Newer versus Older Implant Systems from a Single Manufacturer and Cause-Specific Revision Risk following Primary Total Knee Arthroplasty

Matthew Patrick Kelly[1], Heather Ann Prentice[2], Dhiren S Sheth, Nithin C Reddy, Monti Khatod[2], Liz Paxton[2]
[1]SCPMG, [2]Kaiser Permanente

INTRODUCTION: New implant systems have design modifications that seek to improve total knee arthroplasty (TKA) function, usability, and survivorship. Post-market studies on these constructs help to determine if these goals were achieved, and that no issues were inadvertently introduced. We evaluated revision risk for a newer generation implant system compared to its predecessor from the same manufacturer.

METHODS: We used data from a US-based total joint replacement registry to conduct a cohort study. Patients aged ≥18 years who underwent primary fully cemented TKA for osteoarthritis between 2009-2021 were included. The study sample was restricted to TKA where implant systems from a single manufacturer were used. Only two implant systems from the manufacturer were included in the study cohort: the newer generation (n=19,241) and the older generation (n=36,591) implant system. Multivariable Cox regression was used to evaluate risk for cause-specific aseptic revision including loosening, wear, instability, fracture, arthrofibrosis, and other revision reasons. All models included age, sex, body mass index, race/ethnicity, ASA classification, bilateral procedure, cement viscosity, implant stability, and average annual surgeon volume as covariates. Hazard ratios (HR) and 95% confidence intervals (CI) are presented. $p<0.05$ was considered statistically significant. Results were stratified by time when the proportional hazards assumption was not met.

RESULTS:
In adjusted analysis, the newer generation implant system had a higher risk of revision for loosening compared to the older generation after 4-years follow up (HR=3.99, 95% CI=2.38-6.69, p<0.001), no difference was found in revision risk within the first 4-years of follow up (HR=0.99, 95% CI=0.65-1.52, p=0.965) (Figure 1). No other differences in cause-specific revision risk were observed: wear (HR=1.58, 95% CI=0.62-4.02, p=0.341), instability (HR=1.04, 95% CI=0.68-1.57, p=0.868), fracture (HR=0.66, 95% CI=0.30-1.45, p=0.305), arthrofibrosis (HR=0.66, 95% CI=0.40-1.10, p=0.112), other reasons (HR=0.97, 95% CI=0.61-1.55, p=0.903).
When considering different iterations of the tibial trays for the newer implant system, the higher risk of revision for loosening was observed for the first iteration (HR=2.00, 95% CI=1.37-2.90, p<0.001). No difference was observed for the second iteration when compared to the older generation implant system though the direction of the association was toward a lower risk (HR=0.38, 95% CI=0.13-1.08, p=0.070). There were too few events with the third iteration for comparison in regression analysis (Figure 2).
DISCUSSION AND CONCLUSION: In a large US-based cohort, we found no advantage in implant survivorship with a new design compared to the preceding design from the same manufacturer. The higher risk of aseptic loosening may have been limited to the original first iteration of the newer generation tibial tray, longer follow up for the subsequent trays is needed to ensure aseptic loosening is no longer observed.

Figure 1.

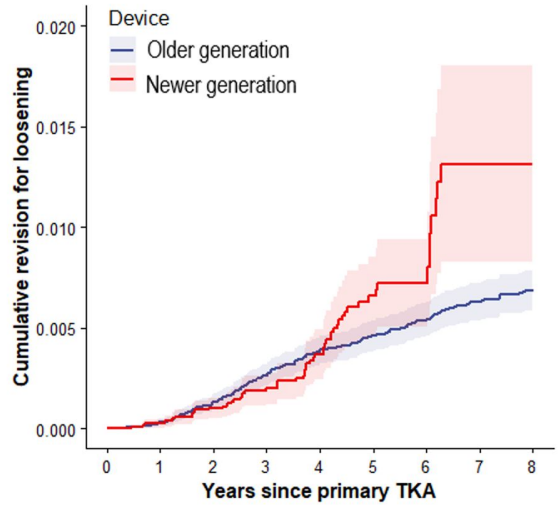

Figure 2.