

Comparison of Functional Outcome of Total Knee Replacement between Cruciate Retaining and Cruciate Substituting Prosthesis in Cipto Mangunkusumo Hospital

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ABSTRAK

Background. Total knee replacement is a procedure of choice in the management of severe osteoarthritis. Currently two types of prosthesis are widely used, cruciate retaining and cruciate substituting. Experts have not yet reached agreement regarding which one is better. This study is aimed to compare functional outcome between cruciate retaining and substituting prosthesis.

Materials and methods. This study was a randomized single-blinded clinical trial. Patients with severe osteoarthritis were divided into two groups and evaluated before operation. First group underwent cruciate retaining total knee replacement, and the other cruciate substituting total knee replacement. Functional outcome was evaluated in 3 and 6 months after operation, regarding the knee flexion angle and International Knee Documentation Committee score.

Results. There were 14 patients. Mean knee flexion angle of cruciate retaining in 3 and 6 months were 105.0 degrees and 113.3 degrees respectively, whereas cruciate substituting were 118.1 degrees and 126.2 degrees. International Knee Documentation Committee score of cruciate retaining in 3 and 6 months were 49.0 and 59.4 respectively, while cruciate substituting were 52.6 and 63.8. There were significant differences in flexion angles between cruciate retaining and cruciate substituting groups at 3 months ($p=0.006$) and 6 months ($p=0.018$). No significant difference was demonstrated in International Knee Documentation Committee score between cruciate retaining and cruciate substituting groups at 3 months ($p=0.053$) and 6 months ($p=0.240$).

Conclusions. Functional outcome regarding the knee flexion angle of cruciate substituting group was 13.1 degrees better in 3 months and 12.9 degrees in 6 months compared to cruciate retaining group. Functional outcome based on International Knee Documentation Committee score did not show significant differences between two groups whether 3 or 6 months after operation.

Keywords: Total knee replacement, cruciate retaining, cruciate substituting, International Knee Documentation Committee score

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Perbandingan Luaran Fungsional *Total Knee Replacement* antara Prostesis *Cruciate Retaining* dan *Cruciate Substituting* di RS Cipto Mangunkusumo

ABSTRAK

Pendahuluan. Operasi *total knee replacement* adalah prosedur pilihan pada penanganan osteoarthritis berat. Terdapat dua jenis prostesis yang umum digunakan, yaitu *cruciate retaining* dan *cruciate substituting*. Belum ada kesepakatan ahli mengenai mana prostesis yang lebih baik. Penelitian ini bertujuan untuk membandingkan luaran fungsional antara pasien yang menjalani *total knee replacement* menggunakan prostesis *cruciate retaining* dan *cruciate substituting*.

Bahan dan cara kerja. Penelitian ini merupakan uji klinis acak tersamar tunggal. Pasien dengan osteoarthritis berat dibagi 2 kelompok kemudian dinilai kondisi praoperasi. Kelompok pertama menjalani *total knee replacement cruciate retaining*, sementara kelompok kedua *total knee replacement cruciate substituting*. Luaran fungsional dinilai 3 bulan dan 6 bulan pasca-*total knee replacement*, berupa sudut fleksi lutut dan skor *International Knee Documentation Committee*.

Hasil. Terdapat 14 pasien. Rerata sudut fleksi lutut kelompok *cruciate retaining* yaitu 105,0° pada 3 bulan dan 113,3° pada 6 bulan, sementara kelompok *cruciate substituting* 118,1° pada 3 bulan dan 126,2° pada 6 bulan. Rerata skor *International Knee Documentation Committee* kelompok *cruciate retaining* yaitu 49,0 pada 3 bulan dan 59,4 pada 6 bulan, sementara kelompok *cruciate substituting* 52,6 pada 3 bulan dan 63,8 pada 6 bulan. Terdapat perbedaan bermakna pada sudut fleksi lutut pascaoperasi antara kelompok *cruciate retaining* dan *cruciate substituting* pada 3 bulan ($p=0,006$) dan 6 bulan ($p=0,018$). Tidak terdapat perbedaan bermakna antara kelompok *cruciate retaining* dan *cruciate substituting* pada skor *International Knee Documentation Committee* pascaoperasi 3 bulan ($p=0,053$) dan 6 bulan ($p=0,240$).

Simpulan. Luaran fungsional berupa sudut fleksi lutut kelompok *cruciate substituting* lebih baik 13,1° setelah 3 bulan dan 12,9° setelah 6 bulan dibandingkan kelompok *cruciate retaining*. Luaran fungsional menggunakan skor *International Knee Documentation Committee* tidak berbeda bermakna antara kelompok *cruciate retaining* dan *cruciate substituting* pada 3 bulan maupun 6 bulan pascaoperasi.

Kata kunci: *Total knee replacement*, *cruciate retaining*, *cruciate substituting*, skor *International Knee Documentation Committee*

Introduction

Total knee replacement (TKR) is a procedure of choice in the management of severe osteoarthritis in older people although without apparent deformity. TKR is also chosen in younger patients with deteriorating knee due to inflammatory arthritis. In those cases, conservative treatment does not provide desired outcome compared to TKR, and also cost-effective.¹

Since the introduction of the widely successful total condylar prosthesis by Insall² in 1974, designs of TKR are

still evolving. Regarding the posterior cruciate ligaments (PCL), currently two types of prosthesis are widely used, cruciate retaining (CR) and cruciate substituting (CS). Experts have not yet reached agreement regarding which one is better.

Proponents of CR stated that retaining the PCL will benefit in increasing the knee stability after TKR, increasing range of motion, while still retaining the knee proprioception.³ In the other hand, proponents of CS claims to have easier deformity correction, also increase

range of motion, while maintaining near-normal knee kinematics.⁴ One author even stated that without a fully intact PCL, the CR implant still function as well as the CS, negating the need of PCL to be preserved.⁵

Studies comparing outcomes between CR and CS has been performed, whether short term functional outcome regarding the rehabilitation process, or medium to long term outcome emphasizing on the survival of the implants. Results were conflicting as some author found better results in one type of implants compared to one another, as Cochrane's meta-analysis in 2005 still cannot provide firm conclusion, indicating that there is a tendency that there were no differences between CR and CS in terms of functional, clinical and radiological outcome.⁶ Therefore the different opinions between both side remains unsettled.

Functional outcome evaluation is important to be performed, whether subjectively by involving the patients or objectively through the clinical judgment of the Orthopedic surgeon. One of the most popular patient reported outcome instrument in osteoarthritis was the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score.⁷ In order to provide a knee specific instrument – instead of disease specific – the International Knee Documentation Committee (IKDC) developed the IKDC 2000 forms, with comparable reliability and response with previous instruments.^{8,9}

To date, there are no published clinical trial studies in Indonesia addressing the outcomes of TKR, in short term which emphasizes in functional outcome, or medium to long term in terms of survival. Whether different designs of CR and CS provide the same short term functional outcome or medium to long term survival as previous studies has yet to be unraveled. While long term outcome might be of more importance to clinicians, patients and families may concern more on the short term outcome, probably will be their basis of making a decision of following the operative treatment or not.

This study aims to compare short term functional outcome between the two types of prosthesis, CR and CS, specifically the range of motion and the subjective outcome based on the IKDC 2000 subjective knee forms. The hypothesis was there were significant differences of functional outcome between the CR and CS.

Methods

This study was a randomized single-blinded clinical trial. This study was undertaken within the period of January 2011-August 2012, towards all patients undergoing total knee replacement (TKR) in Cipto Mangunkusumo

Hospital. Minimal sample size using difference between two means formula were 12 patients. Inclusion criteria were all patients with primary osteoarthritis and having body mass index (BMI) of $<35 \text{ kg/m}^2$, while excluding patients with inflammatory arthritis (rheumatoid arthritis, gouty arthritis) and patients with flexion contracture of >20 degrees.

Patients with severe osteoarthritis and scheduled for TKR were taken for informed consent, and afterwards randomized to receive one of two types of prosthesis, CR or CS. Due to ethical concern, the operator (AMTL) knew about the prosthesis that was going to be used and was involved in evaluating the pre-operative condition of the patients, while the patients did not know which type of prosthesis they received. The ethical concerns was that while pre-operative patient evaluation must be performed by the expert in TKR, during the study there were only one active knee consultant in RSCM; therefore to avoid harm to the patient, single blinding were chosen. After the patients were considered suitable for the group, they had their data taken by the examiner group.

Knee flexion angle were measured from the lateral side using the intersection between lines traversing the greater trochanter to femoral lateral condyle and head of fibula to lateral malleolus. Measurements were performed by team of residents according to the method described, previously rehearsed and evaluated to ensure precision.

Patient reported outcome used were the IKDC subjective knee form (IKDC-SKF) translated to Bahasa Indonesia. The translated version had been trialed before in the outpatient setting to review whether there was any question that was unclear and needed revision. Assessment on the validity, response, or construct of the translated form was not performed. Patient completed the filling of IKDC-SKF by themselves or assisted by their family member.

First group underwent cruciate retaining TKR, and the other cruciate substituting TKR. The operation were all performed by one experienced orthopedic surgeon (AMTL), took place in Cipto Mangunkusumo Hospital. Patients were admitted 1-2 days prior to surgery and given prophylactic intravenous antibiotics. Operating room theatre had the same condition for all patients. Implants used were the PFC Sigma (DePuy J&J) for the CR group and either PFC Sigma or NexGen (Zimmer) for the CS group.

Approach used was the medial parapatellar approach for all patients. Patients in the CR group were re-evaluated peri-operatively to ensure the PCL is still functioning by performing posterior drawer test before operation

Table 1. Baseline characteristics of patients

Characteristics	Cruciate retaining group	Cruciate substituting group
N (patients)	6	8
Age (years old)	63.3 (SD 6.9)	60.2 (SD 7.7)
Sex		
Male	1	3
Female	5	5
Body mass index	28.8 (SD 3.6)	25.5 (SD 3.7)
Varus/valgus	6/2	5/1
Flexion angle (degrees)	126.7 (SD 15,1)	132.5 (SD 7.1)
IKDC-SKF score	28.2 (SD 13.54)	35,3 (SD 12.4)

and evaluating macroscopic features during operation. Femoral cutting was performed first followed by tibial cutting and gap balancing. After trial, the implants were inserted using cement. All procedures were performed bloodless using a tourniquet. After the operation, patients were hospitalized for 5 days, encouraged for early range of motion and weight bearing. Patients were consulted to the Medical Rehabilitation Department prior to surgery thus the rehabilitation processes were maintained by them, lasting for 12 weeks.

Functional outcome was evaluated in 3 and 6 months after operation, regarding the knee flexion angle and IKDC-SKF score. Data were collected by the examiner group during outpatient visits. All the data were analyzed using Statistical Package for Social Sciences (SPSS) version 20. Hypothesis was examined using independent T test or Mann-Whitney test. Statistical significance achieved if p value less than 0.05.

Results

There were 14 patients, 6 in CR group and 8 in CS group. Baseline characteristics were presented in Table 1. No significant differences between the CR and CS groups regarding the mean age, body mass index, and pre-operative flexion angle. During 6 months follow up, there were no complications present, such as thrombosis, dislocation, or infection.

Table 2 summarizes the functional outcome of the CR and CS group after 3 and 6 months. Mean knee flexion angle of CS were better than CR by 13.1 degrees in 3

months and 12.9 degrees in 6 months. Independent T-tests showed that both are statistically significant ($p < 0.05$). The IKDC-SKF score showed the same results where the CS scores were better than CR group during 3 and 6 months follow up, although not statistically significant.

Discussions

Patients enrolled in this study were 14 patients, of which the comparison between males and females were 1:2.5. Previous studies have addressed the possible different outcomes between the sexes.^{10,11} Results are conflicting since Tonelli et al.¹¹ stated that women had worse outcome than men, in the other hand MacDonald et al.¹⁰ had similar clinical outcomes between males and females. In this study there were no differences between the proportion of male to female between the CR and CS group ($p = 0.58$).

Body mass index were also suspected to influence the outcome of the TKR. Increase in BMI of >30 deteriorates the range of motion and functional scores as shown in Yeung et al. study,¹² although in another study Bordini et al.¹³ did not find any differences in survival or complication rates. Again, this study did not show a significant difference between the pre-operative BMIs of the two groups ($p = 0.133$). Range of motion before operation has been shown to influence the knee range of motion after operation, as shown by Statford et al.¹⁴ In this study, the range of motion before operation between CR and CS group were similar ($p = 0.662$). Sex, BMI, and range of motion were factors that may affect the

Table 2. Functional outcome of total knee replacements

Type of outcome	Cruciate retaining group	Cruciate substituting group	P
Flexion angle 3 months	105.0 (SD 6.3)	118.1 (SD 8.0)	0.006
Flexion angle 6 months	113.3 (SD 8.2)	126.2 (SD 9.2)	0.018
IKDC-SKF score 3 months	49.0 (SD 4.0)	52.6 (SD 2.2)	0.053
IKDC-SKF score 6 months	59.4 (SD 4.5)	63.8 (SD 7.8)	0.240

outcome, but in this study they were shown to be similar, eliminating confounding factors.

Functional outcome of CR and CS were different in terms of knee range of motion after 3 and 6 months, both statistically significant. Previous study by Kolisek et al.¹⁵ shown that in 60 months, the CR had better knee range of motion than the CS by 7 degrees, although not significant. Han et al.¹⁶ had similar results between the CR and CS groups regarding the range of motion and subjective outcomes.

In order to determine whether CS is really better than CR, we have to analyze the factors that may influence the outcome; they are the implant design, difference in intra-operative factors, rehabilitation, and time of follow up.

Main design factor contributing to maximum knee flexion were the femoral roll back. Both CR and CS were shown to have similar femoral roll back in the previous studies.^{17,18} Based on the femoral roll back, the implant designs may not contribute to the difference between the CR and CS groups. During the operation, the ligament balancing may contribute to differences in knee flexion after operation. Higuchi et al.¹⁹ stated that in fixed bearing prosthesis, the joint gap during operation had positive correlation with the knee flexion after operation. This study does not measure the joint gap during operation, so this factor may still possibly affecting the difference in flexion outcome.

Incomplete rehabilitation compliance was found in 4 patients, one from CR group, while 3 other are from CS group. Rehabilitation may still play a role in the achievement of flexion ROM within 6 months, as shown in the study by Heiberg et al.²⁰ This led to the possibility of more change in knee flexion ROM after the follow up of 6 months. Thus the incomplete rehabilitation compliance as well as the follow up duration may mask the real outcome of the knee flexion angle in this study.

Using IKDC-SKF scores to evaluate subjective functional outcome after TKR has not been done before, though the IKDC-SKF is intended to measure the knee function for various conditions including knee osteoarthritis.⁸ IKDC-SKF have several components such as symptoms, activity, and knee function, similar to

other scores used such as WOMAC score.⁷

IKDC-SKF score between the CR and CS group were not significantly different, in accordance to previous studies although using different scores, such as the study by Kolisek et al.¹⁵ using knee society functional scores, or Han et al.¹⁶ using WOMAC scores.

Short term functional outcome studies using patient-reported outcome scores may capture the progress of the patient during the early rehabilitative phase after TKR, although some have challenged that they have to be supplemented with a more objective functional outcome, coined as performance-based outcome, such as chair-rising, stair-rising, and six minutes walking test.²¹

It is also worth mentioning that a significant difference of knee flexion angle of 12-13 degrees may not reflect the real clinical settings, as compared to the patient-reported outcome using the IKDC-SKF scores, patient did not reveal that the difference of knee flexion angle equals the difference in their functional outcome.

Limitations of this study were there are biases from patient selection in which single blinding were preferred and minimal inclusion criteria, and from the treatment in which several patients had incomplete rehabilitation compliance. Due to ethical concern, patients should have the best assessment before the operation in order to avoid harm. It is inevitable that the patients be examined by the senior orthopedic surgeon performing the operation, thus the single blinding was preferred. The minimal inclusion criteria may result in incorporation of many confoundings, as controlling more variables will result in better validity. The rehabilitation process were incomplete in 4 patients, thus may affect the functional outcomes measured.

Conclusions

Functional outcome of knee flexion angle of CS group was 13,1 degrees better in 3 months and 12,9 degrees in 6 months compared to CR group. Functional outcome based on IKDC score did not show significant differences between two groups whether 3 or 6 months after operation.

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