

COMPARATIVE STUDY OF FUNCTIONAL OUTCOME COMPARING POSTERIOR CRUCIATE LIGAMENT SUBSTITUTING PRIMARY KNEE ARTHROPLASTY WITH PRIMARY KNEE ARTHROPLASTY USING ULTRACONGRUENT TIBIAL ARTICULAR INSERT AFTER COMPLETE RELEASE OF POSTERIOR CRUCIATE LIGAMENT

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ABSTRACT

Objectives: The aim of the study was to compare the functional outcome of posterior cruciate ligament (PCL) substituting primary knee arthroplasty with primary knee arthroplasty using ultra-congruent (UC) tibial articular insert after complete release of PCL. The study aimed to compare the stability of the knee joint after PCL sacrifice for degenerative arthritis of the knee.

Methods: This was a prospective, randomized, double blind and single-center study. After approval by the Institutional Ethical Committee, 80 patients, 40 in each group ('UC' and posterior stabilized, 'PS') of either sex, aged between 60 and 80 years and willing to participate in the study were included in the study. Patients underwent primary knee arthroplasty with either UC or PS implants using simple random sampling method. Each patient was followed up at 6 months, 1 year and between 5 & 7 years postoperatively and the functional results were assessed using Modified Knee Society Score (Insall modification -1993).

Results: Around 73% of the patients were women and the average age was 67 years in line with the known literature confirming increased incidence of osteoarthritis requiring total knee arthroplasty in women and older individuals. There was a significant relief in pain and improvement in stair climbing ability after surgery. There was a reduction in flexion contractures, medial/lateral instability and anterior-posterior instability postoperatively. The improvement in range of motion was significant in the UC group as compared to PS group. Similarly, the total score was significantly higher in the UC group as compared to PS.

Conclusion: If functional outcomes are taken into consideration, UC prosthesis is better than the PS prosthesis. Further randomized and double-blinded clinical trials with larger sample size and longer duration follow-up need to be conducted to validate the findings.

Keywords: Posterior cruciate ligament, Ultra-congruent tibial articular insert, Total knee arthroplasty.

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INTRODUCTION

Total knee arthroplasty (TKA) has become a standard surgical procedure for alleviation of pain and functional improvement in individuals with osteoarthritis and rheumatoid arthritis of the knee joint. Better knowledge of biomechanics and better implant designs have improved clinical outcome. Two of the most commonly used designs are posterior cruciate ligament (PCL) substitution/PCL sacrificing design and PCL retaining designs (Figs 1-3), though studies have failed to show significant subjective performance or patient satisfaction differences.

On one hand, PCL sacrificing leads to more femoral bone loss to accommodate box and may theoretically lead to fracture in osteopenic bones and early loosening at bone cement interface due to more stress transfer through cam-post. Many authors still argue that it is difficult to balance a diseased or contracted PCL in a reproducible fashion and a significant deformity can be more reliably corrected by PCL substitution. Late rupture of the PCL also can be a cause of late instability in PCL-retaining designs.

PCL retaining prosthesis preserves femoral bone and theoretically may survive longer than PCL substitution (PS) knees. The degree of congruency of an ideal prosthesis design for knee replacement and the interaction with the PCL is controversial. Congruency is very essential as lack of it might lead to increased penetration wear [1]. However,

the tibial articular surface of PCL retaining prostheses is typically less conforming to the femoral component in the sagittal plane to allow femoral rollback. A high level of congruency might result in an increased posterior polyethylene wear or rupture of the PCL due to an imbalanced interaction with its function. An ultra-congruent (UC) implant certainly controls over rollback and also has some advantages over highly congruent prosthesis in cases of retention or sacrifice of PCL [2]. Considering above observations, the study was designed for comparison of the functional outcome of PCL substituting primary knee arthroplasty versus primary knee arthroplasty using UC tibial articular insert after complete release of PCL and compared the result of this study with the results of other similar studies available in the literature.

METHODS

This was a prospective, randomized, double blind and single-center study conducted at a tertiary care center spanning over a period of 7 years. After approval by the Institutional Ethical Committee, patients/subjects for the study were identified among those attending the orthopedic OPD for replacement surgery. By considering the prevalence 5.5% of replacement surgery at our tertiary care center, we had calculated the sample size using following formula: $N=4 \times P \times Q / L^2$ (P is prevalence 5.5%, Q is $100 - P = 94.5\%$ and L is experimental error 5%). The study comprised of detailed information of 80 patients, 40 in each group (UC and PS) of either sex aged between 60 and 80 years

and willing to participate in the study. Patients underwent primary knee arthroplasty with either UC or posterior stabilized (PS) implants using simple random sampling method. Each patient was followed up at 6 months, 1 year and between 5 & 7 years postoperatively and the functional results were assessed using Modified Knee Society Score (Insall modification-1993) as given in Table 3.

Inclusion criteria

(a) Bicompartamental arthritis with complete loss of joint space observed on anteroposterior or lateral radiographs of knee, (b) American Society of Anesthesiologists (ASA) Class I and II physical status patients and (c) willing patients of either sex aged between 60 and 80 years.

Exclusion criteria

(a) History of infective/inflammatory joint disease, (b) any other lower limb bone or joint ailment, (c) severe patellofemoral arthritis, (d) unwilling patients or patients who showed inability to participate in follow-up, (e) secondary knee OA and (f) valgus knee.

Data Collection Technique and Tools: Data was collected by conducting interviews and physical examination of the patients. After recruitment of the patients in the study by taking their informed consent, detailed history regarding name, age/sex, chief complaint & duration, side involved, type of arthritis, any previous knee injury and any other associated medical comorbidity was taken.

General physical and systemic examination was carried out in detail for renal system, cardiovascular system, respiratory system and nervous system for any neurological involvement. Knee examination was done in detail. All routine pre-operative investigations were conducted as per protocol.

The patients were evaluated preoperatively by Modified Knee Society Knee Score and functional scoring systems. The same scoring systems were used for post-operative evaluations.

The scoring system combines a relatively objective Knee Score that was based on the clinical parameters and a functional Score based on how the patient perceived the knee functions with specific activities. The maximum Knee Score was 100 points. To calculate the scores, the answers to the questions and the findings on the examination (using goniometer) were given a value based on the results. To obtain the Knee Score and the functional Score, the results of every question were totaled. Some results were negative to denote that they were deductions.

Data analysis

Baseline study participant characteristics were described using descriptive statistics. Parametric data if passed the tests of normality was analyzed using unpaired t test or else non-parametric test (Mann-Whitney test) was used for analysis. Categorical data was analyzed using the Chi-square test. The significance threshold of p value was set at <0.05. SPSS version 21 was used for analysis of data.

Ethical clearance

Ethical clearance was obtained from an Institutional Ethics Committee of the hospital before the conduct of the study. Written informed consent was obtained from each subject before enrolment in the study.

Pre-operative planning

Pre-operative planning was made by proper assessment of the patient as per the standard protocols.

Anesthesia

Patients were routinely subjected to pre-anesthetic checkup before surgery. Patients were operated either under spinal/ epidural, or general anesthesia depending on the suitability or associated morbidities of the patients.

Prophylactic antibiotics

All patients were routinely given prophylactic antibiotics. A broad-spectrum antibiotic was chosen which covered both Gram-positive and Gram-negative organisms. We used Cefotaxime/Cephazoline and Amikacin in the morning on the day of surgery and were continued till 48 h post-operatively.

Surgical technique

All the knees were replaced in a conventional operation theatre. All operations were done by the same surgical team using medial parapatellar approach. The prosthesis used for total knee replacement was UC or PS of well recognized company of repute.

Post-operative care

We followed 48 h of antibiotic course after surgery. Tablet Aspirin, 350 mg once a day for 6 weeks was given to all patients. We allowed early mobilization to all the patients in the study. Patients were taught in-bed physiotherapy exercises to achieve early rehabilitation. They were allowed to bear weight on the 1st post-operative day and walk with either a walker or crutches as tolerated. The stitches were removed on the 14th post-operative day. Subsequently, patients were allowed to walk with a cane. Patients were clinically evaluated using Modified Knee Society Score (Insall modification -1993) at 6 months, 1 year and 5 years postoperatively.

RESULTS

Total 80 patients were included in this study. Of those, 21 (26.25%) were men and 59 (73.75%) were women. Average age of patients was 67.3±6.563 years. The 13.75% (11) patients were detected with osteoarthritis of the left knee and 11.25% (9) patients were detected with osteoarthritis of the right knee. Bilateral osteoarthritis (L=R) was found in 5% (4) patients and bilateral osteoarthritis (L>R) and (L<R) was found in 40% (32) and 30% (24) respectively.

Knee pain was observed in 100% (80) patients before surgery. After surgery, at 6 months 8.75% patients had knee pain and 91.25% did not have. At 1 year and 5 years, 100% patients were free from knee pain. At 0 month, that is before surgery, stiffness was observed in 100% of patients but at 6 months and beyond none of the patients had stiffness.

Severe stair climbing inability was found in 81.25% patients before surgery (at 0) whereas 98.75% patients had no inability at 1-year and 5-year follow-up postoperatively. Medial/lateral instability of <5 mm was observed in 75% patients and 5–10 mm was observed in 25% at 0 month (i.e. before surgery). At 6 months, 1 year and 5 years of follow-up, medial/lateral instability of <5 mm was observed in 100% patients and none of the patients had medial/lateral instability of 5–10 mm or more than 10 mm. The anterior/posterior instability of <5 mm was observed in 92.5% patients and up to 10 mm was observed in 7.5% at 0 months (i.e. before surgery). At 6 months, 1 year and 5 years, <5 mm was observed in 100% patients and none in 5–10 mm or more than 10 mm category of anterior/posterior instability.

None had extension lag at 0 months, 6 months and 1 year duration of the study. At 0 months (i.e. before surgery), flexion contracture <50 degrees was found in 38.75%, 6–100 degrees was found in 36.25%, 11–200 degrees was found in 23.75% and more than 200 degrees was found in 1.25% patients. At 6 months, 1 year and 1 year & beyond, flexion contracture decreased to 5° in all patients.

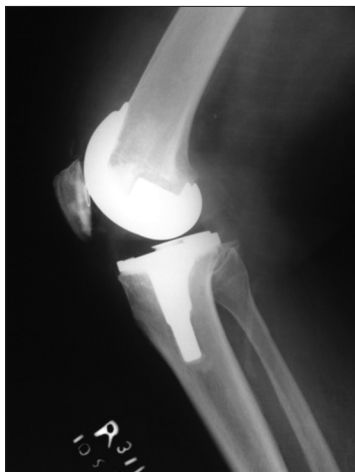
At 0 month (i.e. before surgery), mild pain was reported in 3.75% patients, moderate pain was reported in 93.75% and severe pain was reported in 2.5% patients. At 6 months and at 1 year & beyond, 100% patients were asymptomatic as far as pain is concerned. The total knee replacement surgery in the left knee was carried out in 60% (48) patients and in the right knee 40% (32) patients.

The medial tibial bone defect was found in 28.75% of patients and posterolateral was found in 1.25% patients but 70% patients did not have any tibial bone defect.

Patella preservation was carried out in all the patients (Patellar resurfacing was done in none). UC implant was used in 50% (40) patients and PS was used in 50% (40) patients. Delayed wound healing complication was observed in four patients.



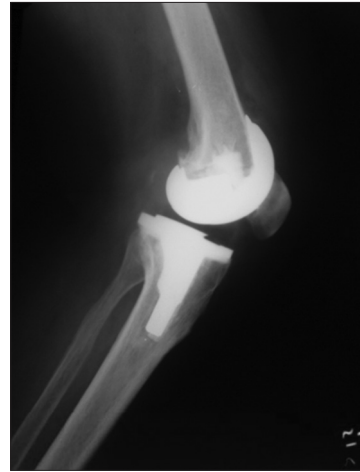
Right knee anteroposterior view



Right knee flexion lateral view



Left knee anteroposterior view



Left knee flexion lateral view

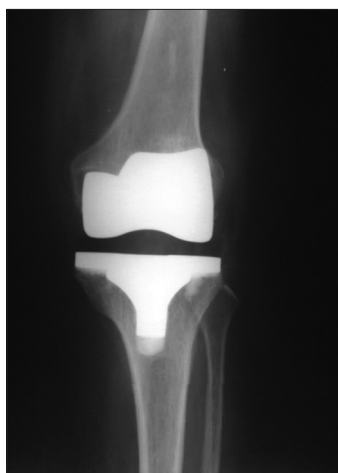
Ultracongruent TKR follow-up at 1 year



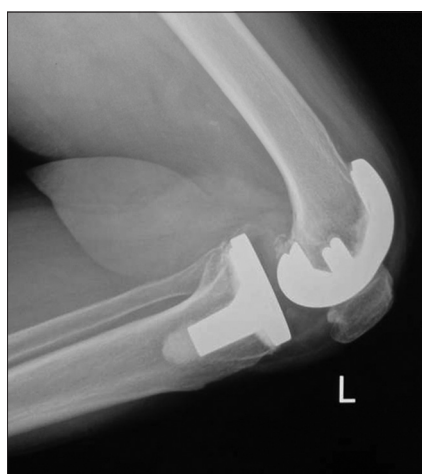
Right knee anteroposterior view



Right knee flexion lateral view



Left knee anteroposterior view



Left knee flexion lateral view

In Table 1, the mean of range of motion at 0 months (i.e. before surgery) was found to be 11.15, at 6 months 14.2 and at 1 year & 5 years it was found to be 14.69. The range of motion compared between UC and PS study groups showed significant results at 6 months $p=0.014$ and 1 year $p=0.003$. This means that the range of motion was significantly higher in the UC study group as compared to the PS study group. (Range of motion is as follows: 1 point= 8°).

In Table 2, both the study groups showed an improvement in malalignment post-surgery.

The total score at 0 month (i.e. before surgery) was comparable between the two study groups. However, at 1 year and 5 years post-surgery, there was a significant improvement in the total score in UC study group as compared to the PS study group.

DISCUSSION

In our study, various parameters including locking, stiffness, stair climbing ability, walking, medial/lateral instability, anterior/posterior instability, flexion contracture and pain (at rest, at pre-operative, and post-operative timelines) were noted. The range of motion, malalignment and total score between two groups UC and PS was compared.

Total 80 patients were included in our study. About 21 (26.25%) were men and 59 (73.75%) were women. Average age of patients in our study was 67.3 years. In similar studies by Kim T *et al.*, 34 knees of 24 patients had TKA with a UC prosthesis for primary osteoarthritis and 15 knees of 14 patients had TKA with PS prosthesis. Thirty-one females and seven male patients were included in their study. The mean age was 70.4 years [3]. In Nagi *et al.* study, ten females were in one group and eight females and two males were in the second group. Average age was 55.9 years in the first group and 60.3 years in the second group [4]. Our study findings were comparable with the available literature [3,4]. Osteoarthritis affects women more often than men and it increases in prevalence and incidence after menopause. Many experimental, clinical and epidemiological studies suggest that loss of estrogen at the time of menopause increases a woman's risk of getting osteoarthritis. Furthermore, osteoarthritis is more common among adults aged 65 years or older [5].

In our study, the knee pain was observed in 100% (80) patients before surgery. After surgery at 6 months, 91.25% did not have knee pain. At 1 year and at 5 years, all 100% patients were free from pain. Pre-operative knee pain was significantly relieved after surgical intervention. The findings of our study related to knee pain were comparable with the reported data [6,7].

Stair climbing inability was found in 81.25% of patients before surgery. However, 98.75% patients had no inability at 1 year and 5 years postoperatively. In similar studies, the stair climbing ability was significantly improved postoperatively when compared with the pre-operative status [4].

In the present study, flexion contracture $<5^\circ$ was found in 38.75%, $6-10^\circ$ was found in 36.25%, $11-20^\circ$ was found in 23.75% and more than 20° was found in 1.25% patients. After surgery, almost 100% patients had no flexion contracture. Immediate post-operative flexion contracture responded well to the physiotherapy. Similar results were observed in other studies also [3].

Table 1: ROM Parameter (Range of motion is as follows: 1 point= 8°)

Parameter	UC		PS		Test used	p value	Significance
	Mean	SD±	Mean	SD±			
ROM	11.13	3.073	11.18	2.669	Mann Whitney test	0.923	
ROM 6 months	14.45	0.815	13.95	0.959	"	0.014	Significant
ROM 1 year and 05 years	14.95	0.597	14.43	0.781	"	0.003	Significant

Table 2: Malalignment result between US and PS study groups

Parameter	UC		PS		Test used	p value	Significance
	Mean	SD±	Mean	SD±			
Malalignment	-4	3.234	-4.15	2.914	Mann Whitney test	0.628	
Malalignment 6 months	-0.05	0.316	-0.05	0.316	"	1.0	
Malalignment 1 year and 05 years	-0.05	0.316	-0.05	0.316	"	1.0	

Table 3: Modified Knee Society Score (Insall modification -1993)

Parameter	UC		PS		Test used	p value	Significance
	Mean	SD±	Mean	SD±			
Score Preoperatively	26	12.374	25.35	12.75	Mann Whitney test	0.806	
Score 6 months	83.925	5.2	85.175	3.8689	"	0.777	
Score 1 year and 05 years	89.65	1.702	89.375	0.8679	"	0.016	Significant

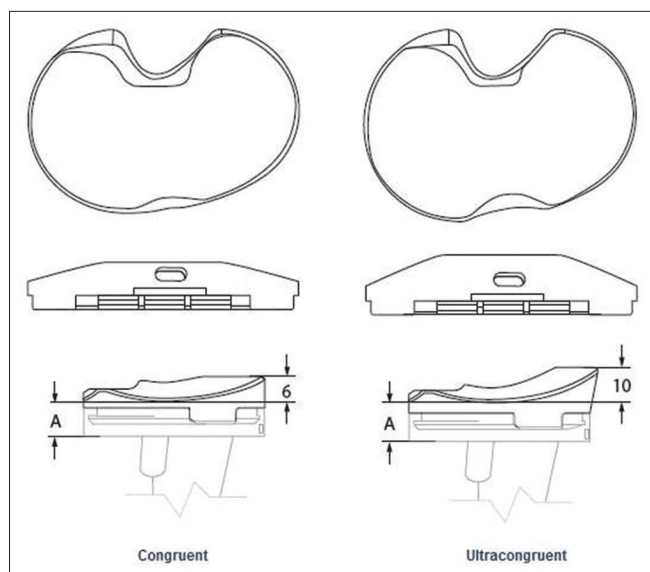


Fig. 1: Comparison of tibial articular surface of congruent and ultracongruent designs

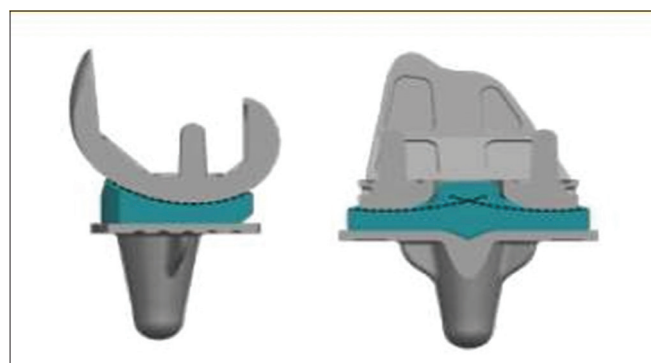


Fig. 2: (a) Specific design features of ultracongruent tibial (b) Articular surface

In our study, preoperatively, medial/lateral instability of <5 mm was observed in 75% patients and 5–10 mm was observed in 25% patients. At 6 months and at 1 year, medial/lateral instability of <5 mm was observed in 100% patients. The anterior/posterior instability of <5 mm was observed in 92.5% patients and 5–10 mm was observed in 7.5% before surgery. After surgery at 1-year and 5-year follow-up, anterior/posterior instability was <5 mm in almost 100% patients. These findings were compared with the available studies on the subject. In the study, the anterior-posterior stability and medial–lateral stability were increased postoperatively in both groups [4].

In our study, the mean range of motion preoperatively was found to be 89.2°, postoperatively at 6 months 113.6° and at 1 year, it was found to be 117.52°. In UC design, range of motion preoperatively was found to be 89.04°, at 6 months 115.6° and at 1 year & 5 years 119.6°. In PCL substitution group, range of motion preoperatively was found to be 89.44°, at 6 months 111.6° and at 1 year & 5 years 115.44°. The range



Fig. 3: (1) Congruent condylar surface, (2) UHMWPE tibial insert, (3) Central stopper to enhance mediolateral stability, (4) Higher anterior lip to prevent femoral paradoxical anterior sliding

of motion compared between UC and PS study showed significant results at 6 months ($p=0.014$) and at 1 year ($p=0.003$) by applying the Mann–Whitney test. The findings of our study were comparable with available literature [3,4]. A study conducted by Kim *et al.* compared the passive kinematics of a mobile-bearing, UC total knee design with a mobile-bearing and PS knee replacement prosthesis. The maximum flexion angle at the final follow-up was 123 degrees in UC group and 118 degrees in the PS group ($p>0.05$) which was an improvement from the baseline range of motion. The range of motion results of our study corroborated by the results of the Kim *et al.* Study [3].

A study was conducted by Nagi *et al.* to compare the PCL sparing and PCL substituting implants for total knee replacement [4]. These investigators observed increase in the range of motion postsurgically which was in line with our study [4]. Another study conducted by Wajsfisz *et al.* compared the intra-operative flexion following TKA. Even though fundamentally it *has been* different from our study since in our study, we compared post-operatively changes in range of motion, it gave us a pointer that no significant difference was found between the standard PCL substitution and the UC design ($p>0.14$) [6].

In Chaidez *et al.* study, 66 arthroplasties were performed. Clinical and functional assessment was done with 2-year follow-up. Mean age was 70.58 years. The limb side was right in 45.5% and left in 54.5% of the patients. The operative time was 76.84 min. The Visual Analog Scale pain score was 2.02. The WOMAC score was 17.11 and the range of motion was $96.5\pm 14.04^\circ$. About 92% of the patients were satisfied with the surgical procedure. The UC insert prosthesis was recommended as an alternative to prevent the possible complications which occurred with the drawer and post-system in this study [7].

Preoperatively, the functional knee score was in the moderate-to-severe category for all the patients. However, postoperatively, there was no functional impairment in approximately 98% patients. In a study conducted by Nagi *et al.*, the functional score too had shown an improvement after TKA [4].

The total score at the 1st-year post-operative follow-up was significantly higher in the UC group as compared to the PS group with the p value being 0.016 after application of the Mann–Whitney test. This was

similar to the study conducted by Nagi *et al.* in which the total score was significantly higher in the UC group [4].

In our study, the knee scores improved from an average of 25 preoperatively to 84 and 89 at 6 months & 1-year follow-up post-operatively after TKA and remained more or less same at 05-years follow-up. In a study conducted by Nagi *et al.* the total knee score improved from 43 preoperatively to approximately 88 points postoperatively [4]. This indicates that the results of our study were similar to the Nagi *et al.* study.

There were a few limitations of our study. Although, our study was conducted over a period of 05 years, many patients were interviewed on phone calls at 05 years and could not be physically examined. However, results were almost similar to that at 1-year follow-up. The cost factor of the implants was not considered in our study. The availability and cost of the implants might influence the choice of the implants. However, these points were not considered in our study. A cost-effective analysis could have been useful to address this point. However, this was beyond the scope of our study.

CONCLUSION

The present study was conducted to compare the functional outcomes comparing PCL substituting primary knee arthroplasty with primary knee arthroplasty using UC tibial articular insert after complete release of PCL. In our study, around 73% of the patients were women in line with the known literature that there is increased incidence of osteoarthritis requiring TKA in women. Furthermore, the average age of study participants in our study was 67 years, which was also in line with the literature that TKA is necessary in older individuals. There was a significant improvement in stair climbing ability and pain relief

post-surgery. There was a reduction in flexion contractures, medial/lateral instability and anterior-posterior instability postoperatively. The improvement in range of motion was significantly better in the UC group as compared to the PS study group. Similarly, the total score was significantly higher in the UC study group as compared to the PS study group.

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