (A) Knee Society Knee Score. (B) Knee Society Functional Score. (C) Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). No statistically significant differences in clinical scores were found between the 2 groups. Upon conducting a paired *t*-test analysis between the pre-isolated polyethylene insert exchange and the last follow-up, a statistically significant improvement in clinical scores was observed. TKA: total knee arthroplasty, IPIE: isolated polyethylene insert exchange. *Excluding patients operated on at outside hospitals, 8 patients were included in group I and 18 patients in group IH for analysis. †A total of 18 patients were included in group I and 18 patients in group IH for the analysis. ‡Statistically significant ($p < 0.05$).

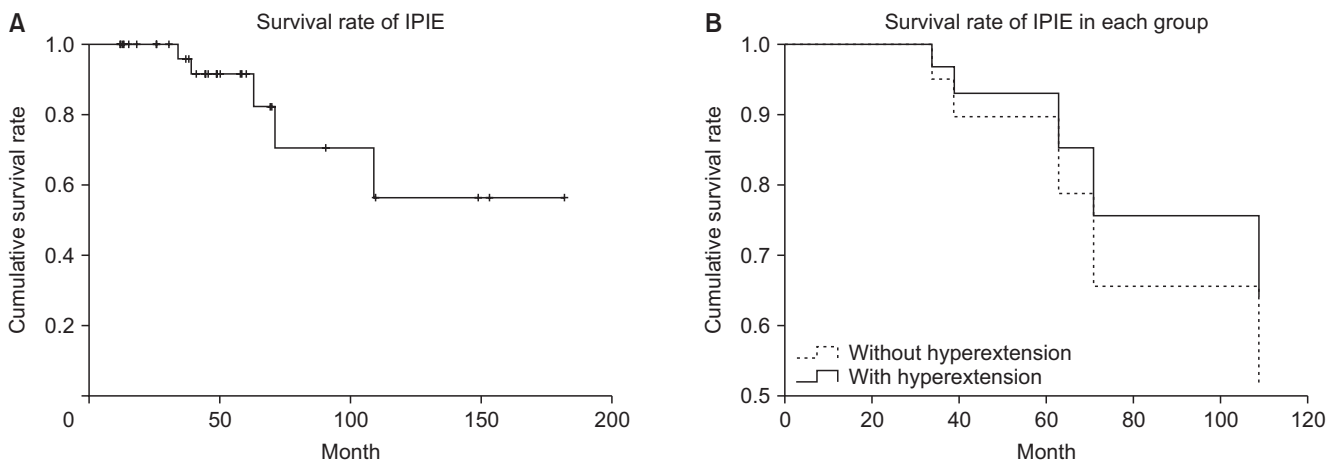

Fig. 3. Kaplan-Meier analysis of survival rate over time. (A) The 5-year survival rate was 83% and the 10-year survival rate was 57%. (B) At the 5-year follow-up, the survival rate was 83% for the group without hyperextension and 93% for the group with hyperextension. However, the Cox regression model did not reveal any statistically significant differences between the groups. IPIE: isolated polyethylene insert exchange.

IPIE performed on patients with mild instability, including hyperextension, only 11% of the patients (5/46) underwent subsequent surgery. The overall survival rate for IPIE was 83% at 5 years and 57% at 10 years, which demonstrated better survival rates compared to previous studies.

Hyperextension or recurvatum after TKA has been challenging to treat. It has been reported that the occurrence of more than 5° of recurvatum is associated with poor functional outcomes.[2,22-24] Previous studies have suggested full revision for correcting hyperextension after TKA, which included tightening the collateral ligaments in extension, placing the femoral component in flexion, and replacing it with a rotating hinge knee (RHK) implant.[6] However, it might be prudent to avoid an RHK whenever possible, even though it is considered a definitive treatment. This is because the use of RHK is associated with more resection of bone, increased risk of revision due to increased torsional load, a higher rate of complications, and higher costs.[25,26] In contrast, IPIE preserves the bone stock and has the advantages of a shorter operation time, decreased blood loss, lower costs, and faster rehabilitation.[8] If the degree of instability is similar in both extension and flexion, an increase in polyethylene thickness should reliably solve this instability problem. However, the appropriateness of IPIE alone as a treatment for patients with hyperextension has not been previously reported. In the current study, it is meaningful that instability was successfully resolved using IPIE alone without the recurrence of hyperextension, and no differences in clinical scores and ROM were observed when compared to the group without hyperextension.

It is important to note that an increase in insert thickness following IPIE may lead to a joint line elevation and the potential development of pseudo-patella baja, and these factors may negatively impact the ROM for the patients.[27,28] Unlike previous studies that involved joint line changes due to an all-component revision, the present study examined changes resulting solely from an insert exchange to investigate whether these alterations had an impact on the ROM or clinical outcomes. However, there was no statistically significant difference in patella height after IPIE based on the presence or absence of hyperextension (0.4 vs. 0.3 for BPR, $p = 0.578$), and there was no significant difference in further flexion before and after IPIE.

A previous study reported that clinical scores improved after IPIE, with no significant differences in improvements in the clinical score or arc of motion between those treated with IPIE and component revision.[12] In the present study, clinical scores improved after IPIE surgery regardless of the presence of hyperextension. However, there were no significant differences in clinical scores or the ROM between the groups with and without hyperextension.

In previous studies, factors such as age, prior revision surgery,[29] and time from the index TKA[13] have been reported to cause subsequent surgery after IPIE. Also, the sex distribution of revision TKA was reported to be predominantly female.[30] However, in this study, no factors associated with clinical failure were identified. By extending the follow-up period and analyzing a larger number of patients in future studies, it may be possible to uncover factors related to clinical failure.

There are several limitations to this study. First, this is a retrospective cohort study with predominately female Asian patients. Therefore, racial or ethnic differences in addition to sex differences may affect instability after TKA. However, additional research is necessary to examine the relationship between these factors and instability. There was also potential for selection bias, which could influence the results of this study. Furthermore, due to the retrospective nature of this study, primary TKA patients whose surgery was performed externally were also included. Consequently, obtaining preoperative data for TKA was not possible, presenting a limitation in terms of comparison. Second, the sample size is relatively small (n = 46). In the present study, a priori power analysis could not be conducted due to the lack of previous study regarding IPIE for instability after TKA regardless of hyperextension, and a post-hoc power analysis could not be conducted due to the absence of a statistically significant difference. This limitation arises from the small number of patients who underwent IPIE for instability after primary TKA. Third, multiple implant designs from several manufacturers were included. Each design may have distinct biomechanical characteristics and influence the outcomes in different ways. Therefore, it might be challenging to generalize the results to a general population. Finally, the subjectivity in determining instability by surgeons can be a potential bias.

The patient survival rate following IPIE was 83% at 5 years with no difference in the recurrence of instability, irrespective of hyperextension. Instability, with or without hyperextension, was resolved using a thicker insert, and there were no differences in the ROM and improvement of clinical scores compared to preoperative measurements. By presenting not only the survival rate of IPIE applied to instability but also treatment outcomes, this study may aid surgeons in making decisions about IPIE.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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