A PROSPECTIVE, SINGLE-CENTRE, NON RANDOMIZED CLINICAL STUDY COMPARING THE FUNCTIONAL DIFFERENCE BETWEEN A STANDARD POSTERIOR STABILIZED TOTAL KNEE ARTHROPLASTY AND A HIGH FLEXION POSTERIOR STABILIZED TOTAL KNEE ARTHROPLASTY IN TERMS OF RANGE OF MOVEMENT (ROM)

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Abstract:
AIM: Total knee arthroplasty has revolutionized the care of patients with end-stage arthritic conditions. Most patients and surgeon believe that limited flexion restricts function after a TKR. As a result, modifications in the design of TKRs have been proposed. Our study was conducted to compare ROM achieved after primary TKA in patients who had conventional TKA with high-flexion knee prosthesis.

Material and methods: A prospective longitudinal analytical study. We included 66 knees from 36 patients. Standard Nexgen LPS prosthesis was implanted in 36 knees of 20 patients (LPS group) and High-Flex prosthesis was implanted in the other 30 knees of 16 patients (High Flex group). Then we analyzed the early clinical outcomes (at 3 months) in two groups.

Results: At 3 months postoperatively, the average gain in flexion was 7.81 (112 -104.19) more in the High flex group as compared to the LPS group (p<=.001)

Conclusion: Based on all the research and experience with this prosthesis, it was concluded that high flexion designs were superior to standard posterior-stabilized total knee arthroplasty design in terms of gaining more flexion and fulfilling activities, such as squatting, kneeling, and sitting cross-legged meet the need of deeper degrees of flexion.

Keywords: High flex TKA prosthesis, Range of movement, Total knee arthroplasty
Introduction

- There is little doubt that total knee arthroplasty has revolutionized the care of patients with end-stage arthritic conditions of the knee by providing significant relief of pain, improving function, walking ability and restoring quality of life.1,2
- The fundamental goal of a total knee replacement (TKR) is to provide relief of pain and a good postoperative range of movement.3
- In the western world, 110° of flexion generally allows for normal function in most activities. However a number of daily activities for Asians are performed while squatting, kneeling or sitting cross-legged, which require a higher degree of flexion 4.
- Most patients and surgeon believe that limited flexion restricts function after a TKR.5

As a result, modifications in the design of TKRs have been proposed.6-7 The Nexgen Legacy posterior stabilised (LPS)-flex fixed TKR system (Zimmer, Warsaw, Indiana) was designed to achieve high flexion.8

In this study, we aimed to analyze the early clinical outcomes after total knee arthroplasty with NexGen Legacy Posterior Stabilized prosthesis (LPS; Zimmer) and the High Flex -specific Nexgen prosthesis in Indian patients.

The NexGen Legacy Posterior Stabilised Total Knee Arthroplasty (LPS; Zimmer, Warsaw, Indiana) is available in both a standard and high flexion design.
- The High Flexion design system9 was designed to allow increased flexion by incorporating an extension of the posterior femoral condyles, along with modification of the cam and tibial spine and the aricular spacer, and a 3° increase in the trochlear groove angle of the femoral component.
- By extending the posterior femoral condyles, contact of the articular surface in flexion is maintained, allowing posterior translation of the femur and flexion beyond 120° without tibio-femoral impingement.
- Increased offset in flexion is achieved by removing an extra 2 mm of bone from the posterior condyles of the femur in order to accommodate the thicker condyles of the femoral component. This extra resection of bone is the only difference in bone preparation between the high flex and the standard design.

Our study was conducted to compare ROM achieved after primary TKA in patients who had conventional TKA with high-flexion knee prosthesis (High Flex)(GROUP 1) and in patients who had standard knee prosthesis (Nexgen LPS) ( GROUP 2).

Material & Method

Study Area

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Study Population

- We included 66 knees from 36 patients.
- Standard Nexgen LPS prosthesis was implanted in 36 knees of 20 patients (LPS group) and High-Flex prosthesis was implanted in the other 30 knees of 16 patients (High Flex group)
- A detailed informed consent form was signed by each patient and all information were kept confidential

With reference to study by Nutton RW et al10, sample size of 25 knees per group was calculated based on a difference of 8 in patients ‘mean change in ROM score from pre-post operative between two groups with a standard deviation of 10, at two –sided alpha of 0.05 , and power of 80 %

Inclusion Criteria

- AGE:50-80 YEARS
- GENDER: Both male and female
- Patients with diagnosis degenerative arthritis
- No previous joint infection
- No inflammatory disease
- A varus deformity of less than 15°
- A valgus deformity less than 5°.
- BMI <35
- THIGH /CALF INDEX>90 °

Exclusion Criteria

- Recent or current knee sepsis
- A remote source of ongoing infection
- Extensor mechanism discontinuity or severe dysfunction
- Recurvatum deformity secondary to muscular weakness
- Atherosclerotic disease of the operative leg
- Unhealthy skin conditions within the operative field
- Venous stasis disease with recurrent cellulitis
Neuropathic arthropathy, A history of osteomyelitis in the proximity of the knee. BMI >35 THIGH /CALF INDEX<90º

Study design
A prospective longitudinal analytical study

Study Duration
One year
All the patients at the time of admission were explained about the cost, merits and demerits of both types of implants and the final decision regarding choice of implant (whether to use Standard Knee Prosthesis or High Flex Knee Prosthesis) was taken by the patient

Analysis of Data
*Statistical testing was conducted with the statistical package for the social science **system version SPSS 17.0.** Continuous variables are presented as mean ± SD, and categorical variables are presented as absolute numbers and percentage. The comparison of normally distributed continuous variables between the groups was performed using Student’s t test. Nominal categorical data between the groups were compared using Chi-squared test or Fisher’s exact test as appropriate. **P<0.05 was considered statistically significant.*

Methodology
- Range of motion and functional outcomes determined with use of standard scoring systems were assessed
- In addition, patients abilities to perform activities requiring deep knee flexion and patient satisfaction were evaluated with use of questionnaires
- Knee function according to the Knee Society objective and functional Scores (KSS) and KOO Score were recorded before and after the operation.
- Final result was taken at 3 months postoperatively

Result
1. Range of Movement:
- ROM measured with a clinical goniometer with patient in supine position.
- Preoperatively, the mean flexion arc was 103.17 ± 6.50 in the High Flex group (GROUP 1) and in the LPS group (GROUP 2) was 105.68 ± 9.80
- Postoperatively, no knee in either group had a measurable flexion contracture.
- The mean range of flexion preoperatively, at 2nd PostOperative Day( POD), two weeks and 1st month did not differ significantly between the two groups.
- At 3 months postoperatively, the average gain in flexion was 7.81 (112 -104.19) more in the High flex group as compared to the LPS group (p<<0.001 ).

Graph 1: Comparison Of Rom Between High Flex Knee And Lps Knee

Table 1: Comparison Of Rom Between High Flex Knee And Lps Knee

<table>
<thead>
<tr>
<th>ROM</th>
<th>Group :HIGH FLEX (n=30)</th>
<th>Group :LPS (n=36)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± Sd</td>
<td>Min - Max</td>
<td>Mean ± Sd</td>
</tr>
<tr>
<td>Preop</td>
<td>103.17 ± 6.50</td>
<td>90 - 110</td>
<td>105.68 ± 9.80</td>
</tr>
<tr>
<td>2nd POD</td>
<td>65.50 ± 10.70</td>
<td>40 - 80</td>
<td>62.97 ± 20.67</td>
</tr>
<tr>
<td>2nd Week</td>
<td>80.17 ± 16.11</td>
<td>40 - 95</td>
<td>75.27 ± 21.28</td>
</tr>
<tr>
<td>1st month</td>
<td>98.33 ± 8.24</td>
<td>80 - 110</td>
<td>94.59 ± 13.09</td>
</tr>
<tr>
<td>3rd month</td>
<td>112.00 ± 5.96</td>
<td>100 - 125</td>
<td>104.19 ± 8.29</td>
</tr>
</tbody>
</table>

2. Clinical Outcome Scores
(a) KSS (KNEE SOCIETY OBJECTIVE AND FUNCTIONAL SCORES):
The Knee Society objective and functional Scores (KSS) did not differ significantly between the two groups either preoperatively or at the time of final follow up.
In the NexGen LPS group, the mean postoperative knee score was 74.95 ± 3.64 (range 70 to 81 points). In the High Flex group, the mean postoperative knee score was 75.81 ±
4.82 points (range 68 to 85 points) according to the system of the Knee Society objective and functional score.

**Graph 2:**
Comparison Of Knee Score Between High Flex And Standard Lps Knee

<table>
<thead>
<tr>
<th>Group 1: HIGH FLEX (n=16)</th>
<th>Group 2: LPS KNEE (n=20)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± Sd</td>
<td>Min - Max</td>
<td>Mean ± Sd</td>
</tr>
<tr>
<td>Knee Score (INSALL Preop)</td>
<td>20.75 ± 3.72</td>
<td>14 - 27</td>
</tr>
<tr>
<td>Knee Score (INSALL) (3 months POD)</td>
<td>75.81 ± 4.82</td>
<td>68 - 85</td>
</tr>
</tbody>
</table>

(b) KOO SCORE (The Knee injury and Osteoarthritis Outcome Score):
It consists of five components. A higher score indicates fewer problems:

(i) Pain:

**Graph 3:**
Comparison Of Pain Score

<table>
<thead>
<tr>
<th>Pain</th>
<th>Group 1 (n=16)</th>
<th>Group 2 (n=20)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± Sd</td>
<td>Min - Max</td>
<td>Mean ± Sd</td>
<td>Min - Max</td>
</tr>
<tr>
<td>3 months</td>
<td>71.70 ± 3.80</td>
<td>67 - 78</td>
<td>71.80 ± 4.22</td>
</tr>
</tbody>
</table>
(ii) SYMPTOMS

Graph 4:
Comparison Of Symptom Score

Table 4:
Comparison Of Symptom Score

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Group 1 (n=16)</th>
<th>Group 2 (n=20)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± Sd</td>
<td>Min - Max</td>
<td>Mean ± Sd</td>
</tr>
<tr>
<td>Preop</td>
<td>30.78 ± 7.92</td>
<td>17.80 - 42.80</td>
<td>29.10 ± 6.97</td>
</tr>
<tr>
<td>3 months</td>
<td>81.46 ± 2.66</td>
<td>78.60 - 85.70</td>
<td>81.24 ± 2.26</td>
</tr>
</tbody>
</table>

(iii) ADL:

Graph 5:
Comparison Of Adl

Table 5:
Comparison Of Adl Score

<table>
<thead>
<tr>
<th>ADL</th>
<th>Group 1 (n=16)</th>
<th>Group 2 (n=20)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± Sd</td>
<td>Min - Max</td>
<td>Mean ± Sd</td>
</tr>
<tr>
<td>Preop</td>
<td>18.37 ± 3.68</td>
<td>13.20 - 23.50</td>
<td>18.45 ± 3.51</td>
</tr>
<tr>
<td>3 months</td>
<td>79.47 ± 2.32</td>
<td>76.40 - 82.30</td>
<td>79.30 ± 2.32</td>
</tr>
</tbody>
</table>
(iv) Sport Score

![Graph 6: Comparison Of Sport Score](image)

**Table 6: Comparison Of Sport Score**

<table>
<thead>
<tr>
<th>Sports</th>
<th>Group 1 (n=16)</th>
<th>Group 2 (n=20)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± Sd</td>
<td>Min - Max</td>
<td>Mean ± Sd</td>
</tr>
<tr>
<td>Preop</td>
<td>15.00 ± 4.47</td>
<td>5 - 20</td>
<td>15.75 ± 4.38</td>
</tr>
<tr>
<td>3 months</td>
<td>67.50 ± 5.16</td>
<td>60 - 75</td>
<td>67.50 ± 5.50</td>
</tr>
</tbody>
</table>

(v) QOL:

![Graph 7: Comparison Of QOL SC](image)

**Table 7: Comparison Of Qol**

<table>
<thead>
<tr>
<th>QOL</th>
<th>Group 1 (n=16)</th>
<th>Group 2 (n=20)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± Sd</td>
<td>Min - Max</td>
<td>Mean ± Sd</td>
</tr>
<tr>
<td>Preop</td>
<td>18.73 ± 7.20</td>
<td>12.50 - 31.20</td>
<td>19.35 ± 6.98</td>
</tr>
<tr>
<td>3 months</td>
<td>74.96 ± 5.59</td>
<td>68.70 - 81.20</td>
<td>74.97 ± 5.37</td>
</tr>
</tbody>
</table>

The KOO SCORE (The Knee injury and Osteoarthritis Outcome Score) did not differ significantly between the two groups either preoperatively or at the time of final follow up.
Group 1:
High Flex Knee Prosthesis

(A) Preoperative Xrays

Lateral View

Group 2:
Lps Standard Knee Prosthesis

(A) Preoperative Xrays

(Latera View

(B) Postoperative Xrays

AP View

Discussion

In this study we compared the functional outcome between conventional and high-flexion TKA by measuring ROM using goniometer and assessing knee society score and KOO score.

1. Range of motion

ROM has been an important measure of outcome and is an important part of most knee scoring systems. The factors that one has some control over include surgical technique and implant prosthesis. Those that cannot be controlled include the patient’s condition at the time of surgery, such as age, weight, gender, height, history of previous surgery, multiple joint arthritis, preoperative knee score including preoperative motion, and complications. Previous studies have examined the factors that influence postoperative ROM in the clinical setting.

The LPS-Flex prosthesis has been the subject of several trials.

- Huang et al. found that the mean flexion in patients with high flexion prosthesis was approximately 10 degree greater than in those with a standard posterior stablized implant.
- We and Laskin have also previously indicated similar findings.
- Also Weeden and Schmidt et
al and Bin and Nam et al surveyed 50 and 180 TKAs and reported flexion gains of 12 and 6 respectively.

- Gupta et al reported a significant improvement using a high flexion rotating platform design when compared with a standard design of rotating platform TKR.
- In a study by Kim YH, Choi Y, Kim JS, the mean preoperative ROM in the supine position were 120° and 123° in the standard and high flex implant groups, respectively. The mean postoperative range of knee motion in supine position was 125° and 126° respectively.
- In contrast, compelling evidence is provided by Kim et al who performed prospective randomised controlled trials comparing conventional knee designs to the high-flexion demonstrated no difference between the two groups.
- Other studies from Asian centres have failed to show an improvement in knee flexion using a high flexion design.
- Also Suggs and Kwon et al and Seon and Song et al found no significant difference in clinical outcome between high flexion and traditional implants.
- Nutton et al, in a randomised controlled trial, reported no significant difference in outcome, including the maximum knee flexion, between patients receiving the standard and the high flexion design of the Nexgen LPS total knee prosthesis.

Table given below gives an overview about recently published studies evaluating traditional TKR and High Flex TKR with main focus on flexion ability.

<table>
<thead>
<tr>
<th>S.NO</th>
<th>Author</th>
<th>Study design</th>
<th>Journal</th>
<th>No. of patients</th>
<th>TKA</th>
<th>Average follow up</th>
<th>Average Flexion angle</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Huang HT, Su JY et al</td>
<td>Matched pair control</td>
<td>J Orthoproplosis 2005</td>
<td>25</td>
<td>High Flex vs Traditional PS</td>
<td>7.4 yrs</td>
<td>110° vs 135°</td>
</tr>
<tr>
<td>2</td>
<td>Ledin GS</td>
<td>Cohort study</td>
<td>Orthopade 2007</td>
<td>10</td>
<td>Traditional PS vs High Flex PS</td>
<td>2 yrs</td>
<td>118° vs 133°</td>
</tr>
<tr>
<td>3</td>
<td>Kim YH, Choi Y et al</td>
<td>RCT</td>
<td>JBJS 2010</td>
<td>118</td>
<td>High Flex CR vs Goutier Flex</td>
<td>3.2 yrs</td>
<td>126° vs 124°</td>
</tr>
<tr>
<td>4</td>
<td>Kim YH, Choi Y et al</td>
<td>RCT</td>
<td>JBJS Ann 2009</td>
<td>50</td>
<td>High Flex CR vs Goutier Flex</td>
<td>2.3 yrs</td>
<td>113° vs 113°</td>
</tr>
<tr>
<td>5</td>
<td>Kim YH, Choi Y et al</td>
<td>RCT</td>
<td>JBJS Ann 2005</td>
<td>50</td>
<td>High Flex CR vs Goutier Flex</td>
<td>2.1 yrs</td>
<td>130° vs 124°</td>
</tr>
<tr>
<td>6</td>
<td>Seon JK, Song EK et al</td>
<td>RCT</td>
<td>Orthopedics 2005</td>
<td>100</td>
<td>High Flex CR vs Goutier Flex</td>
<td>2 yrs</td>
<td>130° vs 128°</td>
</tr>
<tr>
<td>7</td>
<td>Ahlqvist P, Bannister et al</td>
<td>Follow up</td>
<td>JBJS J 1999</td>
<td>60</td>
<td>High Flex CR vs LPS</td>
<td>3 yrs</td>
<td>108° vs 108°</td>
</tr>
<tr>
<td>8</td>
<td>Gill OJ, Judd AB</td>
<td>Follow up</td>
<td>JBJS J 1999</td>
<td>233</td>
<td>High Flex CR</td>
<td>16 yrs</td>
<td>a.a.</td>
</tr>
<tr>
<td>9</td>
<td>Vierne KO, Bilte et al</td>
<td>Follow up</td>
<td>JBJS I 1989</td>
<td>59</td>
<td>High Flex CR</td>
<td>10-12 yrs</td>
<td>101°</td>
</tr>
<tr>
<td>10</td>
<td>Nutton RW, van der Linden M et al</td>
<td>RCT</td>
<td>JBJS I 2006</td>
<td>56</td>
<td>High Flex CR vs LPS</td>
<td>3 yrs</td>
<td>123° vs 127°</td>
</tr>
<tr>
<td>11</td>
<td>Seon JK, Park SY et al</td>
<td>Propective</td>
<td>JBJS I 2009</td>
<td>100</td>
<td>High Flex CR vs LPS</td>
<td>3 yrs</td>
<td>134° vs 135°</td>
</tr>
<tr>
<td>12</td>
<td>Bian S, Malhotta et al</td>
<td>RCT</td>
<td>JBJS 2005</td>
<td>65</td>
<td>High Flex CR vs LPS</td>
<td>6 yrs</td>
<td>106°</td>
</tr>
<tr>
<td>13</td>
<td>Chandrak R, Bapagare LA et al</td>
<td>RCT</td>
<td>JBJS I 2008</td>
<td>106</td>
<td>High Flex CR vs LPS</td>
<td>3 yrs</td>
<td>105° vs 105°</td>
</tr>
</tbody>
</table>

In our study, ROM was measured prior to surgery and at review using a manual goniometer with the arms aligned along the long axis of the femur and tibia on the lateral side of the knee joint.

- Preoperatively, the mean flexion arc in the LPS group was 105.68 ± 9.80 and 103.17 ± 6.50 in the High Flex group.
- Postoperatively, no knee in either group had a measurable flexion contracture.
- The mean range of flexion preoperatively, at 2nd POD, two weeks and 1st month did not differ significantly between the two groups.
- At 3 months postoperatively, the average gain in flexion was 7.81 more in the High flex group as compared to the LPS group (p<<0.001) (TABLE 1)
- The explanation for this significant p-value inspite of a small difference of only 7.81 between the two groups is that p-value is determined by a combination of factors, mainly sample size and standard deviation in particular. P-value is directly proportional to standard deviation and inversely proportional to sample size. However, both these factors jointly determine the p-value rather doing it independently.
- In our study, the sample size was large (66 knees) and the standard deviation was small. This explains the statistically significant difference in range of motion calculated by the independent t-test.
- It was further noted that patients who underwent High Flex-specific total knee arthroplasty had a significantly higher average gain in ROM as compared to corresponding LPS group (p<0.05).

Clinical Outcome Scores

Knee Society Score

- S. Endres and A. Wilke, presented the results of study of 75 Nexgen High flex TKA in a 100% mid term follow up of 5 years In their study,
the mean preoperative KSS was 99 and 5 years postoperatively was 167.

- In a study by Kim T-H, Lee D-H, Bin S-I8 preoperatively the mean knee score was 30.9 points and the mean function score was 44.9 points. Both scores improved after operation.

- Kim YH, Choi Y, Kim JS 26 performed b/l TKA in 85 patients(170 knees) ,the patients received standard LPS-Flex prosthesis in one knee and a LPS –Flex prosthesis in the contralateral knee. At the time of the latest follow-up(after 2.3 years),the knee society knee function , and pain score, were similar in both the standard and gender-specific group

- In our study, as per TABLE 2, The Knee Society objective and functional Scores (KSS) did not differ significantly between the two groups either preoperatively or at the time of final follow up.

- In the NexGen LPS group, the mean postoperative knee score was 74.95 ± 3.64 (range 70 to 81 points).

- In the High Flex group, the mean postoperative knee score was 75.81 ± 4.82 points (range 68 to 85 points) according to the system of the Knee Society objective and functional score

- The KSS did not differ significantly between the two groups either preoperatively or at the time of final follow up(p>0.05).

**KOO Score**

The mean KOO score in terms of Pain, Symptoms, ADL, Sports and QOL also improved in both the Nexgen LPS group and the High Flex group.(TABLE 3-7)

The KOO score did not differ significantly between the two groups either preoperatively or at the time of final follow up(p>0.05).

**Conclusion**

Great progress have been made in the past decades in refinement of knee replacement arthroplasty.

High-flexion knee prosthesis was introduced with the aim of obtaining higher degree of flexion and good survivorship in patients with high functional demands or those requiring squatting, kneeling, etc., which is more common in Indians.

Based on all the research and experience with this prostheses, it was concluded that high flexion designs meet the need of deeper degrees of flexion.Results were equal and comparable to the traditional standard posterior-stabilized total knee arthroplasty design and superior to it in terms of gaining more flexion and fulfilling activities, such as squatting, kneeling, and sitting cross-legged

**References**

1983.