The Gender Solutions Natural-Knee Flex System and Future Directions

Rodney L. Plaster, MD, Kara B. Starkman, PA-C, and Julie McGee, BA

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.

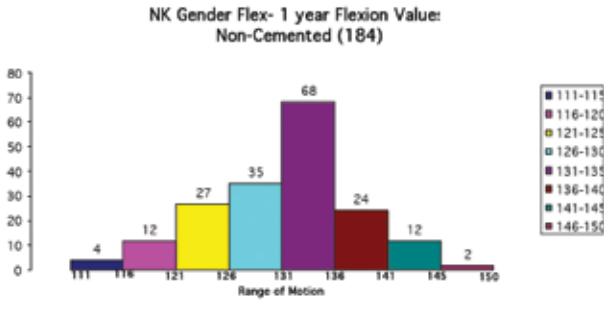

Figure 1. Flexion values at 1 year for the first 184 patients with noncemented Zimmer Gender Solutions Natural-Knee Flex System.

Dr. Plaster is in Private Practice at Eastern Oklahoma Orthopedic Center, Tulsa, Oklahoma, and is Adjunct Assistant Professor, University of Utah, Salt Lake City, Utah, and Assistant Clinical Instructor, University of Oklahoma College of Medicine, Tulsa, Oklahoma.
Ms. Starkman is a Certified Physician's Assistant at Eastern Oklahoma Orthopedic Center, Tulsa, Oklahoma.
Ms. McGee is a Research Assistant with Dr. Plaster.

Address correspondence to: Rod Plaster, MD, Eastern Oklahoma Orthopedic Center, 6475 South Yale, Suite 301, Tulsa, OK 74136 (tel, 918-494-9312; fax, 918-494-9355; e-mail, Joints4yu@aol.com).

Am J Orthop. 2010;39(6 suppl):9-12.

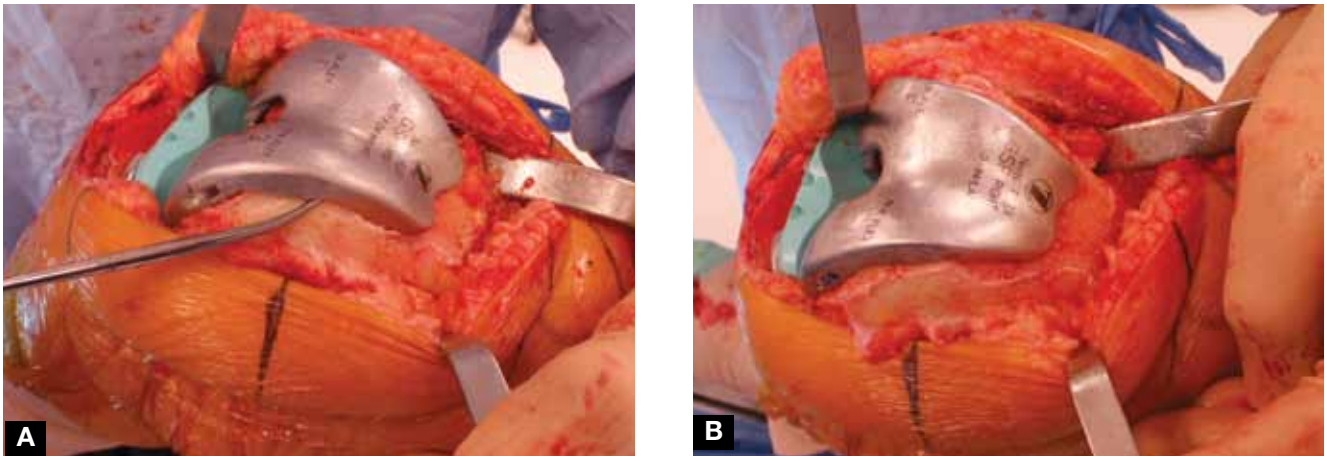

Figure 2. (A) Intraoperative trialing in a female patient. Note anterior cut flush with anterior cortex and overhang at anteromedial corner with a size 3 GSM (wide). With the NK-II system, downsizing by flexing the femur would be necessary. (B) Same patient, with a size 3 GSF (narrow) component. Notice 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.

References

1. Chin KR, Dalury DF, Zurakowski D, Scott RD. Intraoperative measurements of male and female distal femurs during primary total knee arthroplasty. *J Knee Surg.* 2002;15(4):213-217.
2. Conley S, Rosenberg A, Crowninshield R. The female knee: anatomic variations. *J Am Acad Orthop Surg.* 2007;15(suppl 1):S31-S36.
3. Mahfouz M, Booth R Jr, Argenson J, Merkl BC, Abdel Fath EE, Kuhn MJ. Analysis of variation of adult femora using sex specific statistical atlases. Paper presented at: 7th International Symposium on Computer Methods in Biomechanics and Biomedical Engineering; March 2006; Antibes, France.
4. Poilvache PL, Insall JN, Scuderi GR, Font-Rodriguez DE. Rotational landmarks and sizing of the distal femur in total knee arthroplasty. *Clin Orthop.* 1996;(331):35-46.
5. Fehring TK, Murphy JA, Hayes TD, Roberts DW, Pomeroy DL, Griffin WL. Factors influencing wear and osteolysis in press-fit condylar modular total knee replacements. *Clin Orthop.* 2004;(428):40-50.
6. Plaster RL, Bone ingrowth into the Natural TKA system: a 10-16 yr follow-up. Paper presented at: Annual Meeting of the American Academy of Orthopaedic Surgeons; February 2005; Washington, DC.
7. Plaster RL, Starkman KB, McGee J. Natural Knee II: minimum 10 yr follow-up on first 110 implanted without cement. Poster presented at: 8th Congress of the European Federation of National Associations of Orthopaedics and Traumatology; May 2007; Florence, Italy.
8. Fehring TK, Odum SM, Hughes J, Springer BD, Beaver WB Jr. Differences between the sexes in the anatomy of the anterior condyle of the knee. *J Bone Joint Surg Am.* 2009;91(10):2335-2341.
9. Blaha JD, Mancinelli CA, Overgaard KA. Failure of sex to predict the size and shape of the knee. *J Bone Joint Surg Am.* 2009;91(suppl 6):19-22.
10. Csintalan RP, Schulz MM, Woo J, McMahon PJ, Lee TQ. Gender differences in patellofemoral joint biomechanics. *Clin Orthop.* 2002;(402):260-269.
11. Mihalko W, Fishkin Z, Krackow K. Patellofemoral overstuff and its relationship to flexion after total knee arthroplasty. *Clin Orthop.* 2006;(449):283-287.
12. Bengs BC, Scott RD. The effect of patellar thickness on intraoperative knee flexion and patellar tracking in total knee arthroplasty. *J Arthroplasty.* 2006;21(5):650-655.
13. Kim YH, Choi Y, Kim JS. Range of motion of standard and high-flexion posterior cruciate–retaining total knee prostheses: a prospective randomized study. *J Bone Joint Surg Am.* 2009;91(8):1874-1881.
14. Minoda Y, Kobayashi A, Iwaki H, et al. In vivo analysis of polyethylene wear particles after total knee arthroplasty: the influence of improved materials and designs. *J Bone Joint Surg Am.* 2009;91(suppl 6):67-73.