



When to Use a Condylar Constrained Insert in Non-Stemmed Posterior-Stabilized Total Knee Arthroplasty

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Background: The constrained insert with non-stemmed tibial and femoral components can be used in the modern total knee arthroplasty (TKA) when soft-tissue balance and adequate stability from a posterior-stabilized (PS) insert cannot be achieved. This study aimed to identify the prevalence and predictive factors associated with the constrained insert use during primary TKA for varus deformity.

Methods: From August 2016 to March 2019, 554 primary TKAs were consecutively performed by one surgeon. The choice of using a conventional PS polyethylene insert versus a constrained insert was made by the surgeon, depending on the stability detected after an attempt to balance the soft tissue. The decision to convert to a constrained liner was made if the ligament could not be balanced, if flexion-extension gaps were mismatched, or if the varus-valgus opening was 3 mm or more when varus and valgus stress tests at 0° were applied. We retrospectively investigated the preoperative, intraoperative, and postoperative factors associated with the constrained insert use. Multiple logistic regression analysis was used to identify predictive factors of constrained insert use, and a receiver operating characteristic curve analysis was used to pinpoint a cutoff value of tibiofemoral varus angle.

Results: Constrained inserts were used in 130 of 497 varus knees (26.1%). A multivariate analysis revealed that the factors associated with an increased adjusted risk of constrained insert use included preoperative severe varus deformity (odds ratio [OR], 5.78; 95% confidence interval [CI], 2.75–12.16; $p < 0.001$) and severe release of soft tissue through the superficial medial collateral ligament (OR, 6.38; 95% CI, 2.94–13.85; $p < 0.001$). A preoperative anatomic tibiofemoral varus angle of $> 19.8^\circ$ was associated with the use of a constrained articulation with an area under the curve of 0.7 (95% CI, 0.4–0.8).

Conclusions: Prevalence of 26.1% for constrained insert use was found in this study. Preoperative anatomic tibiofemoral varus angle of $> 19.8^\circ$ and severe release of soft tissue through the superficial medial collateral ligament were associated with the use of a constrained articulation. The findings from this study will help surgeons to improve efficiency of surgical sequence planning and provide counseling to patients regarding the associated cost.

Keywords: Total knee arthroplasty, Posterior-stabilized, Varus-valgus constrained prosthesis, Varus

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In complex primary total knee arthroplasty (TKA), when a surgeon faces problems of imbalance of mediolateral gap or improper flexion-extension gap balance, a varus-valgus constrained (VVC) prosthesis is commonly used instead of posterior-stabilized (PS) TKA.¹⁻⁴⁾ The VVC prosthesis can provide substantial varus-valgus constraint and limit

torsion moments due to the enlarged tibial post insert in the tibial tray that fits within the intercondylar notch of the femoral component. Most surgeons use intramedullary stems with constrained components for complex primary TKA to provide load-sharing mechanisms over the diaphyseal bone of the femur and tibia.⁵⁾ However, the use of these stem extensions has a number of disadvantages. For instance, it may increase the risk of embolization from the invasion of the intramedullary canal, increase operating time and cost from the steps of procedures, possibly result in postoperative end-of-stem pain, and cause difficulty for revision if required.⁶⁾

Recently, the constrained insert with non-stemmed tibial and femoral components (stemless VVC) has been used in some modern PS-TKA designs with reportedly acceptable outcomes in the early and mid-term periods when properly used.^{4,6-8)} The stemless constrained inserts can be switched from the PS insert intraoperatively, allowing an instant surgical solution in the operation room. Although a short-term retrieval study reported an increase in the wear around the region of the post of stemless constrained inserts compared to the PS inserts, the increased damage and deviation of the post surfaces were minimal and likely clinically insignificant.⁹⁾ However, studies on the prevalence and indication of constrained insert use in non-stemmed PS-TKA are very limited.

Therefore, this study aimed to answer the following questions: (1) What is the prevalence rate of constrained inserts used in primary TKA for varus deformity? (2) Are there any predictive factors associated with the use of constrained inserts in primary TKA for varus deformity?

METHODS

Study Design

This retrospective study was approved by the Ethical Committee of our institution (IRB No. COA61/2560). From August 2016 to March 2019, 554 minimally invasive total knee arthroplasties (MIS-TKAs) were consecutively performed on 529 patients by a single surgeon (ST) using a fixed bearing PS-TKA (Legion Total Knee System; Smith & Nephew, Memphis, TN, USA). TKA procedures were performed with the possibility of using a conventional PS insert or a constrained insert with the implants depending on the stability detected after an attempt to balance the soft tissue (Fig. 1). All patients with knee osteoarthritis whose symptoms could not be treated with a conservative measure were admitted under the care of one surgeon (ST) for a primary MIS-TKA. Patients were excluded from the study if they had valgus deformity. A total of 497 knees met the inclusion criteria, excluding 52 knees with valgus deformity and 5 knees with incomplete data (Fig. 2).

Clinical Protocol

A standard procedure of a minimally invasive technique without patellar resurfacing was performed. Regional anesthetics were administered to all patients. The tourniquet pressure was at 280 mmHg in all cases. The incision was typically less than 9 cm long, which represented no more than twice the length of the patella. A mini-midvastus approach was performed to allow exposure of the knee without everting the patella. The distal femoral resection was performed using the intramedullary technique at 6° of valgus. The femoral rotation was determined by the posterior femoral condylar axis and Whiteside's line¹⁰⁾ and using the transepicondylar axis in patients with ana-

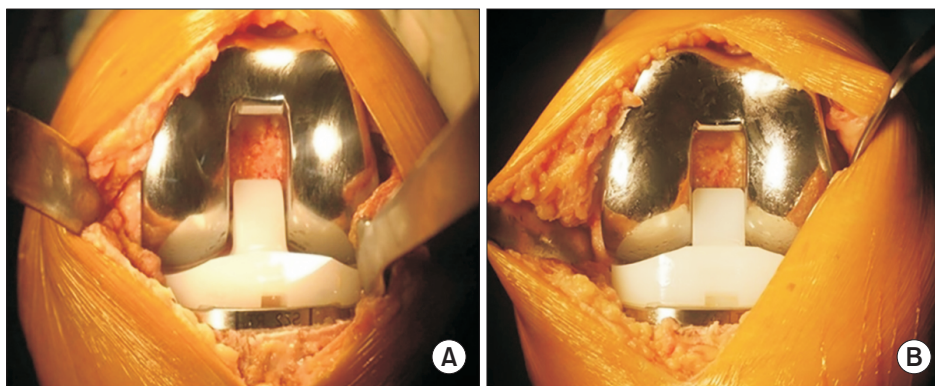


Fig. 1. Comparison between a posterior-stabilized (PS) insert (A) and constrained insert (B). A constrained insert has a thicker and wider post than a PS insert. The constrained insert provides substantial varus-valgus constraint and limits torsion moments due to the enlarged tibial post insert that fits within the intercondylar notch of the femoral component. With this modern total knee arthroplasty design, surgeons can switch from a PS insert to a constrained insert intraoperatively without the use of a stem extension.

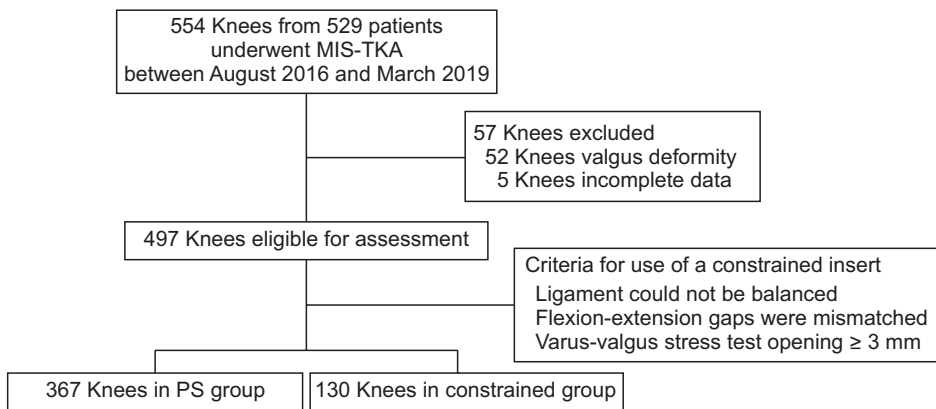


Fig. 2. Study flowchart. MIS-TKA: minimally invasive total knee arthroplasty, PS: posterior-stabilized.

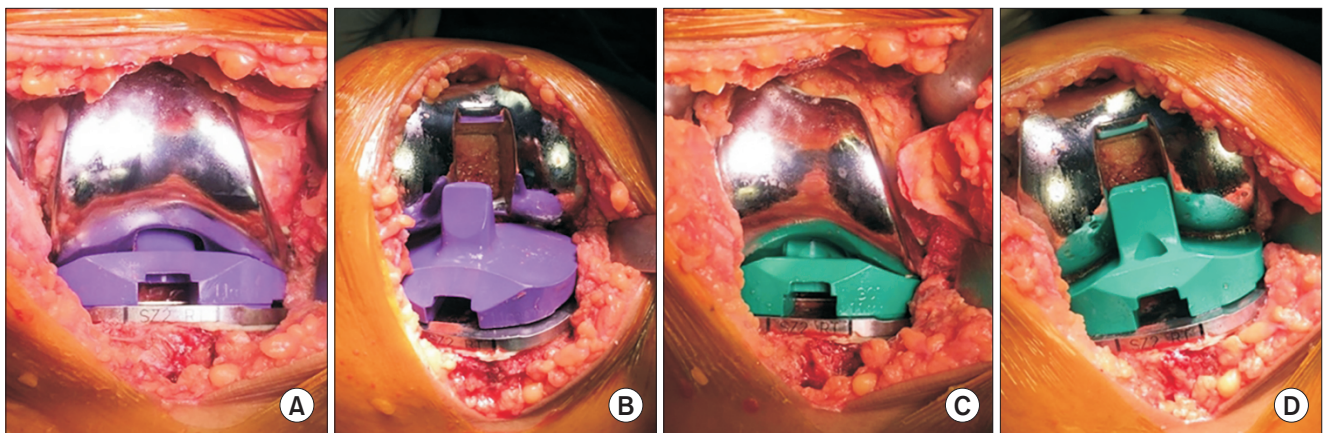


Fig. 3. Decision-making procedure to use the constrained insert. When a conventional posterior-stabilized insert was used, the knee was well-balanced in full extension (A), but unstable in full flexion (B). After replacing with a constrained insert with the same thickness, the knee was well-balanced in both full extension (C) and full flexion (D).

tomical abnormalities. The femoral component size was determined by the posterior referencing instrumentation system. The proximal tibial resection was performed using the extramedullary technique. Tibial components with asymmetric tibial trays were rotated using the functional alignment method. Flexion and extension gap balancing was performed with the use of spacer blocks to obtain equally symmetric gaps. We performed a subperiosteal release of the deep medial collateral ligament (MCL) or medial capsule as the first step in the medial release. Further release of the semimembranosus tendon and postero-medial capsule may have been needed in some cases and was performed as the second step of medial release when necessary. The superficial MCL was the final step of the sequential medial release. We used a periosteal elevator to perform a careful elevation of the superficial MCL posterior to the pes insertion. Both complete and partial releases were included at this final step.^{11,12)}

After implanting the components, a standard PS insert was used in the well-balanced knees if symmetrical

rectangular gaps were achieved and if the medial/lateral opening did not exceed 3 mm when varus and valgus stress tests at 0° were applied.¹³⁾ The decision to convert to a constrained liner was made if the ligament could not be balanced, if flexion-extension gaps were mismatched or if the varus-valgus opening was 3 mm or more when varus and valgus stress tests at 0° were applied (Fig. 3). Femoral and tibial components were cemented in all cases. Both groups received the same postoperative pain control and rehabilitation methods, which consisted of a multimodal approach to avoid parenteral narcotics and provide early postoperative mobilization.

Associated Factor and Data Analysis

To identify the predictive factors associated with the use of a constrained insert in primary TKA, the following factors relevant to pre-, intra-, and postoperative steps were considered as variables in the analysis. Briefly, the analyzed preoperative variables included the following: (1) Quantitative variables: patient's age, body mass index, range of

motion, Knee Society score (KSS),¹⁴⁾ and degree of posterior tibial slope.¹⁵⁾ (2) Qualitative variables: sex, Kellgren and Lawrence radiographic grading (KL grade),¹⁶⁾ alignment measured on anteroposterior (AP) weight-bearing hip-to-ankle standing radiographs, severity of anatomic varus angle quantified by tibiofemoral angle (mild: $< 10^\circ$, moderate: 10° – 15° , and severe: $> 15^\circ$),¹⁷⁾ severity of coronal plane laxity (mild: $< 6^\circ$, moderate: 6° – 9° , and severe: $> 9^\circ$),¹⁴⁾ and severity of sagittal plane laxity (mild: < 5 mm, moderate: 5 – 10 mm, and severe: > 10 mm).¹⁴⁾ The severity of the coronal plane and sagittal plane laxities were assessed by a single surgeon (ST) at the time of admission and prior to surgery in all cases. The analyzed intraoperative variables included degree of soft-tissue release in varus knees (step 1–3: mild, moderate, and severe).

The postoperative variables that were analyzed at 6 weeks included the outliers of the hip-knee-ankle angle (outlier: $> \pm 3^\circ$), the outliers of the posterior tibial slope (outlier: $< 0^\circ$ posterior tibial slope or $> 7^\circ$ posterior tibial slope), and the outliers of the femoral flexion angle (outlier: $< 0^\circ$ femoral flexion angle or $> 5^\circ$ femoral flexion angle).

For the anteroposterior and lateral weight-bearing standing radiographs, the feet were placed apart with the knees in maximum extension and the toes pointing straight. The angles were calculated using a digital vectoral goniometer and the radiographs. Two independent investigators (TW and NK) performed the radiographic measurements. The mean of the 2 results was used in the analysis.

Statistical Analysis

Descriptive statistics included means and standard deviations for continuous variables and frequencies and percentages for categorical variables. Demographic and clinical variables were compared between the PS and constrained groups using paired 2-tailed Student *t*-tests for continuous variables and chi-square test or Fisher exact test for categorical variables.

A univariate analysis of the predictive factors for stemless constrained insert use in primary TKA with varus deformity for all variables was initially performed with a logistic regression for each variable. A multivariate analysis was subsequently performed on the variables that showed a statistically significant correlation in the univariate analysis ($p < 0.05$) with a logistic regression. The results of the regression analyses are presented as odds ratios (ORs) with accompanying 95% confident intervals (CIs). The results were considered to be statistically significant when the null value (1.00) was absent from the CI or the *p*-value was < 0.05 . A receiver operating characteristic

(ROC) curve analysis was performed to calculate the sensitivity and specificity, and the area under the curve (AUC) to identify the cutoff point for a preoperative degree of an anatomic tibiofemoral varus angle needing use of a constrained articulation. The optimal cutoff point was defined as the concentration with the highest sum of sensitivity and specificity.¹⁸⁾ The variable with the greatest AUC was defined as the most effective tool for classifying patients into the 2 groups. Data were analyzed using IBM SPSS ver. 23.0 (IBM Corp., Armonk, NY, USA). The computed power was achieved with an alpha of 0.05, a sample size of 286, and each OR and R-squared attributed to 14 independent variables using Z test with a significance level of 0.05.

RESULTS

Demographic and Clinical Variables Data

A total of 554 knees were identified but 52 were excluded owing to valgus deformity and 5 owing to incomplete data. Thus, a total of 497 knees were included in this study. The constrained insert was used in 130 of 497 knees (26.1%). The preoperative, intraoperative, and postoperative demographics and clinical variables between the PS and constrained groups were compared, which revealed that the following variables were significantly different between the groups: ROM, KSS, severity of varus angle (mild, moderate, severe), severity of coronal plane laxity (mild and severe), severity of sagittal plane laxity (moderate and severe), posterior tibial slope, and degree of soft-tissue release (mild and severe) (Table 1).

Predictive Factors for Constrained Insert Use

Table 2 examines the ORs of the predictive factors for constrained insert use through the multivariate regression analysis. Preoperative, intraoperative, and postoperative clinical factors associated with the increased adjusted risk of constrained insert use were severe varus deformity (OR, 5.78; 95% CI, 2.75–12.16; $p < 0.001$) and severe release of soft tissue (OR, 6.38; 95% CI, 2.94–13.85; $p < 0.001$). No meaningful differences were found in the other factors. An ROC curve was constructed to determine the optimal cut-off value of 19.8° for the tibiofemoral angle that necessitates the use of a constrained insert with an AUC of 0.7 (95% CI, 0.4–0.8) (Fig. 4).

DISCUSSION

To identify the prevalence and predictive factors associated with an increased constrained insert use, a retrospective study was conducted. In this study, the prevalence of

Table 1. Comparison of Demographic and Clinical Variables between the PS and Constrained Groups

Variable	PS group (n = 367)	Constrained group (n = 130)	p-value
Preoperative variable			
Age (yr)	69.5 ± 7.0	68.9 ± 7.3	0.408
Sex (male : female)	69 : 298	16 : 114	0.104
Body mass index (kg/m ²)	26.5 ± 3.8	26.9 ± 4.8	0.348
Range of motion (°)	116.3 ± 20.3	116.1 ± 21.2	0.948
Knee Society score	34.6 ± 14.1	30.3 ± 13.0	0.003*
Severity of varus angle			
Mild	118 (32.2)	12 (9.2)	< 0.001*
Moderate	122 (33.2)	22 (16.9)	< 0.001*
Severe	127 (34.6)	96 (73.8)	< 0.001*
Severity of coronal plane laxity			
Mild	208 (56.7)	53 (40.8)	0.002*
Moderate	115 (31.3)	44 (33.8)	0.662
Severe	44 (12.0)	33 (25.4)	0.001
Severity of sagittal plane laxity			
Mild	66 (18.0)	21 (16.2)	0.689
Moderate	246 (67.0)	64 (49.2)	< 0.001*
Severe	55 (15.0)	45 (34.6)	< 0.001*
KL grade 4	327 (89.1)	121 (93.1)	0.232
Posterior tibial slope (°)	11.5 ± 4.4	12.7 ± 5.5	0.009*
Intraoperative variable			
Degree of soft-tissue release			
1st step (mild)	125 (34.1)	27 (20.8)	0.005*
2nd step (moderate)	217 (59.1)	61 (46.9)	0.018*
3rd step (severe)	25 (6.8)	42 (32.3)	< 0.001*
Postoperative variable			
Outlier of hip-knee-ankle angle	103 (28.1)	46 (35.4)	0.120
Outlier of posterior tibial slope	107 (29.2)	43 (33.1)	0.437
Outlier of flexion angle	141 (38.4)	44 (33.8)	0.399
Tibiofemoral angle (°)	4.9 ± 3.9	5.4 ± 3.7	0.200

Values are presented as mean ± standard deviation or number (%).

PS: posterior-stabilized, KL: Kellgren and Lawrence radiographic grading.

*Indicates significant difference ($p < 0.05$).

Table 2. Multivariable Logistic Regression Analysis to Identify Predictive Factors for the Use of Constrained Insert in Varus TKA

Characteristic	Odds ratio	95% CI	p-value
Preoperative variable			
Age (yr)			
≤ 65	1 (Reference)		
> 65	0.71	0.42–1.18	0.182
Sex			
Male	1 (Reference)		
Female	1.60	0.81–3.15	0.174
Body mass index (kg/m ²)			
Underweight to normal (≤ 22.9)	1 (Reference)		
Overweight to obese (≥ 23.0)	1.02	0.54–1.95	0.945
Range of motion (°)			
≤ 100	1 (Reference)		
> 100	0.87	0.48–1.58	0.645
Knee Society score			
≤ 50	1 (Reference)		
> 50	0.58	0.22–1.52	0.271
Severity of varus angle			
Mild	1 (Reference)		
Moderate	1.54	0.70–3.40	0.286
Severe	5.78	2.75–12.16	< 0.001*
Severity of coronal plane laxity			
Mild	1 (Reference)		
Moderate	0.95	0.55–1.64	0.860
Severe	0.84	0.41–1.72	0.642
Severity of sagittal plane laxity			
Mild	1 (Reference)		
Moderate	0.53	0.28–1.01	0.052
Severe	0.87	0.41–1.84	0.714
KL grading			
3	1 (Reference)		
4	0.74	0.31–1.80	0.509
Posterior tibial slope (°)			
≤ 12	1 (Reference)		
> 12	1.17	0.73–1.87	0.515

Table 2. Continued

Characteristic	Odds ratio	95% CI	p-value
Intraoperative variable			
Degree of soft-tissue release			
1st step (mild)	1 (Reference)		
2nd step (moderate)	1.40	0.79–2.47	0.252
3rd step (severe)	6.38	2.94–13.85	< 0.001*
Postoperative variable			
Outlier of hip-knee-ankle angle			
No outlier	1 (Reference)		
Outlier	1.22	0.74–2.01	0.436
Outlier of posterior tibial slope			
No outlier	1 (Reference)		
Outlier	1.28	0.78–2.11	0.320
Outlier of flexion angle			
No outlier	1 (Reference)		
Outlier	0.73	0.45–1.20	0.219

TKA: total knee arthroplasty, CI: confidence interval, KL: Kellgren and Lawrence radiographic grading.

*Indicates significant difference ($p < 0.05$).

constrained insert use in primary TKA with varus deformity was found to be 26.1%, while preoperative severe varus deformity and severe release of soft tissue through the superficial MCL were found to be the key factors for the use of the constrained insert in primary varus TKA. A preoperative anatomic tibiofemoral varus angle of $> 19.8^\circ$ was associated with the use of a constrained articulation and could be utilized prospectively to predict implant selection.

Stability is essential for successful TKA. Increasing the constraint to achieve stability in complex primary TKA often requires the use of the VVC system to provide wider polyethylene posts and larger femoral component boxes to limit the varus-valgus and torsional movements. However, several concerns with the VVC design persist. One is that a high degree of post-box constraint can increase the load to bone-implant interface, and stem extension is invasive, which can increase the complexity and cost of surgery. The modern TKA design tries to address these pitfalls of the VVC system by providing stemless constrained inserts that can be switched from the PS insert intraoperatively. The use of the stemless insert in a primary TKA may be preferred to the VVC system because the bone defect in

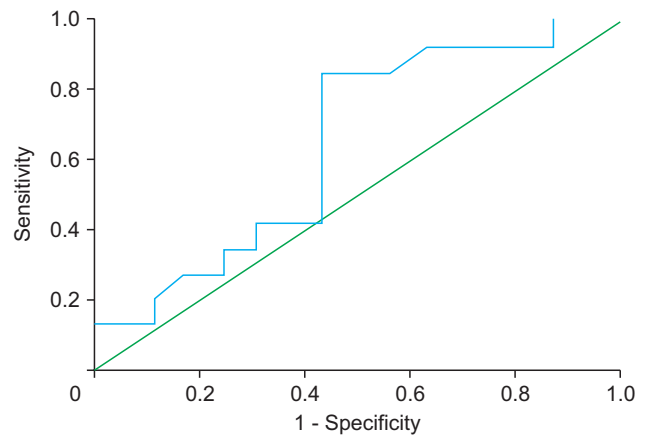


Fig. 4. The receiver operating characteristic (ROC) curve was used to determine the threshold level of the tibiofemoral varus angle above which the risk of constrained insert use was significantly elevated. Diagonal line represents a reference line. The inflection point of the curve corresponds to the preoperative tibiofemoral varus angle of 19.8° , which represents the value with the highest sensitivity and specificity. The area under the curve of 0.7 (95% confidence interval, 0.4–0.8) is the area beneath the ROC.

primary TKA is still minimal. Selective use of the stemless constrained insert is recommended. Therefore, it would be helpful for surgeons prior to the operation to be able to identify the knees with the possibility of using the stemless constrained insert.

To the best of our knowledge, there has never been any study reporting precise factors that can be used preoperatively to help predict the use of the constrained articulation to provide stability of the knee intraoperatively. Previously, a retrospective study found high prevalence of constrained insert use in the patients with severe varus deformity undergoing TKA using the extensive medial soft-tissue release technique.¹³ While the severe varus deformity and severe release of soft tissue might be deemed to play roles in the increased risk for using constrained inserts, there was no direct evidence on this.

Our study therefore aimed to identify predictive factors for the use of the stemless constrained insert in primary TKA to help the surgeon prepare the implant preoperatively. We found that severe varus deformity or severe release of soft tissue was associated with an increased risk of constrained insert use in primary varus TKA without stem extensions. In the current study, we found that the patients with severe varus deformity measured with tibiofemoral angle from radiography had a 5.78-fold higher risk of needing constrained insert use than the patients with mild varus deformity (adjusted OR, 5.78; 95% CI, 2.75–12.16; $p < 0.001$). We identified the optimal value of

19.8° tibiofemoral varus angle that could be utilized prospectively to predict implant selection. This information is important for surgeons to determine the severity of the deformity preoperatively so that implants with the appropriate constraint are made available.

In addition to severe varus deformity factor, this current study performing the classic Insall medial soft-tissue release technique on varus deformity patients found that patients with severe release of the soft tissue or superficial MCL release had an increased risk of constrained inserts used (adjusted OR, 6.38; 95% CI, 2.94–13.85; $p < 0.001$) compared to the patients with mild soft-tissue release. Insufficient medial soft-tissue release resulted in unsatisfactory deformity correction, whereas excessive superficial MCL release relatively increased the flexion-extension gap on the medial side, which could eventually lead to instability of the knee. When faced with this problem, surgeons have 2 options to manage. The first option is to use lateral soft-tissue release for gap balancing and a thick polyethylene often needs to be inserted, which can result in restricted ROM due to higher joint line, patellofemoral maltracking, and extension restriction. The second option, which was used in this study, is to switch to a constrained insert that provides stability and retain the joint line and patellofemoral kinematics. Unlike our study that examined only primary TKAs with varus deformities, an equivalent retrospective study examining primary TKAs with valgus deformities found that medial laxity was the sole independent factor associated with the higher frequency of implantation of constrained prostheses with an OR of 1.9 (1.2–2.7).¹⁹⁾ However, this study did not examine the intraoperative factors on the prosthetic switches to VVC; thus, the severity of soft-tissue release was not considered in the study.

Our study revealed 26.1% prevalence of constrained insert use in primary TKA with varus deformity. Previously, Goudarz Mehdikhani et al.¹³⁾ conducted a similar retrospective study focusing on the patients with severe varus deformity undergoing TKA using the extensive medial soft-tissue release technique and found a higher incidence (> 40%) of constrained insert use in severe varus deformities. However, another study with valgus deformity reported a similar prevalence (26/93 implantations, 27.96%) of constrained prostheses use to ours.¹⁹⁾ Considering the high incidences from our and previous reports, the surgeon should have a constrained prosthesis available, especially

in the cases with the risk factors.

The present study has several strengths. The series of patients were consecutive, and all operations were performed by a single surgeon. Therefore, the surgical technique and decision-making with respect to the use of a PS or a constrained insert were identical. While most previous studies were concerned only with the reliable results of constrained insert use in primary TKA without stem extensions, this present study employed a multivariate logistic regression analysis to estimate the association between constrained insert use and independent predictive factors including various clinical and radiographic parameters.

There are also several limitations of this study. First, the retrospective nature of this study allows demonstration of correlation, not the true causation. Although we adjusted for potential confounders, there may have been additional confounders that we could not control. Second, sample sizes in some categories were relatively limited. Third, clinical and radiological outcomes were not investigated; however, the key objectives of this study were to identify the prevalence and predictive factors associated with the constrained insert use during primary TKA for varus deformity.

In conclusion, the prevalence of 26.1% for constrained insert use was found in our study. Preoperative anatomic tibiofemoral varus angle of > 19.8° and severe release of soft tissue through the superficial MCL were associated with the use of constrained articulation during surgery. Such information is useful for surgeon's counseling to patients regarding the associated cost, improved efficiency of surgical sequence planning, and most importantly, having appropriate prosthetic parts and instruments available prior to surgery.

CONFLICT OF INTEREST

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

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