***CORR* Insights®: Is TKA Using Patient-specific Instruments Comparable to Conventional TKA? A Randomized Controlled Study of One System**

Thomas J. Blumenfeld MD

Received: 19 August 2013 / Accepted: 4 September 2013 / Published online: 18 September 2013
© The Association of Bone and Joint Surgeons® 2013

Where Are We Now?

In 1985, Hungerford and Krackow [2] described the early results of cementless TKA, stating that “technical perfection of alignment and component position are their goals.” For two decades, the attempt to obtain perfection in alignment and component position was performed with intra- and extramedullary guides with the goal of restoring both a “neutral” mechanical coronal axis, and a femoral-tibial component-parallel ROM from full extension to full flexion.

Twenty-eight years later, the goals are the same — even if the tools to achieve them have grown to include

computer navigation, CT or MRI-generated patient-specific guides, and calibrated gap-balancing instruments.

In the paper by Roh et al., the authors examined the accuracy of CT-based patient-specific guides compared to mechanical guides during the single-surgeon performance of TKA in 100 patients (50 patients randomized to each group). The postoperative restoration of a “neutral” mechanical axis was assessed radiographically, whereas a CT scan assessed coronal-sagittal and rotational alignments in both groups. Roh and colleagues defined “outlier” as a patient with a mechanical axis greater than 3° from mechanical neutral.

In short, the patient specific guides did not confer any advantage. Results of the study showed that both groups were similar (12% outliers in the patient-specific group and 10% in the mechanical group). Both groups were also similar in the number of outliers identified using CT scan. Of the surgeries performed with patient-specific guides, 16% (eight out of 50) were abandoned intraoperatively for technical reasons. The authors’ contribution is important, and they are to be commended for performing a rigorous randomized study.

This CORR Insights® is a commentary on the article “Is TKA Using Patient-specific Instruments Comparable to Conventional TKA? A Randomized Controlled Study of One System” by Roh and colleagues available at: DOI: [10.1007/s11999-013-3206-1](https://doi.org/10.1007/s11999-013-3206-1).

The author certifies that he, or a member of his immediate family, has no funding or commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

All ICMJE Conflict of Interest Forms for authors and *Clinical Orthopaedics and Related Research*® editors and board members are on file with the publication and can be viewed on request. The opinions expressed are those of the writers, and do not reflect the opinion or policy of *CORR*® or the Association of Bone and Joint Surgeons®.

This *CORR* Insights® comment refers to the article available at DOI: [10.1007/s11999-013-3206-1](https://doi.org/10.1007/s11999-013-3206-1).

Where Do We Need To Go?

In addition to the current contribution of Roh and colleagues, outliers have been reported in most series examining the use of mechanical, computer navigated, and patient-specific guides. The work of Parratte et al. [3] suggests that a neutral mechanical axis may not be necessary for longevity in TKA. The inability to complete surgeries using patient-specific guides remains an issue, particularly given the cost for imaging and creation of the guides [1]. While we trust the judgment of an experienced

T. J. Blumenfeld (✉)
Department of Orthopaedics, Sutter Medical Center,
University of California at Davis, 1020 29th St., Suite 450,
Sacramento, CA 95816, USA
e-mail: tblumenfeld@jointsurgeons.com

surgeon in abandoning the approach, we ask whether the apparent rotational malalignment determined visually by comparison to gap balancing was an accurate reflection of a true mismatch (the appearance of a trapezoidal flexion space), or whether the guide represented the CT derived “true” alignment of the knee? The possible explanations for the frequent need to abort the patient-specific procedures are many, and they are complex; before answering them, it may be even more important to determine what the correct axes are for proper alignment of a TKA, and it seems to me we are far from even being able to do this.

We need to resolve an issue that encompasses outliers, mechanically neutral total knees, enhanced technologies to improve alignment (navigation), intraoperative component placement (patient-specific guides), and even enhanced (high flexion, gender specific) total knee designs. What are the alignment goals that allow placement of a total knee that will provide pain free function and longevity, for our patients? Are alignment goals true surrogates for function and outcome? Does placement of a mechanical bearing such that the bearing mimics the anatomy of the human knee result in a functional total knee?

How Do We Get There?

First, we need to determine what the alignment goals should be. With the use of computer navigation, precision can be achieved intraoperatively and used for long-term evaluation of alignment as a surrogate for outcome. However, until those studies are done, we are not even certain of the goal we are shooting for. Second, we must further develop postoperative measurement tools designed to evaluate functional outcomes after TKA in a way that facilitates comparing our alignment results with patient-oriented outcomes. More precise conclusions will be drawn in the future about what constitutes a well-done total knee.

A possible approach could include randomizing patients with preoperative varus to receive a total knee with static coronal alignment goals that include neutral mechanical

axis, or residual varus. It seems to me that navigation would be essential for a study like this, but if it is done well, it would help us to ascertain the degree to which alignment affects functional endpoints and implant durability, particularly if the patients can be tracked at 5, 10, and beyond 15 years. It will be especially important to ascertain the influence of alignment outliers in a study like this.

Another approach might be to evaluate kinematic alignment, as opposed to traditional gap-balanced alignment, in a randomized prospective trial comparing the techniques. Here again, functional outcomes, rather than radiographic parameters, should be the emphasis of the postoperative evaluation.

Roh’s study suggests that even in an experienced surgeon’s hands CT-generated guides are inaccurate in nearly one case in every five. The unanswered question is whether or not these inaccuracies are real, or perceived; underlying this is whether a CT-based guide system is of benefit. A cadaveric study comparing CT-based guides to TKA performed with computer navigation, examining alignment and ligament stability throughout the ROM, should be considered. This may help to discern whether it is the creation of the guide from the CT scan, or the underlying concept behind the creation of these guides (match the normal knee’s surface), that leads to potential inaccuracy. Until we know whether CT-based guides are effective, they will remain a costly intervention without proven benefit.

References

1. Barrack RL, Ruh EL, Williams BM, Ford AD, Foreman K, Nunley RM. Patient specific cutting blocks are currently of no proven value. *J Bone Joint Surg Br.* 2012;94:95–99.
2. Hungerford DS, Krackow KA. Total joint arthroplasty of the knee. *Clin Ortho Rel Res.* 1985;192:23–33.
3. Parratte S, Pagnano MW, Trousdale RT, Berry DJ. Effect of postoperative mechanical axis alignment on the fifteen-year survival of modern, cemented total knee replacements. *J Bone Joint Surg Am.* 2010;92:2143–2149.