

Monoblock all-polyethylene tibial components have a lower risk of early revision than metal-backed modular components

A registry study of 27,657 primary total knee arthroplasties

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Background and purpose With younger patients seeking reconstructions and the activity-based demands placed on the arthroplasty construct, consideration of the role that implant characteristics play in arthroplasty longevity is warranted. We therefore evaluated the risk of early revision for a monoblock all-polyethylene tibial component compared to a metal-backed modular tibial construct with the same articular geometry in a sample of total knee arthroplasties (TKAs). We evaluated risk of revision in younger patients (< 65 years old) and in older patients (≥ 65 years old).

Method Fixed primary TKAs with implants from a single manufacturer, performed between April 2001 and December 2010, were analyzed retrospectively. Patient characteristics, surgeon, hospital, procedure, and implant characteristics were compared according to tibial component type (monoblock all-polyethylene vs. metal-backed modular). All-cause revisions and aseptic revisions were evaluated. We used descriptive statistics and Cox regression models.

Results 27,657 TKAs were identified, 2,306 (8%) with monoblock and 25,351 (92%) with modular components. In adjusted models, the risk of early all-cause revision (hazard ratio (HR) = 0.5, 95% confidence interval (CI): 0.3–0.8) and aseptic revision (HR = 0.6, CI: 0.3–1.2) was lower for the monoblock cohort than for the modular cohort. In older patients, the early risk of all-cause revision was 0.6 (CI: 0.4–1.0) for the monoblock cohort compared to the modular cohort. In younger patients, the adjusted risk of all-cause revision (HR = 0.3, CI: 0.1–0.7) and of aseptic revision (HR = 0.3, CI: 0.1–0.7) were lower for the monoblock cohort than for the modular cohort.

Interpretation Overall, monoblock tibial constructs had a 49% lower early risk of all-cause revision and a 41% lower risk of aseptic revision than modular constructs. In younger patients with monoblock components, the early risk of revision for any cause was even lower.

Early total knee arthroplasty (TKA) designs used all-polyethylene tibial components with good success rates (Rodriguez et al. 2001, Vessely et al. 2006, Nouta et al. 2012a). With metallurgical enhancements and polyethylene modifications, metal-backed tibial modularity was introduced onto the market. This enabled decisions regarding soft tissue tensioning to be made even after cementation of the final components. The added benefits of implant inventory reduction and improved polyethylene shelf-life, especially for rarely used sizes, further increased the universal adoption of tibial component modularity. However, micromotion of the modular junction between the polyethylene liner and the tibial base plate created a second interface for polyethylene wear debris production. A few studies have evaluated the role of micromotion and backside wear in the eventual development of osteolysis, and these have indicated that it increases the risk of revision (Wasielowski et al. 1997, Parks et al. 1998).

Clinically, the use of metal-backed TKAs has a high success rate at long-term follow-up (Manley et al. 2008, Bae et al. 2012, Nouta et al. 2012b), but backside wear continues to be an issue that limits implant longevity. In contrast, as demonstrated by radiostereometric analysis (RSA) techniques, the monoblock all-polyethylene tibial component has less component migration and better tibial fixation than fixed, metal-backed designs (Norgren et al. 2004, Hyldahl et al. 2005, Nouta et al. 2012b). This would theoretically decrease or eliminate backside wear and the possibility of eventual revision. Despite this factor and its economic value, the all-polyethylene tibial component has not been widely adopted.

Given the current demographic trends of younger patients seeking reconstructions and the activity-based demands placed on the arthroplasty construct (Kurtz et al. 2009), consideration of the role that implant characteristics play in arthroplasty longevity is warranted. Using a community-based sample of pri-

mary TKAs, we compared the early risk of revision (all-cause and aseptic) of a monoblock all-polyethylene tibial component with that for a metal-backed modular tibial construct of the same articular geometry and from the same manufacturer, while adjusting for potential confounders.

Methods

Study design, inclusion criteria, and data collection

We conducted a retrospective analysis of a prospectively followed cohort of primary TKA patients using data from a community-based Total Joint Replacement Registry (TJRR). Patients with any diagnosis who underwent a primary fixed-bearing TKA from a single implant manufacturer (Depuy) were included in the sample. Cases were registered between April 1, 2001 and December 30, 2010. Data collection, participation, and coverage of the TJRR used to identify the cases and data have been published elsewhere (Paxton et al. 2008, 2010a b, 2012). Briefly, the TJRR uses a hybrid data collection process (paper and electronic) to capture patient characteristics together with implant and surgical information, and also validated algorithms to capture the outcomes of interest. Intraoperative information is collected by the surgeon at the time of the procedure. The TJRR sample included in the study covers 40 medical centers and 233 surgeons in 6 geographical regions of the USA (Southern and Northern California, Colorado, Hawaii, Northwest, and Mid-Atlantic). The voluntary participation of the registry in 2010 was 95% (Paxton et al. 2012).

Exposure of interest

Implants were classified into metal-backed modular components or monoblock all-polyethylene tibial components using their catalog numbers and descriptions. Metal-backed components included Depuy's Press-Fit Condylar (PFC) and Sigma designs. The monoblock all-polyethylene design investigated was Depuy's PFC*Sigma. In these implants, the surface geometry of the tibial liner includes concave portions to accept the femoral bearing surface, which are neither flat nor completely conforming. The surface geometries are identical in the all-polyethylene versions and the modular versions. All implants used during the TKA procedure are recorded using the implant stickers that accompany each implant package. These data are entered manually into the TJRR, and quarterly quality control is conducted to check for data-entry errors and inconsistencies.

Outcome of interest

The endpoint was all-cause revision and aseptic revision. Revision was defined as any operation after the index TKA where a component was replaced. Aseptic revisions were revisions performed for any reason other than infection-related causes. Reasons for revision were recorded by the surgeons

in the operative forms of the TJRR and confirmed with chart review by a trained clinical research associate.

Covariates

Several covariates were investigated as possible confounders or effect modifiers of the association of tibial component design and the outcomes of interest. Covariates investigated included: patient characteristics (age, race, gender, BMI, diabetes status), primary TKA diagnosis (osteoarthritis, osteonecrosis, posttraumatic arthritis, or rheumatoid arthritis), ASA health status score, surgeons' total joint arthroplasty fellowship training status, surgeon and hospital average annual volume, implant stability (cruciate retaining vs. posterior stabilized), implant fixation (cemented, hybrid, or uncemented), patellar resurfacing, operative time, and whether or not the procedure was bilateral.

Statistics

Frequencies, proportions, means, standard deviations (SDs), medians and interquartile ranges (IQRs) were used to describe the study sample. Comparisons between metal-backed modular and monoblock all-polyethylene tibial components used chi-square tests for categorical variables and Student t-tests for continuous variables. Crude revision rates and revision rate per 100 years of observation were calculated for all-cause revision and aseptic revision. Cox proportional hazard models for multivariable survival data (adjusted for surgeon clustering using a sandwich covariance matrix estimator) were used to assess hazard ratios (HRs) and 95% confidence intervals (CIs) for the type of tibial component and risk of all-cause and aseptic revision. Proportional hazard assumptions were evaluated using graphs of survival function against survival time. A model for the entire cohort was developed, as well as models for a younger age group (< 65 years old) and an older one (\geq 65 years old). Covariates were explored as confounders of the association of tibial component and risk of failure. Variables not confounding the association between tibial component type and risk of revision (changed estimates by > 20%) were not included in the final models. The final models were adjusted for age and sex. To account for missing values of some variables, multiple imputations were performed to create 10 versions of the analytic data set and we then used Rubin's combining rules to calculate the final parameter estimates and CIs from the 10 output sets (Rubin 1987). The imputation model used included all covariates, event indicator, and Nelson-Aalen estimator of the cumulative baseline hazard at the time of event or censoring for each case (Moons et al. 2006, White and Royston 2009). The data were analyzed using SAS software version 9.2 and $\alpha = 0.05$ was used as the threshold for statistical significance.

Ethics

Internal Review Board (IRB # 5488) approval was obtained before the study was started.

Table 1. Study sample characteristics by component modularity, 2001–2010

	Total sample		Metal-backed modular		Monoblock all-polyethylene		p-value
	n	(%)	n	(%)	n	(%)	
No.	27,657	100	25,351	91.7	2,306	8.3	
Mean age, years	68.4	9.1	68.1	9.1	71.8	9.0	< 0.001
Age category, years							
< 65	9,215	33.3	8,737	34.8	478	20.7	< 0.001
≥ 65	18,439	66.7	16,611	65.5	1,828	79.3	
Sex							
Female	17,614	63.7	16,170	63.8	1,444	62.6	0.3
Male	10,042	36.3	9,180	36.2	862	37.4	
Race							
White	17,393	62.9	15,716	62.0	1,677	72.7	< 0.001
Hispanic	4,516	16.3	4,206	16.6	310	13.4	
Black	2,154	7.8	2,087	8.2	67	2.9	
Asian	1,407	5.1	1,314	5.2	93	4.0	
Other/Multi	541	2.0	510	2.0	31	1.3	
Unknown	1,646	6.0	1,518	6.0	128	5.6	
Diabetes	7,658	27.7	7,017	27.7	641	27.8	0.9
Mean BMI (mean, SD)	31.4	6.2	31.6	6.3	30.1	5.4	< 0.001
Unknown	515	1.9	463	1.8	52	2.3	
ASA score							
1 & 2	15,861	57.4	14,493	57.2	1,368	59.3	0.003
≥ 3	11,224	40.6	10,314	40.7	910	39.5	
Unknown	572	2.1	544	2.2	28	1.2	
Osteoarthritis	26,880	97.2	24,630	97.2	2,250	97.6	0.2
Osteonecrosis	137	0.5	123	0.5	14	0.6	0.4
Posttraumatic arthritis	250	0.9	237	0.9	13	0.6	0.07
Rheumatoid arthritis	579	2.1	530	2.1	49	2.1	0.91

^a Missing data: age (n = 3, 0.1%), sex (n = 1, 0.0%).

Results

27,657 fixed primary TKAs were included in the study sample. The cohort had a higher percentage of women (63.7%), and the mean age was 68.4 (SD 9.1) years. The majority of patients had a diagnosis of osteoarthritis (97.2%) and were white (62.9%). Of the total, 2,306 (8.3%) had monoblock all-polyethylene tibial components and 25,351 (91.7%) had metal-backed modular components. No monoblock pre-molded composite tibial components were registered. During the study period, 5.4% (n = 1,501) of the cohort died and 8.2% (n = 2,264) were followed for a median time of 1.8 (IQR: 0.8–3.3) years before leaving the health plan and being categorized as lost to follow-up. Patients who were lost to follow-up were younger than those in the cohort (10% were < 55 years of age as compared to 6% of those who remained in the study cohort) but no difference in sex distribution was observed. 12% (n = 272) of the 2,306 monoblock all-polyethylene tibial components and 8% (n = 1,992) of the 25,351 metal-backed modular components were implanted in patients who were lost to follow-up.

The cohort of patients who received monoblock all-polyethylene tibial components had a higher mean age (71.8 vs. 68.1 years, $p < 0.001$), had a higher proportion of whites (72.7% vs. 62%, $p < 0.001$), had lower mean BMI (30.1 vs. 31.6, $p < 0.001$), and had a slightly different distribution of ASA

scores in comparison to the cohort of patients with metal-backed modular tibial components (Table 1).

There was a difference in the proportion of cases operated by surgeons with fellowship training (37.5% in the monoblock all-polyethylene cohort and 42.5% in the metal-backed modular cohort; $p < 0.001$). A higher proportion of monoblock all-polyethylene components were used by surgeons with high annual volumes (70.4% vs. 60.6%, $p < 0.001$). All arthroplasties using a monoblock all-polyethylene component were performed in hospitals with high annual volumes (100% vs. 84.6%, $p < 0.001$). A higher proportion of monoblock all-polyethylene components than metal-backed modular components were posterior stabilized constructs (77.8% vs. 64.8%, $p < 0.001$). In addition, a higher proportion of metal-backed cases than monoblock cases were performed without a patellar resurface (2.4% vs. 1.2%, $p < 0.001$). Cases with monoblock all-polyethylene tibial components had a shorter operative time than those

with metal-back modular components (87.4 vs. 92.7 min, $p < 0.001$) (Table 2).

The crude all-cause revision rate for the overall cohort was 2.07%. The cohort was followed for a median time of 2.9 (IQR: 1.2–5.1) years. The rate was lower for monoblock all-polyethylene components than for metal-backed modular components (0.95% vs. 2.17%, $p < 0.001$). The incidence rate of revision per 100 years of observation for all-cause revision of the monoblock all-polyethylene components was 0.30, and for the metal-backed modular components it was 0.65. For aseptic revisions, this incidence rate was also lower for the monoblock all-polyethylene cohort (0.18 vs. 0.35) (Table 3).

After adjusting for age and sex (no other variables were found to be confounders), in the all-cause revision models, the early risk of revision associated with using a monoblock all-polyethylene tibial component was 0.51 (CI: 0.33–0.78) times the risk of revision with a metal-backed modular component. In the age-specific analysis, in younger patients (< 65 years old), the all-cause risk of revision for a monoblock all-polyethylene component was 0.26 (CI: 0.10–0.72) times lower than that for a metal-backed modular component. In the older group (≥ 65 years old), the risk of early revision was also lower with the monoblock all-polyethylene components (HR = 0.59, CI: 0.35–0.99). In aseptic revision models, monoblock all-polyethylene components were associated with a

Table 2. Surgeon, hospital, procedure, and implant characteristics according to component modularity, 2001–2010

	Total sample		Metal-backed modular		Monoblock all-polyethylene		p-value
	n	(%)	n	(%)	n	(%)	
Total no.	27,657	100	25,351	91.7	2,306	8.3	
Fellowship training	11,644	42.1	10,780	42.5	864	37.5	< 0.001
Surgeon, average annual volume							
< 20	1,639	5.9	1,613	6.4	26	1.1	< 0.001
20–49	9,031	32.7	8,375	33.0	656	28.5	
≥ 50	16,987	61.4	15,363	60.6	1,624	70.4	
Hospitals	40	100.0	40	100.0	13	32.5	
Hospital, average yearly volume							
< 100	558	2.0	558	2.2	0	0.0	< 0.001
100–199	3,358	12.1	3,358	13.3	0	0.0	
≥ 200	23,741	85.8	21,435	84.6	2,306	100	
Implant stability							
CR	9,408	34.0	8,897	35.1	511	22.2	< 0.001
PS	18,223	65.9	16,430	64.8	1,793	77.8	
Unknown	26	0.1	24	0.1	2	0.1	
Fixation							
Cemented	24,987	90.4	22,810	90	2,177	94.4	< 0.001
Hybrid	1,267	4.6	1,244	4.9	23	1.0	
Uncemented	114	0.4	106	0.4	8	0.4	
Unknown	1,289	4.7	1,191	4.7	98	4.3	
Patella not resurfaced	631	2.3	603	2.4	28	1.2	< 0.001
Bilateral procedures	2,821	10.2	2,587	10.2	234	10.2	0.9
Operative time (min), (mean, SD)	92.3	32.4	92.7	32.7	87.4	28.4	< 0.001

CR: cruciate retaining; PS: posterior stabilized.

Table 3. Crude revision rate and revision rate/100 years of observation for all-cause revision and aseptic revision, for the overall cohort and according to component modularity

	Total sample		Metal-backed modular		Monoblock all-polyethylene		p-value
	n	(%)	n	(%)	n	(%)	
Crude revision rate							
All-cause	572	2.07	550	2.17	22	0.95	< 0.001
Aseptic	313	1.13	300	1.18	13	0.56	0.007
Revision rate/100 y of observation	Total y	Rate/100 y	Total y	Rate/100 y	Total y	Rate/100 y	
All-cause	92,273	0.62	84,971	0.65	7,302	0.30	
Aseptic		0.34		0.35		0.18	

lower risk of early revision than metal-backed modular components only in the younger age-specific model (HR = 0.27, CI: 0.11–0.65) (Table 4).

Discussion

With 2.9 years of median follow-up, the fixed monoblock all-polyethylene tibial component was identified as a superior construct for TKA. For arthroplasties performed with a monoblock all-polyethylene tibial component, the all-cause revision rate per 100 years of observation was 0.30. During the same period, for arthroplasties performed with a metal-backed modular tibial component, the crude revision rate per 100 years

of observation was 0.65. Based on adjusted models, the use of a monoblock all-polyethylene component was associated with a 50% lower risk of early revision. In younger patients (< 65 years old), the lower risk of early revision associated with monoblock all-polyethylene components was even more pronounced, as it was approximately 74% lower than that for metal-backed modular components.

Most studies have not found any statistically or clinically significant difference in the risk of revision between arthroplasties performed with either a metal-backed tibial component or a monoblock all-polyethylene tibial component (Gloe et al. 2007b, Bettinson et al. 2009, Cheng et al. 2011, Voigt and Mosier 2011). In a meta-analysis of 9 randomized controlled trials published between 2000 and 2009 using 5 dif-

Table 4. Adjusted risk of all-cause and aseptic revision for all-polyethylene monoblocks compared to metal-backed modular tibial components. Cox proportional hazard models

	HR	95% CI	p-value
All-cause revision models			
Overall	0.51	0.33–0.78	0.002
Patients ≥ 65 years old	0.59	0.35–0.99	0.05
Patients < 65 years old	0.26	0.10–0.72	0.01
Aseptic revision models			
Overall	0.59	0.29–1.19	0.1
Patients ≥ 65 years old	0.75	0.32–1.76	0.5
Patients < 65 years old	0.27	0.11–0.65	0.003

ferent implant systems, Cheng et al. (2011) reported similar clinical results between the 2 groups in terms of knee scores, quality of life, range of motion, radiographic implant alignment, and postoperative complications. In their analysis, they did not find that metal-backed tibial components were superior to the monoblock all-polyethylene tibial construct. Another meta-analysis of 12 studies and 1,798 implants found that the lower-cost monoblock all-polyethylene component had clinical and functional results equivalent to the more expensive fixed metal-backed modular component (Voigt and Mosier 2011). Voigt and Mosier (2011) also reported that there were no statistically significant differences in implant longevity at 2, 10, and 15 years postoperatively. In a prospective randomized controlled trial, Bettinson et al. (2009) reported 10-year survivorships of 97.0% for 304 metal-backed arthroplasties and 96.8% for 262 monoblock all-polyethylene implants. Gioe et al. (2007b) conducted a randomized study and reported a 10-year survivorship of 92% for 97 monoblock all-polyethylene tibial components with revision for any reason and 100% for aseptic loosening. In their study, the survivorship of 70 metal-backed modular components was 89% with revision for any reason and 94% for aseptic loosening. In a case-series study, also by Gioe et al. (2007a), the reported 14-year survivorship of the all-polyethylene cases entered in the institutional registry was 99% comparable with their clinical trial results. In our cohort, however, we found a statistically and clinically significant difference between these 2 tibial constructs. There may be several reasons for the differences between our findings and those published in the literature. Firstly, the previously published studies may have been underpowered. Secondly, from a patient and surgeon point of view, our study sample was diverse, thus allowing us to measure the real-world performance of these constructs. Finally, the follow-up periods of published studies varied from 2 to 10 years, whereas our median follow-up was 2.9 years.

Additional reports on the topic include annual reports from national total joint arthroplasty registries (National Joint Registry for England and Wales 2010, AOA 2011). In the Eighth Annual Report of the National Joint Registry for England and Wales (NJREW), the revision rate at 7 years for all bicondylar

knees (n = 313,069) was 3.9% (National Joint Registry for England and Wales 2010). In that same time period, 3.7% of the 43,708 monoblock tibias were revised. In the NJREW report, no distinction was made between monoblock all-polyethylene tibial components and pre-assembled metal-polyethylene monoblock tibial components, but a slightly lower 7-year revision rate was seen for monoblock tibial constructs. In contrast, the 2012 Report of the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) categorized monoblock tibias into monoblock all-polyethylene components and molded non-modular components (AOA 2011). The incidence rate of revision per 100 years of observation was highest with the monoblock all-polyethylene component (0.74) and lowest with the molded non-modular component (0.58). In comparison, the metal-backed modular revision rate per 100 years of observation was 0.67. The cumulative revision rate at 10 years was 5.1% for the metal-backed modular components, 5.4% for the monoblock all-polyethylene components, and 4.7% for the molded non-modular components. The different lengths of follow-up in the different cohorts and the implant selection criteria are 2 observations of importance, and possibly explain the observed differences when comparing our data to those from the AOANJRR cohort.

The limitations of our investigation were related to the study design, the retrospective nature of the study, and follow-up. However, the outcomes were prospectively ascertained and adjudicated by a trained research coordinator to reduce the possibility of informational bias. It is possible that selection bias may have existed in our sample. In our analysis, we tried to adjust for the variables we found to be confounders of the association between implant choice and risk of revision. However, there may still be certain patient-specific or implant-based characteristics that we have not been able to account for that may have influenced surgical and clinical decision-making. The definition of failure was surgical revision, which does not account for patient function and satisfaction as a measure of success of arthroplasty. Radiographically failing arthroplasties were not accounted for in our study. However, we have no reason to believe that there would be a differential rate of radiographically defined failures between the study groups, and if there was under-ascertainment of failures, this was probably non-differential.

The purposeful restriction of our analysis to a single implant (PFC Sigma) manufactured by the same company (DePuy) with the same articular geometry in both the metal-backed modular component and the monoblock all-polyethylene component allowed us to focus on the role of tibial modularity in arthroplasty survival. This strategy increased the internal validity of our measurements as they applied to Depuy components, but our results may not be generalizable to monoblock all-polyethylene components from other manufacturers with possibly different design features.

Our loss to follow-up, another limitation, was slightly higher in the monoblock all-polyethylene group (12%) than in the

metal-backed modular group (8%). It is unlikely that such a small difference between the cohorts would cause our estimations to be biased to the degree presented here. In addition, the “lost to follow-up” cohort contributed a median of 1.8 years of observation before attrition, thereby contributing to a substantial amount of the follow-up period (in which they did not have a revision). Those lost to follow-up were also younger than the patients who were not lost to follow-up, supporting the idea that if the effects we are seeing are even greater in a younger population, they must not be overestimated since that would be the group most likely to miss event ascertainment. In addition, these are short-term follow-up risk estimations and the results should be interpreted as such. Our conclusions are fit for the follow-up time of our cohort, and we hope that once longer follow-up is available in this study cohort, we will be able to re-evaluate this patient sample.

The strengths of the present study include its large sample size, the diversity of the patient and surgeon sample included, and the internal validity of the TJRR used for the study. Our sample size allowed us not only to evaluate the relationship between implant modularity and outcomes of TKA, but also to evaluate models stratified by age and adjust our analysis for possible confounders of the relationship studied. In addition, the diversity of the sample included in our study (inclusive of non-Medicare aged groups and inclusive of various racial groups) increases the generalizability of our findings to various patient populations. Similarly, the number of surgeons and medical centers that contributed to this study, with several levels of skill, volume, and training, as well as different medical center characteristics increase the external validity of our findings, which we believe are applicable to a range of surgeons and medical centers. Finally, the TJRR collects prospective information on all the registered TKA cases and uses validated algorithms to ascertain the events evaluated in this study. It also adjudicates every outcome via chart review. This mechanism of event ascertainment together with the integrated linkage to healthcare systems and access to patient activity increases the internal validity of the information we are reporting, as information bias is probably minimized.

Conclusion

An analysis of primary TKAs registered in a community-based TJRR showed that in monoblock all-polyethylene tibial components, the risk of revision was approximately 49% (CI: 22–67%) lower in the 2.9 years of median follow-up of our cohort than in patients with metal-backed modular components. For younger patients (< 65 years old), the risk of revision was even lower for the monoblock all-polyethylene component, where the hazard ratio was approximately 0.3 (CI: 0.1–0.7) times that for the metal-backed modular component.

Study concept and design: VM, MCSI, and RSN. Extraction of data and preparation of raw data: MCSI. Statistical analysis: MCSI. Interpretation of

data: VM, MCSI, RSN, DS, and EWP. Drafting of the text: VM and MCSI. Drafting of the tables: MCSI. Critical revision of the manuscript for important intellectual content: VM, MCSI, RSN, DS, and EWP.

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No competing interests declared.

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