Midterm Survivorship of Primary Total Knee Arthroplasty with a Specific Recalled Implant: High Rate of Aseptic Failure

Elizabeth Gausden, Simarjeet Puri, Yu-Fen Chiu[1], Mark P Figgie[2], Thomas P Sculco[1], Geoffrey H Westrich[1], Peter Keyes Sculco, Brian Chalmers[1]
[1]Hospital for Special Surgery, [2]Hosp for Special Surgery

INTRODUCTION:
A specific primary total knee arthroplasty (TKA) implant utilized at our institution was recently recalled for a noted higher incidence of early wear, osteolysis, and loosening. However, the true incidence of this failure mode is unknown. As such, we aimed to analyze the midterm survivorship following primary TKA with this specific implant and identify the most common revision indications.

METHODS:
A cohort of 7,941 primary TKAs utilizing this specific implant performed from 2010-2018 was identified. We retrospectively reviewed 369 of these cases that subsequently underwent revision TKA from 2010-2021. Kaplan-Meier analysis was used to determine survivorship. Cox regression analysis was used to examine the impact of patient variables and year of implantation on revision-free survival.

RESULTS:
The estimated survivorship free of all-cause revision was 98%, 95%, and 86% at 2, 5, and 10 years, respectively. In 209/369 revisions there was a consistent constellation of findings with varying severity, including earlier than expected polyethylene-wear, synovitis, osteolysis, and gross femoral component loosening (Fig 1). This failure mode was the most common revision indication. The mean time from primary TKA to revision for aseptic mechanical failure was 5 years (range, 5 months – 11 years). TKAs done from 2013 through 2018 had increased hazard of revision for aseptic mechanical failure compared to those implanted in 2010 ($p<0.01$) (Table 1).

DISCUSSION AND CONCLUSION: In this series of nearly 8,000 primary TKAs performed with a specific now recalled implant, we identified a lower-than-expected midterm survivorship and higher-than-expected rate of aseptic failure with a consistent presentation of earlier than expected polyethylene wear, synovitis, significant osteolysis, and gross femoral component loosening. Further monitoring of unrevised patients with this implant is required.

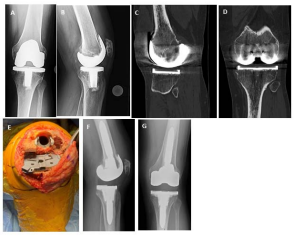

Figure 1: A 68-year-old presents with pain 11 years after primary TKA. Radiographs (A,B) and computed tomography scans (C, D) show a loose femoral component, synovitis, and bulky osteolysis. Intraoperatively (E), cement debonding of the femoral component was also observed. A semiconstrained (F,G) implant with cones and cemented stems was utilized.

Variables	Hazard Ratio	95%CI		P-value
AgeAtSurgery (every 10yr)	0.6	0.5	0.7	<.0001
Sex Male vs Female	1.8	1.4	2.4	<.0001
CCI 1-2 vs 0	1.8	0.9	3.8	0.112
CCI 3+ vs 0	1.9	0.8	4.4	0.155
Year 2011 v 2010	1.2	0.7	2.0	0.460
Year 2012 v 2010	1.6	0.9	2.8	0.086
Year 2013 v 2010	2.1	1.2	3.8	0.014
Year 2014 v 2010	4.0	2.2	7.4	<.0001
Year 2015 v 2010	7.1	3.9	13.0	<.0001
Year 2016 v 2010	5.0	2.5	10.0	<.0001
Year 2017 v 2010	7.3	3.5	15.2	<.0001
Year 2018 v 2010	8.7	3.3	23.1	<.0001