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Satisfactory Short-Term Outcomes of Condylar-Constrained Knee Implants in Primary Total Knee Arthroplasty

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Abstract

Background*: This research set out to assess the functional prognosis of constrained condylar knee (CCK) in patients with severe intraoperative instability and/or coronal deformity undergoing primary total knee arthroplasty (TKA) .****Materials and methods****: A prospective cohort study including 25 knees (21 cases) who underwent primary TKA using CCK implants. Senior surgeon operated all patients during 2020/2021 and followed clinically and radiographically at three, six and 12 months and 2 years postoperative. All cases were implanted with a single-design, second-generation CCK implant with a mean follow-up of 2 years .****Results****: The current research involved 25 knees (21 patients) with mean age 62.8 ± 12.2 years and most of the included patients were females (19; 76%). Preoperatively, valgus was demonstrated in six patients (24%) while varus was reported in 19 patients (76%) with mean preoperative Valgus/Varus angle .9.9 ± 24.4Mean preoperative Knee Society Score (KSS) was 13.2 ± 2.7, mean preoperative functional KSS was 23.8 ± 19.2 and mean preoperative range of movement (ROM) was 107 ± 19.2. After 6 months, mean values of KSS was 86.2 ± 7.59. After 1 year, 2 years & over 2 years, mean values of KSS were 86.2 ± 7.6, 86.2 ± 7.5, 86.3 ± 7.7 respectively. Degree of change in KSS before and after the operation was 69.1 ± 20.9. Mean values of late functional KSS was 62.5 ± 23.3. Degree of change in functional KSS before and after the operation was 36.8 ± 19.1. Postoperative ROM mean value was 120 ± 6.9 with degree of change 12.8 ± 6.3. Three cases reported postoperative complications; one cellulitis, one anterior femoral notching and one peroneal nerve injury. KSS increased from baseline to early postoperative with statistically significant variances (p< 0.001) however, no statistically significant changes were discovered in KSS from early postoperatively to 2 years of follow up .****Conclusion****: Primary TKA utilizing CCK implants in cases with severe coronal abnormalities and/or intraoperative instability had a good short-term survival rate, on par with less limited implants. With positive clinical and radiological results, CCK implants can be thought of as a good alternative in some instances. It is important to exercise caution while utilizing an elevated level of restraint, since less restricted implants should be preferred.*

Keyword: *Implants, Radiological*

1. Introduction

In several series conducted over the past 30 years, TKA has demonstrated remarkable outcomes with insignificant complication rates **[1-4].** The complexity of the procedure or the individual's health of the afflicted limb are two factors that could influence the success rate of TKA. The risk of complications throughout TKA increases to 5% to 41% when the surgeon is confronted with an atypical abnormality of the bone or soft-tissue envelope around the knee **[5–11].** These conditions don't happen very often. As part of their surgical education, surgeons should study documented series that detail the unique circumstances that cause challenging surgeries.

Achieving ideal alignment, sufficient balance, and deformity correction are crucial for a satisfactory result following TKA **[12].** With or without sub-periosteal ligament release, a posterior stabilized (PS) design may usually do this efficiently in primary TKA. But even with primary TKA, there are cases where supplementary restricted prostheses are necessary, such as when soft tissue release alone is not enough to fix bone abnormalities, deformities, or collateral ligament insufficiency **[12–14].** The discharge of soft tissues in such a scenario puts nearby structures at some risk **.[15]**

Due to previous scarring, infection risk, mal-alignment, ligament insufficiency, knee stiffness & significant bone loss, post-traumatic arthritis often presents with technical complications. A CCK prosthesis, which comes with a range of stems and augments, is necessary for these types of abnormalities **.[18–16]**

Patients with rheumatoid arthritis (RA) often need a CCK prosthesis since their knees are severely deformed, ligamentous unstable, and/or have lost bone mass, and standard TKA does not provide enough stability **.[19]**

condylar dysplasia & Bone erosion are common on the concave side of a severe coronal deformity, while tension pressures and stretched soft tissues impact the convex side of the joint in patients with the same condition **[20].** Furthermore, sagittal plane anomalies or torsional deformities are frequently seen in cases with severe varus/valgus deformities. The existence of extra-articular deforming forces is related to a greater likelihood of deformity development and maintenance in patients with severe malalignment**.[21]**

One disadvantage of CCK prosthesis is the potential for mechanical loosening due to load transfer to the appropriate bone ends through intramedullary stems. This can lead to early failure and a periprosthetic fracture **[15, 22, 23].** Another issue with CCK is the wear of the polyethylene inserts **[23].** Revision TKA following CCK prosthesis is a challenging treatment due to the elevated morbidity and operating time caused by stem removal **[22].**

Owing to presence of relatively high number of neglected cases in our population complaining of knee osteoarthritis with severe coronal malalignment, we conducted this study to evaluate functional outcome of such cases.

Materials and Methods

Varus-Valgus Constrained (VVC) knee were primarily implanted in Twenty-five cases using Second-generation condylar-constrained implant (NexGen LCCK; Zimmer, Warsaw, IN, USA). Revision and septic cases were excluded.

Patients were operated during 2020/2021 and followed clinically and radiographically at three, six and 12 months and 2 year postoperative.

The surgeon was given the freedom to choose whether or not to employ a CCK implant based on the patient's deformity, ligamentous stability prior to surgery, collateral ligament competence evaluation throughout surgery & coronal stability following soft-tissue release.

There was just one senior surgeon who preferred PS implants and who oversaw all of the procedures. Spinal anesthesia was utilized to conduct the procedures. Every case involved the use of a tourniquet and the conventional medial parapatellar method through a midline skin incision. When making the distal femoral incision, an intramedullary guide was utilized & the femoral rotation was adjusted to neutral relative to the transepicondylar axis. As part of the surgical procedure, an extramedullary guide was utilized to position the tibial resection perpendicular to the tibia's long axis. At 0° extension, 30-40° mid-flexion & 90° flexion, the varus-valgus stability was assessed utilizing a trial PS component or a spacer block. Following making every attempt to achieve balance, a condylar-constrained implant (LCCK®; Zimmer) if the knee was determined to be unstable due to valgus or varus laxity more than 3 mm across the range of motion, it was utilized.

In every instance, electrocautery was utilized to denervate the patellar muscles. Every single patient consistently received antibiotic-loaded bone cement, namely Refobacin® Bone Cement with gentamicin (Zimmer, Biomet).

Every surgical procedure ended with the application of an intra-articular closed suction drain, which was removed within one to two days following the operation. Thromboembolic disease standard postoperative prophylaxis with low-molecular-weight heparin, multimodal pain treatment, and intravenous perioperative antibacterial prophylaxis were all administered to each patient .

Starting on the first day following surgery, all cases were allowed to put some weight on their feet as they felt comfortable, with the help of a cane or crutches if needed. Active range-of-motion exercises & gradual weight-bearing were involved of the rehabilitation program.

Preoperatively, at 4 weeks following surgery, at 3, 6, and 12 months, & then annually afterward, cases were followed clinically and radiographically. Within a year of the data being collected for this research, every single patient was seen. A grading system developed by the Knee Society was utilized to evaluate knee function.

In order to prepare for release, a plain AP & lateral knee radiograph were taken. We looked for sinking, cracks in the cement mantle, lines, radiolucent zones, and implant migration in the standing AP and lateral radiographs that indicated loosening. A systematic process involving experienced radiology technicians was utilized instead of fluoroscopic views.

Results and Discussion

The current study included 25 knees (21 patients) with mean age 62.8 ± 12.2 years and most of the involved cases were females (19; 76%) ***(figure 1)***. Mean body mass index of the involved cases was 32.9 ± 6.7 Kg/m^2. Nine patients were hypertensive, diabetes was present in five cases, three cases had chronic liver disease and three cases were rheumatoid disease patients ***(table 1).***

The operated side was the right in 14 knees (56%) and the left in 11 knees (44%). Preoperatively, long-standing radiographs demonstrated valgus in six cases (24%) and varus in 19 cases (76%) with mean preoperative coronal angle 24.4 ± 9.9. Median flexion deformity was 16.9 and ranged from zero to 40.7. Mild bone defect was present in seven patients (28%), moderate bone defect was existing in seven cases (28%) & severe bone defect was existing on nine cases (36%) ***(figure 2).*** Mean preoperative KSS was 13.2 ± 2.7, mean preoperative functional KSS was 23.8 ± 19.2 and mean preoperative ROM was 107 ± 19.2 ***(table 2).***

Postoperatively, early postoperative KSS mean values were 85.8 ± 7.65. Three months later, it became 84.4 ± 9.11. After 6 months, mean values of KSS was 86.2 ± 7.59. After 1 year, 2 years and over 2 years, mean values of KSS were 86.2 ± 7.6, 86.2 ± 7.5, 86.3 ± 7.7 respectively. Degree of change in KSS before and after the operation was 69.1 ± 20.9. Mean values of early postoperative functional KSS was 62.1 ± 19.6 and late functional KSS was 62.5 ± 23.3. Degree of change in functional KSS before and after the operation was 36.8 ± 19.1. Postoperative ROM mean value was 120 ± 6.9 with degree of change 12.8 ± 6.3. Three cases reported postoperative complications; one cellulitis, one anterior femoral notching and one peroneal nerve injury *(table 3).*

There were statistically significant differences between pre and postoperative knee radiological findings with higher percent of varus before operation and higher percent of valgus postoperatively. Valgus, Varus, and Valgus/varus angles decreased after the operation with statistically significant differences ***(p= 0.016; 0.004; < 0.001) (figure 3).*** ROM increased postoperatively with statistically significant differences between pre and post-operative ROM ***(107 ± 19.2 vs. 120 ± 6.9; p< 0.001) (table 4).***

KSS increased from baseline to early postoperative with statistically significant variances ***(p< 0.001)*** however, no statistically significant changes were discovered in KSS from early postoperatively to 2 years of follow up ***(figure 4) (table 5).***

Functional KSS increased from baseline to early postoperative with statistically significant variances ***(p< 0.001)*** however, no statistically significant changes were showed in functional KSS among early and late follow up ***(figure 5) (table 6).***

Table (1): Demographics and baseline medical condition of the included patients:

	Total cohort (n= 25) No. (%)
Sex - Male - Female	 6 (24%) 19 (76%)
Age (years) Mean ± SD	62.8 ± 12.2
Body mass index (Kg/m^2) Mean ± SD	32.9 ± 6.71
Hypertension	9 (36%)
Diabetes	5 (20%)
Chronic liver disease	3 (12%)
Rheumatoid disease	3 (12%)

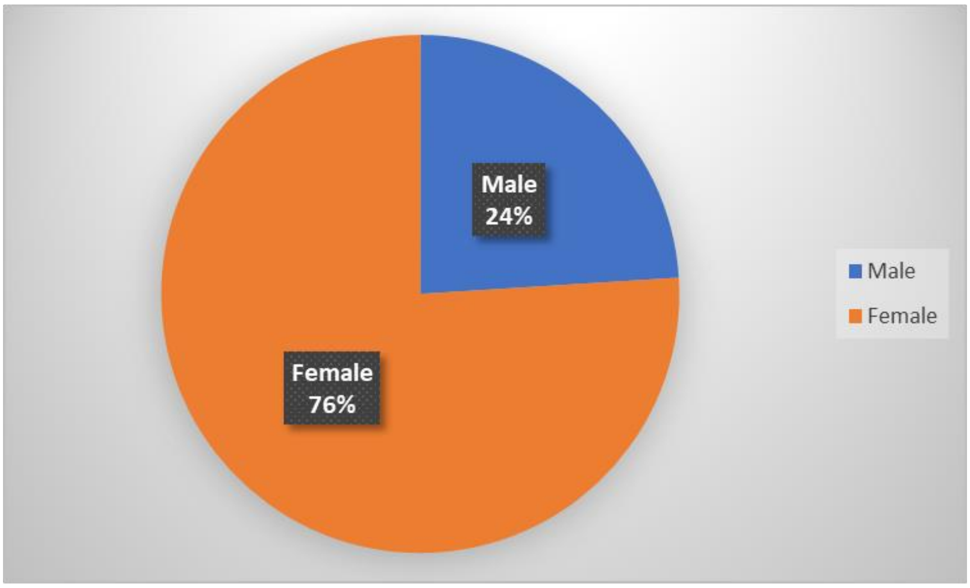

Figure (1): Sex distribution between the included patients

Table (2): Preoperative assessment of the included patients:

	Total cohort (n= 25) No. (%)
Side - Right - Left	 14 (56%) 11 (44%)
Radiology - Windswept deformity - Bilateral Valgus	 4 (16%) 2 (8%)
Preoperative radiographic findings - Valgus - Varus	 6 (24%) 19 (76%)
Preoperative Valgus/varus Mean ± SD	24.4 ± 9.9
Flexion deformity Median (min, max)	16.9 (0, 40.7)
Bone defect - None - Mild - Moderate - Moderate lateral - Severe	 1 (4%) 7 (28%) 7 (28%) 1 (4%) 9 (36%)
Preoperative KSS Mean ± SD	13.2 ± 2.7
Preoperative functional KSS Mean ± SD	23.8 ± 2.2
Preoperative ROM Mean ± SD	107 ± 19.2

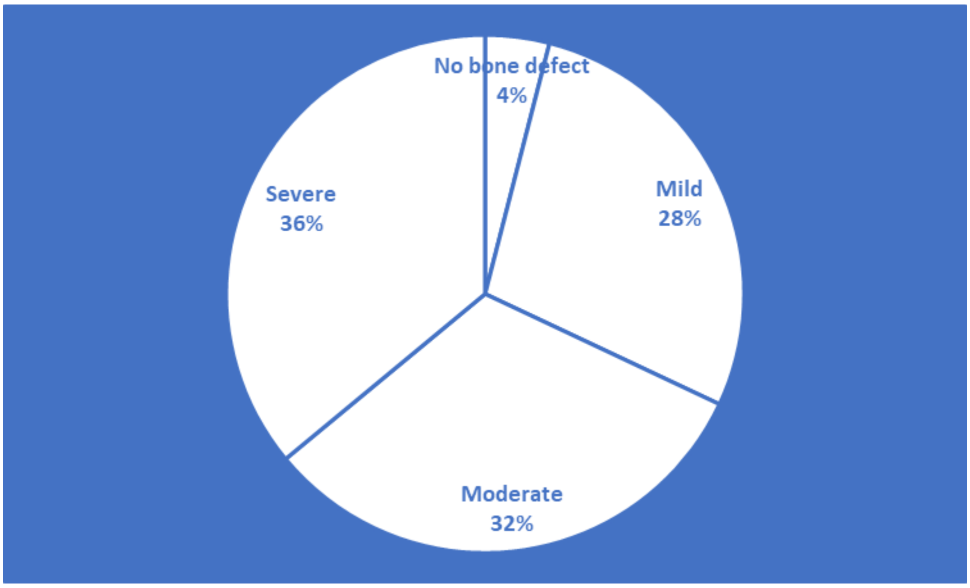

Figure (2): Frequency of bony defect severity

Table (3): Postoperative assessment and follow up:

	Total cohort (n= 25) No. (%)
Preoperative radiographic findings - Valgus - Varus	 20 (80%) 5 (20%)
Change of radiographic findings between pre and post operative	15 (60%)
Early Postoperative KSS Mean ± SD	85.8 ± 7.65
3 months Postoperative KSS Mean ± SD	84.4 ± 9.11
6 months Postoperative KSS Mean ± SD	86.2 ± 7.59
1 years Postoperative KSS Mean ± SD	86.2 ± 7.6
2 years Postoperative KSS Mean ± SD	86.2 ± 7.5
>2 years Postoperative KSS Mean ± SD	86.3 ± 7.7
Delta KSS Mean ± SD	69.1 ± 20.9
Early Postoperative functional KSS Mean ± SD	62.1 ± 19.6
Late Postoperative functional KSS Mean ± SD	62.5 ± 23.3
Delta functional KSS Mean ± SD	36.8 ± 19.1
Postoperative ROM Mean ± SD	120 ± 6.9
Delta ROM Mean ± SD	12.8 ± 6.3
Postoperative complications - Anterior notching - Cellulitis - Peroneal nerve injury	 1 (4%) 1 (4%) 1 (4%)

Table (4): Comparison between pre and post-operative radiologic findings, angles, and ROM:

	Preoperative	Postoperative	Test of significance	P value
Radiology No. (%): - Valgus - Varus	6 (24%) 19 (76%)	20 (80%) 5 (20%)	X^2= 15.7	***0.0007***
Valgus angle Mean ± SD	21.1 ± 11.6	2.3 ± 1.1	t= 3.59	***0.016***
Varus angle Mean ± SD	1.76 ± 0.43	1.2 ± 0.4	t= 5.8	***0.004***
Valgus/varus angle Mean ± SD	24.4 ± 9.9	2.2 ± 1.1	t= 10.86	***<0.001***
ROM mean ± SD	107 ± 19.2	120 ± 6.9	t= -3.8	***<0.001***

(X^2) Chi square test; (t) Paired t- test; Level of significance< 0.05.

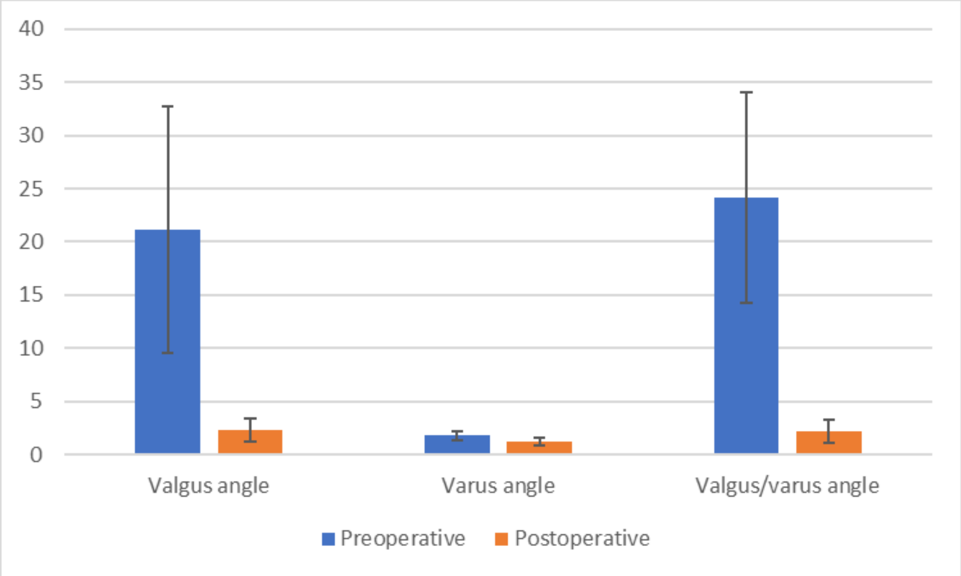

Figure (3): Changes in valgus and varus angles pre and postoperative

Table (5): Pre and postoperative serial changes in KSS:

	Pre	Early post	3 months	6 months	1 year	2 years	>2 years	F	P value
KSS	13.2 ± 2.7	85.8 ± 7.65 a	84.4 ± 9.11 a	86.2 ± 7.59 a	86.2 ± 7.6 a	86.2 ± 7.5 a	86.3 ± 7.7 a	501	***<0.001***

(F) Repeated measures analysis of variance (ANOVA) test; (a) post- hoc analysis where significance against preoperative was < 0.05

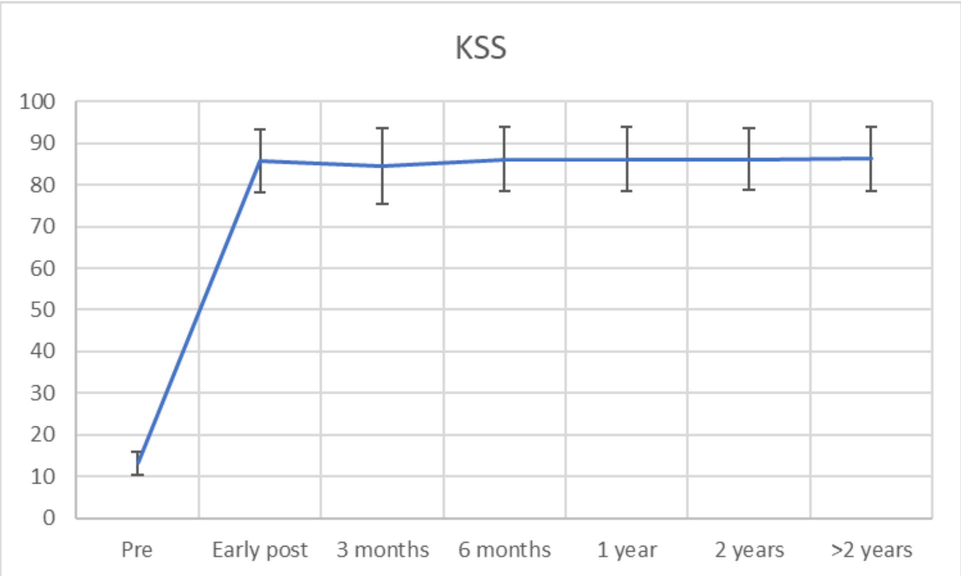

Figure (4): Serial changes in KSS

Table (6): Pre and postoperative serial changes in functional KSS:

	Pre	Early post	Late post	F	P value
Functional KSS	23.8 ± 2.2	62.1 ± 19.6	62.5 ± 23.3	51	***<0.001***

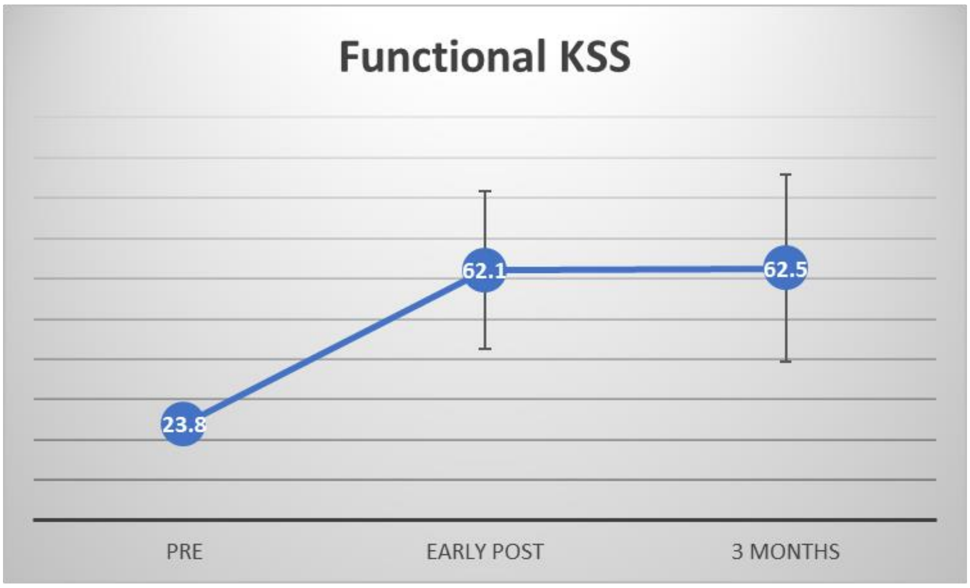

Figure (5): Serial changes in functional KSS

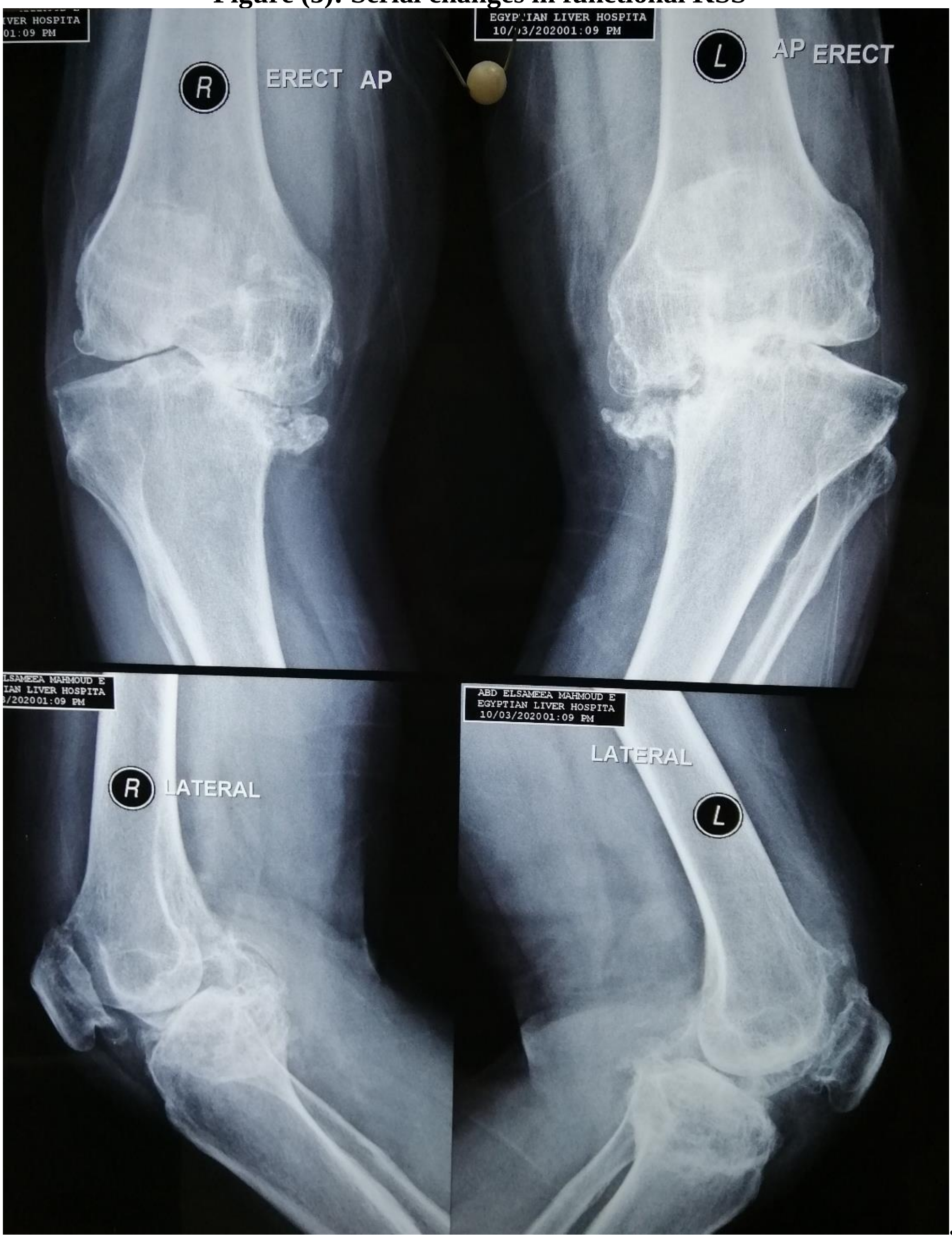

Figure (6): Preoperative AP standing and lateral radiograph for a case with bilateral osteoarthritis with severe varus malalignment and bone defect.

Figure (7): Postoperative long-standing AP radiograph of the same patient with bilateral primary stemmed CCK with tibial augments for bony defects.

Discussion

Inadequate intraoperative ligament balance is a common source of instability following primary TKA **[12]**, which ranks high among the reasons for revision TKA, accounting for as many as 21% of signs at 2 years & 27% at 5 years **[24, 25]**. Iatrogenic intraoperative damage or significant coronal distortion might cause knee collateral ligaments to be insufficient. When a well-balanced & stable knee cannot be achieved intraoperatively with PS, a Cruciate-Retaining (CR), Medial Pivot (MP), or mid-level constrained (MLC) implant, a VVC implant may be required **[26]**. The surgeon's personal choice will ultimately determine the level of intraoperative instability that necessitates a greater degree of restraint, as this has not been precisely explained yet. But there's a catch: more restriction means more mechanical stress at the bone-cement interface, which means more chances of aseptic loosening of implant components, micromotions, osteolysis & implant failure **[27]**. So, it's not all sunshine and rainbows. Regardless, a prior systematic review **[28]** found a 95.2% overall survivorship rate at a mean of 7 years of follow-up after all-cause revision, indicating that VVC implants do not have a significantly higher early failure rate nevertheless, on the contrary, have a mid-term survivorship rate that is comparable to lesser constraint implants.

In light of these findings, CCK implants have an elevated overall survival rate at a mean follow-up of 2 years & a survival rate from aseptic loosening of 100%, which is on par with implants with less restrictions. They are utilized in primary TKA procedures when there are significant coronal deformities and/or when a standard PS implant cannot provide enough stability throughout the procedure. Consistent with these results, a recent meta-analysis and systematic review by Avino et al. **[29]** found that 3,620 CCK prosthesis in primary TKA had a substantial improvement in clinical outcomes, with a revision frequency of 7 percent at 10-year follow-up.

One of the most difficult aspects of knee reconstruction is primary TKA when there is significant coronal deformity and/or intraoperative instability of the knee. For a stable and well-balanced knee after primary TKA, the gold standard implants with minimal restriction and sufficient soft-tissue balancing should be considered. Enhanced restriction is required to prevent instability and early revision when soft-tissue methods fail to provide intraoperative stability across full range of motion. Among the most prevalent causes for early failure and revision TKA, which can reach 27% following 5 years, is instability **[30].** There are a number of conditions that might require the usage of a CCK implant. These involve severe axial abnormalities, inadequacy of the collateral ligament, significant bone loss & chronic laxity more than 7-10 mm **[12, 31, 32].** But we still haven't settled on a precise level of instability that necessitates more restrictions. Furthermore, CCK implants offer a more dependable alternative to hinged designs in primary TKAs, ensure an adequate midterm survival, and provide greater varus-valgus stability than CR and PS designs.

Consistent with prior research on main CCK, our findings show that there were no instances of implant failure due to aseptic loosening during midterm follow-up in primary TKA **[33–40].** Other research' findings are consistent with our own **[37, 39, 41–44].** During a mean follow-up of 2 years, no complications involving the tibial post mechanism were identified. Studies have shown that CCK implants in primary TKA had a survival frequency of over 95% at the midterm follow-up. Also, whereas a cohort of 127 primary TKAs with CCK implants had a prevalence of up to 3.2% of periprosthetic fractures, we did not find any such instances in our dataset.**[38]**

Implant survival was 100% at 6-year follow-up in a cohort of 21 knees implanted in very young cases (mean 54 years) **[45].** Despite a significant prevalence of stiffness (23.8%), the researchers reported satisfactory functional results. Primary CCK may be a good choice for younger, more active individuals in addition to older, less active patients, according to their findings. Consistent with Badawy et al. **[46],** concerning the Norwegian Arthroplasty Register, there is a rise in reoperation & revision rates at 2- and 5-year follow-up for complicated primary TKAs that need a larger level of restriction. These rates are attributed to variables other than implant design. Although the midterm survivability was comparable to unrestricted implants, they discovered that revisions were more usually caused by infection. Midterm aseptic survivability was similar for CCK implants and unrestrained implants in their research. For patients with modest coronal deformities, a new and promising option is the mid-level constrained (MLC) articular bearing. In comparison to a CCK insert, it has less restriction on rotation and varus-valgus lift-off due to its broader post.**[48 ,47]**

Medical intervention improved one incidence of cellulitis, which we recorded as a postoperative complication in 4% of patients. Infection was shown to be the most prevalent complication & the primary cause of reoperation in previous research (2 of 47, 4.3%). Specifically for primary osteoarthritis, a trend toward a greater incidence of infections correlated with hinged as well as restricted prostheses at 3 years (1.2% vs. 0.7% for non-constrained CR or PS implants) was observed in a registry-based analysis by Jamsen et al. **[49].** Regarding revision rates for infection, Cholewinski et al**. [23]** stated 4.7% (2 of 43 knees) and Luque et al. **[50]** stated 6.7% (6 of 99 knees) in their respective series of 43 & 99 knees, with an average follow-up of 12 and 7 years, respectively.

On average, the Knee Society knee score went elevated 69.1 ± 20.9 points among the preoperative state and the most recent follow-up, while the functional score went up 36.8 ± 19.1 points. A significant enhancement in clinical outcomes was observed & ROM for flexion following primary CCK surgery, as was seen in other investigations **[23, 35, 37, 39, 40, 50].** The range of motion was enhanced by an average of 12.8 ± 6.3° of flexion, which is consistent with previous reports in the literature **[37-39, 45, 51]** and greater than what Feng et al. **[34]** found. At 6 months and 2 years, Puah et al. **[41]** found no significant variations in ROM or functional ratings among main CCK implants & PS implants.

This research does have a few limitations. To start, there wasn't a control group with lesser restriction implants that was matched for baseline characteristics, and the patient cohort was limited. Second, the surgeon's personal preference and level of expertise were considered when deciding whether or not to insert a CCK implant throughout surgery, which might have introduced selection bias. Thirdly, the average age of the cases who had the implants was 62 years old; nevertheless, the outcomes could be different in younger patients who are more active and have greater expectations. As a fourth point, proper documentation of implant survivability in these cases necessitated long-term follow-up.

Conclusion

In instances of severe coronal deformities or when standard implants (CR, PS, MS) fail to achieve intraoperative stability, CCK implants may be deemed a feasible alternative for primary TKA. Comparable to less constrained implants, they exhibit favorable survivorship & functional outcomes throughout midterm follow-up. CCK implants may become less necessary in primary TKA because of the current presentation of mid-level constrained implants. Nevertheless, since elevated mechanical stresses may have an impact on long-term survivability, An elevated degree of restriction should be applied with caution and cases should be meticulously chosen; implants with a lesser degree of constraint should be prioritized.

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