

# High Flexion Total Knee Arthroplasty – Mid-Term Follow Up of 5 Years

S. Endres\* and A. Wilke

Orthopädie und Unfallchirurgie Elisabeth-Klinik Bigge/Olsberg, Heinrich-Sommer-Str. 4, D-59939, Olsberg, Germany

**Abstract:** Because of demographic changes, ever greater demands are made of knee replacement systems by patients and surgeons. To meet these demands, knee joint systems with increased flexion are currently being marketed. The main hypothesis of the present study was to evaluate the functional outcome of a high flexion TKA in amid-term follow up. 75 consecutive patients (29 men and 46 women) who had primary arthritis of the knee with similar deformity and range of motion undergo TKA using a NexGen Cr Flex mobile.

Knee Society knee and functional scores and range of motion were assessed.

The follow-up duration was 5 years. There was a highly significant improvement in comparison to the preoperative status ( $p < 0.005$ ). The maximum flexion was  $122^\circ$  in mean and the mean KSS was 167 (SD: 21) at final follow up. Despite positive results in the first 5 postoperative years, the NexGen Cr Flex mobile TKA shows no advantages with regard to ROM and KSS compared to the recent literature. Long-term studies are needed to determine a superiority of high flexion knee implants versus traditional TKA's.

**Keywords:** NexGen Cr Flex mobile, mid-term Follow Up, high flexion.

## BACKGROUND

Increasing efforts have been made over the past years to improve the flexion properties of TKA's by refining their design. The basic principle in doing so has been to reduce the back side radius of the condyle of the femoral component, which, in combination with partial posterior coupling, has achieved a maximum flexion angle of over  $120^\circ$  [1]. Although this means that resection of more bone from the posterior femoral condyle is unavoidable, this permits a range of motion extending to deep kneeling and squatting.

Due to demographic changes increasingly young patients require TKA, and this means that the expectations of surgery (e.g. flexion over  $120^\circ$ ) are also increasing. It is no longer enough to ensure freedom from pain and to allow everyday activities. In most cases patients expect a free range of motion which is often promised by the advertisement of high flex TKA's [2].

A knee flexion of  $90^\circ$  to  $100^\circ$  is enough to allow most activities of daily living for elderly people in western countries. Climbing up and down the stairs and sitting on a chair requires  $90$  to  $120^\circ$ . This range of motion can be achieved with traditional TKA designs whose maximal flexion angle has been reported to range between  $100$  and  $110^\circ$  [3]. Apart from being influenced by the condition of the patient and surgical technique, the final outcome of a TKA, depends also on the implant design. Therefore, implant manufacturers have attempted to design TKAs that better accommodate knee mechanics in high flexion up to  $155^\circ$

[4, 5] to allow patients activities such as squatting and sitting cross-legged which require knee flexion of  $110$  to  $130^\circ$  [3].

Recently there have been published similar studies evaluating high flexion knee implants. Kim *et al.* compared the results of a standard high flexion total knee replacement versus a gender specific high flexion implant type [6]. They found no significant differences between the two groups with regard to the clinical and radiological results, patient satisfaction or complication rate. Another study by Kim *et al.* showed after a minimum duration of follow-up of two years, that there was no difference in range of motion or clinical and radiographic results between knees that had received high-flexion posterior cruciate-retaining total knee prosthesis and those that had received a high-flexion posterior cruciate-substituting total knee prosthesis [7].

We want to present the results of 75 NexGen® CR-Flex Mobile TKA's performed by a single surgeon (prosthetic system with high flexion capacity, Zimmer) in a 100% mid-term follow up of 5 years and try to compare the functional outcome with the recent literature on TKA's, especially on traditional TKA's

## METHODS

### Study Design

Between January 2005 and January 2006 75 NexGen® Cr-Flex Mobile (Zimmer) TKA's were performed by the author due to primary osteoarthritis. None of the patients received a bilateral TKA (Table 1).

The study protocol of this retrospective study, including the consent forms, was approved by the institutional review board of the University hospital of Marburg, Germany. A detailed informed consent form was signed by each patient, and all information was kept confidential.

\*Address correspondence to this author at the Orthopädie und Unfallchirurgie Elisabeth-Klinik Bigge/Olsberg, Heinrich-Sommer-Str. 4, D-59939 Olsberg, Germany; Tel: 0049 2962 803 421; Fax: 0049 2962 803 199; E-mail: s.endres@elisabeth-klinik.de

**Table 1. Patient Characteristics Preoperative (All Patients Received a Total Knee Arthroplasty Only on One Side)**

	(Mean Values)
KSS	99 (SD: 12)
Maximum Flexion	82° (SD: 6.5°)
Flexion contracture	8.9° (SD: 9.1°)
BMI	26.6 (SD: 2.8)
Age	65.4 (SD: 8.1)
Gender	m/w = 29/46
Varus/Valgus	54/21
Lost to follow Up	None

Patients received preoperative single shot antibiotic prophylaxis with Cefuroxim 1.5g (if renal function allowed). A tourniquet was used after exsanguination using an Esmarch bandage. All patients received thromboprophylaxis with Mono-Embolex 0.3 once daily.

All TKA procedures were performed by the author (single surgeon) using the anterior Payr-approach with medial arthrotomy. Soft tissues were released in a stepwise manner to achieve ligamentous balance in extension.

Thus, flexion and extension gaps were approximately equal. Sufficient laxity was achieved to enable full extension and flexion and anterior translation, but not too loose to cause abnormal AP motion with resulting impingement or bearing spin out. Tensioning devices were not routinely used. The proximal tibia was resected with the anterior cruciate ligament sacrificed. The PCL was preserved with a bone block.

Both the femoral and the tibial component were completely cemented (Palacos®). Primary patellar resurfacing was not performed in any of the patients.

### Hospital Care and Rehabilitation

All patients were inpatients and were observed postoperatively for one day on an intermediate care ward. Physiotherapy was started on the day after surgery with walking exercises on two forearm crutches with maximum weight-bearing and exercise on CPM (continuous passive motion). Lymph drainage was added on the second postoperative day.

### Investigation Parameters

The follow up was done by the author. ROM, KSS [8] and radiological findings (knee in 3 planes) were evaluated before and 5 years after surgery. Performance of the replaced knee and overall function were assessed using the Knee Society knee and functional scores (maximum score 200, 100 each). The scoring system combines a relatively objective Knee Score that is based on the clinical parameters and a functional Score based on how the patient perceives that the knee functions with specific activities. The

maximum Knee Score is 100 points and the maximum functional Score is 100 points (Overall 200 points).

The range of motion especially the maximum passive flexion were assessed using a goniometer with the arms aligned along the long axes of the femur and tibia on the lateral side of the knee joint.

ROM was assessed as primary outcome whereas KSS as secondary outcome. Radiographic assessment was done to identify possible complications like radiolucent lines at the bone cement interface, patella tracking, limb alignment and positioning of the implants. It wasn't done as a third outcome measurement.

Radiographic assessment consists of a standing scanogram of the leg and lateral radiography to assess tibiofemoral alignment and component positioning. The Merchant's view was used to assess patellar tracking. The axial patellofemoral position was defined as central (<5° tilted) or as having medial tilt (>5° tilted, with the medial side depressed) or lateral tilt (>5° tilted, with the lateral side depressed) as described by Bindelglass and Vince [9].

### Statistical Methods

Data were collated and interpreted by the author to minimise intra-observer error. Differences were compared using t-test. A p value of <0.05 was considered significant. The scores and ROM's followed a normal distribution.

### RESULTS

The follow-up period was 5 years. 75 (100%) knees were followed up clinically and radiological.

### Scores and Range of Motion (Table 2)

The Range of Motion improved continuously, so a mean flexion of 122° (SD: 10.6°) and a flexion contracture of 3.9° (SD: 6.6°) was achieved after five years. The mean preoperative KSS was 99 (SD: 12; max. 200). 5 years postoperative an improvement was evident. The mean KSS at that time was 167 (SD: 21; max. 200).

Over the period of 5 there was a highly significant improvement in comparison to the preoperative status (p<0.005 for KSS and ROM).

**Table 2. Comparison ROM and Knee Society Knee and Function Score Preoperative and at Final Follow Up**

	NexGen Cr Flex Mobile
<b>Maximum Flexion</b>	
Preop	82° (SD: 6.5°)
Final	122° (SD: 10.6°)
<b>Flexion Contracture</b>	
Preop	8.9° (SD: 9.1°)
Final	3.9° (SD: 6.6°)
<b>Knee Society Knee and Functional Scores</b>	
Preop	99 (SD: 12)
Final	167 (SD: 21)

## Radiographic Assessment

The tibiofemoral angle was 5–8° valgus in 26 knee joints, 0–4° valgus in 15 joints, and 0–8° varus in 34 knee joints. The mean posterior slope of the tibia was 6.4° (SD: 1.8°). None of the joints showed signs of aseptic loosening at follow-up. The patella was centrally positioned in 67 cases (<5° tilt), showed medial tilt in no cases, lateral tilt without subluxation in 6 cases, and lateral tilt with subluxation in 2 cases (>5° lateral tilt).

## Complications

3 patients developed postoperative complications requiring treatment. 2 of these patients developed deep vein thrombosis and had to be treated with anticoagulants for 3 months. The 1 remaining patient demonstrated in the first postoperative week unsatisfactory ROM (<60° flexion), so that a mobilisation under general anaesthesia in combination with a peridural catheter for analgesia was done. Implant-specific complications like aseptic loosening, dislocation of the polyethylene insert, etc. were not seen over the 5 year follow up. 8 patients with lateral tilt of the patella and subluxation underwent revision surgery during the first postoperative year with patellar resurfacing, which improved their condition.

## DISCUSSION

The aim of a TKA design is to restore function and normal knee kinematics so as to minimise the risk of implant

failure, particularly in younger patients who are subject to higher revision rates [10]. Mobile bearings are superior to fixed bearings because of the reduced shear stress within the polyethylene and improved wear properties.

The aim of the present study was to evaluate a new multi-radius designed TKA (Zimmer Warsaw, Indiana, USA NexGen Cr-Flex Mobile) in mid-term follow up with regard to the functional outcome and to compare the results to the recent literature, especially with the results of traditional TKA's.

The main difference to traditional TKA's is on the one hand the fact that the NexGen CR-Flex Mobile has a groove on the anterior sliding surfaces that provides more room for the patellar tendon on increasing flexion. And on the other hand, that the rotational center of the polyethylene inlay is located on the medial tibial plateau and not centrally as with most other TKA's. In addition, the radius of the posterior femoral condyle is so that an optimal tibiofemoral contact area can be ensured even on deeper flexion.

But the success of a TKA depends critically on its service life and also on the reduction of pain and restoration of function. As a result of the changed demands that are made of a TKA nowadays, systems with extended flexion have come on the market.

Postoperative knee flexion after total knee arthroplasty (TKA) is important and correlates closely with patient satisfaction and functional level. Many factors may affect postoperative range of flexion after TKA but as shown by

**Table 3. Overview About the Recent Literature Especially with Regard to Function/Flexion Ability After TKA**

Author	Study Design	Journal	Number of Patients	TKA	Average Follow Up	Average Flexion Angle
Huang HT, Su JY <i>et al.</i>	Matched pair control	J Arthroplasty 2005	25 patients	High Flex vs Traditional PS	2.4 years	138° vs 126°
Laskin RS	Cohort study	Orthopedics 2007	80 Patients	Traditional PS vs High Flex PS	2 years	118° vs 133°
Kim YH, Choi Y <i>et al.</i>	RCT	J Bone Joint Surg Br. 2010	138 patients (bilateral)	High Flex CR vs Gender Flex	3.25 years	126° vs 124°
Kim YH, Choi Y <i>et al.</i>	RCT	J Bone Joint Surg Am. 2009	250 patients (bilateral)	High Flex CR vs High Flex PS	2.3 years	133° vs 135°
Kim YH, Sohn KS, Kim JS	RCT	J Bone Joint Surg Am. 2005	50 patients (bilateral)	Traditional LPS vs LPS Flex	2.1 years	135.8° vs 138.6°
Seon JK, Song EK <i>et al.</i>	RCT	Orthopedics 2005	100 patients	Traditional CR vs High Flex	2 years	130.7° vs 128.5°
Aglietti P, Buzzi R <i>et al.</i>	Follow Up	J Arthroplasty. 1999	60 patients	Traditional LPS vs LPS Flex	10 years	106°
Gill GS, Joshi AB	Follow Up	Am J Knee Surg. 2001	223 patients	Traditional TKA CR	16.8 years	n.a.
Vince KG, Insall JN <i>et al.</i>	Follow Up	J Bone Joint Surg Br. 1989	58 patients	Traditional TKA CR	10-12 years	91.2°
Nutton RW, van der Linden ML <i>et al.</i>	RCT	J Bone Joint Surg Br. 2008	56 patients	Traditional PS vs High Flex PS	1 year	121° vs 127°
Seon JK, Park SJ <i>et al.</i>	Prospective	J Bone Joint Surg Am. 2009	100 patients	Traditional CR vs High Flex CR	2 years	134.3° vs 135.3°
Bhan S, Malhotra R <i>et al.</i>	Prospective	J Bone Joint Surg Am. 2005	32 patients	Traditional CR	6 years	106.9°
Chaudhary R, Beaupré LA <i>et al.</i>	RCT	J Bone Joint Surg Am. 2008	100 patients	Traditional CR vs Traditional PS	2 years	105.9° vs 105.8°

Kawamura et Bourne [11] the preoperative range of flexion and the preoperative tibiofemoral varus/valgus angles were the factors that affected postoperative range of flexion. The tilt angles of the patella and the patellar button may also be factors that affect the postoperative range of flexion. Other factors like BMI (Body Mass Index), surgical approach, age of the patient or patella tilt did not show any correlation with the achievable flexion angle.

Previous studies have produced conflicting findings. For example: Huang *et al.* [5] found that the mean flexion in patients with high-flexion prosthesis was approximately 10° greater than in those with a standard posterior stabilised implant. Laskin [12] has also previously indicated similar findings. However, some authors [13, 14] have not noted increased flexion when using high-flexion rather than traditional prostheses.

The KSS improved from a mean of 99 before surgery to a mean of 167 at final follow up. Our scores were similar to those of other traditional TKA's. The maximum flexion of 122° in mean was achieved by the patients already after 2 years [12] and is similar to recent studies [6, 7, 13-24]. Table 3 gives an overview about recently published studies evaluating traditional TKA's and high flexion TKA's with main focus on the flexion ability.

But, in addition to pain reduction and restoration of functionality, survivorship is also a decisive consideration in the success of TKA's. Thanks to its extended posterior condyle radius which has been broadened all around, the NexGenCr-Flex Mobile System offer a larger contact surface on deep bending and therefore spreads the contact stress over a large area. This may guarantee optimum contact area and counteracts a high degree of polyethylene wear which may lead to an increased survivorship. But this needs to be proven in a long term follow up over 10 to 15 years.

The present study has some limitations. First, the use of KSS addresses functionality in a very limited way. The WOMAC and SF-36 are more responsive measures of the outcomes of TKA's [25]. Secondly, the mid term follow up makes it difficult to draw conclusions regarding the theoretical advantage of the high flex knee replacement system regarding the lifespan. Despite these problems, we believe that we were able to give accurate information after careful assessment of the performance of this high flexion TKA.

Despite positive results in the first 5 postoperative years, the NexGen Cr Flex mobile TKA shows no significant advantages over time compared to traditional TKA's or other high flexion TKA's especially with regard to function and range of motion.

So called high flexion TKA's have to proof their superiority in the long term follow up (10 to 15 years), with the focus on the degree of polyethylene wear and the possible consequence of aseptic loosening.

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Received: January 14, 2011

Revised: February 13, 2011

Accepted: February 14, 2011

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