A Prospective Study Comparing Mobile-bearing versus Fixed-bearing Type in Total Knee Arthroplasty Using the Free-Hand-Cutting Technique

Prakit Tienboon MD*,
Nara Jaruwangsanti MD*, Paiboon Laohasinnurak MD*

** Department of Orthopaedics, Faculty of Chulalongkorn University, Bangkok, Thailand*

Background: *The mobile-bearing knee prosthesis was claimed to get more flexion in the laboratory testing and may provide better functional outcome than the conventional fixed-bearing prosthesis in patients. To prove this hypothesis in the patients between those two type prosthesis about flexion and functional out come was our study goal.*
Material and Method: *The prospective randomized control trial: The Free-Hand-Cutting technique underwent TKR (100 mobile bearing and 100 fixed bearing). Post operative clinical outcomes were compared in range of movement, Knee Society Score, Function Knee Score and Oxford Knee Score at 2 months, 6 months, 1 year and 2 years.*
Results: *The mobile-bearing type prosthesis provided more flexion than the fixed-bearing knee prosthesis. But the same clinical out come was observed.*
Conclusion: *The mobile-bearing type prosthesis gave more functional out come but not significant in daily patient activity compare to the fixed bearing knee prosthesis.*

Keywords: *Mobile-bearing, Fixed-bearing, Range of motion (ROM), Knee society score, Functional score, Oxford knee score*

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The Total Knee Arthroplasty or TKA is considered as a today's world standard treatment[1,2] in severe osteoarthritis and some other limit pathology. The definite indications for TKA should be emphasized on proper age (over 65 year old or better over 70 years) severe knee joint degeneration with failure to conservative treatment, severe knee deformity or knee instability and so all. In addition the patients who had severe knee pathology and unable to take medicine is also the good TKA candidate. The conventional technique of Total Knee Arthroplasty is not too complicated for Doctors' talented and trained to be an expert in this field. Although the total knee implants have been developed for over 50 years along many other matters that not been able to solve and fix completely[3,4]. Today, many engineers are trying to create a total knee arthroplasty implant with the use of a durable nature and close to the knee as much as possible[5-7]. The invention of total knee arthroplasty has been evolved into the medical market. Benefit to the knee prosthesis have been developed with high efficiency can be produced to replace the previous technique knee arthoplasty successfully. Mobile-bearing total knee arthroplasty is one that has been invented with the movement of polyethylene liner on tibial tray. Mobile-bearing is different from the previous model called Fixed-bearing which polyethylene liner fixed on tibial component[9]. Computers also have been used in the lab to analize the trial of mobile-bearing total knee arthoplasty in order to enhance the movement of the knee, to bend more and can be used longer duration. The movement of polyethylene will reduce friction and pressure causing in reduce wearing and loosening[8-14]. Motion of the knee occurred at two difference parts. First was between smooth surface of tibial tray and smooth surface of polyethylene. Second was between curve of femoral condyle and groove of the polyethylene. In the fix bearing knee prosthesis, the high friction, high stress and high strain occurred more at the fixed tibial tray and tibia bony contact surface. The loosening effect was seen at this part quite often. Better function is the purpose of mobile bearing even though some studies was not difference in many studies[15-24].

Correspondence to:
Tienboon P, Department of Orthopaedics, Faculty of Chulalongkorn University, Patumwan, Bangkok 10330, Thailand.
Phone: 08-1836-7893
E-mail: drprakit@gmail.com

Objective

To compare the clinical out come of two types of total knee arthroplasty, Mobile and Fixed Bearing type prosthesis by using range of motion (ROM), Knee Society Score[25], Function Score[25] and Oxford Knee Score[26] as measurement.

Material and Method

Implant types

Two-difference models prosthesis, Mobile-bearing total knee arthroplasty model DePuy Press Fit Condylar (PFC) Sigma RP-F (Johnson & Johnson) versus fixed-bearing model DePuy Press Fit Condylar (PFC) Sigma (Johnson & Johnson) were selected in this research. The fixed-bearing (DePuy Press Fit Condylar (PFC) Sigma) condyle was designed radius of curvature to have a bend radius of 3 in the laboratory up to 125 degrees. The Mobile-bearing (DePuy Press Fit Condylar (PFC) Sigma RP-F) was designed to have femoral roll back combined with tibial component which can be rotated 20 degrees bend in the laboratory 150 degrees.

Inclusion criteria

Male or female patients at risk of Osteoarthritis, Rheumatiod Arthritis or Failed HTO age started from 65 years old. Patients with knee score < 60, functional score < 60 and oxford score < 20 before the operation[25,26]. Patients who are able to give voluntary, written informed consent to participate in this investigation and from whom consent have been obtained. Patients able to understand this investigation co-operate with the investigation procedures and are willing to return to the hospital for all the required post-operative follow-ups. Patients who present with idiopathic osteoarthritis that in the opinion of the clinical investigator requires a primary total knee arthroplasty. Patients were selected randomly with any surgical procedure either mobile bearing or fixed bearing.

Exclusion criteria

Patients with a history of septic knee, patients who, in the opinion of the Investigator, have an existing condition that would compromise their participation and follow-up in the present study. Subjects who are known drug or alcohol abusers or with psychological disorders that could affect follow-up care or treatment outcomes. Subject who have participated in a clinical study with an investigational product in the last month (30 days). Subjects who are currently involved in any personal injury litigation claims. Subject with a known history of poor compliance to medical treatment. Subjects who have BMI > 40. Subjects who have wish to have a simultaneous bilateral procedure. However, subjects have had a staged bilateral procedure may be included as long as the previous procedure was performed 9 or more months prior to their inclusion in the present study.

Collecting research data

This research was done under the permission of Johnson & Johnson Company using randomized selection technique. There were 200 patients included during 2004-2010; of 100 patients with knee replacement prosthesis mobile-bearing, another 100 patients on fixed-bearing input equally. This research had been approved by the Ethic Board of the Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand before starting the project. All patients were diagnosed with the condition x-ray of the knee before were selected into inclusion criteria. They also filled in personal information and questionnaire using to analyze and evaluate clinical outcome from Knee Society score, Function Score and Oxford Knee Score respectively. The present study was follow-up by 2 month, 6 month, 1 year and 2 year. There was no patient left the project during the research period.

The present study was reported average, standard deviation, median and interquartile range in order to explain the variable basis such as age, BMI, Knee Society Score, Function Score and Oxford Knee Score Percentage and frequency were used to explain in gender as a variable basis.

This research compared the performance between both group were assessed using the Knee Society Score and Function Score (maximum score at 100) score; 0-60 = poor, score 60-69 = average, score 70-79 = good, score 80-100 = excellent[25]. Evaluation in the daily life was with Oxford Knee Score; (maximum score, 48) score 0-19 = poor, score 20-29 = average, score 30-39 = good, score 40-48 = excellent[26] between two groups. The range of motion were assessed using a goniometer[27].

Thus, the evaluation of these two treatments Fixed Bearing and Mobile Bearing measured by the comparison of Knee Society Score and Function Score was regrouped according the American Knee Society scoring system[25] and the Oxford knee score[26]. There after, the research will use statistics from Chi-square or Fisher's exact test to test the difference score at 2 month, 6 months 1 year and 2 year. Statistic significant was set at 0.05, statistic analysis program was STATA version

11.0.

Free-hand-cutting technique

The free hand cutting, our own surgical technique of surgery was one of the main principles in this research and was used to perform the total joint replacement for all 200 knees. The skin incision and joint exposure was an anterior approach as standard exposure. The key steps of the surgery for the bone cutting were step of the femoral cutting.

Step 1

Anterior femoral cutting: the authors cut the anterior prominence part of femoral condyle along the anterior blow surface of the whole femoral shaft and parallel to the bi-epicondyle axis. After the finished cutting, the cancellous cutting surface, piano lid like shape at anterior condyle area was seen which a larger part on the lateral site.

Step 2

Distal femoral cutting; the cutting was set at 95 degree to the previous first cut of the anterior condyle surface and 5-9 degree vulgus alignment. The cutting thickness of the distal condyle was about 8 mm. by average. Normally, it was just pass the intercondylar groove of femur. The 95 degrees template was placed to confirm the corrected cutting plain. The vulgus alignment was roughly set for this first cut. The correct vulgus alignment will be set later after finish tibia cutting. more vulgus or varus leg alignment can be removed later and also for increasing the extension gap.

Step 3

Posterior femoral cutting; the cutting in this part was so simple. The direction of cut was 5 degrees divergence to the anterior cutting surface. These mean after the corrected prosthesis size was selected. Template or trial prosthesis can be used to mark the posterior condyle for cutting.

Step of the tibia cutting: the tibial plateau was cut perpendicular to the proximal third of tibia crest at about 6-8 mm thickness. Preparing for the tibia prosthesis was the same as standard procedure.

For fixed bearing knee prosthesis: the posterior slope was about 5-7 degree. For the mobile bearing type prosthesis: the posterior slope was 0 degree. Measurement for the tibia prosthesis size was done by put the center mark of tibia tray along the same line of proximal one third of the tibia crest. This was usually just medial to the tibial tubercle. From this point to the point just lateral edge of the plateau will be the correct prosthesis size.

The patella bone was replaced with 3 pegs polyethylene prosthesis. The proper alignment of the leg, balancing of the flexion and extension gap and ligaments was checked and adjusted.

Results

The research found that the patients with fixed bearing are 11 male (11%) and 89 female (89%) versus with Mobile bearing are 18 male (18%) and 82 female (82%). The average age is 68 years old and 70 year olds respectively as shown Table 1.

Evaluation of results from Knee Society Score, Function Score and Oxford knee Score at 8 weeks (2^{nd} month) post-operative of both fixed bearing and mobile bearing groups found 72% and 76%, respectively, have Knee Society Score in the fair range (KS 60-69) 59% and 53%, respectively, have Function Score in the fair range (FS 60-69). And 100% and 100%, respectively, have the Oxford knee Score in the fair range (OKS 20-29). Chi-square test shows no statistical differences between the Knee Society Score, Function Score and Oxford Knee Score in their own groupings as shown in Table 2.

The assessment of Knee Society Score, Function Score and Oxford Knee Score at 6^{th} month in fixed bearing and mobile bearing group found that 92% and 90%, respectively, have Knee Society Score in the good range (KS 70-79). 82% and 76%, respectively, have Function Score in the good range (FS 70-79). And 100% and 100%, respectively, have Oxford Knee Score in the good range (OKS 30-39). Chi-square test shows no statistical difference between the Knee Society Score, Function Score and Oxford Knee Score in their own groupings as shown in Table 3.

At 1^{st} year, assessment of Knee Society score, Function Score and Oxford Knee Score of fixed bearing and mobile bearing group show the excellent score that 97% and 95%, respectively, have Knee Society Score in the excellent range (KS 80-100). 82% and 81%, respectively, have Function Score in the excellent range (FS 80-100). And 98% and 91%, respectively, have Oxford knee Score in the good range (OKS 30-39). Chi-square test shows no statistical differences between the Knee Society Score and Function score in their own groupings, However it shows statistical significant difference between the group with Oxford Knee Score (p-value = 0.03) as shown in Table 4.

At 2^{nd} year, assessment of Knee Society Score,

Table 1. Shown the basis of the comparison between patients with Fixed Bearing and Mobile TKA before surgery

	Fixed-bearing	Mobile-bearing
Gender		
Male	11 (11)	18 (18)
Female	89 (89)	82 (82)
Age		
Average	68.43 (10.47)	69.91 (6.42)
Median	69 (62.75,75)	70 (66,74.75)
Body mass index (BMI)		
Average	25.18 (3.76)	27.49 (19.83)
Median	24.61 (22.83, 27.00)	24.97 (23.14,27.06)
Knee Society Score		
Average	50.15 (12.34)	51.8 (12.08)
Median	53 (41.5,60)	53 (45,60)
Function Score		
Average	39.53 (11.33)	37.92 (12.07)
Median	40 (30, 50)	40 (30,49)
Oxford Knee Score		
Average	22.9 (3.92)	22.88 (4.09)
Median	22 (20, 25)	23 (20,26)

BMI,body mass index ,gender, age Knee Society Score ,Function Score, Oxford Knee Score. Statistic significant were not diffences

Table 2. The comparison of results of TKA both Fixed Bearing and Mobile Bearing in knee straight and knee bent at the 2nd month

	Fixed-bearing	Mobile-bearing	p-value
Knee Society Score			
60-69	72 (72)	76 (76)	0.519
< 60	28 (28)	24 (24)	
Function Score			
60-69	59 (59)	53 (53)	0.393
< 60	41 (41)	47 (47)	
Oxford knee Score			
20-29	100	100	
< 20	0	0	

(Chi-squared test)

Table 3. Shown the comparison of results of TKA both Fixed Bearing and Mobile Bearing in knee straight and knee bent at 6th month

	Fixed-bearing	Mobile-bearing	p-value
Knee Society Score			
70-79	92 (92)	90 (90)	0.621
< 70	8 (8)	10 (10)	
Function Score			
70-79	82 (82)	76 (76)	0.298
< 70	18 (18)	24 (24)	
Oxford knee Score			
30-39	100	100	
< 30	0	0	

(Chi-squared test)

Table 4. Shown the comparison of results of TKA both Fixed Bearing and Mobile Bearing in knee straight and knee bent at the 1st year

	Fixed Bearing	Mobile Bearing	p-value
Knee Society Score			
80-100	97 (97)	95 (95)	0.47
< 80	3 (3)	5 (5)	
Function Score			
80-100	82 (82)	81 (81)	0.856
< 80	18 (18)	19 (19)	
Oxford Knee Score			
30-39	98 (98)	91 (91)	0.03
< 30	2 (2)	9 (9)	

(Chi-squared test)

Table 5. Shown the comparison of results of TKA both Fixed Bearing and Mobile Bearing in knee straight and knee bent at the 2nd year

	Fixed Bearing	Mobile Bearing	p-value
Knee Society Score			
80-100	98 (98)	97 (97)	0.651
< 80	2 (2)	3 (3)	
Function Score			
80-100	83 (83)	83 (83)	1.000
< 80	17 (17)	17 (17)	
Oxford Knee Score			
40-48	98 (98)	92 (92)	0.052
< 40	2 (2)	8 (8)	

(Chi-squared test)

Function Score and Oxford Knee Score of fixed bearing and mobile bearing group show the excellent score that 98% and 97%, respectively, have Knee Society Score in the excellent range (KS 80-100). 83% and 83%, respectively, have Function Score in the excellent range (FS 80-100). And 98% and 92%, respectively, have Oxford Knee Score in the excellent range (OKS 40-48). Statistic analysis of the Knee Society Score, Function Score and Oxford Knee Score with Chi-square test was not difference as shown in Table 5.

The average hospital stay was 6.15 and 6.79 days statistic analysis with Mann-Whitney U test shows no difference between the 2 groups. The measurement of extension and flexion in fixed bearing and mobile bearing show the flexion > 130 degree was 32% and 47%. The statistic analysis was difference (p-value = 0.03) as shown in Table 6.

Complications

There 5 cases complication in the present study. Superficial wound infection occurred in one of fixed bearing case. Patella Clunk occurred in one case of Mobile bearing at 1 year. 3 female cases of mobile bearing had tibial loosening. One case occurred at 1 year. Other two cases occurred at 4 year. All cases were Re-operated for refixed tibial tray to good position.

Radiological results

The radiological results in both groups were not different. All patients had complete radiological follow-up. In both groups there were good alignment of the knee, the position of the femoral and tibial components in the coronal and saggital planes, the patellar angles, the pre- and the post-operative central of joint lines (Fig. 1-5). The results of Knee Society Score, Function Score and Oxford knee Score in both groups shown comparison chart as in Fig. 6-8.

Discussion

There are three teams joining in this research,

Table 6. Shown the comparison of results of TKA both Fixed Bearing and Mobile Bearing in Flexion-Extension at the 6th month

	Fixed Bearing	Mobile Bearing	p-value
Length of hospital stay			
Mean (Standard deviation)	6.15 (1.91)	6.79 (3.89)	0.678*
Median (IQR)	6.00 (4.25, 8.00)	6.00 (5.00, 7.00)	
Extension			
Flexion Contracture	0	0	-
Full Extension	100	100	
Flexion (degree)			
≥ 130°	32 (32)	47 (47)	0.03
< 130°	68 (68)	53 (53)	

*Mann-whitney u test

Table 7. Shown the comparison Flexion-Extension in total patients

	Extension-Flexion									
	0-90°	0-95°	0-100°	0-110°	0-115°	0-120°	0-125°	0-130°	0-135°	0-140°
Fixed-bearing	2	2	14	8	7	33	2	18	13	1
Mobile-bearing	3	2	9	8	5	19	7	27	18	2

Fig. 1 Radiographs of patient a 75 year-old woman who had osteoarthritis both knee. a) Pre-operative Anteroposterior both knee. b) Post-operative anteroposterior views with fixed-bearing right knee taken 7 years and mobile-bearing left knee taken 6 year post-operativly showing are good fixed with free-hand-cutting technique

Fig. 2 Radiographs of patient a 73-year-old woman who had Osteoarthritis right knee. left) Pre-Operative Anteroposterior views. Middle and right) Post-operative anteroposterior and Lateral views with mobile-bearing knee taken 2 years post-operativly showing are good fixed with free-hand-cutting technique.

Surgeon-Researcher-Statistic analysis. Each team working was individually for the data correction. The surgeon team did the surgery, follows the patient and advised for the better post-operative treatment program. The researcher did all the data collection by pre and post-operative patient clinical interview, measure the range of knee motion, follow the knee x-ray etc. The statistic analysis interpreted the entire raw data by statistic method then send back to surgeon for announcement. The outcome in this research was the real data without bias. For the surgical technique, the authors have been using this Free Hand Cutting technique over 30 years for the total knee replacement. The technique was developed and corrected to prevent and protect any intra-operative untoward surgical event. Stepping of the bony cutting technique was set up to get very high standard. And the out come of prosthesis position, gap balancing and ligament tension were the same in all 200 knees in this research. In case of severe tibia bone loss, the authors used bony augmentation from the intercondylar groove. The bone graft was nicely healed and gave very good tibia tray

Fig. 3 Radiographs of patient a 72-year-old woman who had Osteoarthritis right knee. left) Pre-Operative Anteroposterior views. Middle and right) Post-operative anteroposterior an lateral views with fixed-bearing knee taken 5 years post-operativly showing are good fixed with free-hand-cutting technique

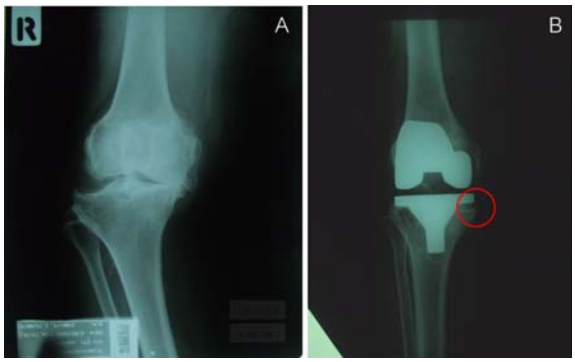

Fig. 4 Radiographs of patient a 73-year-old woman who had severe Osteoarthritis right knee. a) Pre-Operative Anteroposterior views. b) Post-operative anteroposterior view in fixed-bearing knee with autogenous bone graft augmentation at medial tibial plateau taken 6 months post-operativly showing are good fixed with free-hand-cutting technique

support. In case of tight collateral ligament, the authors released all of them until good tension was obtained. To obtain the flexion and extension balance, this technique was superior surgical technique than standard one. After complete cutting the tibia, the authors tested the flexion gap first then extension gap. Because in this technique, the posterior condyle was cut quite thin. So the authors never had over flexion gap. The authors also cut the distal femur rather thin. So the extension gap was usually little tight. In this case, the authors cut more at distal femur until the gap was equal balance. The most popular polyethylene size was number 8 mm the higher number was used in a very few case and also never over 12 mm. The hospital

Fig. 5 Radiographs of patient a 72-year-old woman who had severe Osteoarthritis right knee. left) Pre-Operative Anteroposterior views. Middle) Post-operative anteroposterior view with autogenous bone (from intercondylar notch of femur) graft tibial weight augmentation. right) Lateral views with fixed-bearing knee taken 1 year post-operatively showing are good fixed with free-hand-cutting technique

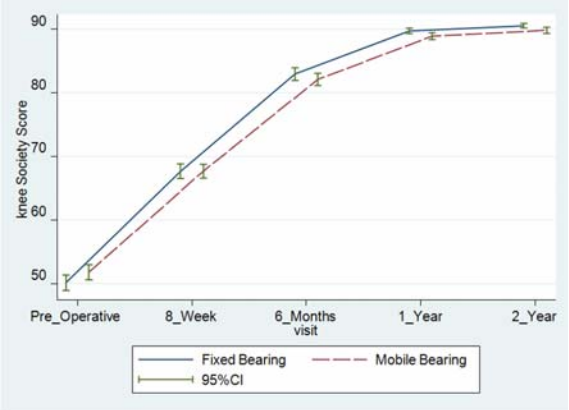

Fig. 6 shown the Oxford knee Score comparison between fixed bearing and mobile bearing in TKA

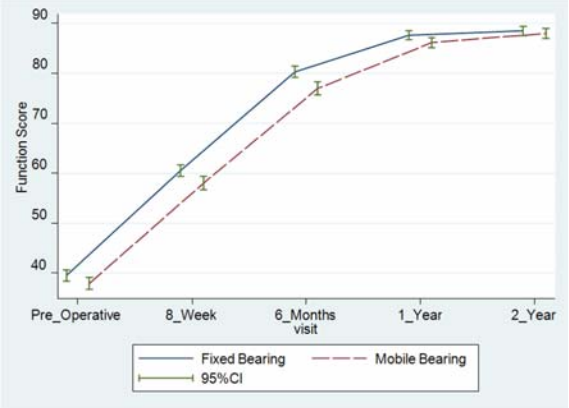

Fig. 7 Shown the Function Score comparison between fixed bearing and mobile bearing in TKA

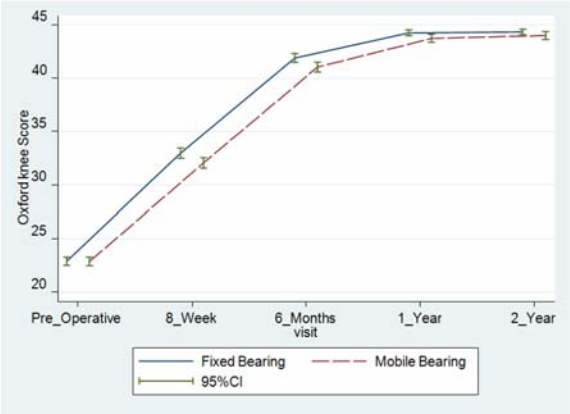

Fig. 8 Show the Oxford knee Score comparison between fixed bearing and mobile bearing in TKA

stay was found longer than usual because it was started form the first day of admission, not after the post-operation. Most of the patient stayed in hospital for four and a half day and some only three and a half day if measure after postoperative date. From the statistic analysis found that group of the mobile bearing knee provided better knee flexion than fixed bearing knee in term of the ratio at over 130 degrees knee flexion. But the over all clinical results was not significantly difference in both group when compared by the knee Society score and Function Score at 6 months, 1st and 2nd year. In the other hand, if the authors did analyse by Oxford Knee Score, the fixed bearing knee had higher score compare to the mobile bearing prosthesis that had higher degree of knee flexion.

Conclusion

This study confirmed that mobile bearing knee prosthesis improved knee flexion compare to fixed bearing knee prosthesis, however there was no different in functional outcome.

Potential conflicts of interest

None.

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การศึกษาเปรียบเทียบข้อเข่าเทียมชนิด mobile และ fixed bearing โดยการผ่าตัดด้วยเทคนิค free-hand-cutting

ประกิต เทียนบุญ, นรา จารุวังสันติ, ไพบูลย์ เลาหสินนุรักษ์

ภูมิหลัง: ข้อเข่าเทียมชนิดหมุนได้ถูกออกแบบมาให้คาดหวังว่าจะทำให้ข้อเข่างอได้มากกว่าข้อเข่าเทียมชนิดปกติ และทำให้การใช้งานน่าจะดีกว่าเช่นกัน การวิจัยนี้พิสูจน์สมมุติฐานดังกล่าวในผู้ป่วยว่าจะเป็นจริงหรือไม่

วัสดุและวิธีการ: การศึกษาแบบไปข้างหน้า เพื่อศึกษาและเก็บข้อมูลในผู้ป่วยที่ผ่าตัดเปลี่ยนข้อเข่าเทียมโดยเทคนิค Free-hand-cutting ทั้งหมด 200 ราย โดยแบ่งเป็นข้อเข่าเทียมชนิดหมุนได้ 100 รายและข้อเข่าเทียมชนิดปกติ 100 ราย โดยวิธีการเลือกแบบสุ่ม วัดผลโดยดูองศาการงอ และประเมินผลการผ่าตัดโดยใช้ Knee Soceity Score, Function Score และ Oxford Knee Score

ผลการศึกษา: ข้อเข่าชนิดหมุนได้สามารถทำให้ผู้ป่วยงอเข่าได้มากกว่าข้อเข่าเทียมชนิดปกติอย่างมีนัยสำคัญทางสถิติ โดยพบว่าสัดส่วนของผู้ป่วยที่งอเข่าได้มากกว่า 130 องศามีมากกว่าในกลุ่มผู้ป่วยที่ผ่าตัดเข่าชนิดปกติ แต่อย่างไรก็ตาม การงอเข่าที่ได้มากกว่านั้นไม่ได้ทำให้เกิดความแตกต่างต่อผู้ป่วยในทางคลินิก เมื่อเปรียบเทียบผลการผ่าตัดทั้งสองกลุ่มโดยใช้ Knee Soceity Score, Function Score และ Oxford Knee Score ในเดือนที่ 6, ปีที่1 และปีที่ 2 ไม่พบว่ามีความแตกต่างกัน อย่างมีนัยสำคัญทางสถิติงกลุ่มโดยใช้ ไรก็ตามการงอเข่าที่ได้มากกว่านั้นไม่ได้ทำให้เกิดความแตกต่างต่อผู้ป่วยในทางคลินิก เมื่อเปรียบเทียบผลการ

สรุป: ข้อเข่าเทียมชนิดหมุนได้ทำให้ผู้ป่วยงอเข่าได้มากกว่าข้อเข่าเทียมชนิดปกติแต่ระดับของความพึงพอใจในการใช้งานไม่แตกต่างกัน