# Higher Aseptic Revision Risk following Primary Total Knee Arthroplasty for a Newer Generation Implant System Compared to its Predecessor from the Same Manufacturer

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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=47,869) and the older generation (n=39,474) 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:
In adjusted analysis, the newer generation implant system had a higher risk of revision for loosening compared to the older generation (HR=1.51, 95% CI=1.10-2.06, p=0.011), as well as a higher risk for instability (HR=1.43, 95% CI=1.15-1.79, p=0.001). No other differences in cause-specific revision risk were observed: wear (HR=1.20, 95% CI=0.65-2.22, p=0.564), fracture (HR=0.89, 95% CI=0.44-1.81, p=0.740), arthrofibrosis (HR=1.01, 95% CI=0.69-1.49, p=0.946), other reasons (HR=1.06, 95% CI=0.74-1.53, p=0.751).
When stratifying by implant constraint, the higher risk of aseptic revision (HR=1.25, 95% CI=1.03-1.51, p=0.024), loosening (HR=1.44, 95% CI=1.01-2.07, p=0.046), and instability (HR=1.33, 95% CI=1.05-1.70, p=0.020) was still observed for newer compared to older generation posteriorly stabilized (PS) implants.
For minimally stabilized implants, only a higher risk for instability (HR=2.00, 95% CI=1.13-3.52, p=0.017) was observed for newer generation cruciate retaining (CR) compared to older generation CR, while higher risks for aseptic revision (HR=1.58, 95% CI=1.09-2.28, p=0.015) and instability (HR=2.17, 95% CI=1.15-4.09, p=0.016) were observed for newer generation ultra-congruent (UC) versus older generation CR implants.
DISCUSSION AND CONCLUSION: In a large US-based cohort, we found a higher risk for aseptic revision, loosening, and instability for a new TKA implant design compared to a preceding design from the same manufacturer. When restricted to PS implants, the same associations were observed. When restricted to minimally stabilized implants, newer generation CR and UC had a higher instability revision risk compared to older generation CR.