Clin Orthop Relat Res (2017) 475:4–8 / DOI 10.1007/s11999-016-5143-2

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

Published online: 10 November 2016

Editor's Spotlight/Take 5

Editor's Spotlight/Take 5: The Chitranjan S. Ranawat Award: No Difference in 2-year Functional Outcomes Using Kinematic versus Mechanical Alignment in TKA: A Randomized Controlled Clinical Trial

Seth S. Leopold MD

For many years, there had been little argument about how to align a TKA: Put the center of the knee under the center of the hip and over the center of the ankle. More recently, though, the concept of kinematic alignment has garnered more attention. Kinematic TKA alignment seeks to restore the "prearthritic" anatomy of a patient's knee, typically providing for a bit of residual tibial varus and femoral valgus compared to what surgeons used to mechanical-axis alignment might aim for. The rationale for this approach is that it may more-closely replicate the dynamic function of a normal knee, perhaps decreasing the need for soft-tissue releases; some work suggests kinematic TKA alignment may be associated with better scores for pain and function [2, 3].

This set of potential benefits may come at a cost. Many (though not all [3]) studies on kinematic alignment use patient-specific guides, which generally are more expensive. And leaving tibial components in varus (as is commonly done with kinematic alignment) may result in a higher risk of aseptic loosening over time.

An award-winning paper from this year's Knee Society Proceedings by Bill Farrington's group at North Shore Hospital in Auckland, New Zealand, took a careful look at kinematic and mechanical-axis alignment, comparing them in a well-designed randomized trial. In short summary, they found no differences in Oxford Knee Scores, WOMAC scores, or complications between these surgical approaches at 2 years. Given the costs and uncertainty associated with kinematic alignment, this work would seem to put the ball deeply into the court of those who wish to justify the use of that approach.

This paper is important even if one does not perform TKA, since it provides an aspirational standard for investigators who wish to answer important research questions in any discipline within orthopaedic surgery.

A note from the Editor-In-Chief: In "Editor's Spotlight," *one of our editors provides brief commentary on a paper we believe is especially important and worthy of general interest. Following the explanation of our choice, we present* "Take Five," *in which the editor goes behind the discovery with a one-on-one interview with an author of the article featured in* "Editor's Spotlight."

The author certifies that he, or any members of his immediate family, have no 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 comment refers to the article available at: doi:10.1007/s11999-016-4844-x.

S. S. Leopold MD (✉)
Clinical Orthopaedics and Related Research, 1600 Spruce Street, Philadelphia, PA 19013, USA
e-mail: sleopold@clinorthop.org

Editor's Spotlight/Take 5

The authors defined a clinically important difference (five points on the Oxford score), powered the study to detect this difference, and accounted for all of their patients. They reported a set of no-difference conclusions; doing so is critically important [4]. They present the no-difference findings with modesty and clarity, and ask fair questions about the risks associated with a technique they explored. This is exactly the kind of work that should inform our practices. Although this randomized trial is at odds with an earlier randomized study on the topic that favored kinematic alignment [1], Mr. Farrington's work provides plausible explanations for this difference and seems (at least to me) more generalizable than that earlier report [1].

It is fair to say that the book is far from closed on kinematic alignment. But this study gives knee surgeons a reason to think twice before adopting this bit of surgical novelty. Please join me as I go behind the discovery with Mr. Farrington, senior author of "The Chitranjan S. Ranawat Award: No Difference in 2-year Functional Outcomes Using Kinematic versus Mechanical Alignment in TKA: A Randomized Controlled Clinical Trial," about new technology, issues associated with discovering and reporting no-difference results, and what it takes to perform a well-controlled randomized trial.

Take Five Interview with Bill Farrington FRCS, FRACS, senior author of "The Chitranjan S. Ranawat Award: No Difference in 2-year Functional Outcomes Using Kinematic versus Mechanical Alignment in TKA: A Randomized Controlled Clinical Trial"

Seth S. Leopold MD: *Congratulations on publishing this well-designed and well-executed randomized trial, and also on your prestigious Knee Society award. Would you be willing to share your feelings about the two surgical approaches as they were prior to the start of this study, and how your feelings changed once you analyzed the results?*

Bill Farrington FRCS, FRACS: Thank you, Seth. It was a pleasant surprise and we feel greatly honored by the award. In 2011, my colleagues and I first heard about kinematic alignment (KA) and we were excited that this new technique might improve function for many of our patients undergoing TKA. Traditional teaching for TKA alignment is to place the components, and therefore joint line, perpendicular to the mechanical axis of the limb; that is, mechanical alignment (MA). We began using computer navigation about 7 years ago to improve our accuracy in achieving MA. However, our experience was similar to many others and to the many

Bill Farrington FRCS, FRACS

papers published on mechanical alignment, which didn't show an improvement in functional outcome compared to conventional instrumentation despite an improvement in accuracy. The technique of KA aims to position the components closer to how the knee was aligned prior to the onset of arthritis. In many patients, this places the femoral component in more valgus and the tibial component in more varus. This makes many TKAs easier to balance, as fewer soft-tissue releases are called for. So we started the study hoping to see an improvement in function with this KA compared to mechanical alignment. However, as we analyzed the results at the 6-, 12- and 24-month marks, we were surprised to find how close the short-term functional outcomes of the two techniques were to each other. We powered our study for a five-point

Editor's Spotlight/Take 5

difference in the Oxford Knee Score (OKS), which has been shown to be the minimum clinically important difference (MCID) when comparing two groups after TKA. Our results showed both groups were within one or two OKS points of each other all the way through, and so we did not demonstrate a difference between the two arms of the study.

Dr. Leopold: *Given the differences between your study and the earlier one that favored kinematic alignment, what do you consider the current state of the art for TKA alignment? Would you leave this to "surgeon's discretion" or would principles of evidence-based medicine rather say that until it is definitively shown to be beneficial it should be limited to prospective trials, and why do you think so?*

Mr. Farrington: KA in its current form shows short-term functional results comparable to MA, but KA's long-term survivorship is unknown. Outside of a research setting, I would suggest caution to surgeons who are considering changing their approach away from an MA to a KA technique until the long-term data are available. If either technique is performed well, the patient should have a similar chance of a good to excellent result in the first few years after surgery. There are likely to be many patients where the position of the implants would be similar (within a few degrees) whether they are put in with a mechanical or kinematic alignment philosophy. However, there would also be patients where the implant position will be considerably different depending on the technique chosen, and the long-term survivorship of TKA performed using KA is currently unknown. MA has been the technique of choice for many years around the world, and both the Australian and New Zealand Registries show a 94% survival at 15 years [1, 5]. It will be a tall order for KA to improve on this.

Dr. Leopold: *As you know, it is very difficult to complete a well-designed randomized trial; your experiences may help young investigators who wish to emulate your achievement. What challenges did you experience in the course of designing and executing this randomized trial, and how did you overcome them?*

Mr. Farrington: It's important to build a good team around you. These studies are time-consuming, often taking much longer to complete than one expects at the outset. They also require patience, resilience, considerable resources, and effort. However, in the long run, they are worth all the hard work as they are more robust, provide better evidence, and help advance the science of surgery. A well set-out randomized controlled trial improves with age like a good wine. Many colleagues may offer to help out initially for a short period of time or for only certain parts of the project. So it's important that one decides on a core group of investigators and that they remain engaged and involved with the project all the way through. The setup of a study is much like the foundation of a building. It is what gives it long-term strength. So take time to get it right when beginning and ask for assistance from others in your institution/department. We also divided up certain tasks that helped to focus what was expected of us and what needed to be done. The Ethics approval, pilot study, and setup of the processes took much longer than I envisioned, requiring considerable patience. Coffees, cakes, and "thank you's" go a long way to smooth the process! We were fortunate enough to employ a research coordinator who helped collate all aspects of the study. This role also helped develop an "institutional memory" of how to navigate through the various processes and why we made certain decisions. This assisted when we came to analyze and write up the study as well as helping with subsequent studies. We found advice was given freely from so many people and proved invaluable, so let other people know what you are doing.

Editor's Spotlight/Take 5

Dr. Leopold: *Many new approaches are introduced into arthroplasty, and into orthopaedic surgery more generally, but so few are examined as thoroughly as you evaluated kinematic alignment. What would it take to close the gap between the introduction of new, and often expensive, technologies and the demonstration of efficacy across our specialty?*

Mr. Farrington: Enthusiasm for new techniques in arthroplasty often outpaces the evidence, and as you say, it is hard to rigorously evaluate them in a timely fashion before they roll out for general use. Usually just changing a surgical technique, but using the same implants or technology in surgery, does not provide a large advantage. Examples of this would be mini-incision surgery in arthroplasty, which has conferred little benefit to patients, and in some cases has resulted in potentially avoidable complications. Our study is another example of this, where altering the position of the components has not conferred short-term functional benefit and could potentially compromise long-term survival. Most studies on techniques alone do not have as much funding associated with them, and so studies set up to evaluate them may not be as thorough or extensive. The age of big data is here, and it would be good to see more global collaboration and communication on these types of studies. Cloud-based technology may well assist building bigger multi-center studies that are easier to do which would overcome the problem of slow recruiting with low numbers at single centers.

We believe the more radical the change with a new surgical technique or technology, the greater the potential for altering patients' outcomes in a positive or negative way. Such changes require more rigorous study, in particular randomized controlled trials.

Dr. Leopold: *Where is your group going from here? What topics are you exploring, and how are you exploring them?*

Mr. Farrington: We will continue to follow these patients clinically and radiographically, and 5-year analysis of this cohort is beginning now. We believe longer term-followup is essential to understand the effects of KA on implant durability. We are also combining data with other centers that have performed KA, in the hope of gaining further information on the effect of alignment on outcome using subgroup analysis. We are also investigating the use of robotic surgery, as we feel there is still so much human variation (error) in surgery—both in what we do and what we observe.

Safety, accurate data analysis, and consumer satisfaction are important areas in many industries at present. Healthcare as a whole is lagging behind in these important domains. One sector that has been leading the way is the airline industry. There are many analogies to this industry that we as surgeons can learn from. An obvious example is the widespread impact of the surgical safety checklist. Computers and robotics have proved invaluable in commercial planes and my colleagues and I see a lot of value in bringing this type of new technology into the operating theatre. We are looking at a number of projects where we can try to eliminate as much human bias and error and gain extremely accurate, reliable data.

References

1. Australian Orthopaedic Association. National joint replacement registry. Hip, knee & shoulder arthroplasty. Annual report 2016. Available at: https://aoanjrr.sahmri.com/documents/10180/275066/Hip%2C%20Knee%20%26%20Shoulder%20Arthroplasty. Accessed October 19, 2016.
2. Dossett HG, Estrada NA, Swartz GJ, LeFevre GW, Kwasman BG. A randomised controlled trial of kinematically and mechanically aligned total knee replacements: Two-year clinical results. *Bone Joint J*. 2014;96:907–913.
3. Howell SM, Papadopoulos S, Kuznik KT, Hull ML. Accurate alignment and high function after kinematically aligned TKA

Editor's Spotlight/Take 5

performed with generic instruments. *Knee Surg Sports Traumatol Arthrosc*. 2013;21:2271–2280.
4. Leopold SS. Editorial: No-difference studies make a big difference. *Clin Orthop Relat Res*. 20156;473:3329–3331.
5. New Zealand Orthopaedic Association. The New Zealand joint registry sixteen year report. January 1999 to December 2014. Available at: http://nzoa.org.nz/system/files/Web_DH7657_NZJR2014Report_v4_12Nov15.pdf. Accessed October 19, 2016.