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Mid-term Outcomes of Primary Constrained Condylar Knee Arthroplasty for Severe Knee Deformity*

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Summary: This study aimed to examine the clinical and radiographic outcomes of primary total knee arthroplasy (TKA) with use of NexGen® Legacy® Constrained Condylar Knee (CCK) prosthesis for severe knee deformity. Clinical data of 46 patients (48 knees in total, aged 61 years on average) with severe knee deformity who underwent TKA with NexGen® Legacy® CCK prosthesis between December 2007 and February 2012 were retrospectively analyzed. There were 34 knees with severe valgus with incompetent medial collateral ligament, 11 knees with severe flexion contracture with inability to achieve knee balancing in flexion and extension by posterior soft tissue release, 2 knees with Charcot arthritis with severe varus and bone loss, and 1 with traumatic osteoarthritis with severe varus and ligamentous instability. The mean duration of follow-up was 71 months (range 40–90 months). The New Knee Society scoring (NKSS) system and the Hospital for Special Surgery (HSS) score were used to evaluate the functional and clinical outcomes. Visual Analogue Scale (VAS) was used for pain measurement and Knee Society criteria for evaluation of radiological images. The results showed that, in the total 48 knees, 1 case of loosening due to short-stem tibial component at 3 months post-operatively underwent revision. The 6-year prosthesis survival rate in this cohort was 97.9%. There was no component infection occurring within 6 years. Significant post-operative improvements were found in NKSS and HSS scores. Patient satisfaction was significantly increased. Pain score was decreased significantly. Total functional score was improved from 31.46±11.43 to 86.42±8.87, range of motion (ROM) from 42.42°±23.57° to 95.31°±23.45° and the flexion contracture from 5.31°±7.87° to 0.92°±1.80°. Preoperative radiographic study showed excessive valgus (≥7°) in 37 knees, and varus deformity in 3 knees. Post-operative femorotibial alignment was valgus 3.88°±1.76° in 48 knees. Antero/posterior (A/P) view of X-ray films showed 4 radiolucent lines (RLL) in 48 tibial components. It was concluded that TKA with CCK is effective for the treatment of the severe unstable knee that cannot be balanced by soft tissue.

Key words: constrained condylar knee; total knee arthroplasy; New Knee Society score; Hospital for Special Surgery score; severe deformity of knee

The internal and external stability is one of the key factors of long-term success of the knee joint replacement. Mild rotatory and medio-lateral instability of the knee joint can be balanced by the release of the contracted collateral ligaments with the extent depending on the degree of deformity. It is unusual to use a prosthesis with more constraint than a posterior cruciate ligament stabilizer (PS) in primary total knee arthroplasty (TKA). However, severe bone defect and ligament insufficiency often occur in severe deformity of the knee joint, and soft tissue release is not an option for the better outcome. Thus more constrains are needed to fix the joint in order to obtain a stable balance post-operatively[1]. Although the hinged knee arthroplasty can provide a good stability of the knee joint, the high complication rates and poor long-term follow-up results limit its use.

Constrained Condylar Knee (CCK) prosthesis is usually indicated when there is persistent laxity of 7 mm or above or obvious deformity and bone loss. This prosthesis has tibial and femoral modular offset stems and augments in different sizes and angles, which allows 5° rotation and 3° of unconstrained varus or valgus[2]. In the case of severe deformity and instability, these augments with intramedullary stem can be used according to the extent of instability and bone loss. The indications of primary TKA with CCK include medial collateral insufficiency, intraoperative inadequate flexion extension balance, severe varus or valgus deformity, lateral collateral insufficiency and severe bone loss[3, 4].

There are some drawbacks of CCK, though, such as an increased risk of mechanical loosening because of the increased constraint or the presence of polyethylene particle shedding, particularly by tibial post[5]. That the revision is difficult to undergo because of extensive bone loss is another potential risk. Other complications after use of CCK are unclear in clinical practice, as there is a scarce of clinical studies on TKA with CCK.

CCK prostheses are usually used in revision after

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TKA. Few studies reported use of CCK prostheses for primary TKA and they only focused on short-term effectiveness of the surgery and reported high rate of clinical success. The purpose of the present study was to examine the mid-term outcomes of primary TKA in which constrained condylar prostheses were implanted for the treatment of severe deformity of the knee.

1 MATERIALS AND METHODS

1.1 Patients

Fifty-two cemented NexGen Legacy CCK prostheses (Zimmer, USA) were implanted in 50 patients by using primary TKA for treatment of severe deformity and instability in the Joint Surgery Unit of Department of Orthopaedics, Union Hospital, Wuhan, China. Three patients were lost of follow-up, and one patient died due to pulmonary infection 1 month after operation (this patient had rheumatoid arthritis, with 10-year large-dose corticosteroid history). Forty-six patients with 48 CCK prostheses used were eventually included. The indications for use of CCK prostheses were severe valgus (>7°) with incompetent medial collateral ligament in 34 knees, severe flexion contracture with inability to achieve knee balancing in flexion and extension by posterior soft tissue release in 11 knees, Charcot arthritis with severe varus and bone loss (AORI II) in 2 knees, traumatic osteoarthritis with severe varus and ligamentous instability in 1 knee. The decision to use CCK prosthesis was made by the surgeon intraoperatively, when the stability could not be obtained with a PS prosthesis intraoperatively. This cohort consisted of 27 (58.7%) men and 19 (41.3%) women. The mean age was 61 years (range, 29–81 years). The mean follow-up was 71 months (range 40–90 months). There were osteoarthritis in 15 patients, post-traumatic osteoarthritis in 14, rheumatoid arthritis in 10, Charcot arthropathy in 2, gout in 3, post-tubercular osteoarthritis in 1 and post-septic arthritis in 1. All the surgeries were performed by the same surgical panel in the same operative setting. The scheduled follow-up time was 1.5 months, 3 months, 6 months, 1 year and yearly afterwards. All patients were discharged on the 14th post-operative day and rehabilitation was continued with the same protocol for all cases. The main baseline patient characteristics are listed in table 1.

Table 1 Main baseline patient characteristics

Demographic parameters (n=46)	n (%) or $\bar{x}\pm s$	Range
Age (years)	61±11.9	29–81
Male/female	27/19	
BMI (kg/m^2)	23.3±1.9	20.6–26.8
Right/left knee	28/20	
Diagnosis		
Osteoarthritis	15 (32.6)	
Post-traumatic osteoarthritis	14 (30.4)	
Rheumatoid arthritis	10 (21.7)	
Charcot arthropathy	2 (4.3)	
Gout	3 (6.5)	
Post-tubercular arthritis	1 (2.2)	
Post-septic arthritis	1 (2.2)	

1.2 Operative Technique

Preoperative clinical examination with data collection and basic investigations were performed. All the patients were intravenously given prophylactic antibiotics half an hour before the operation and continued for 48 h. Initial templating of pre-operative X-Ray was carried out in all knees.

A standard medial parapatellar incision was made when the knee was flexed at 90 degree, extending from 5 cm above the superior pole of the patella to below the tibial tubercle.

A hole just anterior to the insertion of anterior cruciate ligament (ACL) was drilled initially. After extramedullary alignment and proper rotation were maintained, tibial depth resection gauge was inserted to measure the tibial cut. The reaming was done gradually with increased size of the reamer until the reamer fully covered the medullary cavity. The tibia diameter was determined, the rotation of the tibia was adjusted, and the thickness of the osteotomy was decided by the normal side platform. The decision of using tibial lengthening bar with offset was determined by the position of the tibial gasket. In some cases if the bone loss was prominent and tibial augmentation was necessary in that case we could use different angled cutting sluts of tibial cutting guide. Intramedullary guidance with broach was applied for measurement of appropriate distal femoral cut parallel with the transepicondylar line in 5°–7° valgus angle of the anatomical axis. The femoral osteotomy size was measured, the appropriate module was selected and the rotation of osteotomy module according to the epicondyles was determined. The balance and stability of the flexion and extension gap were tested with a spacer block, and then osteotomy of the mandibular condyle was performed. After completion of tibial and femoral preparation, tibial and femoral provisionals of appropriate size were inserted. Proper thickness of polyethylene articular insert was measured using the block. Flexion extension gap and varus valgus alignment was measured and perfectly aligned. In our series, patella resurfacing was not done routinely; we performed routine patellar denervation with the electrocautery and removal of any osteophyte, when necessary. Peri-articular soft tissue was injected with the solution of corticosteroid, bupivacaine and epinephrine for the post-operative analgesia (not used in patients with hypertension). Final patellar prosthesis was appropriately implanted first, tibial and femoral prosthesis were impacted onto the tibia and femur with the help of cement simultaneously. An appropriately sized polyethylene articular insert with the long stem was placed.

Antibiotics were post-operatively used to prevent the infection and anticoagulants were initiated in selected patients who were prone to have deep vein thrombosis (DVT). Analgesic agents were routinely administered. Passive mobilization of the knee was started from the next day of operation followed by active rehabilitation. Early weight bearing was encouraged. Early and late complications like venous thrombus embolism (VTE), infection, bleeding, dislocation, implant loosening, and periprosthetic fracture, were continuously monitored in the ward and even during the follow-up. Immediate post-operative X-ray was taken three days post-operation

and drainage tube was removed. Patients were discharged on the 14th post-operative day. In every follow-up visit routine X-ray (knee antero/posterior [A/P] and lateral view) was taken for evaluation. Clinical and functional improvements were recorded using NKSS and HSS questionnaire and visual analogue (VAS) score.

1.3 Data Collection

The study data were collected from the hospital database and the questionnaire prepared according to New Knee Society Score (NKSS) and the Hospital for Special Surgery (HSS) score. Preoperative and post-operative data were recorded. Demographic information like age, sex, height, weight, ethnicity, side of operating knee and primary diagnosis were recorded. Patients were divided into different subgroups according to objective knee indicators, which involved alignment, instability, and joint motion recorded by clinicians. All other parameters were recorded by patients. Score was given for each of the questions. If the patients did not return to the hospital, we contacted them by telephone. Due to irregular follow-up of patients, last post-operative follow-up scores were obtained for comparison with pre-operative scores. The HKA angle and radiolucent lines were measured using Knee Society criteria.

1.4 Statistical Analysis

All the collected data were analyzed using the Kaplan-Meier method. Repeated measures analysis of variance (ANOVA) was used to analyze preoperative and post-operative means of variables. Values of $P<0.05$ were considered significant.

2 RESULTS

2.1 Clinical Results

Follow-up on the 46 patients showed that the mean NKSS score was improved from 30.52±14.22 (range, 8–65) preoperatively to 89.69±8.37 (range, 66–99) postoperatively, the mean HSS score from 35.95±15.74 (range, 0–68) to 71.40±25.16 (range, 12–92), patient satisfaction score from 8.38±4.015 (0–16) to 37.88±4.646 (24–40) and patient expectation score from 10.31±1.662 (9–14) preoperatively to 14.31±1.138 (12–15) post-operatively. The results indicated significant post-operative improvement in knee scores ($P<0.05$). VAS showed that pain was significantly decreased from 6.29±2.25 (range, 0–9) to 1.21±1.09 (range, 0–4) ($P<0.05$).

Additionally, the total functional score was increased from 31.46±11.43 (range, 10–59) to 86.42±8.87 (range, 62–99), and range of motion from 42.42°±23.57° (range, 0°–100°) to 95.31°±23.45° (range, 30°–140°). The mean preoperative flexion contracture was 5.31°±7.87° (range, 0°–45°), and the mean post-operative flexion contracture was 0.92°±1.80° (range, 0°–10°) (fig. 1). Significant differences were found in the above parameters between pre-operation and post-operation ($P<0.05$).

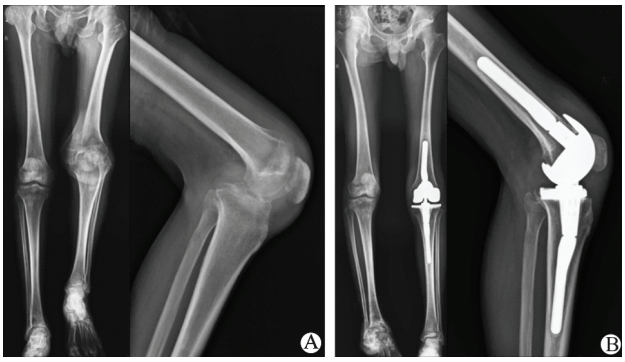

Fig. 1 CCK prosthesis implanted in a 46-year-old man with gout arthritis
A: a 30° flexion contracture before the operation. CCK was used because of failure to achieve adequate balancing by posterior soft tissue release and PS prosthesis; B: total-leg and lateral radiograph showing 0° flexion contracture 4 years after the operation

2.2 Survivorship Analysis

For the total 48 knees, with failure defined as revision for any reason, the 6-year prosthesis survival rate was 97.9%. One case of symptomatic loosening because of the short-stem tibial component at 3 months had revision to a long-stem extension (fig. 2). There were no components developing infection or aseptic loosening within 6 years. As mentioned previously, 1 patient died because of pulmonary infection 1 month after operation.

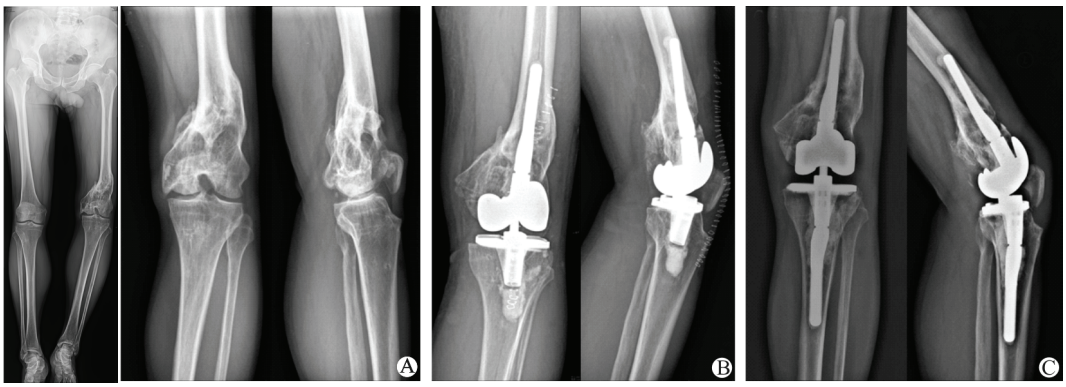

Fig. 2 A/P and lateral radiograph of a 59-year-old man with post-traumatic osteoarthritis
A: preoperative A/P and lateral radiograph of left knee and 15° varus deformity; B: post-operative radiograph of the patient with tibial loosening; C: 3-year post-operative radiograph of the same patient after undergoing tibial component revision with long stem showing no radiographic signs of loosening, but asymptomatic patella baja

2.3 Radiographic Results

Radiological assessment was performed before operation and in every follow-up visit. A/P and lateral view of the knee was taken to compare with the immediate post-operative X-rays to look for the position of the implant, radiolucent lines (RLLs), possible loosening, peri-prosthetic fracture, heterotrophic ossification and any other complications.

Preoperative radiographic study showed excessive valgus (≥7°) in 37 knees (mean, 10.48°±2.55°; range, 7°–15°). Three knees had a varus deformity (mean, 11.74°±4.71°; range, 5°–25°), and 9 knees had no deformity (valgus 3°–7°). The post-operative femorotibial alignment was valgus (mean, 3.88°±1.76°; range, 2°–9°) in 48 knees (fig. 3). A/P radiographic review showed there were 4 RLLs in 48 tibial components. However, all of them were <1 mm and non-progressive. No RLL was observed in femoral components.

2.4 Complications

As showed in table 2, 5 patients suffered venous thrombosis, and after curative-dose low molecular heparin, all of them had favorable outcomes. One patient suffered loosening at 3 months, and after revision, he obtained satisfactory results. One patient suffered peri-prosthetic fracture, and she was managed non-operatively, and had a good effect. One patient sustained peroneus communis nerve palsy post-operation, and after conservative treatment for 6 months, the motor function was restored only with mild numbness on the foot back. One patient suffered heterotopic ossification and another one suffered asymptomatic patella baja (fig. 2). These were other common complications of knee joint replacement, which had no correlation with prosthesis selection.

Table 2 Complications in 48 primary CCK knees

Complications	Knees, *n* (%)	Re-operation, *n* (%)
Venous thrombosis	5 (10.4)	
Implant loosening	1 (2.1)	1 (2.1)
Peri-prosthetic fracture	1 (2.1)	
Peroneus communis nerve palsy	1 (2.1)	
Heterotopic ossification	1 (2.1)	
Patella baja	1 (2.1)	
Infection	0 (0)	
Total	10 (20.8)	1 (2.1)

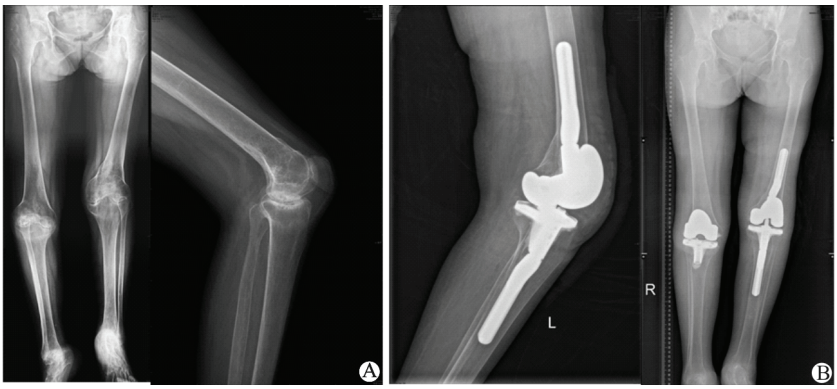

Fig. 3 A/P and lateral radiograph of a 70-year-old woman with rheumatoid arthritis, a valgus deformity of 15° and bone loss
A: preoperative radiograph. The choice of CCK prosthesis for the left knee was made intra-operatively because the medial collateral ligament was loose and use of PS was unable to achieve stability; B: radiographs 6 years after CCK TKA showing valgus 0° and non-progressive lucent line

3 DISCUSSION

Total knee arthroplasty is challenging in patients with severe deformity and instability. However, the outcomes of the replacement have been improved satisfactorily through proper preoperative assessment and education of patients and intraoperative study of biomechanics and proper choice of implant[6]. Mild to moderate deformities can be corrected with the soft tissue release, but in severe deformity and instability, only soft tissue release is not adequate enough where constrained design is mandatory[1]. Previous studies about CCK arthroplasty mainly focused on valgus arthritic knees or revision TKA. There were relatively few studies reporting the results of CCK in primary TKA. In one study, 28 arthritic valgus knees after primary CCK arthroplasty performed well during the mean period of 7.8 years of follow-up[7]. Another recent study reported 194 patients (228 knees) undergoing revision TKA with the use of constrained condylar knee prosthesis, and the mean KSS scores, function scores, and Western Ontario and McMaster Universities Osteoarthritis index scores were improved significantly in the mean 14.6-year follow-up[8]. Because it is unusual to use CCK in primary TKA, relatively few studies investigated the results of CCK components. One study on 68 matched pairs demonstrated when PS or CCK inserts were used in primary TKA, the range of motion between the PS and CCK groups at each of the post-operative intervals was similar, and both the individual items and combined scores of the KSS were similar between groups at 6 weeks, 4 months, and 1 year

post-operation[9]. Recently, Cholewinski *et al* reported 43 knees after primary CCK TKA with at least 10 years' follow-up. It was found that functional gains after CCK TKA were similar to those reported after standard posterior- stabilized TKA, but the complication rate was higher, and the survival rate decreased compared to standard TKA[5].

In our study, we evaluated the mid-term outcome of use of the NexGen® Legacy® CCK in primary TKA for 46 cases of severely deformed and unstable knees by using NKSS and HSS. We evaluated all the parameters before and after surgery. The expected outcome was achieved. The mean NKSS score was improved from 30.52±14.22 preoperatively to 89.69±8.37 post-operatively, the mean HSS score from 35.95±15.74 to 71.40±25.16, and the total functional score from 31.46±11.43 to 86.42±8.87. Similar improvement was observed by Hartford and Anderson in their complex primary and revision TKA using the constrained condylar prosthesis [2, 10].

The highest rate complication in our study was venous thrombosis (10.4%). The only revision operation was performed in a patient because of loosening. A study showed that infection was the leading complication and the most common reason for re-operation and prosthetic revision[5], but in our study no infection occurred, probably due to our strict control of the operation time and the anti-infective therapy. The incidence of periprosthetic fractures was reported to range from 0.3% to 2.5% after primary TKA[11]. In the present study, the incidence was found to be 2.1%. RLLs were found in 8.3% of cases. All of them were in the medial tibial tray on the AP view and were <1 mm and non-progressive. The complications were comparable with those from previous studies[12, 13].

To our knowledge, no study has investigated the post-operative satisfaction and patient expectation in CCK design. In a study by Noble *et al*, post-operative fulfillment of expectations depended on factors like age, post-operative stiffness, symptoms improvement and medicine use[14]. Lingard *et al* reported that satisfaction and expectations were not related preoperatively but post-operatively and they were related to function and pain[15]. In the current study we looked at the expectation and satisfaction preoperatively and post-operatively. Improvement in satisfaction was observed in all parameters of knee society score except advanced activities which include complex motions of knee related activities like squatting, kneeling, running, etc.

Preoperative and post-operative pain score differed significantly in the present study. This possibly results from the fact that patients with various pathological conditions like charcot arthropathy and post-traumatic arthritis didn't experience preoperative pain. Post-operatively, some pains did not subside in all the patients, like post-operative pain, surgery related pain, or pain caused by bursitis tendonitis, subclinical synovitis, infrapatellar fat pad impingement, etc[16, 17]. Patients with rheumatoid arthritis were more satisfied than others in terms of post-operative pain relief, which is possibly explained by the sedentary life style and continuous treatment with disease-modifying anti-rheumatic drugs (DMARDs) in these patients[18, 19].

Use of a CCK prosthesis in primary TKA is unusual and infrequent. There are several potential dangers of using TKA components with varus-valgus constraint, including tibial post wear, osteolysis and loosening caused by the transmission of the varus-valgus stress to the bone-cement interface[20]. The indications for the CCK included medial collateral insufficiency, severe valgus deformity, severe flexion contracture, and severe bone loss (AORI Ⅱ, AORI Ⅲ). Primary CCK knees should only be used in severe deformities in which ligament balancing techniques are not successful in creating a stable knee with posterior stabilized components[21]. A high rate of success with survivorship of 97.9% and a low rate of loosening (2.1%) in our study were achieved, indicating good results at mid-term follow-up.

Throughout the average follow-up period of 71 months (40 months–90 months), no complications, like osteolysis, prosthetic infection and polyethylene possibly requiring revision surgery, occurred. It was reported that infection was the leading complication and the most common reason for re-operation and prosthetic revision[5], but in our study, there was no prosthetic infection occurring. All patients had satisfactory range of motion postoperatively except one male patient. This patient had the range of motion of 30 degrees only. However, he was satisfied with the replacement surgery and refused further manipulation. Despite the controversies towards total knee replacement in patients with charcot arthropaty, we performed two NexGen® Legacy® CCKs (LCCK) for patients with charcot arthropaty and 73- and 48-month follow-up saw no complications. They were equally satisfied with the replacement surgery. Parvizi *et al* had warned the use of nonconstrained design in charcot arthropathy due to potential risk of symptomatic instability and failure needing revision surgery[22].

In conclusion, NKS score and HSS score can be used as a tool to assess post-operative outcomes in CCK arthroplasty. Despite severe deformity in preoperative conditions like traumatic osteoarthritis, rheumatoid arthritis and charcot arthropathy, post-operative outcomes were satisfactory in this cohort. CCK components can be only used in knees with severe deformity in which ligament balancing techniques are not successful in creating a stable knee with posterior stabilized components. Mid-term follow-up revealed good results. Improvement in ROM in our study is as comparable to that in other previous studies[5, 21]. Charcot arthropathy may benefit from CCK more than from other implants.

However, the long-term success with CCK is unclear. To overcome our limitations, further studies are recommended focusing on LCCK in large sample, representative population, longer follow-up period and in comparison to other instrument.

Conflict of Interest Statement

The authors declare that there is no conflict of interest with any financial organization or corporation or individual that can inappropriately influence this work.

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