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Editor's Spotlight/Take 5

Editor's Spotlight/Take 5: No Benefit After THA Performed With Computer-assisted Cup Placement: 10-year Results of a Randomized Controlled Study

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Orthopaedic surgery is arguably the most successful specialty in the 20th century in terms of the amount of suffering it has relieved. The claim becomes even more legitimate if we focus on the second half of the 20th century. Total joint replacement, more-modern approaches to skeletal trauma (particularly intramedullary nailing of long-bone fractures), and arthroscopic surgery all transformed not just their respective sub-subspecialties, but the lives of hundreds of millions of patients with common and disabling problems.

It seems, though, that the last 30 years have been less transformative. Companies introduced "me-too" implants that showed only substantial equivalence to less-expensive devices, rather than superiority [8]. Surgeons deployed procedures before reasonable standards of efficacy were met [2, 9]. Physicians injected millions of patients with products that demonstrated little benefit in rigorous trials [3, 6]. All of these interventions exposed patients to risks and increased costs to healthcare systems. The fact that we need concepts like the minimum clinically important difference and the minimum detectable change to characterize our treatment outcomes are poignant signs of how little we sometimes require of novel interventions, which expose patients to risk and healthcare systems to cost.

The intellectually rigorous orthopaedic surgeon must remain agnostic on the subject of computer-assisted surgery, based on the data we now have. Numerous short-term followup studies suggest navigation can improve surgical accuracy [7, 10], though not all do [5]. Improved alignment in knee arthroplasty might improve implant longevity; improved alignment in hip arthroplasty might reduce the likelihood of dislocation. Both are laudable goals, but they are as-yet unproven [1, 4] despite widespread usage and considerable expense. Prior to this month's issue of *Clinical Orthopaedics and*

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."

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Related Research® we have had no robust, long-term studies comparing computer-navigated arthroplasty to freehand surgical techniques. We therefore are proud to share a 10-year followup from a randomized trial performed by Professor Jean-Noel A. Argenson's group in Marseille, France, which found no advantage to computer-assisted acetabular component placement compared to standard surgical techniques.

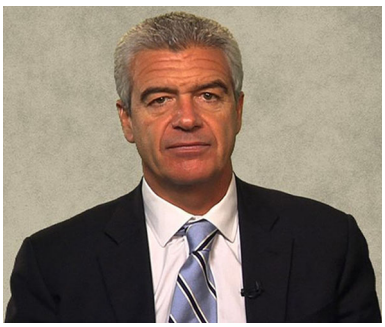
This study is special because it does so much more than merely compare implant alignment. It focuses on the outcomes that matter to patients—hip scores, implant wear, and reconstructive survivorship. Surgeons do not treat radiographs, they treat other human beings. Our studies need to reflect this, particularly before we incorporate expensive new approaches into practice. This study sets an aspirational standard for other studies of new technologies by asking the right questions, by assessing outcomes at long-term followup, and by accounting for all the patients it enrolled. It probably does not close the door on computer navigation, but it certainly puts the ball deep in the court of navigation's proponents; they now need to demonstrate both accuracy and clinical relevance.

Join me in the Take-5 interview that follows with Professor Argenson, as we discuss the standards that ought to apply to new technologies before they see widespread use in practice.

Take Five Interview with Jean-Noel A. Argenson MD, PhD, Senior Author of "No Benefit After THA Performed With Computer-assisted Cup Placement: 10-year Results of a Randomized Controlled Study"

Seth S. Leopold MD: *It seems as though everything today is improved by the use of computers; why do you think it has been so hard to develop computer-navigation systems that offer clear advantages to surgeons and patients?*

Jean-Noel A. Argenson MD, PhD: My partners and I are convinced that computer technology may indeed improve our ability to perform THA. The kinds of technology already in use (or that are on the near-term horizon) include templating software for precise preoperative planning, the creation of patient-specific guides or implants for the surgery itself, and navigation tools to guide the surgeon or the robot to better position the components. However, computer-navigation now faces several issues limiting its applicability, including little if any reduction in the frequency of complications (as we showed here), high costs and difficulty in incorporating evolutionary improvements over time without substantial



Jean-Noel A. Argenson MD, PhD

increases in those costs, adequate strategies for sharing the development costs between payers and implant manufacturers, and increased surgical time. In addition, while there is no doubt the information provided by the computer is precise, the problem is that it relies directly on the information given to the computer during the registration process, which is a source of inconsistency. Finally, we must recognize that there is considerable uncertainty about what our actual target alignment(s) should be, since it appears they may vary from patient to patient.

Dr. Leopold: *What standards should surgeons apply before adopting potentially helpful but expensive technologies in practice?*

Dr. Argenson: There are three main standards: (1) Safety for our patients, (2) reproducibility from one surgeon to

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another, and (3) immediate- and long-term benefits of the intervention. This last point is the difficult one, since there is no reason to wait for long-term proof if we are convinced of the benefit. At the same time, we need to recognize that we can sometimes be mistaken. For example, this study found little benefit from the use of this rather expensive technology in terms of the kinds of outcomes that patients care about—such as hip scores or dislocation—but we needed 10 years to learn this with any certainty. In addition the pricing issue must be considered: Can we balance the cost of the technology against the costs of the complications it seeks to help minimize, along with the likelihood that the technology might indeed reduce or avoid this complication?

Dr. Leopold: *Obviously, new techniques continue to be developed, and perhaps proponents of those techniques will say that your study tested "2005 technology" when it comes to navigated hip surgery. How generalizable are your findings to the computer-assisted techniques that are available today?*

Dr. Argenson: This is indeed a good point, which we consider in every discussion we have with our patients before scheduling total hip or knee arthroplasty. When we talk about the future longevity of the procedure, we can only refer to published studies with long-term followup referring to implants or techniques we were using 10 or 15 years ago. This does not take into consideration the progress made during the elapsed time, which can include for computer assisted techniques: Better registration processes, reduced sizes of rigid bodies, and better fixation of cutting guides incorporating the navigated devices.

Dr. Leopold: *One complication that navigation seeks to help hip arthroplasty surgeons avoid is dislocation. Obviously a study with 60 patients in each arm will not be sufficiently large enough to detect differences in uncommon complications like dislocation. By contrast, sufficiently large randomized trials following patients for suitably long periods are impractical. How might this question be answered? Stated otherwise, is it the job of navigation advocates to prove the efficacy of an expensive technique, or should surgeons adopt it in the hopes of avoiding a potentially devastating complication?*

Dr. Argenson: Although THA has been among the most important surgical procedures developed during the last 50 years, every attempt needs to be made to reduce complications. Dislocation is a devastating complication, and the steps we can take to reduce its frequency include positioning the components as accurately as we can, selecting surgical approaches that spare or reconstruct the soft tissues involved in the stability of the hip, and choosing the diameter of femoral head that best balances the competing imperatives of joint motion and wear. If a new technology may help one or several of these aspects, it is our role to investigate such technology and bring it into surgical practice.

Dr. Leopold: *One element of your study's design might have confused some readers; you describe a randomization process that allocated patients into the treatment (computer-assisted) arm of your study, and then a process of case-matching of the control patients. Typically, randomization would allocate patients to both arms (treatment and control) of a study. Can you explain a bit more about how your design worked, and why you chose it?*

Dr. Argenson: Yes, this is correct, and we can see how this might surprise some readers. We designed the protocol to facilitate patient inclusion and shorten the inclusion period. The IRB and the statisticians accepted this design, and we believe it is robust.

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