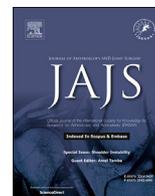




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Mid to long-term outcomes of the primary constrained condylar knee arthroplasty



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ABSTRACT

Background: The design of the constrained condylar knee (CCK) implant is meant to provide significantly more varus-valgus and anterior-posterior stability than a standard implant system. We hypothesized that while an increased constraint in design may lead to radiographic signs of loosening, the pain and functional outcome scores for patients with constrained implants remain acceptable at a mid to long term follow-up.

Methods: 113 patients who underwent a primary TKA with a CCK implant by a single surgeon between the years 2008–2015 were contacted. 28 patients (30 knees) responded and returned for evaluation, which consisted of a Knee Society Score questionnaire and repeat radiographs. The average time to follow-up was 49.5 months.

Results: Pain outcome scores (total of 30 knees) included, 19 excellent (63.3%), 7 good (23.3%) and 4 poor outcomes (13.3%). Function scores included 19 excellent (63.3%), 2 good (6.6%), 4 fair (13.3%), and 5 poor (16.7%) outcomes. There was a significant difference ($p = 0.032$) in pain scores between patients with no signs of radiographic lucency (mean pain score of 88.6) and patients with signs of implant loosening (mean pain score of 78.3). There was no significant difference in functional scores.

Conclusion: The CCK implant is an acceptable option for a total knee arthroplasty which requires the extra stability not provided by a standard implant system. More studies with larger sample sizes, different populations and longer follow-up are needed to further evaluate outcomes in CCK implant recipients.

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1. Introduction

A primary total knee arthroplasty is a safe option with predictable outcomes for patients with painful arthritis who have failed other interventions. The incidence of both primary and revision total knee arthroplasty has significantly increased over the last decade due to many factors including an aging population and more widespread availability. Additionally, the volume of primary

total knee Medicare patients has increased by 161.5% between the years 1991 and 2010.⁸ The need for primary and revision total knee replacements is estimated to more than triple by 2030.⁷ With this increase in demand, there has also been an increase in research into different operative techniques and implant designs. As more patients gain access to orthopaedic care, including those with baseline deformity or ligamentous laxity, CCK implants are more frequently used in obtaining a stable well-aligned knee.

Historically, a constrained total knee arthroplasty has been most often used in revision surgeries. It has also been used during surgeries in which the surgeon is unable to balance a knee intra-operatively.⁵ Indications include a knee with medial or lateral ligamentous insufficiency, loss of bone stock, significant deformities and neuropathic or rheumatoid arthropathy.² The design

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of the implant provides varus-valgus and anterior-posterior stability that cannot be obtained with routine coronal plane balancing alone. Along with this increase in implant constraint, there exists a potential increase in implant wear and failure rates. Previous studies have reported the revision rate for primary TKAs using a constrained implant is more than two times higher compared to unconstrained knees at 10 years.³ The overall revision rate for constrained total knee implants has been reported up to 22% at 10 years, and up to 35% for revision knees, with the most common reason being infection.²

At our institution the use of a constrained total knee implant has been utilized in many primary total knee cases. Specifically, it has been used in patients who are found to have medial or lateral laxity that is unacceptable for standard posterior stabilized total knee

implants intra-operatively. The purpose of this study was to retrospectively review a population of patients that have undergone primary total knee arthroplasty using a constrained condylar knee implant, and evaluate them based on pain, function, and radiographic scales. We hypothesized that despite the increased constraint of their implant, patients would still have positive outcomes as measured by pain and function scores.

2. Methods

After IRB approval, a retrospective chart review was performed on a single-surgeon patient population between the years 2008 and 2015. A cohort of patients who underwent a primary TKA using a constrained condylar implant between 2008 and 2015 with a

Knee Society Score

Clinician's name (or ref) Patient's name (or ref)

During the past 4 weeks..... [Click here for part 2 - FunctionScore](#)

Part 1 - Knee Score

Pain <input type="radio"/> None <input checked="" type="radio"/> Mild / Occasional <input type="radio"/> Mild (Stairs only) <input type="radio"/> Mild (Walking and Stairs) <input type="radio"/> Moderate - Occasional <input type="radio"/> Moderate - Continual <input type="radio"/> Severe	Flexion Contracture (if present) <input type="radio"/> 5°-10° <input type="radio"/> 10°-15° <input checked="" type="radio"/> 16°-20° <input type="radio"/> >20°
	Extension lag <input type="radio"/> <10° <input type="radio"/> 10-20° <input type="radio"/> >20°

Total Range of Flexion <input type="radio"/> 0-5 <input type="radio"/> 6-10 <input type="radio"/> 11-15 <input type="radio"/> 16-20 <input type="radio"/> 21-25 <input type="radio"/> 26-30 <input type="radio"/> 31-35 <input type="radio"/> 36-40 <input type="radio"/> 41-45 <input checked="" type="radio"/> 46-50 <input type="radio"/> 51-55 <input type="radio"/> 56-60 <input type="radio"/> 61-65 <input type="radio"/> 66-70 <input type="radio"/> 71-75 <input type="radio"/> 76-80 <input type="radio"/> 81-85 <input type="radio"/> 86-90 <input type="radio"/> 91-95 <input type="radio"/> 96-100 <input type="radio"/> 101-105 <input type="radio"/> 106-110 <input type="radio"/> 111-115 <input type="radio"/> 116-120 <input type="radio"/> 121-125	Alignment (Varus & Valgus) <input checked="" type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 - 10 <input type="radio"/> 11 <input type="radio"/> 12 <input type="radio"/> 13 <input type="radio"/> 14 <input type="radio"/> 15 <input type="radio"/> Over 15°
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Stability (Maximum movement in any position) Antero-posterior <input checked="" type="radio"/> <5mm <input type="radio"/> 5-10mm <input type="radio"/> 10+mm	Mediolateral <input checked="" type="radio"/> <5° <input type="radio"/> 6-9° <input type="radio"/> 10-14° <input type="radio"/> 15°
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Print page Close Window Reset

Final Knee Score is

To save this data please print or [Save As CSV](#)

NB: This page cannot be saved due to patient data protection so please print the filled in form before closing the window. (NB: consider a negative outcome as zero)

[Click here for part 2 - FunctionScore](#)

Grading for the knee Society Score

Score 80-100 Excellent Score 70-79 Good Score 60-69 Fair Score below 60 Poor

Fig. 1. Knee Society Score Pain form utilized during patient encounters.

minimum of 1 year follow-up was identified. All of the patients underwent surgery in the same medical center with a single surgeon. Each received a Zimmer Legacy Constrained Condylar Knee (LCKK, Warsaw, IN) implant after intraoperative evaluation of ligamentous laxity performed by the attending surgeon.

All patients underwent medial parapatellar or midvastus approach. After initial bone cuts were made the flexion and extension gaps were examined, and trial components placed. If the coronal plane balance and alignment of the knee could not be restored with bone cuts or soft tissue balancing the decision was made intra-operatively to transition to LCKK stemmed implants. Stem size was determined by reaming both tibial and femoral canals with progressively larger reamers until adequate diaphyseal fit was obtained. All implants were cemented utilizing a metaphyseal cementing technique.

Patients who met inclusion criteria were contacted via a written letter requesting participation in the study. A total of 113 letters were sent with 28 patients consenting to return for pain, functional

and radiographic evaluation. Two of those 28 patients had undergone bilateral TKA with constrained implants for a total of 30 knees to be evaluated. A small monetary incentive in the form of a gift card was offered to the patients as compensation for their time. Those who consented to participating in the study were seen in the office for a single follow-up visit. During this visit they filled out a Knee Society Score pain and function questionnaire (Figs. 1 and 2), had repeat radiographs and were examined by one of the authors. The KSS is a validated outcome measurement that includes subjective patient responses on pain and daily function levels as well as an objective score based on range of motion measurements, laxity, and overall clinical alignment.¹ These physical exam findings were evaluated with goniometer measurements in the office. Additionally, an AP and Lateral radiograph was obtained of each operative knee. Immediate post-operative radiographs were obtained from the hospital database for comparison to the new images (Fig. 3). Each radiograph was evaluated independently by two musculoskeletal radiologists for any radiographic changes. The radiologists

Knee Society Score - Function

Clinician's name (or ref)

Patient's name (or ref)

Please answer the following questions.

Part 2 - Function
Walking
<input checked="" type="radio"/> Unlimited
<input type="radio"/> >10 blocks
<input type="radio"/> 5-10 blocks
<input type="radio"/> <5 blocks
<input type="radio"/> Housebound
<input type="radio"/> Unable
Stairs
<input checked="" type="radio"/> Normal Up and down
<input type="radio"/> Normal Up down with rail
<input type="radio"/> Up and down with rail
<input type="radio"/> Up with rail, down unable
<input type="radio"/> Unable
Walking aids used
<input checked="" type="radio"/> None used
<input type="radio"/> Use of Cane/Walking stick deduct
<input type="radio"/> Two Canes/sticks
<input type="radio"/> Crutches or frame

Function Score (Knee Society Score) is (NB: consider a negative outcome as zero)

To save this data please print or

NB: This page cannot be saved due to patient data protection so please print the filled in form before closing the window.

Reference for score: Insall JN, Dorr LD, Scott RD, Scott WN. Rationale of the Knee Society clinical rating system. Clin Orthop Relat Res. 1989 Nov;(248):13-4. link to pubmed

Reference for Grading: Asif S , Choon DS . Midterm results of cemented Press Fit Condylar Sigma total knee arthroplasty system. J Orthop Surg (Hong Kong). 2005 Dec;13(3):280-4.

Fig. 2. Knee Society Score Function form utilized during patient encounters.



Fig. 3. The immediate postoperative AP (A) and Lateral (B) x-rays of a patient were independently evaluated and compared to AP (C) and Lateral (D) x-rays at follow up by a radiologist.

were blinded to all demographics, dates of surgery as well as patient KSS responses. Each knee x-ray was compared to its initial post-operative radiograph, evaluated for loosening and given a grade of 1–3. A Grade 1 corresponded to no radiographic changes compared to initial radiograph. A Grade 2 corresponded to evidence of lucency around the implant. This was further subdivided into A and B groups. A Grade 2A was assigned for lucency around a single component. A Grade 2B was assigned for lucency around both the femoral and tibial components (Fig. 4). A Grade 3 was assigned for

any grossly loose implants with changes in position or alignment. The mean scores of all the KSS results were then compared the independent radiographic grade (Table 1). An unpaired *t*-test was used to evaluate for significance between the groups.

3. Results

A total of 28 patients responded to our written request for participation. Of those, 17 were male (60.7%) and 11 were female

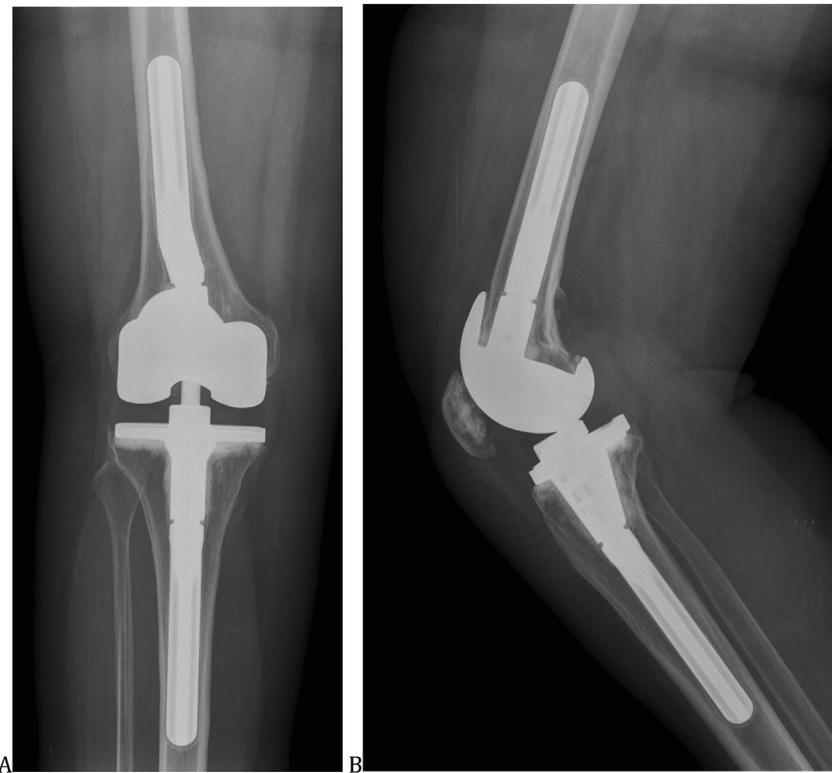


Fig. 4. Example of AP (A) and Lateral (B) radiographs showing Grade 2B loosening around both tibial and femoral components.

Table 1

This data includes the average pain and function scores for patients grouped by their radiographic grade of loosening.

Radiographic Score	Number of Patients	Average Pain Score	Average Function Score
1 - No Loosening	11 (36.7%)	88.6	83.5
2a - Single Component Loosening	17 (56.7%)	79.6	75
2b - Both Component Loosening	2 (6.7%)	78	76.6

(39.2%). The mean patient age at the time of surgery was 64.4 years (Range 45–84 years) and the mean BMI was 31.7 (range: 24.2–42.5). The average time to follow-up was 49.5 months (range 18–98 months). Of the 28 patients, 2 had undergone TKA of the contralateral knee using a constrained implant for a total of 30 knees evaluated in this study. The patients that had bilateral TKA with constrained implants filled out separate score sheets for each knee. None of the patients who followed-up had undergone repeat surgery.

The Knee Society scores are based on a weighted scale of 0–100 with Excellent outcomes being 80–100, Good 70–79, Fair 60–69, and Poor outcomes <60. In our study, 19 results were excellent (63.3%), 7 were good (23.3%) and 4 had poor pain outcomes (13.3%). Within the function score results, 19 were excellent (63.3%), 2 were good (6.6%), 4 were fair (13.3%), and 5 were poor (16.7%).

The independent radiographic evaluation found that 11 TKAs were a Grade 1 and had no evidence of lucency or changes compared to the initial post-operative x-rays (36.7%). 17 had a Grade 2A with lucency around a single component (56.7%) and 2 had a Grade 2B with lucency around both the tibial and femoral components (6.7%). No x-rays showed any significant changes in overall alignment or gross loosening of the implant (Grade 3).

We then compared the KSS scores with the radiographic grading to see if there was any correlation. Patients without evidence of changes on x-rays (Grade 1) had a mean pain score of 88.6. Patients with evidence of radiographic loosening (Grade 2) had a mean pain

score of 78.3. The difference between the two groups was found to be significant ($p = 0.032$) with the mean difference of 10.3 (CI 95%, 0.93 to 19.18).

The average function score for Grade I and Grade II knees was 83.5 and 76.6, respectively, however this difference was not statistically significant. If further subdivided based on Grade 2A or 2B, patients graded 2A had a mean pain score of 79.6 and mean function score of 75, the 2B group had a mean pain score of 78 and mean function score of 90. Neither the pain nor function score difference was statistically significant among the Grade 2 knees ($p > 0.05$).

4. Discussion

Constrained condylar primary total knee arthroplasty is an appropriate option for patients with knees that continue to be unstable after attempted intra-operative soft tissue balancing. The current available evidence is mixed as to whether increasing constraint definitively leads to an increased rate of loosening, complications, and revisions.^{2–4,6,9} Some authors report no significant difference in survivorship analysis or aseptic loosening of posterior stabilized knees vs. constrained condylar knees at long-term follow-up, while some studies report double to triple the revision rate.^{2–4,6,9,10} It is important to note when comparing these two patient groups, that the patients requiring constrained condylar knees typically have more significant knee disease.

In our patient series, we report 86% good to excellent pain

outcomes at an average of 4.2 year follow-up. Functional scores were mostly excellent, however, a few patients rated their current function as poor (16.7%). Radiographic loosening around at least one component was evident in 19 of 30 patients (63.4%), which may be a precursor to aseptic loosening of the implant. This is higher than what has been reported in other studies, which cite non-progressive radiolucent lines around the tibial or femoral components at 9–16%.¹⁰ This loosening might be clinically significant as patients with some evidence of loosening tended to have higher pain scores than patients with no evidence of lucencies ($p = 0.032$). Lucency around a single component vs. both components did not seem to be clinically significant ($p > 0.05$). We found no patients that required LCKK revision during our study period, which is indicative of the longevity of this implant despite the potential development of radiolucencies.

A limitation of this study was the inability of 85 of the 113 patients to come for follow-up examination. The 28 patients (30 knees) that did come for evaluation may represent a sampling error. It is possible that these patients that came for evaluation may be doing better or worse than those that did not come. Multiple patients that were able to follow-up did eventually request to see the primary surgeon, which may indicate that these patients were more likely to participate in the study due to an ongoing problem with their knee. We are unsure of how many of the patients were not able to follow-up due to moving from the area or death. Secondly, KSS scores were obtained only on the return visit, rather than both pre and post-operatively, limiting its utility in evaluating any changes in pain and function. Finally, we did not have a control group undergoing a standard posterior stabilized total knee arthroplasty during the same time period to compare our findings to. However, this would be difficult to do radiographically, as the majority of the radiolucency was seen at the stems, which are not present in a standard implant. Additionally, patients requiring a CCK implant typically have much more progressed level disease making their preoperative KSS scores likely much lower than their

standard posterior stabilized counterparts. This could have a significant effect on the final data and without preoperative KSS evaluation for all patients may lead to incorrect conclusions about pain and function scores in CCK implant recipients.

In conclusion, the constrained condylar implant is an acceptable implant for primary total knee arthroplasty. Our patient series had no revisions and excellent pain and good to excellent functional outcome scores at mid to long-term follow-up. Further studies with larger sample sizes and longer-term outcomes are needed to confirm this trend.

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