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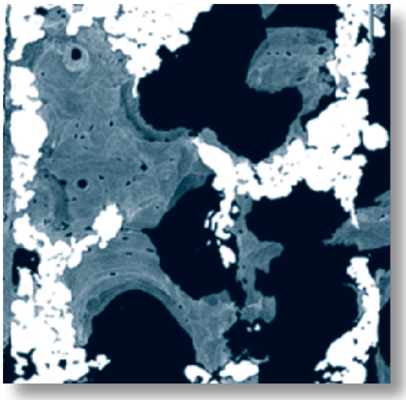

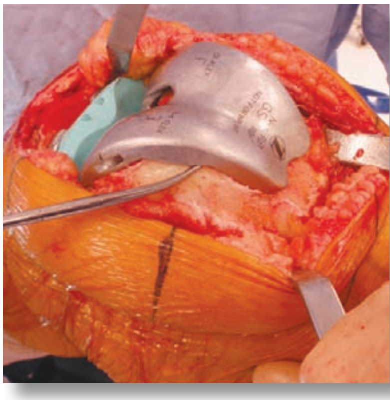

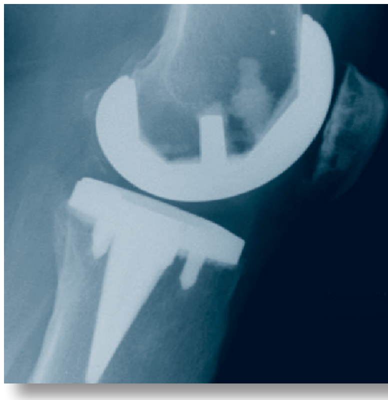

The 25-Year Experience With the Natural-Knee® System

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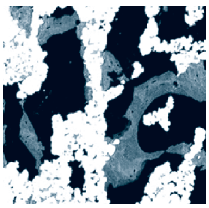

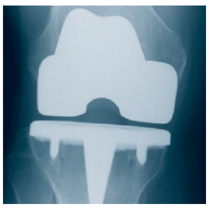

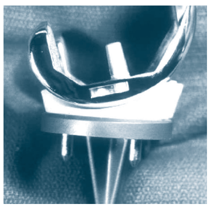

The Design Principles of the Natural-Knee System

Aaron A. Hofmann, MD

Abstract

The clinically successful Natural-Knee system was introduced 25 years ago. More than 1 million patients have been treated with this design since the first implantation in October 1985. This article reviews the design principles and evolution, over 25 years of clinical performance, of this cementless and cemented system, in which measured resection techniques are used to anatomically resurface the knee joint.

The Natural-Knee (NK) knee replacement system (Figure 1) was conceived by Dr. Aaron A. Hofmann in 1985 working with the talented engineers Joe Skraba and Jim Dales. The design principles of this system were based on restoration of anatomy and alignment of the knee joint. Bone resection, followed by an equal amount of prosthetic replacement, provides the knee with near normal varus-valgus and rotational stability throughout full range of motion. Cementless replacement required an understanding of cancellous bone structure, the nature of human cancellous bone healing and biology, and incorporation of host autograft bone for improving skeletal attachment. In addition to incorporating these important design parameters into the system, we instituted, at the time of the design program, a commitment to careful patient follow-up studies[1,2] and institutional review board (IRB)–approved implant retrieval investigations[3,4] to validate the clinical performance and design principles of the NK system.

Careful observations of the anatomy of the human knee joint helps the orthopedic surgeon to realize that there are variations (0°-10°) in the posterior slope[5] of the tibial plateaus. There is also an asymmetric natural bone adaptation of the proximal tibia to accommodate the larger surface area on the medial compartment of the knee compared with the lateral aspect of the articulating tibial surface. Bloebaum and colleagues[6] found that, when the tibia was resected with the patient's own anatomical slope, the bone was stronger, and anterior medial tibial component subsidence was avoided. In addition, when the asymmetric geometry of the resected tibia was matched by the tibial component, the surface area of the component fit the patient's anatomy better—affording excellent implant stability and preventing the clinical complication of pes bursitis, which is caused by medial tibial component overhang. Symmetric tibial component designs may leave the medial compartment compromised as well, because of limited implant coverage from accommodating the smaller surface area on the lateral compartment of the tibia.[6] Symmetric tibial components are also more difficult to place in the appropriate rotation. Anatomical studies have demonstrated that the lateral side is 4 to 5 mm smaller than the medial side in the anteroposterior plane.[7,8] Fixation of the tibial component is augmented by 4 peripheral pegs and a central keel with the option of cancellous screw fixation. A well-fixed, stable implant contributes significantly to the long-term success of the arthroplasty.

The femoral component of the NK system was the first to have a stepped anterior chamfer cut to allow bone resection and replacement with a deeply grooved trochlea, anatomically restoring the patellofemoral joint.[8] As a result, patellofemoral stability is achieved with few lateral releases and avoids abnormal patellofemoral compressive forces.

Initial component stability and coverage of the bone with cementless implants also require a knowledge of the structure and healing principles of the predominant cancellous bone type (94%) in the knee joint.[6] To examine the biological principles of tissue healing, we conducted an IRB-approved bilateral human knee study to confirm that the autograft bone slurry made at the time of surgery from the underside of the resected tibia, and then placed between the knee components and host bone, was effective in optimizing the skeletal attachment of femoral, tibial, and patellar components clinically and was confirmed in implant retrievals.[4,9-11]

Figure 1. Natural-Knee system.

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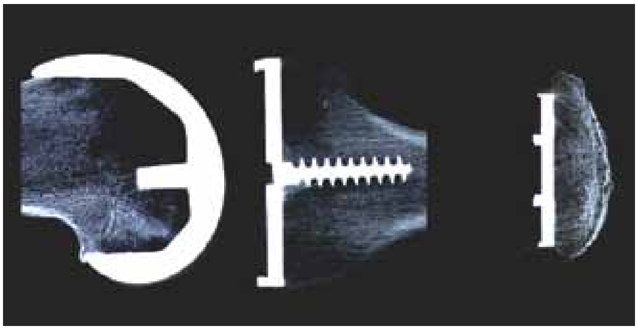

Figure 2. High-resolution contact radiographs of 3-mm-thick sections of all femoral, tibial, and patellar components from 24-year retrieval.

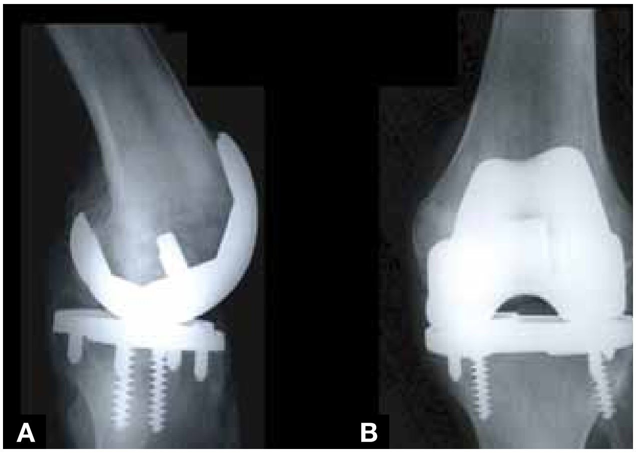

Figure 3. (A, B) Postmortem contact radiographs from 85-year-old female donor at 25-year follow-up.

Cancellous-structured commercially pure titanium (CSTi) coating was chosen as the porous coating to ensure optimal material porosity for bone ingrowth and to provide a high-contact roughened surface area for osseointegration of bone (Figure 2). Another design feature unique to the CSTi coating is its ability to be bone-sparing when revision is required for infection or osteolysis. When revisions were clinically indicated, the operative results clearly demonstrated that the host bone tissue would be spared by separating off at the CSTi coating–bone interface, preserving bone stock. This important design feature helps reduce the need for extensive allograft bone use during revision procedures.

Results were supported in IRB-approved postmortem donor implant retrieval studies showing excellent bone attachment.[3,4] These investigations demonstrated consistent attachment of cancellous bone to CSTi coating in patients with the NK system at follow-up of up to 25 years (Figures 3, 4). This attachment is considered an important advantage in supporting the excellent 98% survival rate of the NK system at 10- to 14-year follow-up.[2,12]

The issue of patient knee instability secondary to compromised or resected posterior cruciate ligament (PCL) was addressed by introducing the ultracongruent polyethylene insert design with the NK system (Figure 5). The geometry of the polyethylene insert—raised anterior flange (up to 12 mm) and increased radius—prevented excess anterior-posterior femoral translation during flexion in a PCL-deficient knee. An additional advantage is the decrease in femoral inventory requirement, as cruciate-retaining and -sacrificing primary knees share the same femoral component. This design concept avoids the clinical compromises that existed in the post and cam knee design types.[13] The literature demonstrates that post breakage and cam articulation wear were major clinical concerns. There were also

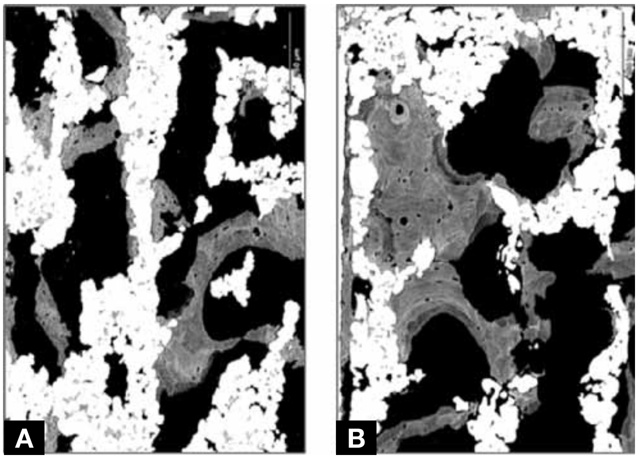

Figure 4. (A, B) Bone ingrowth into Cancellous-Structured Titanium (CSTi) coating of donor's postmortem femur and tibia at 25-year follow-up.

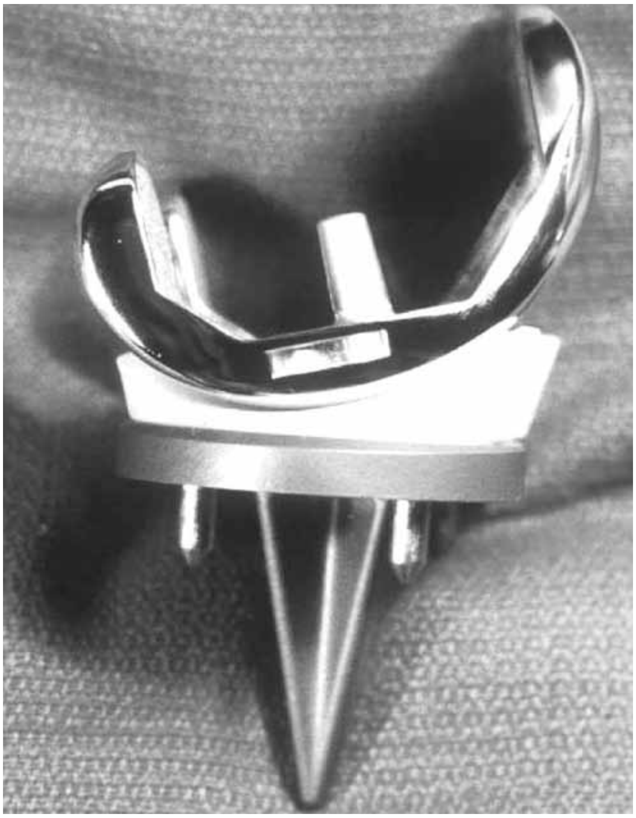

Figure 5. Profile of ultracongruent tibia on Natural-Knee system.

complications when the cam portion dislocated over the post during deep knee flexion and required intervention. Patellar clunk was also a concern, with soft tissue proximal to the patella becoming entrapped within the intercondylar cutout for the cam and requiring additional surgery. These issues were avoided with the ultracongruent design.

Design Changes and Advances

The early NK-I system had a titanium alloy femoral component with CSTi coating. By 1990, the metallurgy was perfected to attach the CSTi coating to the cobalt-chrome alloy substrate; the bimetal femoral component along with the instrument advances were then introduced.

The ultracongruent insert was introduced for PCL-insufficient knees in 1991. In ongoing developments, including introduction of the NK-II system in 1995, the search continued for the ideal polyethylene material to prevent articulating and backside wear. The mechanical capture for the tibial insert was improved to prevent backside wear, and the reversible asymmetric baseplate was replaced with dedicated left and right modular tibia to further improve coverage of the tibia. The rotating mobile bearing version was introduced to the European market in 2000, and it continues to be popular. Low-wear highly cross-linked polyethylene with oxidative resistance for congruent and ultracongruent polyethylene has been available since February 2001.[14] Highly cross-linked polyethylene patellar components were made available for cementing purposes and the patellar and ultracongruent tibial polyethylene was introduced at the same time. A modular cobalt-chrome tibial component was introduced in 2003 to accommodate stem extensions and the varus-valgus constrained insert and is the current mainstay for cemented primary and revision surgery.

As with all knee replacement systems, the limits of polyethylene wear continue to be an issue. Nevertheless, clinical results and implant retrieval data support the design and surgical principles behind the clinical success of the NK system.[2,12]

Author's Disclosure Statement and Acknowledgments

Dr. Hofmann wishes to note that he is Consultant to Zimmer, Inc. The author thanks Roy Bloebaum, PhD, for his scientific encouragement over 22 years and Jeremy McCandless, MD, for his assistance in manuscript preparation.

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The Natural-Knee System: 25 Years of Successful Results

Kenneth A. Gustke, MD

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-

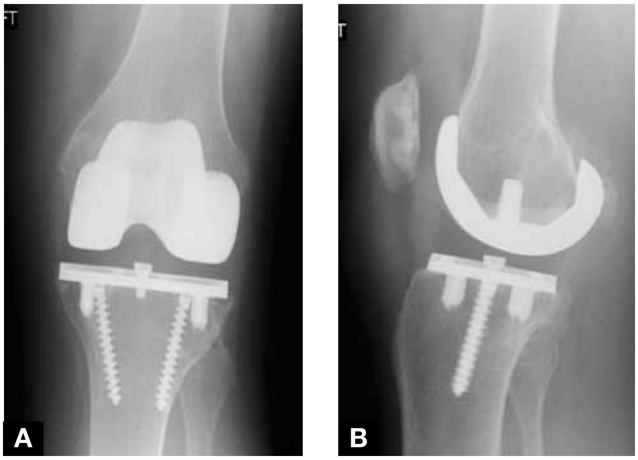

Figure 1. (A, B) At 22 years, radiographs of Natural-Knee I (NK-I) system with cementless fixation of femoral component and resurfacing tibial baseplate.

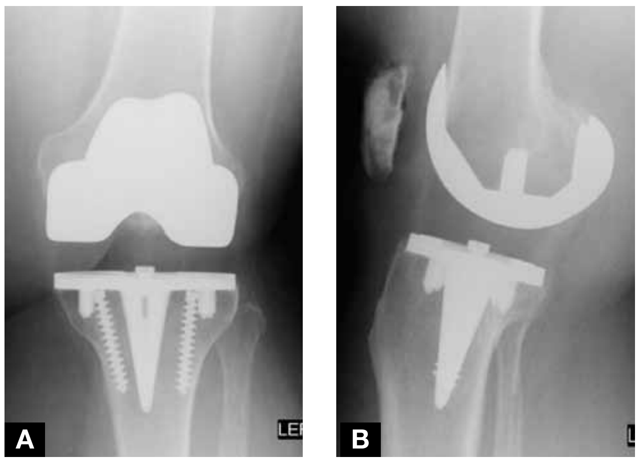

Figure 2. (A, B) At 15 years, radiographs of NK-I system with cementless fixation of femoral component and stemmed tibial baseplate.

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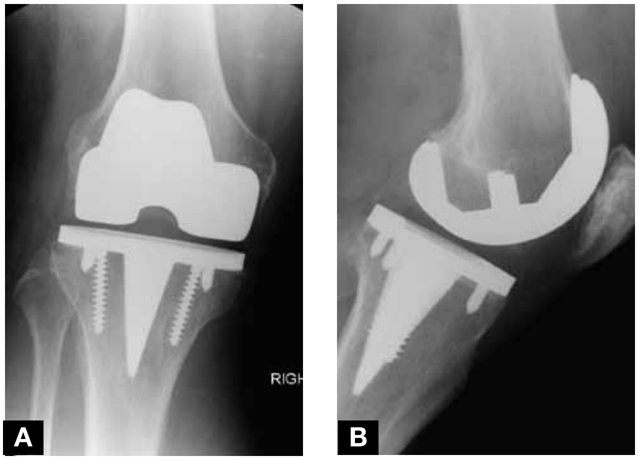

Figure 3. (A, B) At 13 years, radiographs of NK-II system with cementless fixation of femoral component and stemmed tibial baseplate and supplemental screws.

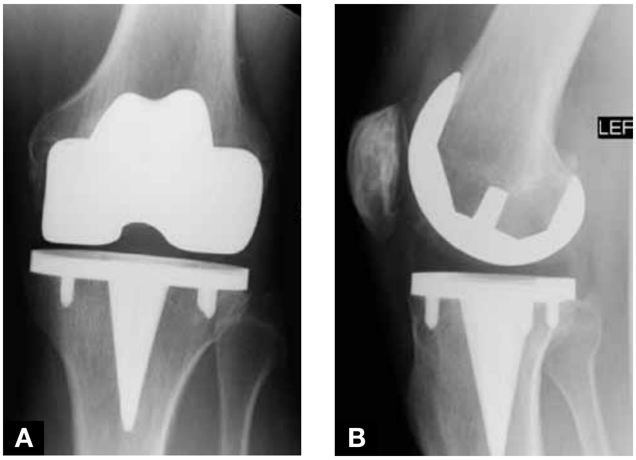

Figure 4. (A, B) At 9 years, radiographs of NK-II system with cementless fixation of femoral component and stemmed tibial baseplate without supplemental screws (other knee of patient in Figure 3).

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.

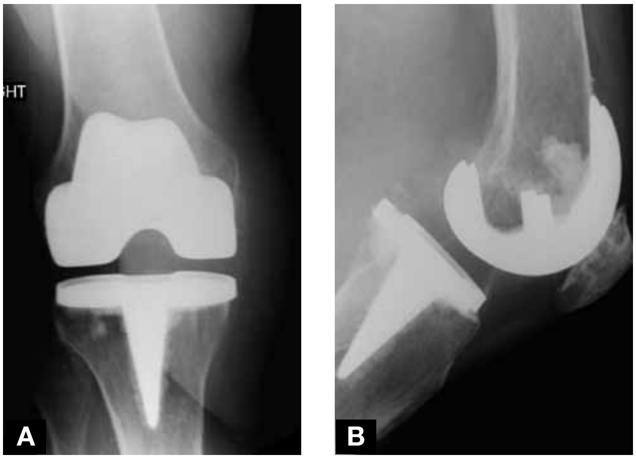

Figure 5. (A, B) At 18 years, radiographs of NK-I system with cemented fixation of femoral component and tibial baseplate without peripheral pegs.

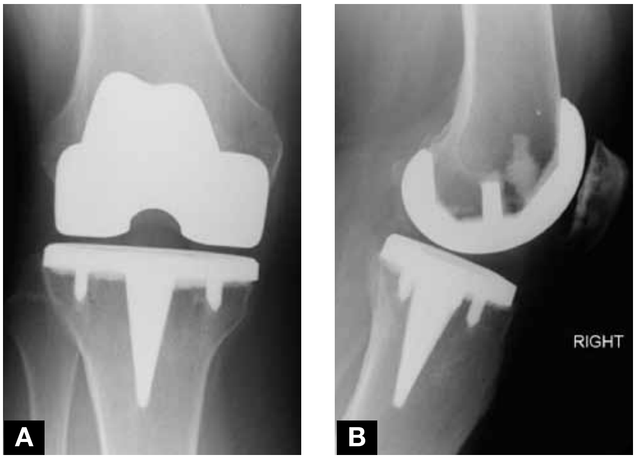

Figure 6. (A, B) At 14 years, radiographs of NK-II system with cemented fixation of femoral component and tibial baseplate with peripheral pegs.

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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The Gender Solutions Natural-Knee Flex System and Future Directions

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Abstract

The morphology of the distal femur varies. Whether or not the variability falls strictly along gender lines, a better fit to the distal femur can be obtained without intraoperative compromises by making available both a narrow and a wider medial-lateral/anterior-posterior aspect ratio. In our 1-year outcomes of the first 360 patients who received the Zimmer Gender Solutions Natural-Knee Flex System, mean flexion was 131° (10° better than mean flexion with the earlier Natural-Knee I and II systems), and the lateral release rate decreased to 2%. We no longer need to downsize during surgery to achieve good fit in femurs—in female patients typically—with narrower medial-lateral/anterior-posterior aspect ratios.

The 25-year (1985–2010) clinical success of the Zimmer Natural-Knee (NK) Series has been remarkable. Compared with other designs in 1985, the first NK system (NK-I) had a very low-profile anterior condyle and a deep trochlear groove, and its instrumentation was simple and reproducible. In 1995, the NK-I system was modified to the NK-II. Clinical scores and patient outcomes for both series were excellent. Common intraoperative practice, however, was to "downsize" the measured femoral component after trialing to prevent overhang medial-lateral or popliteal impingement. Although downsizing works clinically, and the increased surgical time involved is minimal, this practice has its theoretical disadvantages.

The evolution of the NK II series into the Gender Solutions Natural-Knee Flex version (NK-GF) in 2007 was an opportunity to provide subtle improvements in fit and function using distal femoral morphology data.[1-4] A slightly larger lateral condyle allows more rotation with rollback, and condylar relief is provided for the posterior cruciate ligament (PCL) and popliteus. Posterior condylar changes coupled with moving the polyethylene contact point posteriorly allow deeper flexion without impingement. The femoral inventory was almost doubled to allow a choice of 2 implants for a better fit medial to lateral for the same anterior-to-posterior measurement. The design goals for the NK-GF were a more anatomical fit, better flexion, and overall improved functional outcome.

Modular polyethylene insert materials have progressed along with the designs. The initial NK-I system polyethylene would undergo subsurface oxidation, resulting in delamination. Introduction of oxygen-free processing and polyethylene "improvements" in the 1990s solved the delamination issue, but the wear particles were much smaller and, in some cases, not well tolerated. In several series, investigators reported a higher than expected failure rate in previously well-functioning knee systems.[5] Highly cross-linked polyethylene (Durasul Poly, developed by Sulzer/Centerpulse Orthopedics, Austin, Tex, and now Prolong Poly produced by Zimmer) became available for knees around 2001, and its use, compared with that of conventional polyethylene, has been associated with much improved outcomes in our clinical series.

Materials and Methods

From 1987 to the present, I have prospectively entered data for 4532 NK cases into an evolving database that includes preoperative and interval postoperative data. Porous ingrowth Cancellous-Structured Titanium (CSTi) implants, including metal-backed patellas, were used for all healthier, younger patients (age, <70 years). Data have been added for 699 (419 noncemented, 280 cemented) NK-I systems, 3042 (1789 noncemented, 1253 cemented) NK-II systems, and 791 (435 noncemented, 356 cemented) NK-GF systems.

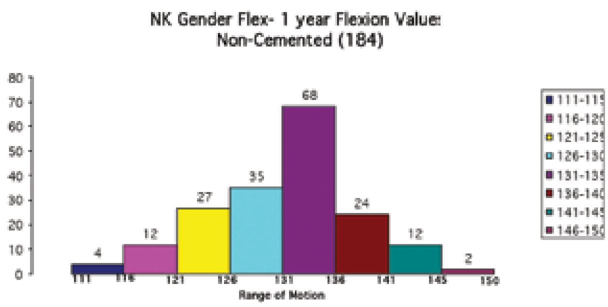

Figure 1. Flexion values at 1 year for the first 184 patients with noncemented Zimmer Gender Solutions Natural-Knee Flex System.

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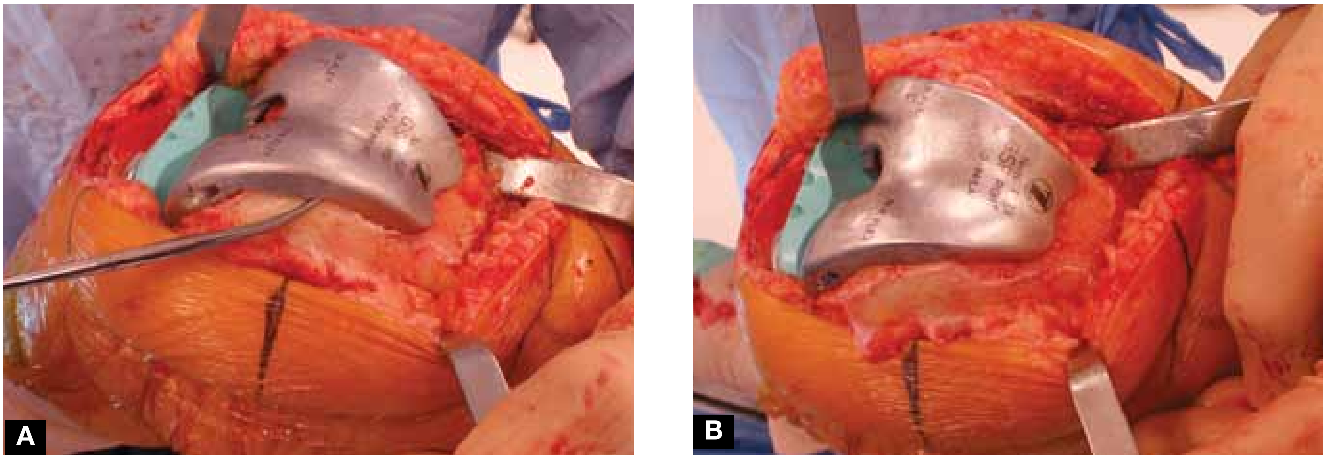

Figure 2. (A) Intraoperative trialing in a female patient. Note anterior cut flush with anterior cortex and overhang at anteromedial corner with a size 3 GSM (wide). With the NK-II system, downsizing by flexing the femur would be necessary. (B) Same patient, with a size 3 GSF (narrow) component. Notice that there is no overhang and no concern about notch impingement or anterior notching, which is possible in downsizing techniques for a posterior referenced system.

Complete 1-year data are available for 360 (184 noncemented, 176 cemented) NK-GF systems. Ninety percent of these systems were PCL-retaining. In all noncemented systems, ingrowth was aided by use of specific techniques, including keeping the saw blade cool, grafting the interface with bone slurry, and having the patient engage in protected weight-bearing during recovery. Full weight-bearing was allowed at 4 to 6 weeks, and after 4 months all restrictions, including sporting activities, were lifted. In all cemented systems, only pulse lavage and surface cement techniques were used.

Results

I presented the NK-I results in 2005.[6] Among the group of 320 patients who received implants, there was complete 10- to 16-year data on 174 ingrowth knees. Nine (5%) of these knees underwent partial revisions for polyethylene wear and no patient had failure of bone ingrowth, even as they aged. The larger polyethylene delamination particles were tolerated well by the bone with no metaphyseal cyst formation or clinically significant osteolysis in any patient. Preoperative and postoperative Modified HSS (Hospital for Special Surgery) scores were 65 (fair) and 96 (excellent), respectively, and mean preoperative and postoperative flexion was 105° and 120°, respectively.

In 2007, I presented the NK-II results.[7] Preoperative and postoperative Knee Society (KS) Assessment scores were 62.5 and 86.3 (ie, fair and excellent, respectively), and preoperative and postoperative KS Function scores were 57.0 (ie, poor) and 79.5 (ie, good).

The early NK II results (pre-cross-linked polyethylene—2001) were influenced by a polyethylene change for the worse that led to the creation of small wear particles. It was postulated that these may have contributed to tibial metaphyseal cysts resembling an intraosseous ganglion at the tip of the medial screw. Synovial fluid pressure may have played a role, as analysis showed only a minimal presence of polyethylene particles. There were no ingrowth failures, and all implants were stable at 10 years; however, 10% of patients had undergone polyethylene exchange to cross-linked polyethylene and grafting of the cyst, without removal of the implants. In all, the bone defect has healed. Even 5-year data showed significant cysts in 13% of non–cross-linked polyethylene porous implants—a finding similar to that for other designs at the time.[5] By contrast, the 5-year data also showed that, when highly cross-linked polyethylene was used for the same implant/technique, there was a complete absence of significant metaphyseal cysts. As we approach 10-year follow-up (2011), we have yet to see cyst formation with use of highly cross-linked polyethylene in noncemented NK-II systems. The introduction of cross-linked polyethylene solved the cyst generation problem just as it was being recognized clinically. Only 2% of metal-backed patellas have been revised for endoskeleton damage at 10 to 16 years in both series.

Note that these metaphyseal cysts were never seen in cemented implants. No revisions or polyethylene exchanges have been performed in cemented NK-II implants. Only older, less active patients received cemented implants in my series.

Natural-Knee Gender Flex: A Preliminary Early-Outcomes Report With 1-Year Data on 360 Patients

At both 6 weeks and 1 year, the NK-GF series is obtaining better flexion (131°, 1 year, noncemented) compared with our NK I and NK II series series (120°-121°, 1 year). Ninety-one percent of the NK-GF systems obtained flexion of more than 121° at 1 year (Figure 1). Preoperative and 1-year postoperative KS Assessment scores were 48.3 and 92.0, respectively, and preoperative and 1-year postoperative KS Function scores were 47.5 and 90.1, respectively. Forty-six percent of patients were able to kneel without discomfort, and another 41% were able to kneel with discomfort.

Discussion

This NK-GF series is limited in scope because of its short follow-up, but nevertheless there has been a 10° increase in mean range of motion (ROM) over that found in the previous NK series. One-year postoperative KS scores and patient satisfaction are excellent, suggesting that there are no problems with the design modifications, but longer term follow-up is needed.

Gender Specificity

Use of the term *gender-specific* has led to many strong opinions and much debate. Conflicting data are emerging regarding the degree to which distal femoral differences can be attributed only to sex [8,9]; often, ethnicity and morphotype are involved as well. The basic premise of *Gender Solutions Technology* is that, for a given anterior-posterior dimension to the femoral condyles, usually women are more narrow than men. In addition, for women, the anterior condylar height is less,[2,4,8] and the trochlear angle is slightly more.[10]

Some of the femoral components in the NK-II series—mostly those used in female patients—fit perfectly anterior to posterior but were too wide (Figures 2A, 2B). Surgical compromise in the form of downsizing was needed to prevent medial/lateral overhang resulting in medial and lateral retinacular tensing, patellofemoral overstuffing,[11] and collateral or popliteal tendon impingement. Downsizing required flexing the distal cut, which slightly flexed the femur to prevent anterior notching in the posterior referenced NK system. In theory this can result in impingement of the intercondylar notch on the polyethylene eminence, followed by wear or polyethylene backside micromotion with every step in extension. The technique obviously has worked, given our outcomes over the past 20 years, but having a narrower version available for each anterior-posterior dimension has completely eliminated the need for downsizing. It should be noted that some small male patients require the narrower "female" version, and some morphotypical, "large-boned" female patients require the wider "male" version. Perhaps a less controversial sizing nomenclature for each anterior-posterior dimension would include *3-Narrow* and *3-Wide*. For my series, however, 98% of patients have received femoral components consistent with their gender.

Regardless of which nomenclature is used for extra sizes, their availability has solved a surgical/clinical problem of the medial-lateral/anterior-posterior aspect ratio. I no longer need to downsize; in each case, I can achieve good medial-lateral fit without compromise. Similar issues have been solved in hip systems. For example, use of both standard- and increased-offset femoral stems is now the norm, and the result is improved restoration of anatomy.

High-Flexion Design

The NK system has always had a low anatomical anterior profile and a deep trochlear groove. In addition, the technique for the NK series demands reproducing the patient's tibial posterior slope, which makes balancing the PCL easier, preventing tightening with flexion. These concepts have led to increased flexion even in the NK-I and NK-II series (120°-121°) and to an extremely low patella complication rate. However good 120° flexion is, though, some patients want more, either for specific activities or cultural reasons. ROM can decrease when the patellofemoral joint is overstuffed by height or even width when the condyles place pressure on the medial or lateral retinaculum.[11,12] Our goal is to normalize this portion of the anatomy.

Some argue that having an implant that averages the wide spectrum of anatomical differences is adequate, and that having 2 options per size, each averaged to opposite ends of the spectrum, is not necessary and somehow constitutes deceptive marketing. In my surgical experience, however, having 2 options allows me to obtain a better fit and avoid the compromises of slight overhangs and downsizing, which could result in notching or impingement on the eminence and poly micromotion. Availability of a thinner, narrower anterior condyle has meant I have had to perform partial lateral releases in only 2% of my NK-GF knees, compared with upward of 20% in previous series. The result has been less pain and swelling.

Application of these concepts, combined with posterior condylar radii changes, has led to a mean ROM of 130° in the NK-GF series, or 10° more than the 120° ROM obtained in the NK-I and NK-II series. Does that mean that NK-GF systems "score" or function better? I agree with investigators who say current knee scores do not accurately reflect the subtle differences that can be important in individual outcomes. For instance, is the case of an NK-II system that eliminates pain but provides flexion of only 114° a problem that needs solving? Although that degree of flexion falls into the range usually considered excellent, it may be a problem for someone who is still unable to get in and out of his classic Corvette. Other series of knees claiming high-flexion design have varied results and questionable benefits as currently measured,[13] except perhaps for stair climbing/descent. Continued follow-up and better patient evaluations will tell the long-term story.

Highly Cross-Linked Polyethylene (Durasul/Prolong Poly)

Our NK II data have made it clear that using Durasul Poly (beginning 2001) solved our early wear and tibial metaphyseal cyst issues seen with conventional polyethylene. Our 5-year and upcoming 10-year data on cross-linked polyethylene are confirming that. For the NK-GF series, additional steps were taken to decrease particle generation on the backside. Not adding a matte finish to the tray decreased backside wear 40%. The NK II snap mechanism was one of the tightest on the market in 1995, but additional changes to the lock and fit in the NK-GF series decreased anterior-posterior micromotion by 60% and medial-lateral micromotion by 76%.

Future Directions

Until breakthroughs occur in the development of more natural hydrophilic surfaces, polyethylene wear will continue. Volumetric wear seems to be significantly reduced with high cross-linking, but particle shape and size are dramatically different. The smaller debris may be more bioreactive in some patients.[14] We are encouraged that highly cross-linked polyethylene seems to be functioning very well as we approach the 10-year mark in our NK-II series. Ongoing research into the macrophage response and into individual responses is needed, as our patients are living longer, are becoming more active with their implants, and have higher expectations. Will we develop medications that can moderate individual responses and decrease inflammation? Will these medications be used prophylactically? At what costs? Will we be able to manage wear mechanically (eg, with use of a particle filter), as we do with cars?

Over the short term, while new concepts and technologies are being developed, we must follow our patients closely and listen to their concerns. We need to expand investigation to higher functioning patients and perform more detailed analyses before we can know whether our application of current concepts is resulting in improved function.

Bone is a living tissue and responds to stress in accordance with Wolff's law. We have shown since 1985 that bone ingrowth remains strong as people age and that the bone remains healthy. New technologies of ingrowth material appear to hold great promise, so much so that we can actually encourage our patients to return to sports in order to keep their bones strong. Will a flexible subarticular interface (subchondral plate) be a matrix for a more durable biomaterial surface? Something with a more natural feel? In the meantime, good 20- to 30-year results, with the options of partial revisions and healthy bone to work with, constitute a success.

Conclusions

No one argues with the fact that surgeons discover a range of shapes while performing primary total knee arthroplasties: Medial-lateral/anterior-posterior aspect ratios are wider in some knees, and narrower in others; some knees have thick anterior condyles above the anterior femoral cortex, others thin; and trochlear groove angles vary. Having 2 width options (with the same anterior-posterior sizing measurements) for each knee eliminates the need for intraoperative adjustments and the potential for misfitting and overhang. Mean flexion is 10° more in my NK-GF series than in my previous series, and in the NK-GF series there has been a noticeable absence of need for lateral releases. Although preliminary results look very promising, long-term follow-up is obviously needed.

Authors' Disclosure Statement

Dr. Plaster wishes to note that his only current contract with Zimmer, Inc., is a general consulting agreement and that he is not currently receiving any royalty-based income from Zimmer, Inc., for its Gender Solutions Natural-Knee Flex System (NK-GF) but has in the past. In addition, Dr. Plaster wishes to disclose past research grants related to the NK II System as well as involvement on instrument design teams.

Ms. Starkman and Ms. McGee report no conflicts of interest but note that they work directly with Dr. Plaster and that they may thus be considered to share in his disclosures.

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