SHORT-TERM RESULTS OF CRUCIATE-SUBSTITUTING CEMENTED TOTAL KNEE ARTHROPLASTY

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Abstract

Background: Total Knee Arthroplasty (TKA) is indicated in individuals with painful, disabling arthritis, having radiographic evidence of joint damage and not responding to conservative treatment, thus resulting in diminished quality of life. The goal of TKA is to relieve pain, provide motion, maintain stability and correct deformity.

Aim: To evaluate short-term clinico-radiological results and complications of TKA.

Material and methods: A prospective randomized controlled study was conducted between December 2006 and June 2009 on 41 patients (61 knees) who underwent TKA and were followed for one year or more. Mean follow-up was 19.69±5.69 months (minimum-12, maximum-30).

Posterior Cruciate Ligament (PCL)- substituting cemented Press Fit Condylar (PFC) Sigma prosthesis (Deputy Orthopaedics) was used in all cases. Fixed-bearing design was used in 39 patients (57 knees) while mobile-bearing rotating-platform design (PFC-sigma-RP) was used in 2 patients (4 knees). Patella was resurfaced in 2 patients (2 knees). Pain (using Visual analogue scale-VAS), fixed flexion deformity (FFD), maximum flexion and Knee Society Score (KSS) were evaluated preoperatively and postoperatively. Radiological analysis included assessment of femoral-tibial alignment, radiolucencies and patellar tracking. Changes at 3, 6, 12 and 24 months were statistically analyzed.

Observations and results: Mean age was 61.17 ± 9.51 years (range 40-77 years). Male to female ratio was 1:2.4. Osteoarthritis (OA) with varus deformity was present in majority. By the end of 1 year, most patients had either no pain or only mild occasional pain. Preoperatively 93% patients had poor functional score (FS) and 98% knees had poor knee score (KS). After TKA, about 85% patients had excellent or good FS while nearly 97% knees had excellent or good KS. Near maximum improvement in KSS is achieved by the end of 1 year with no further significant improvement thereafter. The mean maximum flexion was 114.75° preoperatively and 113.77° at 1 year which was not statistically significant. There were very few complications. Infection was present in 3 cases while peroneal nerve palsy in one. There were no progressive radiolucencies, polyethylene wear, implant failure, patello-femoral complications or clinical deep venous thrombosis (DVT). One knee with mobile-bearing prosthesis had insert spin-off after 2 weeks.

Conclusion: TKA is a very successful, safe and cost-effective treatment for patients with knee arthritis who do not respond to nonsurgical therapies. Cemented TKA is still the gold standard and fixed-bearing, cruciate-substituting prosthesis continues to function well after 2-years of follow-up.

Keywords: Knee arthritis, cemented cruciate-substituting Total knee arthroplasty, short-term results.
Introduction

Knee arthritis in advanced stage, can lead to severely deformed and painful knees with loss of functions and movements, crippling the individual and lowering the quality of life. Total Knee Arthroplasty (TKA) is indicated in such cases with radiographic evidence of joint damage and not responding to conservative treatment. The goal of TKA is to relieve pain, provide motion, maintain stability and correct deformity.

Factors related to a surgeon’s experience, surgical technique and choice of prosthesis may have important influence on both short-term and long-term outcomes of TKA.

Prosthesis design has evolved over time. Many designs such as mobile-bearing or cruciate-retaining have theoretical advantages, but durability and success rates appear similar with most commonly used designs.1

There has been a rapid increase in the incidence of patients undergoing TKA in Lucknow, Uttar Pradesh, India over the past 10 years. However, no study to the best of our knowledge, has reported results of TKAs in the city. This study was aimed to evaluate short-term clinico-radiological results and complications of cruciate-substituting cemented TKA in knee arthritis patients with the following objectives:

1. To determine mean age and sex distribution of patients.
2. To detect relative incidence of various types of knee arthritis.
3. To evaluate short-term results of TKA using KSS.
4. To determine short-term complications of TKA.

Material And Methods

A prospective randomized controlled study was conducted in the Department of Orthopaedics, Integral Institute of Medical Sciences and Research, Lucknow (Uttar Pradesh), India on 41 patients (61 knees) who underwent TKA for debilitating knee arthritis between December-2006 and June-2009 at a premier institute for joint replacement in Lucknow. Patients with ipsilateral hip and knee involvement/replacement were excluded.

Clinical assessment of patients was done preoperatively and postoperatively at 3, 6, 12 and 24 months based on Insall’s modified Knee Society Score (KSS) which included:

a) Knee Score (KS): Points given on basis of questionnaire and physical examination of patient evaluating pain relief, range of motion (ROM) and stability in antero-posterior (AP) and medio-lateral planes including deductions for flexion contractures, extension-lag and malalignment. Maximum achievable KS was 100.

b) Functional Score (FS): Points given on basis of questionnaire for assessment of ability to walk, go up/downstairs and getting up from chair. Maximum achievable FS was 100.

Scores were rated as follows:

85 – 100 : Excellent
70 – 84 : Good
60 – 69 : Fair
Less than 60 : Poor

Pain was also assessed separately using the Visual Analogue Scale (VAS) as follows:

0 – 1 : No pain
2 – 4 : Mild pain
5 – 7 : Moderate pain
8 – 10 : Severe pain

ROM and degree of varus/valgus deformity were assessed using a combination of visual inspection and goniometer recordings.

Preoperative short – leg roentgenograms of affected knee included a standing - AP, recumbent-lateral and skyline view.

PCL- substituting cemented PFC-Sigma prosthesis (Depuy Orthopaedics, Warsaw, Indiana) was used in all cases. Fixed-bearing design was used in 39 patients (57 knees) while mobile-bearing or rotating-platform design (PFC-Sigma-RP) was used in 2 patients (4 knees).

Surgical Technique

All knees were operated by conventional technique without computer assisted surgery (CAS) under epidural ± spinal anaesthesia using tourniquet. Preoperative intravenous antibiotic (Cefuroxime) was given before tourniquet inflation.

Joint was exposed by medial parapatellar approach (Figure-1). Cruciates and menisci were routinely sacrificed. Tibial cut was made perpendicular to the mechanical axis using an extramedullary alignment device with 30° posterior slope and tibial tray size assessed. Distal femoral cut was made using an intramedullary jig. Extension gap was evaluated with spacer block. After femoral sizing using anterior-reference guide, the anterior-posterior-chamfer cutting block was placed and flexion gap assessed. Anterior, posterior and chamfer cuts were made followed by intercondylar notch cut (Figure-2). All osteophytes were removed. Adequate soft tissue balancing was achieved by doing meticulous medial or lateral release depending on the deformity. Flexion and extension gaps were reassessed. Trial implantation was done and tibial tray rotation was set according to the femoral component contact in extension. This was
followed by tibial plateau preparation for the cruciform keel tray. Where significant tibial bone defects were present, long-stem tibial component was used with or without bone graft fixation using cancellous screws. Both components were fixed with Gentamycin impregnated Polymethyl methacrylate (PMMA) bone cement. Polyethylene tibial insert was put and joint reduced (Figure-3). Patella was resurfaced in 2 knees (Figure-4). Patellar denervation was done in all cases. Patellar tracking was checked – 2 knees required lateral retinacular release. Injection tranexamic acid was given at the time of cement mixing – about 15 minutes before tourniquet deflation. Haemostasis was secured and suction drain was routinely put. Quadricep mechanism was repaired and closure was done in layers. A compressive dressing was applied.

Postoperative management included antibiotics, 2nd injection of tranexamic acid (3 hours after 1st dose) and thromboprophylaxis using low molecular weight heparin (LMWH) from 2nd day. Postoperative analgesia was achieved by continuous infusion of 0.5% bupivacaine and fentanyl via epidural catheter for 3 days, followed by oral/parenteral analgesics. Cryotherapy was applied in cases of intractable pain and swelling. Static quadriceps exercises and straight-leg-raising were started from day one. Suction drain was removed on 3rd day. Patients were allowed full weight bearing with walker from 3rd day as allowed by the particular knee reconstruction and the individual patient. Knee bending was allowed once straight leg raising was achieved or after 5-6 days whichever was earlier. Continuous Passive Motion (CPM) was used in patients with poor ROM. Postoperative rehabilitation protocol included gait training, calf massage (to prevent DVT) and instructions for performing basic activities of daily living. Most patients were discharged on 7th-8th postoperative day. LMWH was given till hospital stay. Stiches were removed after 2-3 weeks and patients were followed in OPD at 3, 6, 12, and 24 months. At each visit the patients were assessed according to KSS.

Immediate postoperative x-rays included recumbent-AP and lateral views. Thereafter at each follow-up standing-AP, recumbent-lateral and skyline views were taken. Roentgenographic data was recorded for each knee using the **Knee Society radiographic evaluation system** which included measurement of radiolucent lines and femoral-tibial alignment.

**Data recording and Statistical analysis**

Data was tabulated using Microsoft Excel. Preoperative and postoperative comparison was made between pain score (VAS), maximum flexion, fixed flexion deformity, FS, KS and x-rays. Changes in scores at 3, 6, 12 and 24 months were statistically analyzed. Students t-test (Unpaired t-test for flexion, FFD, KS; Paired t-test for FS) was performed using GraphPad Instat statistical software (GraphPad Software, San Diego, CA). P-values less than 0.05 were considered significant (es-extremely significant; ns-not significant).

**Observations And Results**

Forty one patients (61 knees) were followed for one year or more and were evaluated at 3 months, 6 months and 1 year. Thirteen patients (21 knees) out of the 41 patients were further followed up to 2 years. Median duration of follow-up was 18 months with a
mean of 19.69±5.69 months (minimum 12, maximum 30).

Twenty patients underwent bilateral TKA (2 simultaneous) while 21 underwent unilateral. Cemented fixed-bearing implant (PFC-Sigma) was used in 39 patients (57 knees) while mobile-bearing implant (PFC-Sigma-RP) was used in 2 patients (4 knees). Patella was resurfaced in 2 knees.

**Results of clinical evaluation**

**Pain**, according to VAS, decreased significantly from a mean preoperative score of 8.20 to 1.54 at 3 months, 0.55 at 6 months and 0.05 at 12 months.

The mean preoperative **maximum flexion** was 114.75°. It decreased to a mean of 96.51° at 3 months, then increased gradually to 105.00° at 6 months and 113.77° by the end of 1 year. Final difference at 12 months was not statistically significant.

**Fixed Flexion Deformity (FFD)** had a mean value of 14.95° preoperatively which dropped significantly to a mean of 2.33° at 3 months. Thereafter, the mean FFD was 2.25° at 6 months and 1.92° at 12 months, showing that change in FFD after initial 3 months was not statistically significant.

The mean **FS** preoperatively was 33.12 and after 3, 6 and 12 months it progressively increased to 54.71, 69.32 and 83.68 respectively which was statistically significant.

The mean **KS** underwent a significant increase from 31.36 preoperatively to 74.57 at 3 months, 81.39 at 6 months and 86.87 at 12 months.

Comparison between preoperative and postoperative pain (VAS), flexion. FFD, FS and KS at 3, 6, 12 months is shown in tables 4, 5, 6 and graphs 4, 5, 6, 7, 8 respectively.
At 1 year 70.73% patients had excellent and 14.63% had good FS. The KS was excellent in 77.04% knees and good in 19.67% as shown in table-8 and graph-9.

Radiographic evaluation

On preoperative radiographic evaluation 50 knees (81.96%) had varus with mean femoral-tibial alignment of $12.06^\circ$ (range $0^\circ$ – $30^\circ$) while 11 knees (18.03%) had valgus with mean femoral-tibial alignment of $10.18^\circ$ valgus(range $2^\circ$–$25^\circ$). The ratio of varus to valgus knees was reversed in the postoperative evaluation. Fifty two knees (85.25%) had valgus (range $30^\circ$–$80^\circ$) with a mean femoral-tibial alignment of $5.59^\circ$ valgus while 9 knees (14.75%) had varus (range $30^\circ$–$80^\circ$) with a mean femoral-tibial alignment of $2.33^\circ$ varus (table-10).

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N</th>
<th>Preop</th>
<th>6 months</th>
<th>Change from preop - 6 months</th>
<th>Mean</th>
<th>t-score</th>
<th>P value</th>
</tr>
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<tbody>
<tr>
<td>Pain(VAS)</td>
<td>61</td>
<td>8.20±1.18</td>
<td>5.05±0.28</td>
<td>3.14±0.92</td>
<td>7.64</td>
<td>50.41</td>
<td>&lt;0.001(0)</td>
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<tr>
<td>Flexion</td>
<td>61</td>
<td>14.75±2.62</td>
<td>8.00±1.35</td>
<td>6.74±2.33</td>
<td>9.75</td>
<td>4.81</td>
<td>&lt;0.001(0)</td>
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<tr>
<td>FFD</td>
<td>61</td>
<td>14.95±2.68</td>
<td>10.50±2.35</td>
<td>4.45±2.33</td>
<td>2.22</td>
<td>4.27</td>
<td>&lt;0.001(0)</td>
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<tr>
<td>FS</td>
<td>41</td>
<td>33.12±17.27</td>
<td>22.68±12.77</td>
<td>10.42±6.69</td>
<td>36.19</td>
<td>14.82</td>
<td>&lt;0.001(0)</td>
</tr>
<tr>
<td>KS</td>
<td>61</td>
<td>31.36±17.62</td>
<td>10.55±17.62</td>
<td>20.81±17.62</td>
<td>50.03</td>
<td>26.47</td>
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Changes from 3 – 6 months and 6 – 12 months postoperatively were further assessed as shown in table-7.
Preoperatively only 5 knees (8.2%) were in the suggested limits of 7±3° valgus. Postoperatively 12 knees (19.67%) were outside the suggested limits of 7±3° valgus, all being less than 4° valgus.

Overall 10 knees (16.39%) had radiolucencies on x-rays at the last follow-up. Nine knees(14.75%) had radiolucencies in tibial component; 8 were less than 4mm and non-progressive and hence considered non-significant while 1 had a score of 6 and required watch for progression. Only 1 femoral component showed radiolucent line in zone 1 which was 1mm.

Complications

There were 3 infections. One knee got infected after 1 year of index surgery in a patient having diabetes mellitus. It was managed by arthroscopic lavage and synovial biopsy which revealed tuberculous infection. Patient responded to anti-tubercular treatment and is asymptomatic on follow-up without any signs of radiographic loosening. The second knee in a 77 years male got infected 3 months after TKA. He was managed twice by arthroscopic lavage and synovectomy and once by arthrotomy and debridement but went on to develop chronic infection requiring revision TKA. The third knee in a 75-year male had a superficial infection after one year which subsided with antibiotics.

Lateral peroneal nerve palsy, leading to foot drop, occurred in one patient which recovered spontaneously within 6 months.

There were no patello-femoral complications in the form of patello-femoral instability, patellar fracture, patellar component lossening or failure, patellar clunk syndrome or extensor mechanism tendon rupture.

One knee, in a 64 years old lady with mobile-bearing prosthesis, had a tibial insert spin-off within 2 weeks of surgery due to lateral collateral ligament tear which was found peroperatively and had to be repaired. The insert was exchanged and protected weight bearing on knee brace with delayed knee mobilization was advised subsequently. The cause of collateral ligament tear was attributed to early over zealous attempt to attain full flexion or a twisting injury.

Case example: 67 years / Male with bilateral OA knees

The success of prosthesis in TKA is based on pain relief, restoration of function and implant survival. The strongest evidence exists over a follow-up period of upto 2 years, but the studies that extend to 5 and even 10 years of follow-up show positive results as well. Many designs are available today having excellent or good outcome at mid-term and long-term follow-up with a 90-99% survivorship. The PFC-Sigma TKA(Deupy Johnson & Johnson) is extensively implanted worldwide. Although various studies worldwide have reported outcomes and survivorship analysis of the PFC-Sigma prosthesis, there is no such reported study from this part of the country. The goal of this study was to evaluate the short-term clinico-radiological results of cruciate-substituting PFC-Sigma TKA.

In this study, the mean age was 61.17 ± 9.51 years. Most patients were in the age group of 60-69 years(39.02%). In a meta-analysis of 62 studies on TKA between 1995 and 2003, the evidence report by the Agency for Healthcare Research and Quality(AHRQ) revealed that the average age of patients was approximately 70 years and very few of them were over 85 years.

There was a female predominance (70.73%) in the whole study group with a male:female ratio of 1:2.42. All patients in RA group were females. This is consistent with the Swedish Knee Arthroplasty Register(SKAR) which reports male:female ratio of 1:2 in OA group and 1:3 in RA group. The AHRQ evidence report also states that two-thirds of patients were female.

Most patients in this study had OA (82.93%) while only 12.19% had RA. According to the evidence report by
AHRQ on TKA, nearly 90% patients had OA. Konig A et al. (2000) in their analysis on 253 primary TKAs found that improvement in pain rating had the largest increase of all KSS variables, contributing 60% to the KS increase. Pain improved in 95% of the knees. They stated that pain is the most rewarding indication for TKA, followed by deformity and poor walking ability. Pain was the major indication for surgery in this study also which decreased drastically postoperatively and majority patients had either no pain or occasionally mild pain after 1 year which is consistent with the findings of Clayton et al.

Deformity was the second major indication for surgery. Preoperatively only 8.2% knees were in the normal range of 7±3° varus while postoperatively 80.33% knees were in this range i.e only 19.67% knees were outside the normal range. This figure of under 20% co-relates well with other similar series like Clayton et al. (2006)13. One limitation of this study was that malalignment measurements were obtained from short-leg x-ray films which donot show hip and ankle. It has been estimated that short-leg views overestimate varus by a mean of 1.6 degrees.17

The mean FFD preoperatively was 14.95° which decreased to a mean of 1.92° at 1 year. There was no significant change in maximum flexion after TKA compared to the preoperative status. However, the ROM increased because of decrease in flexion contracture.

At 1 year, 85% patients had excellent or good FS while 97% had excellent or good KS suggesting stable knees with minimal deformity and good ROM in majority. About 14.63% patients had FS<70 after 1 year. This is lower compared to 22% as reported by Clayton et al.13 However, FS is highly influenced by comorbid conditions and other joint involvement. The limitation of this study was the absence of complete comorbidity data. The KS<70 was present in 3.28% knees after 1 year follow-up which is lower compared to 8.6% as reported by Clayton et al.13 Thirteen patients (21 knees) who were further followed up for 2 years, did not show any significant improvement after 1 year in pain, flexion, flexion contracture, FS or KS.

Progressive radiolucencies on radiographical analysis are signs of osteolysis and impending implant failure. Bozic et al. (2005)16 found that 21% patients had 1-mm radiolucencies at 5-8 year follow-up. Bertin (2005)19 found that 8.6% of patients had a non-progressive radiolucency at 5-7 year follow-up. Dalury et al. (2008)12 in their mid-term results with PFC-Sigma TKA reported no implants as being radiographically loose or at risk of loosening and only 1.5% knees required observation for progression after 6 years follow-up. In this study using the Knee Society radiographic evaluation system, 10 knees (16.39%) had radiolucencies – 9(14.75%) in tibial component while only 1(1.63%) in femoral component. Only 1(1.63%) required watch for progression while rest(14.75%) were <4 mm and considered insignificant. No progression of radiolucent lines and hence radiographic loosening was present at the last follow-up.

Complications following TKA include wound healing problems; infection; DVT and PE; pneumonia; patellar complications; joint instability, stiffness and malalignment; nerve and vascular injuries.1 There were few complications in this series.

Infection is the most dreaded complication affecting TKA. Three knees got infected and were attributed to old age and/or comorbid conditions like DM. One had tuberculosis on synovial biopsy and responded to antitubercular treatment after arthroscopic lavage and debridement while the second developed chronic infection even after debridement and required revision surgery. The third was only a superficial infection and subsided with antibiotics. Overall the infection rate was 4.92% with 1.68% requiring revision. There were no implant failures and no implants at risk. Large series reported by Hanssen and Rand20, and Wilson et al.21 showed infection incidences of 2.5% in 18,749 TKAs and 1.6% in 4171 TKAs respectively.

Patello-femoral complications, including patello-femoral instability, patellar fracture, patellar component loosening or failure, patellar clunk syndrome and extensor mechanism tendon rupture have been cited as the common reasons for reoperation. Various studies22,23,24 have found no significant difference between resurfaced and non-resurfaced patella. Hence, many authors advocate TKA without patellar resurfacing for patients with adequate patellar cartilage.25 Patella was resurfaced in only 2 cases in this study and no patello-femoral complications were encountered.

The incidence of Deep Venous Thrombosis (DVT) after TKA without prophylaxis is 50-80% in the ipsilateral extremity and 3-5% in the contralateral extremity.26 Isolated proximal venous thrombosis is infrequent compared with THR.26 The incidence of fatal PE is low (0-0.8%)27,28. Only clinical detection is unreliable. Although the gold standard for detection of DVT is contrast venography, the non-invasive
Doppler ultrasound is the current trend with its sensitivity and specificity approaching the former. Ventilation-perfusion lung scan and pulmonary angiography are used for the diagnosis of PE. The commonly used forms of prophylaxis include aspirin, LMWH, warfarin, heparin and compression devices. Although various studies have shown decreased incidence of DVT with different protocols, the most efficacious prophylaxis protocol for DVT is still controversial and there is still no ideal method for DVT prophylaxis. 26 Due to lack of diagnostic tests in this study, clinical signs and symptoms had to be relied upon for diagnosis. However, there was no case with any clinical evidence of DVT in this study. In the absence of reliable non-invasive diagnostic testing, routine DVT prophylaxis after TKA was recommended by the American College of Chest Physicians (ACCP) in the 8th Consensus Conference on Antithrombotic Therapy, 2008. In this study also routine prophylaxis with LMWH was used from second postoperative day till hospital stay. Calf massage was advised with encouragement for early mobilization.

Peroneal nerve palsy is an infrequent complication after TKA and seen commonly after correction of severe flexion and/or valgus deformities. 26 Asp and Rand (1990) reported an incidence of 0.3% in 8754 TKAs performed at the Mayo Clinic. 29 The prevalence of peroneal nerve palsy in SKAR was 1.8% in 2273 RA patients. 25 In this study one patient (1.63%) had peroneal nerve palsy which recovered spontaneously within 6 months.

One knee with a mobile-bearing prosthesis had tibial insert spin-off within 2 weeks of surgery due to lateral collateral ligament tear which was found peroperatively and had to be repaired. The insert was exchanged and protected weight bearing on knee brace with delayed knee mobilization was advised subsequently. The lateral collateral ligament tear was attributed to early over zealous attempt to attain full flexion or a twisting injury. Dalury et al. (2008) 12 in his study with PFC-Sigma TKA, reported a similar revision secondary to ligament disruption after a fall.

The success of TKA depends upon implant survival which can be assessed by revision rates and radiological or functional failure. Most series of TKAs report survivorship of 90–99% at 10 years. 5–10 The PFC-Sigma has a reported survivorship of 97% by Clayton et al. 13 after 5 years and 99.6% by Dalury et al. after a mean follow-up of 87 months. 12 Although this study is too short it shows similar survival rate after a mean follow-up of 2 years, during which there were no problems with polyethylene wear, osteolysis and loosening of the prosthesis. There were no revisions required because of aseptic loosening while only one knee (1.63%) required revision due to infection. The overall survival after 2 years was 98.37%.

Conclusion

Cemented TKA is still the gold standard treatment for patients with painful, debilitating knee arthritis not responding to conservative management and have radiological changes. The fixed-bearing, cruciate-substituting prosthesis continues to function well after a mean follow-up of 2 years. It has shown to be a very successful, safe and cost-effective treatment for alleviating pain and restoring function in such patients despite variations in patient health status and characteristics; materials and implant designs; surgeon’s skill and technique; infection control methods and postoperative rehabilitation programme including physiotherapy and DVT prophylaxis. Improvements can be made in overall success of TKA by addressing each of these areas of variation through further research.

References

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References

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References


