





CLINICAL ARTICLE

A Comparison Between Unstemmed and Stemmed Constrained Condylar Knee Prostheses in Primary Total Knee Arthroplasty: A Propensity Score-Matched Analysis

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Objective: To compare and analyze the clinical outcomes between unstemmed and stemmed constrained condylar knees (CCK) in complex primary total knee arthroplasty (TKA) in terms of implant survivorship, change in outcome evaluations, and complications.

Methods: We reviewed 156 consecutive patients who received primary TKA using PFC[®]SIGMA[®]TC3 (TC3) of constrained condylar design between January 2009 and January 2017 at our institution. After removing patients who met exclusion criteria, 25 patients were identified as unstemmed TC3 cases and 81 as stemmed TC3 cases. Propensity score matching was used to select 25 stemmed cases as a control group for the unstemmed group with comparable preoperative conditions including preoperative demographics, preoperative diagnosis, preoperative range of motion, main reason to use TC3, ASA score (American Society of Anesthesiologists), and follow-up duration. Preoperative and postoperative clinical evaluations including Knee Society Score (KSS), Hospital for Special Surgery (HSS) score, the 12-Item Short-Form Health Survey (SF-12), and the range of motion (ROM) were obtained and compared. The instability, periprosthetic fracture, radiolucent lines, polyethylene wear, and heterotrophic ossification were assessed according to the anteroposterior and lateral radiographs of the knee. The complications and implant survivorship between the two groups were also recorded and compared.

Results: After the index surgery, both groups showed substantial improvement in KSS (knee and function), HSS score, SF-12, and ROM compared with baseline. There was no significant difference in the mean KSS scores (knee and function), HSS score, SF-12, and ROM between the unstemmed and stemmed group postoperatively. No statistically significant difference was found in the overall complication rate between the two groups. The overall Kaplan–Meier survivorship was 98.0% (95% confidence interval 94.1%–100.0%) at 7 years. No significant difference was found in the survival rate between the unstemmed group (100.0%) and the stemmed group (96.0%) at 7 years (log rank, $P = 0.317$). The mean duration of follow-up was 7.0 years for unstemmed group and 7.7 years for stemmed group.

Conclusions: In patients with adequate bone stock receiving complex primary TKA, unstemmed CCK could achieve similar clinical outcomes at mid-term follow-up as stemmed CCK.

Key words: Constrained condylar; Knee clinical outcomes; Stem extension; Total knee arthroplasty

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Introduction

Total knee arthroplasty (TKA) is a successful and reproducible procedure for end-stage knee disorders¹. The key to a successful outcome of TKA is to achieve appropriate alignment, adequate deformity correction, and balance which can be accomplished efficiently by posterior stabilized (PS) design. However, there are certain clinical situations, such as incompetent collateral ligaments, severe axial deformities, broad bone defects, or inability to achieve a balanced flexion and extension gap, which require additionally constrained prosthesis in primary TKA²⁻⁴. Constrained condylar knee (CCK) was designed as a non-hinged semi-constrained implant to help stabilize the knee in these challenging settings. Through a tall and wide tibial post, constrained condylar knee prosthesis improves coronal and sagittal stability while exerting less stresses at the implant, cement, and bone interfaces than hinged alternatives.

Normally, enhancing constraint has been in conjunction with intramedullary stem extensions, which have been reported as having an excellent ability to decrease stress at the bone implant interface and satisfying clinical outcomes in the primary TKA⁵⁻¹⁰. However, stem extensions may also lead to several adverse effects, including chance of thigh and leg pain, chance of embolization, the technical challenge of preparing intramedullary canals, increased costs and surgical time, and more surgical difficulties at later revision¹¹⁻¹³. Therefore, unstemmed CCK devices were designed to provide increasing constraint without using stem extensions, which also have been reported with clinical success in the primary TKA settings¹⁴⁻¹⁷.

However, unstemmed CCK has been questioned as it might not disperse as much stress as stemmed CCK, which may cause early component loosening and polyethylene wear. To date, only one unmatched study has compared and analyzed the outcomes of unstemmed CCK and stemmed CCK for primary TKA¹⁸. We hypothesized that patients who received primary TKA using unstemmed CCK could achieve similar satisfactory results as patients using stemmed CCK. Therefore, the aim of this study was to compare the clinical and radiographic outcomes involving the use of unstemmed and stemmed CCK for complex primary TKA. Specifically, we asked (i) whether patients with TKA using unstemmed CCK have an increased revision risk for mechanical reasons compared with patients who underwent TKA with stemmed CCK, (ii) whether differences in the clinical ratings exist between patients using unstemmed CCK and stemmed CCK in TKA, and (iii) whether patients who underwent TKA using unstemmed CCK have an increased complication risk compared with patients who underwent TKA with stemmed CCK.

Materials and Methods

Methods

After approval from the institutional review board of our hospital, we retrospectively review all 156 patients who underwent primary TKA using modular TC3 (PFC[®]SIGMA[®]TC3,

DePuy Johnson & Johnson) (Fig. 1) between January 2009 and January 2017. Informed consent was obtained from all patients. Inclusion criteria were as follows: (i) patients aged older than 18 years with end-stage knee disorders; (ii) primary TKA performed between January 2009 and January 2017 using TC3 implants; (iii) patients who were retrospectively recruited and provided informed consent. Exclusion criteria were as follows: (i) only one stem extension placed in primary TKA; (ii) TKA associated with oncologic resection; (iii) patients who were lost to follow-up and could not be contacted.

Three patients died for reasons unrelated to the surgery, 11 patients were lost to follow-up and could not be contacted by telephone and e-mail, and 36 patients had only used one stem to augment fixation. The remaining cases were included as 25 unstemmed cases and 81 cases with two press-fit stem extensions. Propensity score matching was used to select 25 stemmed cases as a control group for the unstemmed group according to age, gender, body mass index, American Society of Anesthesiologists score, preoperative diagnosis, preoperative range of motion, main reason to use TC3, and follow-up duration. Detailed demographic characteristics of the two groups are illustrated in Table 1. According to the surgery records, the main reason to use TC3 implants was divided into (i) issues of soft tissue balance including incompetent collateral ligaments and unbalanced flexion and extension gap and (ii) bone defects¹⁹. The two groups were compared in clinical and radiographic outcome and implant survivorship.

Surgical Technique

The surgery processes were as follow: (i) all TKA procedures were performed under general anesthesia and placed in supine position; (ii) all TKA procedures were performed using an anterior midline skin incision with medial parapatellar approach²⁰; (iii) intramedullary guides were used for the femur cut and extramedullary guides were used for the tibia cut. Distal femoral rotation was determined based on the transepicondylar axis and Whiteside's line. Spacer block was used to assess the balance of the flexion and extension gap, ligament and retinacular release was conducted for severe valgus or varus deformity as described by Insall *et al.*²⁰; (iv) cement, bone allograft, or augment implant were used to manage the bone defects in both groups; (v) uncemented femoral and tibial stem extensions were used in the stemmed group (Fig. 2). Postoperatively, patients were braced and allowed to bear weight as tolerated.

All operations were performed using the same surgical technique by five experienced senior surgeons. The decision to use constrained condylar knees and stem extensions was determined by the surgeon according to the preoperative and intraoperative conditions²¹. Second-generation CCK prostheses (TC3) were used when stability could not be realized by posterior-stabilized (PS) implants. The main reason to use TC3 implants was summarized in Table 1.

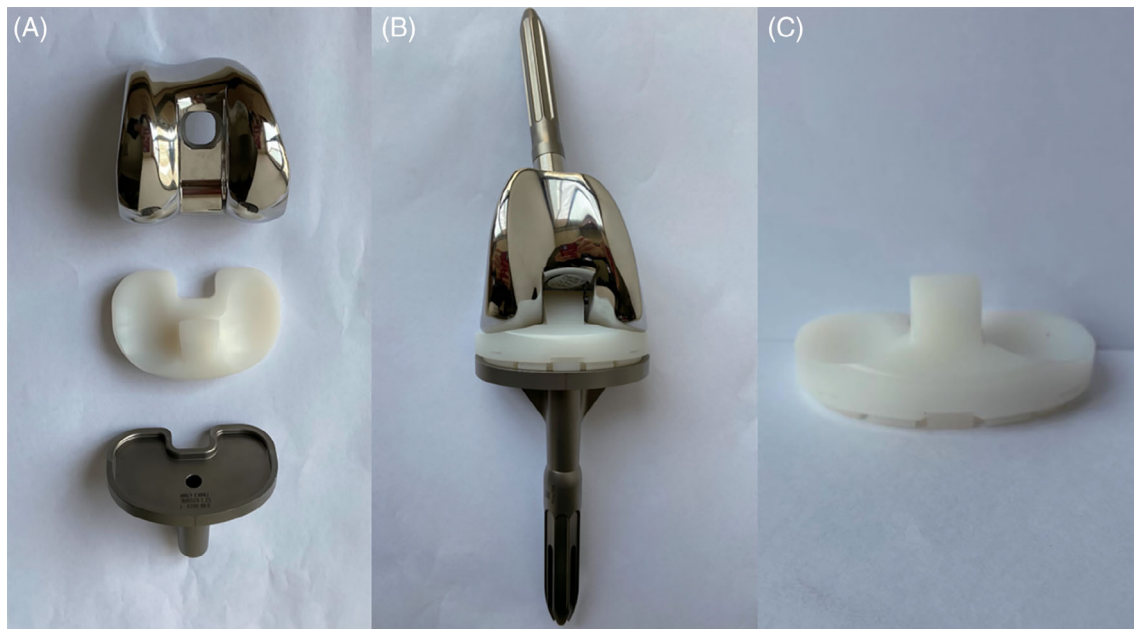


Fig. 1 (A) The view of the unstemmed constrained condylar prosthesis (PFC[®]SIGMA[®]TC3, DePuy Johnson & Johnson) used in this study. (B) Shows the view of the stemmed constrained condylar prosthesis used in this study. (C) Shows the frontal view of the TC3 insert with a tall and wide tibial post.

Knee Society Score Assessment

The Knee Society Score (KSS) system was used to evaluate the outcome of TKA. The KSS was divided into two parts including a knee score that rated the knee joint itself and a functional score that rated the patient's ability to walk and climb stairs, while flexion contracture, extension lag, and misalignment were dealt with as deductions²². The scores

of two parts ranged from 0 to 100, with higher values reflecting better outcomes.

Hospital for Special Surgery Score Assessment

The Hospital for Special Surgery (HSS) score was a disease-specific test which assessed the knee disabilities and methods of treatment, especially TKA²³. HSS score assessed domains including pain, function, range of motion, muscular strength, deformity, and instability. The clinical results were rated as excellent (≥ 85 points), good (70–84 points), fair (60–69 points), or poor (< 60 points) according to the HSS scoring system, which had a maximum of 100 points (best possible outcome).

12-Item Short-Form Health Survey Assessment

The 12-Item Short-Form Health Survey (SF-12) was used to measure the health of included cases. It is a generic health rating scale to evaluate physical and mental health of patients including physical component summary (PCS) and mental component summary (MCS)²⁴. PCS was rated according to physical functioning, role physical, body pain, and general health, and MCS was evaluated based on role emotional, mental health, vitality, and social functioning.

Clinical Assessment

ROM, direction of deformity, and extent of deformity were recorded. The ROM was measured by subtracting flexion from extension. We also measured the incidence of complications,

TABLE 1 Baseline characteristics of all recruited patients

Variable	Unstemmed group (n = 25)	Stemmed group (n = 25)	P-Value
Age (y)	59.6 ± 11.0	57.9 ± 11.3	0.597
Female gender	21	20	1.000
Body mass index (kg/m ²)	21.7 ± 2.1	22.2 ± 3.3	0.526
ASA score			1.000
1	12	12	
2	13	13	
Normal/varus/valgus (n)	3/12/10	4/8/13	0.630
Preoperative diagnosis			0.477
Osteoarthritis	11	7	
Rheumatoid arthritis	10	9	
Post-traumatic	3	7	
Post-septic	1	2	
Main reason to use TC3			0.725
Issues of soft tissue balance	21	19	
Bone defects	4	6	
Average Follow-up (y)	7.0 ± 2.1	7.7 ± 2.6	0.256

ASA, American Society of Anesthesiologists.

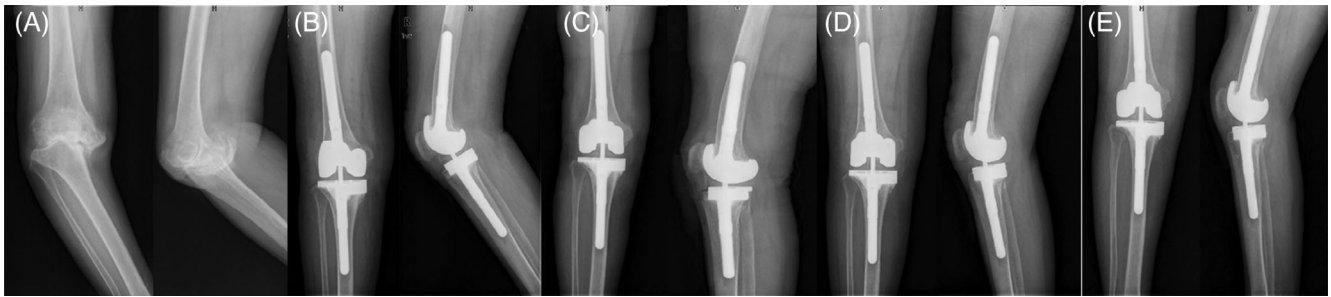


Fig. 2 A male aged 59 years underwent a primary TKA using stemmed CCK due to rheumatoid arthritis. (A) Anteroposterior and lateral views of the right knee preoperatively. (B) Postoperative anteroposterior and lateral views of the right knee. (C) Periprosthetic infection of the right knee 15 days postoperatively. (D) Anteroposterior and lateral views after the treatment of debridement and liner replacement. (E) Anteroposterior and lateral views of the right knee with stable fixation and no reactivation of infection at 8-year follow-up.

including infection, patella baja, patella clunk syndrome, peroneus communis nerve palsy, the end of stem pain, and implant loosening. The rate of survivorship was determined according to the revisions and implant removal for any reasons.

Radiographic Assessment

Radiographs (serial standardized anteroposterior and lateral radiographs of knee) were taken for patients preoperatively and at each follow-up, using a standardized radiographic technique (Figs 3 and 4). Radiographs were evaluated for instability, heterotrophic ossification, periprosthetic fracture, radiolucent lines, and polyethylene wear. Progressive and non-progressive radiolucent lines in femoral and tibial components were assessed based on the Knee Society Roentgenographic Evaluation system of Ewald²⁵. For the assessment of interobserver variability, all clinical and radiological measurements were performed independently by two trained investigators.

Statistical Analysis

Propensity scores depending on logistic regression were used to match the unstemmed group and stemmed group.

Student's t-test and the Wilcoxon rank-sum test were used to analyze continuous variables while comparing between two groups. The paired t-test was used to analyze the continuous variables for each group. Categorical values were analyzed using the chi-squared or Fisher's exact test. Implant survivorships were evaluated with Kaplan–Meier survival analysis using the endpoints of revision for any reason. All statistical analyses were performed using SPSS Statistics software version 25.0 (IBM, Armonk, NY). *P* values <0.05 were considered statistically significant.

Results

KSS, HSS, and SF-12 Improvement

The preoperative and postoperative clinical ratings were summarized in Table 2. After the index surgery, both groups showed substantial improvement in the KSS (knee and function), HSS score, and the mental and physical components of the SF-12 score compared with baseline. There was no significant difference in clinical outcome as measured by the KSS (knee and function), HSS score, and the mental and physical



Fig. 3 A female aged 63 years underwent a primary TKA using unstemmed CCK due to severe osteoarthritis. (A) Anteroposterior and lateral views of the left knee preoperatively. (B) Postoperative anteroposterior and lateral views of the left knee at 1-week follow-up. (C) Anteroposterior and lateral views of the left knee at 4-year follow-up examination. The femoral and tibial components were solidly fixed.

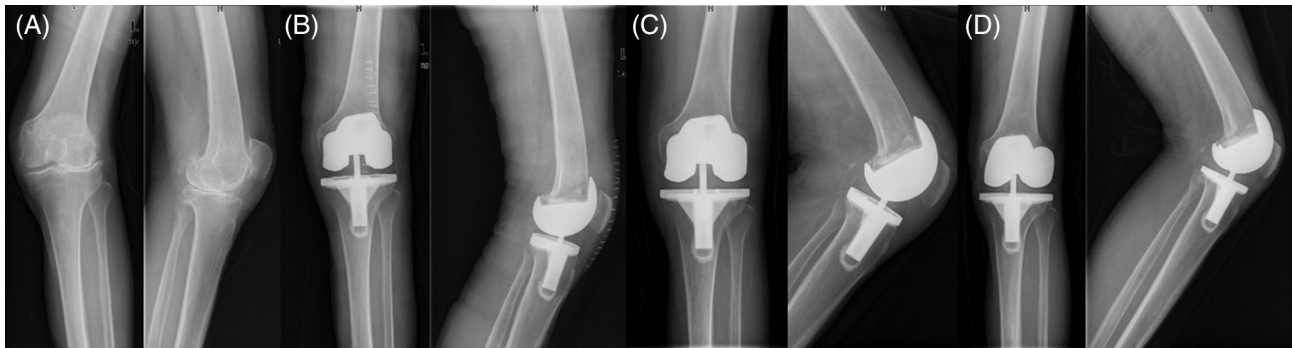


Fig. 4 A male aged 74 years received a primary TKA using unstemmed CCK due to severe osteoarthritis. (A) Anteroposterior and lateral views of the left knee preoperatively. (B) Postoperative anteroposterior and lateral views of the left knee at 1-week follow-up. (C) Anteroposterior and lateral views of the left knee at 5-year follow-up examination. (D) Anteroposterior and lateral views of the left knee at 11-year follow-up examination. The femoral and tibial components were stable without radiolucent line.

components of the SF-12 score when the two groups were compared before the index surgery and at last follow-up. We also performed subgroup analysis based on different direction of the coronal deformity (valgus and varus) between the unstemmed and stemmed group before the index surgery. At the most recent follow-up for patients with preoperative varus knees, the mean KSS (knee plus function) was 172.8 ± 14.0 in the unstemmed group and 162.9 ± 15.7 in the stemmed group ($P = 0.155$), the mean HSS score was 86.3 ± 7.2 in the unstemmed group and 80.8 ± 8.1 in the stemmed group ($P = 0.129$), and the mean SF-12 (PCS plus

MCS) was 44.8 ± 3.0 in the unstemmed group and 45.0 ± 3.4 in the stemmed group ($P = 0.865$). For patients with preoperative valgus knees, the mean KSS (knee plus function) was 176.0 ± 8.9 in the unstemmed group and 171.3 ± 9.6 in the stemmed group ($P = 0.244$), the mean HSS score was 86.8 ± 6.9 in the unstemmed group and 85.9 ± 6.7 in the stemmed group ($P = 0.762$), and the mean SF-12 (PCS plus MCS) was 45.9 ± 2.8 in the unstemmed group and 44.1 ± 2.5 in the stemmed group ($P = 0.117$) at last follow-up.

Clinical Evaluation

After the index surgery, both groups showed substantial improvement in the range of motion compared with baseline. There was no significant difference in the range of motion when the two groups were compared before the index surgery and at last follow-up. Including all cases of primary TKA using TC3, Kaplan–Meier survivorship with an endpoint of revision was 98.0% (95% confidence interval 94.1%–100.0%) at 7 years. In comparison between the two matched groups, no significant difference was found in the survival rate of the unstemmed group (100%) and the stemmed group (96.0%, 95% confidence interval 88.2%–100.0%) at 7 years (log rank, $P = 0.317$) (Fig. 5). As aforementioned, one patient (4.0%) who received primary TC3 implant with stem extensions required a revision surgery 15 days postoperatively due to periprosthetic infection.

Radiographic Evaluation

Preoperative deformities were measured for each group according to radiographs of the full-length view of the lower extremities. In the unstemmed group, there were 10 valgus deformities (on average by $22.0^\circ \pm 10.3^\circ$) and 12 varus deformities (on average by $17.1^\circ \pm 5.9^\circ$). The remaining three were neutral or had little deformity. In the stemmed group, there were 13 valgus deformities (on average by $27.5^\circ \pm 10.8^\circ$) and eight varus deformities (on average by

TABLE 2 Preoperative and postoperative clinical data

Variable	Unstemmed group (n = 25)	Stemmed group (n = 25)	P-Value
ROM (°)			
Preoperative	82.4 ± 30.1	71.8 ± 31.4	0.229
Last follow-up	104.1 ± 13.2	99.6 ± 15.4	0.271
KSS-knee score			
Preoperative	36.6 ± 10.5	33.0 ± 10.9	0.239
Last follow-up	86.2 ± 6.5	84.5 ± 7.5	0.400
KSS-function score			
Preoperative	37.2 ± 16.2	35.4 ± 13.1	0.668
Last follow-up	87.2 ± 9.8	85.4 ± 9.8	0.519
HSS score			
Preoperative	34.7 ± 10.1	32.6 ± 10.4	0.468
Last follow-up	85.9 ± 7.1	84.6 ± 5.7	0.470
SF-12			
PCS			
Preoperative	11.5 ± 3.0	10.2 ± 3.1	0.160
Last follow-up	21.1 ± 1.7	20.8 ± 1.6	0.556
MCS			
Preoperative	13.9 ± 2.5	13.1 ± 2.7	0.288
Last follow-up	24.1 ± 2.5	23.8 ± 2.1	0.586

Continuous data: mean (standard deviation); HSS, Hospital for Special Surgery; KSS, Knee Society Score; MCS, mental component summary; PCS, physical component summary; ROM, range of motion; SF-12, 12-item short-form health survey questionnaire.

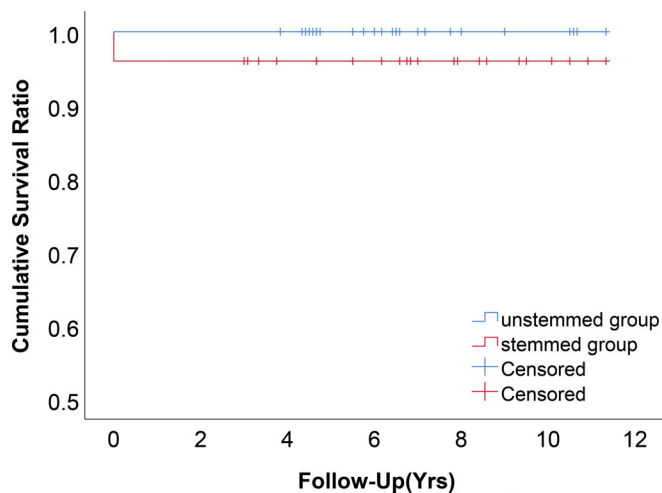


Fig. 5 Kaplan–Meier survival curves with endpoints of revision for any reason

22.5° ± 12°). Four patients were neutral or had little deformity. In both groups, all knees had alignment deviations within ±3° postoperatively. All radiolucent lines noted in the present study were non-progressive (<2 mm). No obvious polyethylene wear was observed in all cases at the latest follow-up. In the unstemmed group, one knee had non-progressive radiolucent line in the tibia (zone 4) and one knee in the femur (zone 1) while one knee had non-progressive radiolucent line of the tibia (zone 1) in the stemmed group. Instability, heterotrophic ossification, periprosthetic fracture, and polyethylene wear were not found in either group during the follow-up.

Complications

Complications of the two groups were displayed in Table 3. Infection was discovered in three patients of the stemmed group, two superficial infection and one periprosthetic infection. The two patients with diagnosis of superficial infection were treated with intravenous antibiotics, irrigation, and debridement. The infecting organism of cultures were *Non-tuberculous mycobacteria* and *Staphylococcus epidermis*, respectively. The periprosthetic infection was discovered in one case 15 days postoperatively and the infecting organism of culture was *Pseudomonas aeruginosa*. The patient received debridement, liner exchange and chronic antibiotic suppressive therapy. At the final follow-up, the knee prosthesis was stable, and no reactivation of infection was presented. One patient in the unstemmed group underwent peroneus communis nerve palsy and recovered fully after neurotrophic therapy within 6 months and one patient in the unstemmed group received arthroscopic debridement for patella clunk syndrome.

Discussion

Constrained condylar knees are rarely needed in primary TKA; many studies have recommended the CCK with stem extension in complex primary TKA to help stabilize the

knee^{5–10}. To reduce negative effects of stem extension such as possible end of stem pain, possible embolization and so on, manufacturers provide unstemmed CCK design. Although unstemmed CCK has been shown to provide excellent knee stability^{14–17}, concerns of its ability to offload stress still exist. There is a lack of sufficient evidence to demonstrate whether satisfactory outcomes of unstemmed CCK in primary TKA can be achieved as stemmed CCK. Furthermore, to our knowledge, only one unmatched study has previously compared outcomes of 2-year follow-up between unstemmed CCK and stemmed CCK in primary total knee arthroplasty¹⁸. Therefore, we attempt to address this issue by comparing the clinical and radiographic outcomes of CCK involving the use or nonuse of stem extensions for primary TKA.

Implant Survivorship

In the present study, relatively young patients were included (mean age 59.6 ± 11.0 years in unstemmed group and 57.9 ± 11.3 years in stemmed group) and received constrained condylar implants with or without stem extensions for primary TKA. Although studies have reported that survival rate of CCK was lower in younger patients due to the higher activities^{26,27}, the survival rate in the present study was higher relative to several former studies^{14–16}. The possible explanations may include: first, the fibrous tissue caused by long-term severe knee disorders resulted in activity restrictions; second, because of cultural differences between West and East and the terrible experience of severe knee deformity, no sports fanatic was included in the present study, and the compliance of included patients were extraordinarily high. In addition, there were no statistically significant differences in the survival rate between the two groups. However, Ruel *et al.*¹⁶ observed that there was a significant number of cases of isolated femoral loosening observed in cohort of unstemmed CCK and Moussa *et al.*¹⁸ found that there was a trend toward a higher revision rate with unstemmed CCK due to aseptic loosening compared with stemmed group. In the present study, no aseptic loosening in the unstemmed group was observed. A possible interpretation might be that patients in the unstemmed group may have better bone quality than the stemmed group despite propensity score matching being used to acquire comparable preoperative conditions between the two groups, and only 16% patients in the unstemmed group presented with broad bone defect. Therefore, this demonstrated that CCK without stem extension did not have a markedly negative effect on implant survivorship among patients with adequate bone quality. Furthermore, Costa *et al.*²⁸ reported that stemmed CCK implants were at a higher revision rate due to periprosthetic infection, which was further confirmed by the present study.

Clinical Outcomes

It is generally recommend to use the least amount of constraint to acquire the most amount of stability, which results in satisfactory clinical evaluation in conducting TKA. In the

TABLE 3 Complications and revisions

Complications	Unstemmed group (n = 25)	Stemmed group (n = 25)	P-Value
Superficial infection	0	2	0.490
Patella baja	1	0	1.000
Peroneus communis nerve palsy	1	0	1.000
Patella clunk syndrome	1	0	1.000
End of stem pain	0	4	0.110
Revision	0	1	1.000
Periprosthetic infection	0	1	
Femoral loosening	0	0	
Tibial loosening	0	0	
Liner exchange	0	1	

present study, there were no statistically significant differences in the clinical evaluation between the two groups including KSS, HSS, and SF-12 scores at mean 7-year follow-up, and the mid-term results are encouraging. Lachiewicz *et al.*⁶ reported the results of second-generation stemmed constrained condylar prosthesis in primary TKA, at a mean follow-up of 5.4 years, with lower clinical ratings than the present study. The possible interpretations of better clinical score in the present study may include: first, older patients with a mean age of 73.9 years were included in their study, which may had a negative influence on the clinical ratings as reported in the literature, as the high activities of the younger patients obtained better clinical outcomes^{26,27}; second, the end of stem pain with an incidence from 0% to 19% might cause unsatisfactory clinical ratings when achieving a tight press-fit with stem extension in the patulous distal femur or tibia^{11,12}. Cemented stems were used to avoid this difficulty and reported excellent results in the short term²⁹⁻³¹. However, if the necessity of revision for these cemented implants occurred later, the cement in the intra-medullary canal might be difficult to remove, which made the revision process complex. Young patients had higher rates of failure of TKA, and registry data showed that there was worse implant survivorship in the under-55 age group whose 10-year cumulative risk of revision for TKA is between 9% and 11%³². Therefore, after strict clinical assessment, unstemmed CCK might be an alternative choice for relatively young patients in complex primary TKA.

Complications

Although there were no statistically significant differences in the overall complication rate between the two groups, there was a trend toward a higher complication rate due to infection in the stemmed groups. It was reported that the risk of infection in TKA was associated with a longer operative duration³³⁻³⁵. Furthermore, malalignment of the prosthetic component might occur if there was impingement between the stem and the cortical bone of the tibial or femoral, especially in Asian patients where deformed or bowed intra-medullary canals are a common phenomenon, such as femoral lateral bowing in the coronal plane³⁶⁻³⁸. To avoid the malalignment and improper location of the stem in the

canal, intra-operative X-ray was frequently used. The duration of the index surgery was prolonged by preparing the canal for stems, placing the stems, and then confirming their location with X-ray, which also increased the complexity of the surgery, let alone that each extra step raised the possibility of complications.

Limitations

Several limitations exist in the present study. First, the sample size was relatively small. Second, the retrospective nature of the present study decreased the level of evidence. Third, a mean 7-year follow-up is not enough, and larger sample size and longer-term follow-up would provide more meaningful data. Fourth, the surgeries were conducted by five senior joint surgeons; therefore, the differences in surgical manipulations between surgeons may cause potential statistical bias. Fifth, indication for using stem extension was not standardized but left to the judgment of the surgeons, which might lead to relatively mild bone defects in the unstemmed group despite the usage of propensity score matching to acquire comparable baseline. Therefore, we think prospective randomized controlled study between unstemmed and stemmed CCK in a much larger group of patients with adequate bone stock in complex primary TKA should be carried out in the future.

Conclusions

Although the present study demonstrates that unstemmed CCK have excellent clinical outcomes at mid-term follow-up, it must be emphasized that using the least amount of constraint to acquire the most amount of stability remains an important principle of TKA. In addition, since CCK without using stem extension might not offload more stress at the bone-implant interface than stemmed CCK but could avoid the challenge of later revision and certain complications, unstemmed CCK could be an alternative choice in complex TKA. In conclusion, this study demonstrates that unstemmed CCK prostheses can achieve similar clinical results at mid-term follow-up as stemmed CCK in primary complex TKA, not at the cost of significantly decreasing the survivorship.

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Authorship Declaration

All authors listed meet the authorship criteria according to the latest guidelines of the International Committee of Medical Journal Editors and are in agreement with the manuscript.

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