The Natural-Knee System: 25 Years of Successful Results

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Abstract

The Natural-Knee (NK) total knee arthroplasty (TKA) system has been in use for 25 years. The unique features of this system include a deep trochlear groove, an asymmetrical tibial baseplate, use of Cancellous-Structured Titanium coating for preferred bone ingrowth, and a bimetal cementless femoral component. So far, 3135 NK total knee replacements have been reviewed. Cementless femoral and tibial components were used in 22% of these cases, cementless femoral and cemented tibial components in 3%, and cemented femoral and tibial components in 75%. The revision rate was 1.6%. Only one revision was to correct uncomplicated aseptic loosening.

The first Natural-Knee system (NK-I) was introduced by Intermedics Orthopedics in a multicenter Food and Drug Administration (FDA) trial in October 1985 and to the US market in 1986. Many of the unique features of the NK-I passed into the second-generation NK-II system, introduced in 1995, and then into the Gender Solutions Natural-Knee Flex (or NK Gender Flex, NK-GF), introduced in 2007 by Zimmer, Inc. Several of these unique features have become industry advancements in other knee manufacturers' implants.

These unique features include a deep trochlear groove on the femoral component, for better patellofemoral biomechanics; an asymmetrical tibial component baseplate, for improved prevention of subsidence and less soft-tissue impingement; and a deep-dish polyethylene insert as an alternative to a posterior stabilizer with posterior stability provided throughout the entire range of motion (ROM). The tibial component has 2 peripheral pegs in the center of the medial compartment and 2 peripheral pegs in the center of the lateral component. These pegs, positioned in the strongest area of tibial bone, provide more stability than an isolated central stem does.

A stemless porous tibial component was introduced first (Figure 1). After several years, a porous tibial baseplate with peripheral pegs and a central stem was added (Figure 2). Screws, initially a source of baseplate stability (Figure 3), have seldom been used over the past 5 to 10 years (Figure 4). Weight-bearing as tolerated after surgery is now allowed, even without use of screws. Unlike the porous tibial component, the initial NK-I nonporous tibial component had only a central stem and no peripheral pegs. When these implants were used, the stem was also cemented (Figure 5). Later, peripheral pegs were added to the nonporous stem to allow for more conservative use of tibial surface cementing, without cementing of the stem (Figure 6). The noncemented components have a Cancellous-

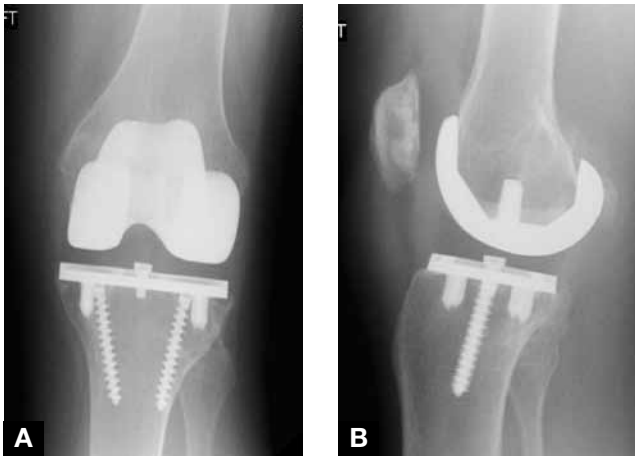

Figure 1. (A, B) At 22 years, radiographs of Natural-Knee I (NK-I) system with cementless fixation of femoral component and resurfacing tibial baseplate.

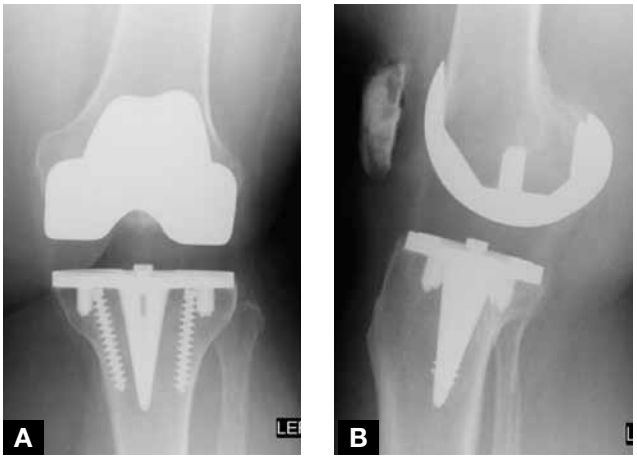

Figure 2. (A, B) At 15 years, radiographs of NK-I system with cementless fixation of femoral component and stemmed tibial baseplate.

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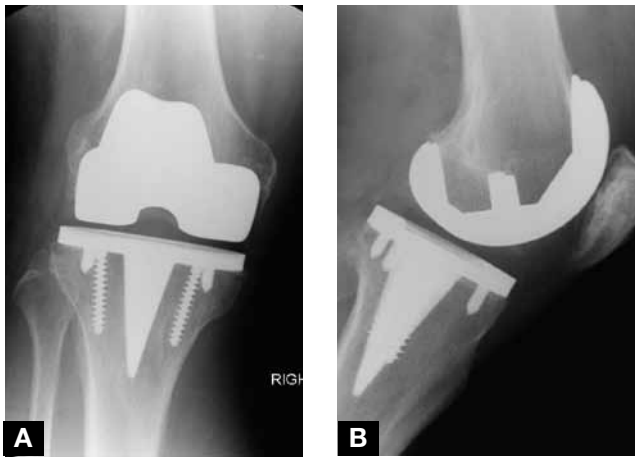

Figure 3. (A, B) At 13 years, radiographs of NK-II system with cementless fixation of femoral component and stemmed tibial baseplate and supplemental screws.

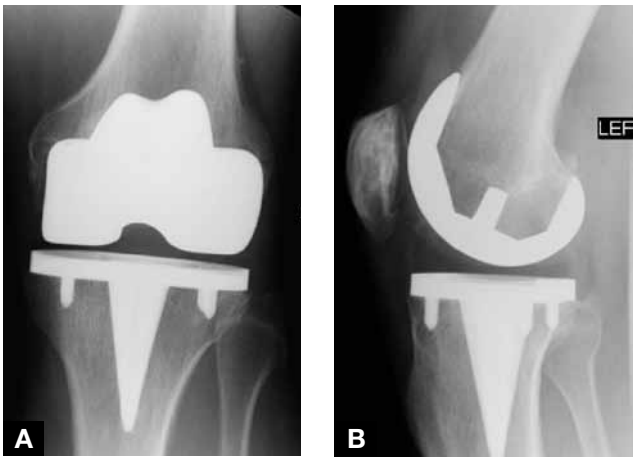

Figure 4. (A, B) At 9 years, radiographs of NK-II system with cementless fixation of femoral component and stemmed tibial baseplate without supplemental screws (other knee of patient in Figure 3).

Structured Titanium (CSTi) porous coating, which has a unique surface geometry replicating that of normal cancellous bone.[1] The surface has pores of various sizes and a high (60%) pore volume for bone ingrowth. Several years after CSTi porous coating was introduced, a newly developed unique sintering process allowed it to be applied to a preferred cobalt-chrome articular-surface femoral component.

In 2001, the NK-II was the first total knee arthroplasty (TKA) system to be used with highly cross-linked polyethylene (Durasul Poly, developed by Sulzer/Centerpulse Orthopedics, Austin, Tex, and now produced by Zimmer, Inc.). This polyethylene is treated with high-dose-rate electron beam irradiation of 9.5 mrads and then melted above the crystalline melting point to completely eliminate the free radicals that lead to oxidation.[2] When the NK-GF system was introduced in 2007, highly cross-linked polyethylene with a lower electron beam irradiation dose (Prolong Poly, Zimmer, Inc.) to improve fracture toughness was used.

The NK system has relatively simple instrumentation. It uses a measured resection technique so that the amount of bone resected equals the amount of prosthesis replaced. A posterior referencing system is used for femoral component positioning to create an anatomical posterior femoral joint line position. The proximal tibial resection is made at an angle that matches the patient's posterior tibial slope. This match provides better posterior cruciate ligament (PCL) balance and femoral rollback when the PCL is retained and increases tibial component load-bearing capacity.[3]

Methods

I began using the NK device in 1986 and have now used it in 3135 (370 NK-I, 2375 NK-II, 390 NK-GF) primary TKAs. Mean follow-up was 5.7 years. Of these patients, 1254 were male and 1881 female. Mean age was 68 years. Osteoarthritis was present in 92% of cases.

The deep-dish ultracongruent polyethylene tibial insert was not available until 1992, and a posterior stabilizer was not available until 1995, so prior to these dates all TKAs were performed with congruent tibial polyethylene inserts with the intention to save the PCL. Additional tibial slope resections or partial PCL releases were performed as necessary to properly tension the PCL and avoid excess femoral rollback should the PCL be too tight. After the ultracongruent liner became available, all surgeries were still performed with the intention to retain the PCL, but, when the PCL was too tight or ruptured with an intraoperative forced posterior drawer test, an ultracongruent insert was used rather than trying to balance the ligament. An ultracongruent insert was preferred to a posterior stabilizer insert. A varus/valgus constrained liner was introduced to the system in 1998 for cases in which mediolateral balancing was not possible. Congruent polyethylene inserts were used in 40% of the cases in this series, ultracongruent inserts in 58%, posterior stabilizer inserts in 1%, and varus/valgus constrained inserts in 1%.

My practice is to use cementless fixation for younger patients with excellent bone quality. The assumption has been that cementless fixation provides longer implant durability for these higher demand patients. Cemented fixation was used for elderly patients and for patients with poor bone quality. Cemented all-polyethylene tibial components were used in unhealthy patients and in patients older than 80. Cementless femoral and tibial components were used in 22% of the cases in this series; cementless femoral components with cemented tibial components (hybrid) in 3%; cemented femoral and cemented modular tibial components in 66%; and cemented femoral and cemented all-polyethylene tibial components in 9%. Mean age was 57 years for patients with cementless fixation, 63 years for patients with hybrid fixation, 70 years for patients with cemented modular tibial components, and 85 years for patients with all-polyethylene tibial components.

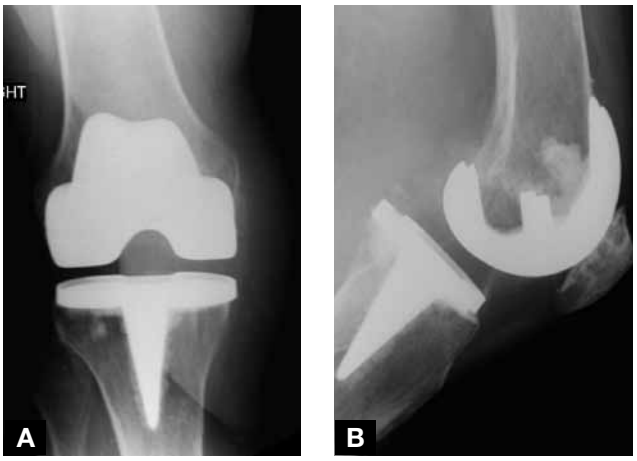

Figure 5. (A, B) At 18 years, radiographs of NK-I system with cemented fixation of femoral component and tibial baseplate without peripheral pegs.

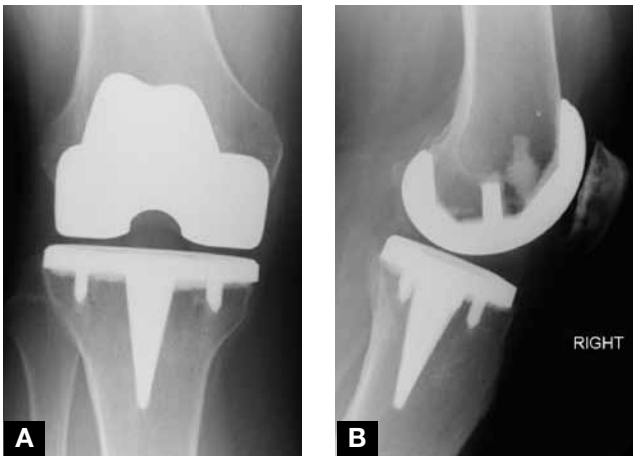

Figure 6. (A, B) At 14 years, radiographs of NK-II system with cemented fixation of femoral component and tibial baseplate with peripheral pegs.

Patellar resurfacing was performed in all but 29 patients. Metal-backed patella components were used initially when the femoral and tibial components were inserted without cement. Some patients with metal-backed patellar components experienced early wear and metallosis. Subsequently, all patellar components were inserted with cement.

Results

Mean preoperative Knee Society (KS) score was 45. Mean KS scores at 5, 10, 15, and 20 years of follow-up were 96, 95, 97, and 92. Mean preoperative KS Function score was 48. Mean Function scores at 5, 10, 15, and 20 years of follow-up were 80, 76, 73, and 73. Similar results were found when mean KS scores were compared by mode of fixation. Mean KS scores for cementless fixation cases at 5, 10, and 15 years were 94, 94, and 97. Mean scores for hybrid knees at 5, 10, and 15 years of follow-up were 97, 99, and 98. Mean scores for cemented knees with modular tibial baseplates at 5, 10, and 15 years of follow-up were 95, 90, and 68. Mean scores for cemented knees with all-polyethylene baseplates at 5 and 10 years of follow-up were 94 and 97. The mean preoperative and postoperative Knee Society scores are listed in the Table.

Mean preoperative ROM was 5° to 113°. Mean ROM at 5, 10, 15, and 20 years of follow-up was 1° to 117°, 0° to 118°, 0° to 118°, and 0° to 110°.

Fifty-one (1.6%) of 3135 knees underwent revision surgery. Thirty-seven percent of the revisions were for polyethylene wear from a metal-backed patella. Of the 105 metal-backed patellas used in this series, 19 (18%) have been revised (all were early-design patellar components). Of the 3001 cemented patellar components, none was revised for polyethylene wear or aseptic loosening. Two were revised for late PCL rupture; these revisions were fairly simple, requiring only insertion of an ultracongruent liner. Twelve knees were revised for septic loosening but only 5 for aseptic loosening. Four of these 5 cases involved recalled tibial components that were contaminated with oil, which inhibited bony attachment. Therefore, there was only 1 case of uncomplicated aseptic loosening. The patient's cementless NK-II system was revised 2 months after a major fall.

Discussion

One of the goals for the NK system was to achieve equal or better results with cementless (vs cemented) fixation. Hofmann and colleagues[4] reported on a series of 141 NK systems with cementless fixation after 10 years. Survivorship was 99.1% for femoral, 99.6% for tibial, and 95.1% for patellar components. These results are comparable to those in my series. Cementless components have had excellent results in younger patients with higher activity levels and demands. In a study of 75 NK-TKAs

Table. Mean Preoperative and Postoperative Knee Society Scores

			KS Score by Mode of Fixation			
	KS Score	KS Function Score	Cementless	Hybrid Knees	Cemented With Modular Tibial Baseplates	Cemented With All-Polyethylene Baseplates
Preoperative	45	48	44	41	44	43
5-year follow-up	96	80	94	97	95	94
10-year follow-up	95	76	94	99	90	97
15-year follow-up	97	73	97	98	68	—
20-year follow-up	92	73	—	—	—	—

Abbreviation: KS, Knee Society.

for patients younger than 50 after 9 years, there were no revisions for loosening or implant failure.[5] Given its excellent clinical results with cementless fixation, the NK system in 1997 became one of only a few TKA systems to be FDA-approved to receive premarket approval for cementless application. We have reviewed the cemented NK components I have implanted with a minimum of 10 years' follow-up and have found more than 97% survivorship (K. A. Gustke, J. Huang, and S. Russinoff, unpublished data, 2010). In addition, excellent mean knee flexion was achieved, similar to the 120° flexion reported at 10 years by Hofmann and colleagues.[4] The ultracongruent tibial polyethylene liner has been shown to function well. Survivorship of 100% with no instability issues over a period of 4 to 8 years and no decrease in ROM compared with that of cruciate-retaining inserts has been reported.[6]

Metal-backed patellar components have shown early wear-through,[7-9] and such was the case in the present series. The NK metal-backed component design was changed. The polyethylene was extended over the edge of the metal backing. A surgical technique of countersinking was promoted. The newer-design NK metal-backed patellas have had successful results in other series.[10]

Summary

My 24 years of experience with the NK system have shown that the implant has outstanding durability. Other than the septic revisions and the revisions for recalled tibial components, there has been only 1 known revision, for aseptic loosening. Both cementless and cemented components performed well when appropriately selected according to patient age and bone quality. The early-design metal-backed patellar components have had high failure rates. Better results would be expected with the second-generation metal-backed patellar components with wraparound polyethylene and a reliable ingrowth surface. Despite the low incidence of revisions for polyethylene wear, these revisions are expected to increase with longer follow-up. However, we anticipate that use of highly cross-linked polyethylene tibial inserts will match the long-term durability that seems to have been achieved with both biologically fixed and cemented NK implants.

Author's Disclosure Statement

Dr. Gustke wishes to note that he is Codesigner of the Natural-Knee II and Gender Solutions Natural-Knee Flex total knee arthroplasty systems and Consultant to Zimmer, Inc.

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