The Reverse Fragility Index: Interpreting the Current Literature for Long-Term Survivorship of Computer-Navigated versus Conventional Total Knee Arthroplasty A Systematic Review and Cross-Sectional Study of Randomized Controlled Trials

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INTRODUCTION: Despite multiple randomized controlled trials (RCTs) reporting no advantage in the survivorship of computer-navigated over conventional total knee arthroplasty (TKA), its use is increasing. We utilized the concept of reverse fragility index (RFI) to assess the strength of neutrality of RCTs evaluating the long-term survivorship of computer-navigated and conventional TKA.

METHODS: A systematic review was performed including all RCTs through August 23, 2021 investigating the long-term outcomes of computer-navigated versus conventional TKA. Randomized trials with mean follow-up of >8 years and survivorship with end points of revision were included. The RFI quantifies a study's strength of neutrality by calculating the minimum number of events necessary to flip the result from non-significant to statistically significant. The RFI at a threshold of P < 0.05 was calculated for each study reporting non-significant results. The reverse fragility quotient (RFQ) was calculated by dividing the RFI by the study sample size.

RESULTS: There were 10 clinical trials, 2518 patients, and 38 all-cause revisions analyzed. All 10 studies reported non-significant results. The median RFI at the P < 0.05 threshold was 4, meaning that a median of 4 events was needed to change the results from non-significant to significant. The median RFQ was 0.029, indicating that the non-significance of the results was contingent on only 2.9 events per 100 participants. The median loss to follow-up was 27 patients. In all studies, the number of patients lost to follow up was greater than their respective RFI.

DISCUSSION AND CONCLUSION: The equipoise in long-term survivorship of computer-navigated and conventional TKA rests on fragile studies astheir statistical non-significance can be reversed by changing the outcome status on only a handful of patients—a number that was always smaller than those lost to follow up. Routine reporting of RFI in trials with statistically non-significant findings may provide readers with a measure of confidence in the neutrality of results.