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# Clinical Outcomes in High Flexion Total Knee Arthroplasty Were Not Superior to Standard Posterior Stabilized Total Knee Arthroplasty. A Multicenter, Prospective, Randomized Study

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ABSTRACT

High flexion prostheses have been introduced to achieve high flexion and improve clinical outcomes. Controversy exists in the literature regarding outcomes of high flexion vs. standard implants. This multicenter study compares outcomes in patients receiving a high flexion prosthesis vs. standard prosthesis. 278 high flexion and standard knee prostheses were used. Patients were followed for two years and evaluated prospectively. The mean HSS was 87.3 for the standard group and 88.9 for the flexion group. At two-year follow up the standard prosthesis group had mean flexion of 121° and the high flexion group had mean flexion 120°. No knee had aseptic loosening, infection, or osteolysis. At two-year follow up, there were no significant differences in range of motion, clinical outcome, or radiographic evaluation. Pre-operative motion and functional status have greater impact on clinical outcome than implant alone.

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Range of motion in total knee arthroplasty is a key determining factor in a patient's overall functional outcome [1]. The fact that most knees do not flex more than 120° after surgery has been studied extensively, but no one theory sufficiently explains this phenomenon [2–5]. To improve deep flexion after total knee arthroplasty high flexion designs have been developed in the last decade.

The NexGen LPS Flex total knee system (Zimmer, Warsaw IN) was designed to achieve high knee flexion, increase surface area articulation, and improve patient outcomes. Compared to the standard, the NexGen LPS Flex has 3 principle design modifications: extension of the posterior femoral condyles and posterior condylar radii to increase contact area, an increased cam height, and cut out in the polyethylene insert to prevent patellar tendon impingement.

Theoretically these design modifications may lead to better postoperative range of motion, increase longevity, and provide improved clinical outcomes. However, there are conflicting reports in the literature on the early results of high flexion prosthesis. A previous meta-analysis including six studies did show a significant difference in favor of the high flexion design but, only two of those studies were randomized controlled trials [6]. In another systematic review no difference was found between the prostheses but, data synthesis and quantitative analysis were not performed [7]. Several authors have also reported on early increased loosening at high flexion angles in the high-flexion prosthesis [8,9]. Because of this conflicting data regarding motion, loosening, and outcomes from individual centers, we performed a pooled data multicenter prospective randomized trial to assess differences in pain, functioning, aseptic loosening, and range of motion in the NexGen LPS and NexGen LPS-Flex total knee systems.

## Materials and Methods

### *Demographics*

Between 2002 and 2007, 278 total knee arthroplasties were performed at nine clinical centers associated with a university. The study was approved by the institutional review board and informed consent was obtained. Randomization of the total knee prosthesis, NexGen LPS standard or LPS-High Flexion (Zimmer, Warsaw IN), was determined on a sequential pool on the basis of a table of random numbers. The patient demographics are summarized in Table 1. The mean age of the patients at the time of operation was 65 years (range 43–80). 140 patients were men and 138 were women. 124 patients had previous knee surgery (25 open meniscectomies, 68 arthroscopic meniscectomies, 24 arthroscopies, 2 arthroscopic loose body removal, 2 prepatella bursa removals, 1 popliteal cyst excision, 1 MCL reconstruction, 1 PCL reconstruction) The preoperative diagnosis for 267 patients was osteoarthritis, 3 had post-traumatic arthritis, 2 inflammatory arthritis, 1 avascular necrosis, and 5 had rheumatoid arthritis. The mean patient height and standard deviation were 66.8 ± 4 inches and the mean weight

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**Table 1**
Comparisons Between LPS and LPS-Flex.

| Characteristic | | Overall (n = 278) | LPS-FLEX (n = 138) | STD (n = 140) | *P* Value |
|---|---|---|---|---|---|
| Gender | Female | 138/278 (49.6%) | 71/138 (51.4%) | 67/140 (47.9%) | 0.631 |
| | Male | 140/278 (50.4%) | 67/138 (48.6%) | 73/140 (52.1%) | |
| Patient Age | | 64.4 ± 8.3 (278) | 64.8 ± 8.5 (138) | 64.0 ± 8.1 (140) | 0.348 |
| Weight | | | 190.2 ± 32.9 (138) | 192.3 ± 41.2 (140) | 0.801 |
| Patient Height (Inch) | | 66.8 ± 4.0 (278) | 66.3 ± 4.1 (138) | 67.3 ± 3.8 (140) | 0.052* |
| Preoperative Diagnosis | OSTEOARTHRITIS | 265/277 (95.7%) | 131/137 (95.6%) | 134/140 (95.7%) | 0.633 |
| | RHEUMATOID ARTHRITIS | 5/277 (1.8%) | 3/137 (2.2%) | 2/140 (1.4%) | |
| | POST-TRAUMATIC ARTHRITIS | 3/277 (1.1%) | 2/137 (1.5%) | 1/140 (0.7%) | |
| | INFLAMMATORY ARTHRITIS | 2/277 (0.7%) | 0/137 (0.0%) | 2/140 (1.4%) | |
| | AVASCULAR NECROSIS | 1/277 (0.4%) | 0/137 (0.0%) | 1/140 (0.7%) | |
| | OTHER | 1/277 (0.4%) | 1/137 (0.7%) | 0/140 (0.0%) | |

and standard deviation were 190.2 ± 32.9 lb for the flex group and 192.3 ± 41.2 for the standard group.

### *Surgical Technique*

The operative procedures were performed at nine separate centers with some surgical technique differences with regard to implantation of the total knee arthroplasties however; they did share the following general characteristics. All procedures were performed via a midline skin incision approximately ten centimeters with a medial para-patellar arthrotomy. The cruciate ligaments were sacrificed in all patients. The magnitude and angles of the bony resections were standardized across treatment groups. The distal femoral resection was made with an intramedullary guide to resect 10 mm of bone from the most prominent femoral condyle at an angle of 5° of valgus. The tibial resection was made using an extramedullary guide with the goal of producing a neutral cut in the coronal plane and 7° of posterior slope in the sagittal plane. The anterior, posterior, and Chamfer cuts were made with a posterior femoral condylar referencing guide in 3° of external rotation. In the NexGen LPS-Flex group, 2 additional mm of posterior femoral condylar bone was resected compared to the NexGen LPS group. Posterior condylar osteophytes were resected in all patients. Ligament balancing was aided with the use of spacer blocks with the goal of creating symmetrical gaps of equal magnitude in flexion and extension. Superficial MCL release was required in 7 patients including four in the high flexion group and three in standard group. The amount of bone removed during patellar resection was equal to or slightly greater than the thickness of the patellar component. All implants were cemented. The capsule was closed in 30° of flexion in all patients.

### *Rehabilitation*

Starting on the second post-operative day, the patients used a continuous passive motion machine applied for at least 6 h per day. Also on post-operative day two, active and passive range of motion was initiated, as well as ambulation with crutches or a walker once a day with physical therapy supervision. The patients used crutches or a walker with full weight bearing for six weeks and used a cane as needed subsequently.

### *Clinical Evaluation*

Clinical and radiographic evaluations were made pre-operatively, 6 weeks post-operatively, 6 months, one year, and two years. Each knee was rated pre-operatively and post-operatively by the systems of the Knee Society and the Hospital for Special Surgery. Patients also completed the Short Form 36 (SF-36) questionnaire.

Active range of motion was determined preoperatively and post-operatively with a 12-in goniometer at 6 weeks, 6 months, 1 year, and two years. Clinicians were blinded with regard to which total knee prosthesis was implanted.

Radiographic evaluations were made pre-operatively and post-operatively by obtaining AP, Lateral, and skyline views. Evaluations were made at 6 weeks, 6 months, 1 year, and 2 years. Assessments were made based on limb alignment and component position. Radiolucencies and bone loss were also noted on AP, Lateral, and sunrise views. Skyline views were also examined for patellar tilt, subluxation, and dislocation.

## Results

### *Clinical Outcomes*

#### *Knee Score*

The pre-operative and post-operative knee scores are summarized in Table 2. The Hospital for Special Surgery (HSS) and Knee Society Scores (KSS) did not differ significantly between the two groups pre-operatively ($P = 0.790$ and $P = 0.490$, respectively) or post-operatively ($P = 0.9177$ and $P = 0.2313$, respectively). The mean pre-operative HSS score for the standard knee prosthesis group was 62.3 (mean ± SD 10.3) and 62.8 (mean ± SD 10.5) in the high-flexion group. In the NexGen LPS group, the mean postoperative HSS score was 87.3 (mean ± SD 12.7) and 87.7 (mean ± SD 12.7) for the Knee Society Score. In the NexGen LPS Flex Group, the mean postoperative HSS score was 88.9 (mean ± SD 7.6) and 89.8. (mean ± SD 9.9) for the Knee Society Score.

#### *Range of Motion*

The mean pre-operative and post-operative range of motion is summarized in Table 2. Preoperatively, the mean flexion contracture was 4.5° (mean ± SD 4.6°) for the NexGen LPS Group and 4.7° (mean ± SD 5.2°) in the NexGen LPS-Flex Group. At two years the mean flexion contracture in the NexGen LPS-Flex group was 0.3° (mean ± SD 2.9°), and 0.4° (mean ± SD 2.3°) in the NexGen LPS Group. The flexion preoperatively in the NexGen LPS Group was 114.7° (mean ± SD 11.0°) and 113° (mean ± SD 11.2°) in the NexGen LPS Flex Group. At two-year follow up, the mean post-operative flexion in the standard group was 121.0° (mean ± SD 9.7) and 120.9° (mean ± SD 10.4°) in the high flexion group. There was no significant difference between the two groups with regard to flexion contracture preoperatively ($P = 1.000$) or at the two-year follow up ($P = 0.713$). There was also no significant difference with regard to flexion between the two groups preoperatively ($P = 0.248$) and at two-year follow up ($P = 0.797$).

### *Quality of Life Outcomes*

The NexGen LPS Group had SF-36 Physical Scores of 32.5 (mean ± SD 8.3) preoperatively and 48.1 (mean ± SD 8.8) at the two-year follow up. The NexGen LPS Flex Group had SF-36 Physical Scores of 33.8 (mean ± SD 9.3) preoperatively and 49.7 (mean ± SD 8.1) at

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