Letter to the editor: how large a study is needed to detect TKA revision rate reductions attributable to robotic or navigated technologies? A simulation-based power analysis

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Letter to the Editor

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Letter to the Editor: How Large a Study is Needed to Detect TKA Revision Rate Reductions Attributable to Robotic or Navigated Technologies? A Simulation-based Power Analysis

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To the Editor,

We read the study, "How Large a Study is Needed to Detect TKA Revision Rate Reductions Attributable to Robotic or Navigated Technologies? A Simulation-based Power Analysis" by Hickey et al. [1] with great interest. Their main conclusion was that it would take an impractically large number of patients (and a very long time) to answer the question of whether robotic or navigated TKA approaches are advantageous, which suggests that any advantage of those technologies in terms of reducing revision risk is likely to be quite small, if it is present at all. The situation described by the authors is a common problem for most prosthetic joint replacement studies using revision as an endpoint. We see this in studies on new arthroplasty designs, fixation methods, and surgical techniques [3].

One of the major causes of revision arthroplasty is aseptic loosening, as pointed out by Hickey et al. [1]. It may take 10 years or more before loosening causes symptoms, becomes visible on conventional radiographs, or potentially leads to revision surgery. However, radiostereometric analysis (RSA) makes it possible to detect implant loosening early postoperatively (6 months to 12 months), which is why it's been used for more than 40 years [5, 7]. Indeed, RSA allows in vivo three-dimensional measurement of implant migration relative to the bone with an accuracy of 0.2 mm for translations and 0.5° for rotations [2]. Therefore, the sample size and follow-up time can be greatly reduced. Only a relatively small number of patients followed for a relatively short period of time (2 years) is required to produce similar results as long-term studies (10 years or more) with thousands of patients [5, 8]. For instance, knowing what we know today, it would have been possible to detect Boneloc (Biomet Inc) bone cement as a potential disaster at 6-month follow-up using RSA [5].

To our knowledge, two randomized controlled trials (RCTs) [4, 9] on computer-assisted surgery (CAS) in TKA used RSA to measure tibial baseplate migration. van Strien et al. [9] and Petursson et al. [4] studied the effect on tibial baseplate migration 2 years after surgery randomizing 57 and 54 patients, respectively. They found no clinically relevant differences in tibial migration. The authors of both studies did not expect to find a difference between groups in the long term. A meta-analysis by Rhee et al. [6] using nine RCTs with long-term follow-up confirmed this assumption by finding no differences in functional outcomes and survivorship between CAS and conventional TKA [6]. The findings of these RSA-based studies [4, 9] are supportive of the main findings of Hickey et al. [1] in that they suggest there is likely to be little, if any, clinical benefit from robotic surgery in terms of the clinically important endpoint of tibial revision.

Work in an RSA setting can provide answers like the above without the substantial delay associated with large, long-term randomized trials, which

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would be expensive and impractical to conduct. Based on this, we believe RSA can and should play an important role in the evaluation and phased introduction of new implants, fixation approaches, and surgical techniques.

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