

**A Comparative study of the clinical results of different models of Total Knee Arthroplasty (Natural Knee II, Nexgen, PFC-Sigma, All-poly Nexgen ,All-poly PFC Sigma and Inor knee ) at 3 months post operative (immediate post- operative results)**

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## Abstract

Background- This study was conducted to evaluate the difference, if any, in the immediate post-operative results (at 3 months follow up) between the different models of TKR of different companies.

Materials and methods-A total of 33 total knee replacements done by me between Dec.2006 to Feb 2011 using- 10 models of Natural knee II,-7 models of PFC sigma,- 8 models of Nexgen,- 3 models of Inor knee,- 3 models of all poly<sup>6</sup> PFC-sigma , 1 model of all-poly<sup>6</sup> Nexgen and 1 model of PFC-sigma RPF knees were evaluated for knee function using the American Knee Society Score<sup>1</sup> and the Knee Society Radiographic Assessment<sup>2</sup> at 3 months post-operatively. All patients had osteoarthritis. All cases were done unilaterally; 9 cases underwent knee replacement in their contralateral knees (staged bilateral knee replacement). Some had symptomatic opposite knees while some did not have any problem in the opposite knee. The mean age of patients was 64.8 years. There were 14 male and 10 female patients.

Results: - 2 patients were lost to follow-up due to infection (although their infection was controlled with the use of iv vancomycin; they did not want to continue taking vancomycin for a long duration, because of its high cost, so they consulted other doctors and were lost to follow up at 3 months .So Although a total of 33 knees were done, only 31 knees were evaluated at 3 months. 9 cases underwent knee replacement in their contralateral knees (staged bilateral knee replacement). So a total of 22 patients were evaluated at 3 months post-operative. Patients were evaluated at 3 months for knee function using the American knee society score. The knee score in Nexgen , PFC sigma, Inor knee and All-poly models of Nexgen and PFC-sigma was comparable (93) but Natural knee II had lower knee score (87) at 3months,primarily due to point deductions in knee score from the fixed flexion deformity seen in patients, due to the use of ,ultra-congruent inserts of Natural knee II. Radiographic Assessment based on American Knee Society Radiographic criteria<sup>2</sup> yielded similar results in all models of TKR except Natural knee II, which had a lower score because of lower implant bone surface area

ratio. (percentage area of tibial surface covered by implant.)

Conclusion:- Total knee arthroplasty using different models of TKR had excellent results with restoration of knee function, excellent relief of pain, and excellent range of motion. The mean Knee Score increased from 38 preoperatively to 93 postoperatively and the mean functional score increased from 43 preoperatively to 96 postoperatively. Using American knee society score the results are comparable in all available models except Natural knee II, which had a lower knee score (87 instead of 93 in other knee models) due to (a) fixed flexion deformity because of use of ultra-congruent insert<sup>3</sup>,(b) and a lower radiographic score because of use of asymmetric tibial base plates<sup>4</sup> with larger medial side than lateral side, which leaves large areas of peripheral portions of lateral tibial plateau uncovered by implant and decreases the implant/bone surface area ratio.

Keywords: knee, replacement, arthroplasty, Natural knee II, Nexgen, PFC-Sigma, Inor knee, all-poly knee.

## Introduction

Total knee replacement is now an established procedure for advanced stage arthritis of knee. Different companies have introduced different models of total knee prosthesis and each company claims its design is better than others. Some companies like Zimmer have introduced more than one design (Nexgen and Natural knee II) with different design modifications<sup>3, 4</sup>. It is very difficult for a young surgeon to choose a model of knee, which best fits the needs of the patients, because of the presence of so many models of TKR and so many claims about the superiority of one model of TKR over another model. When it is so difficult for a surgeon, to choose the right model of knee, the patient is even more confused. The Total Condylar Prosthesis was designed by Insall and others, at the Hospital for Special Surgery in 1973. The Total Condylar Prosthesis had a small range of flexion. The early clinical reviews of the Total Condylar Prosthesis, documented an average flexion of only 90 to 100 degrees. This was because the Total Condylar Prosthesis did not allow 'femoral roll back'. By not 'rolling back' the posterior femoral metaphysis in a Total

Condylar Knee impinged against the tibial articular surface, at approximately 95 degrees of flexion .To correct these problems ;the Insall- Burstein Posterior Cruciate Substituting or Posterior Stabilized Design<sup>5</sup> was developed in 1978; by adding a central cam mechanism to the articular surface geometry of the Total Condylar Prosthesis. The cam on the femoral component engages a central post on the tibial articular surface at approximately 70 degrees of flexion and causes the contact point of the femoral tibial articulation to be posteriorly displaced, thus effecting ‘femoral roll back’ and allowing further flexion. Most current total knee designs ( which were used in this study) are derivatives of the Insall-Burstein and Kinematic designs. In most of the designs (Nexgen, Natural knee II, PFC-sigma) the trochlear groove has been deepened and its congruency with the patellar component was optimized to allow a broad surface of contact, which extended the range of motion and thereby reduced the compressive forces of the patellofemoral articulation<sup>13, 14</sup>. Of particular interest to this study were two design modifications in Natural knee II, which were not present in the other models of

TKR which were used in this study. The tibial base plate of Natural knee II is asymmetric, with the medial half being bigger than the lateral half<sup>4</sup>. In all other models of TKR used in this study both lateral and medial parts of the tibial base plate is equal in size. Secondly, in Natural knee II, to prevent bone loss from femoral notch cut, an ultra-congruent polyethylene insert<sup>3</sup> is used instead of the traditional congruent posterior stabilized insert.

## MATERIALS AND METHODS USED

The mean age of patients was 64.8 years. There were 14 male and 10 female patients. A total of 33 total knee replacements done by me between Dec.2006 to Feb 2011 using - 10 models of Natural knee II,-7 models of PFC sigma- 8 models of Nexgen, - 3 models of Inor knee,- 3 models of all poly<sup>6</sup> PFC-sigma , 1 model of all-poly Nexgen and 1 model of PFC-sigma RPF knees ;were evaluated for knee function using the American Knee Society Score and the Knee Society Radiographic Assessment at 3 months post-operatively All patients selected had osteoarthritis. None had rheumatoid arthritis. All patients had advanced degenerative changes

in their knees, with moderate to severe restriction of movements. All had varus deformity. There were no cases of valgus deformity. All models of TKR were cruciate substituting models (posterior stabilized). Cruciate retaining models were not used. The different models of TKR used in this study were PFC sigma, all-poly PFC sigma, Natural knee II, Nexgen, all-poly Nexgen, PFC sigma RPF and Inor Knee. 2 patients were lost to follow-up, due to infection (although their infection was controlled with the use of iv vancomycin; they did not want to continue taking vancomycin for a long duration, because of its high cost, so they consulted other doctors and were lost to follow up at 3 months). Though a total of 33 knees were done, only 31 knees were evaluated at 3 months. 9 cases underwent knee replacement in their contra-lateral knees (staged bilateral knee replacement). So a total of 22 patients were included in this study at 3 months follow-up.

All surgeries were performed with midline incision and medial parapatellar approach. Patella was everted laterally. All medial osteophytes were removed. Medial soft tissues including superficial medial collateral

ligament was appropriately released. Tibial cut was made with extra medullary jig, and femoral cuts were made with intra medullary jig. A trial reduction was done and the knee checked for soft tissue balance, stability and flexion/extension gaps. Tibial and femoral components were implanted using 2 separate packets of cement. Patella was not resurfaced in any case. Physiotherapy was started after 3 post operative days and partial weight bearing allowed after 4 days. Full weight bearing was started as tolerated by patients. At 3 months post-operative (which is the generally agreed recovery time for TKR) these patients were evaluated for knee function, using American knee society score<sup>1</sup>. The American knee society scoring system<sup>1</sup> comprises of a Knee Score and a Functional score. The maximum score for each is 100.

Knee Society Knee Score<sup>1</sup>

Patient category

- A. Unilateral or bilateral (opposite knee successfully replaced)
- B. Unilateral other knee symptomatic
- C. Multiple arthritis or Medical infirmity

Pain	Points
None	50
Mild or occasional	45
Stairs only	40
Walking and stairs	30
Moderate	
Occasional	20
Continual	10
Severe	0
Range of Motion	
(5° =1 point)	25
Stability (maximal movement in any position)	
Antero posterior	
< 5mm	10
5-10	5
10mm	0
Mediolateral	
<5°	15
6°-9°	10
10°-14°	5
15°	0
Subtotal	_____

Deductions (minus)		_____
Flexion Contracture		_____
5 <sup>0</sup> -10 <sup>0</sup>	2	
10 <sup>0</sup> -15 <sup>0</sup>	5	
16 <sup>0</sup> -20 <sup>0</sup>	10	
>20 <sup>0</sup>	15	
Extension lag		
<10 <sup>0</sup>	5	
10 <sup>0</sup> -20 <sup>0</sup>	10	
>20 <sup>0</sup>	15	
Alignment		
5 <sup>0</sup> -10 <sup>0</sup>	0	
0 <sup>0</sup> -4 <sup>0</sup>	3 points each degree	
11 <sup>0</sup> -15 <sup>0</sup>	3 points each degree other	
	20	
Total deductions		_____
<b>KNEE SCORE</b>		_____
(If total is minus number, score is 0)		

FUNCTIONAL SCORE	POINTS
Walking	50
Unlimited	40
> blocks	30
5-10 blocks	20
< 5 blocks	10
House bound	0
Unable	
Stairs.	
Normal up and down	50
Normal up down with rail	40
Up and down with rail	30
Up with rail, unable down	15
Unable	0
Subtotal	
Deductions (minus)	
Cane	5
Two canes	10
Crutches or walker	20
Total deductions	—
Functional Score	—

Scores of 80- 100 are rated as excellent, 70-79 as good, 60-69 as fair and less than 60 as poor.

Also in 1989 the Knee Society introduced the Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System<sup>2</sup> to standardize the roentgenographic parameters to be measured when reporting roentgenographic outcomes of TKR ; which includes component alignment, tibial surface coverage, radiolucencies and a patellar problems list, that includes angle of the prosthesis, eccentric component placement, subluxation and dislocation.

Out of the radiographic parameters<sup>2</sup>, tibial surface coverage by implant was of interest specially when comparing the asymmetric tibial base plates of Natural Knee II with symmetric tibial base plates of other knees.

### Outcome and Analysis

As already stated a total of 33 patients were operated, out of which 2 patients were lost to follow-up due to infection (although their infection was controlled with the use of IV vancomycin, they did not want to continue taking vancomycin for a long duration, because of it's

high cost, so they consulted other doctors and were lost to follow up at 3 months. So a total of 31 knees were evaluated at 3 months post-operative. All patients had osteoarthritis. No patient had rheumatoid arthritis. Patients were evaluated at an average of 3 months postoperative. The mean age was 64.8. There were 14 male and 10 female patients.

### Clinical Results

The mean knee score pre-operatively was 38 and the mean functional score was 43. At 3 months follow up the mean knee score for Natural knee II patients was 87 and mean functional score for Natural knee II patients was 96. For Nexgen, PFC Sigma, Inor and All-poly PFC Sigma and Nexgen the mean knee score at 3 months follow-up was 93 and the mean functional score was 96. All patients, including those with Natural knee II, had excellent result (score 80-100), according to American Knee Society Score.

### Pain

Preoperatively 21 patients had severe pain while walking, while 13 patients had severe pain even at rest.

Post-operatively 19 patients had No pain and 3 patients had mild or occasional pain.No patient had pain on climbing stairs or walking. No patient had moderate or severe pain. The mild or occasional pain seen in 3 patients was localised to anterior aspect of knee.Overall pain relief after TKR with all models was excellent and no difference was noted in pain relief between different models.

#### Range of Motion

Pre-operatively the mean flexion was 100 degrees .Post-operatively the mean flexion was 125 degrees.No difference was noted in the mean flexion between different models of TKR. Pre-operatively 13 knees had no fixed flexion deformity while 18 knees had a mean fixed flexion deformity of 14 degrees.At 3 months post-operative, knees which were fitted with models of TKR other than Natural knee II had no fixed flexion deformity, while knees which were fitted with Natural knee II, had a mean fixed flexion deformity of 11 degrees. There was no extension lag either pre or post-operatively.

### Ability to walk

Post-operatively the ability to walk increased dramatically in all patients. At 3 months follow-up all patients were able to walk unlimited. 9 patients had limited walking at 3 months post-operatively because of symptomatic other knee, but after replacement of their contralateral knee, they were also able to walk unlimited at 3 months follow-up.

Patients who were fitted with Natural knee II (ultra congruent insert) and had residual fixed flexion deformity at 3 months post-operative were also able to walk unlimited.

### Ability To Climb Stairs

All patients were able to climb up and descend down stairs without support at 3 months. Patients who were fitted with Natural knee II( ultra congruent insert) and had residual fixed flexion deformity at 3 months post operative, were also able to climb and descend stairs without support

Complications:-

Two patients had infection. Although, their infection was controlled with i.v. vancomycin, they did not want to take complete course of vancomycin (due to its high cost) and they consulted other doctors for stoppage of i.v. vancomycin. These patients were lost to follow up and were not available for assessment at 3 months post-operative.

#### Radiological Results:-

Patients who were fitted with ultra congruent insert of Natural knee II had lowest implant bone surface area ratio (percentage of tibial surface covered with implant) as compared to the patients who were fitted with other models of TKR. Because I did not have access to the software needed to calculate the exact percentage of implant/ bone surface area ratio, the exact figure in numerical terms is not quoted in this study, but post-operative x-rays show large parts of the peripheral lateral tibial plateau uncovered, in cases in which Natural knee II has been used, while post-operative x-rays of other models of TKR show adequate coverage of peripheral lateral tibial plateau. Also as these knee were evaluated

at 3 months post-operative, the knee society radiographic parameter of radiolucency at the bone implant interface was not evaluated with much interest, as, 3 months is a very short time frame to compare radiolucency between different models of TKR. Also the Knee Society Radiographic parameter of component alignment was not evaluated with much eagerness as component alignment depends on the surgeons ability and not on the different designs of different models of TKR

## DISCUSSION

Total Knee replacement is the treatment of choice for advanced degenerative changes of osteo-arthritis. Although TKR gives excellent relief of pain, residual pain after TKR is the most common patient complain. In my series, relief of pain after TKR was excellent with most patient complaining of NO pain after 3 months follow-up. Those who had mild occasional pain had anterior knee pain.

As all cases in my series were of osteo-arthritis, patella was not resurfaced in any case<sup>7, 8, 9, 10, 11, 12</sup>. Although Ranawat Soudry et al, Enis et al and others have

advocated universal patellar resurfacing with clinical series indicating that knee scores after patellar resurfacing are slightly better because of less residual peripatellar pain and improved quadriceps strength; other authors including Abraham et al and Keblish, Varma and Greenwald<sup>11</sup> have advocated selective resurfacing of the patella. The major argument in favour of selective resurfacing of the patella is that complications of resurfaced patellae account for most of the re-operations after TKR in many series. Also with selective resurfacing of the patella using a femoral component that incorporates an anatomically shaped femoral trochlea, these authors reported essentially equal Knee scores for resurfaced and unresurfaced groups. A prospective study by Keblish Varma and Greenwald<sup>11</sup> included patients with bilateral arthroplasties in which one knee had a resurfaced patella and the other had its original unresurfaced patella. The patients had no subjective preference between the two knees nor was there any difference in stair-climbing ability or the incidence of anterior knee pain. In a 10 year follow-up of resurfaced and non-resurfaced patella using the Freeman-Samuelson

prosthesis Kulkarni et al reported 97% or more survivorship of the patella in both groups. They stated that the geometry of the trochlea has more influence on the fate of the patellofemoral joint than the decision to resurface or not. The desirability of resurfacing continues to be debated and the results of selective patellar resurfacing appear to be design- dependent; favoring an anatomical femoral component trochlear design. According to Scott and Reily<sup>12</sup> indications for leaving the patella unresurfaced are a primary diagnosis of osteoarthritis, satisfactory patellar cartilage, patellar cartilage with no eburnated bone, congruent patellofemoral tracking, a normal anatomical patellar shape, and no evidence of crystalline or inflammatory arthropathy. Patient weight also appears to be a factor with lighter patients tending to do well with unresurfaced patellae.

Another purpose of this study was to compare the results of the ultra congruent posterior stabilizing tibial inserts<sup>3</sup>, with the traditional posterior stabilized design. The amount of knee flexion achieved with ultra congruent

posterior stabilized tibial inserts of Natural Knee II was the same (125-135 degrees) as with the traditional posterior stabilized inserts of PFC sigma and Nexgen<sup>13, 14</sup>. The major advantage of using ultra congruent posterior stabilized insert in Natural knee II is that the femoral box cut is smaller and bone is preserved in the intercondylar notch of femur. Also the numbers of steps of making notch cut are reduced with the use of ultra congruent posterior stabilized insert which decreases the operative time. This bone preservation in notch cut gives two further advantages. One, it decreases the risk of femoral fractures after notch cut; and secondly greater bone preservation in primary arthroplasty means greater bone availability in the inter-condylar notch at the time of revision surgery.

Out of the traditional posterior stabilized inserts; the biggest box cut is of PFC-sigma. (Nexgen has a smaller box cut than that of PFC sigma.) But in my series NO femoral fracture was seen after the femoral box cut of PFC sigma or Nexgen. None of the knees operated in this study has come back for revision surgery. So this study could not evaluate the effect of greater femoral bone loss

on knee scores after revision surgery with the use of traditional posterior stabilized inserts as opposed to the ultra-congruent inserts of Natural knee II.

But the biggest problem encountered with the use of the ultra-congruent insert is the creation of a fixed-flexion deformity post-operatively even in knees which did not have any fixed-flexion deformity preoperatively.

This fixed-flexion deformity<sup>15, 16, 17, 18</sup> created due to the use of the ultra-congruent insert of Natural Knee II is supposed to resolve over a period of 6 months as the POSTERIOR CAPSULE STRETCHES. These patients were put on physiotherapy (quadriceps static and dynamic exercises to resolve the fixed flexion deformity by stretching of the posterior capsule.

A very interesting finding seen after physiotherapy was started with these patients was that, in the same time span, increments in knee flexion is more with physiotherapy and decrease in fixed-flexion deformity is less with physiotherapy i.e improvement in knee flexion responds better to physiotherapy than resolution of fixed flexion deformity in the same time frame. From an average knee flexion of 90 degrees at the fifth post-

operative day, knee flexion increased to 125-135 degrees at 30 post-operative days; but in the same time frame, fixed flexion deformity did NOT even decrease by average of 5 degrees, with physiotherapy. This created a second problem that, most of the patients lost faith in my advice that, fixed flexion deformity would resolve with physiotherapy over a period of 6 months.

Patients who were fitted with ultra-congruent insert of Natural knee II were available for follow up at 3 months post operative. In 3 months the fixed flexion deformity had resolved by an average of 5 degrees. Patients were not available for follow up at 6 months, so this study could not determine whether all fixed flexion deformities resolved at 6 months or not.

The resolution of fixed flexion deformity<sup>15, 16, 17, 18</sup> with time is a matter of debate McPherson et al<sup>15</sup> evaluated 29 patients with flexion contracture less than 30 degrees and found that all resolved. Tanzer and Miller<sup>16</sup> evaluated patients with a mean flexion contracture of less than 15 degree postoperatively and found that these resolved as well. However in 41% of these cases they did a posterior capsular stripping at the time of primary surgery. In

contrast Firestone et al<sup>17</sup> found that any patient left with a significant residual flexion contracture at the end of the procedure (average 8.6 degree) deteriorated with time increasing to an average flexion contracture of 13.4 degree. Tew and Forster and Schurman et al<sup>18</sup> in separate reports found no improvement in flexion contractures beyond what could be corrected at the time of surgery.

The second area of concern on this study was the use of asymmetric tibial base plates<sup>4</sup> in Natural knee II, with medial side bigger in size than the lateral side. The justification for the use of this design modification being that the natural tibia is asymmetric, with larger medial side as compared to smaller lateral side. It is to be pointed that the tibial base plates in the other conventional models (PFC-sigma, Nexgen) are symmetrical with equal medial and lateral sides. All patients (male and female) in this study belonged to Punjabi ethnic population. Although in this study i did not have the means to evaluate conclusively, whether the proximal tibia is symmetric or asymmetric ,in ethnic Punjabi population, but the use of asymmetric tibial base plates of Natural Knee II with larger medial and smaller

lateral tibial base plates always resulted ,in a large peripheral portion of the lateral tibial plateau uncovered by the implant. The size of the tibial base plate which completely covered the lateral tibial plateau almost always led to a large implant overhang in the medial side. Therefore the tibial base plate size which did NOT create a soft-tissue over hang in the medial side were selected, and every time that left a large peripheral portion of the lateral tibial plateau uncovered. This anomaly decreased the Implant bone surface area ratio or the percentage of tibial surface covered by implant in the American Knee Society<sup>1</sup> Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System<sup>2</sup>.

On the other hand when the conventional tibial base plates with equal medial and lateral sides were used this problem was not encountered. Therefore it is to be concluded that in the ethnic Punjabi population; designs with asymmetric tibial base plates (Natural knee II) are not recommended for usage over designs with symmetric tibial base plates ( PFC- sigma, Nexgen). A shortcoming of this study is that other ethnic Indian population were not covered in this study. So the results of this study

cannot be extrapolated to other Indian ethnic groups without prior clinical trials and meticulous evaluation. Furthermore it is to be emphasized that despite these problems, patients who were fitted with Natural knee II; at 3months post-operative were able to walk unlimited (full 50 points) and climb and descend stairs normally (full 50 points) despite presence of residual fixed flexion deformity.

A review of literature shows that weight bearing, walking and stair climbing with fixed flexion deformity requires a greater effort from quadriceps. Therefore by putting more effort on their quadriceps, patients can mask the effects of fixed flexion deformity and the Functional Knee Score of the Knee Society remains same in different models of TKR , although the Knee Score decreases because of the point deductions because of the presence of fixed flexion deformity with the use of the ultra congruent insert of Natural Knee II. As the knees were evaluated at 3 months post-operative, this study could not evaluate what effect, these problems would have on the long term survival of the implant.

Also as these knees were evaluated at 3 months post-operative, the knee society radiographic parameter of radiolucency at the bone implant interface was not evaluated with much interest, as, 3 months is a very short time frame to compare radiolucencies between different models of TKR. Also the Knee Society Radiographic parameter<sup>2</sup> of component alignment was not evaluated with much eagerness as component alignment depends on the surgeons ability and not on the different designs of different models of TKR.

#### Conclusion and Recommendation:-

The first conclusion of this study is that total knee arthroplasty using different models of TKR gives excellent results with restoration of knee function, excellent relief of pain and excellent range of motion. The mean Knee Score increased from 38 preoperatively to 93 postoperatively and the mean functional score increased from 43 preoperatively to 96 postoperatively. Therefore the first recommendation of this study is that in patients with advanced osteoarthritis, total knee replacement should be the treatment of choice.

The second conclusion of this study is that using American Knee Society Score the results are comparable in all available models of TKR except Natural knee II which had a lower knee score due to (a) fixed flexion deformity because of use of ultra-congruent insert (b) and a lower radiographic score because of use of asymmetric tibial base plate with larger medial side than lateral side, which leaves the peripheral portion of the lateral tibial plateau uncovered by implant and decreases the Implant/bone surface area ratio.

Therefore the second recommendation of this study is that (except for Natural knee II) there is nothing much to choose between different models of TKR of different companies as far as the immediate post-operative results at 3 months are concerned. However it is to be emphasized that this study does not deal with the midterm or long term differences in results of different models of TKR.

The third recommendation of this study is that Natural knee II with its asymmetric tibial base plates and ultracongruent insert is not PREFERABLE for implantation on ethnic Punjabi population.

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