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Do "Premium" Joint Implants Add Value?

Analysis of High Cost Joint Implants in a Community Registry

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Abstract
Background Numerous joint implant options of varying cost are available to the surgeon, but it is unclear whether more costly implants add value in terms of function or longevity.
Questions/purposes We evaluated registry survival of higher-cost "premium" knee and hip components compared to lower-priced standard components.
Methods Premium TKA components were defined as mobile-bearing designs, high-flexion designs, oxidized-zirconium designs, those including moderately crosslinked polyethylene inserts, or some combination. Premium THAs included ceramic-on-ceramic, metal-on-metal, and ceramic-on-highly crosslinked polyethylene designs. We compared 3462 standard TKAs to 2806 premium TKAs and 868 standard THAs to 1311 premium THAs using standard statistical methods.
Results The cost of the premium implants was on average approximately $1000 higher than the standard implants. There was no difference in the cumulative revision rate at 7–8 years between premium and standard TKAs or THAs.
Conclusions In this time frame, premium implants did not demonstrate better survival than standard implants. Revision indications for TKA did not differ, and infection and instability remained contributors. Longer followup is necessary to demonstrate whether premium implants add value in younger patient groups.
Level of Evidence Level III, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Each author certifies that he or she has no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.
Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.
This work was performed at the HeathEast Joint Registry, HealthEast Hospitals, St. Paul, MN.

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Introduction

TKA and THA have emerged as two of the twentieth century's most common and reliable surgical procedures [5, 9, 16, 18, 27]. The aim of the surgery is to provide a pain-free, stable, mobile, and durable joint. Recent advances in joint arthroplasty technology have focused on improving motion and kinematics in TKA, improving arc of motion and stability in THA, and improving wear characteristics in both—all at increased cost over earlier designs.

Implant expense has traditionally been one of the costlier parts of the hospital bill for total joint arthroplasties (TJAs) [16, 19, 25]. Increasingly, efforts have been made to minimize costs associated with TJA surgery and hospitalization in an era of dwindling Medicare reimbursements and push for national healthcare reform [5, 17]. Surgeons might reasonably be expected to weigh these cost considerations against their desire to use new technology that may afford better function, fewer complications, and/or improved longevity of TJA for their patients. However, whether the new technology associated with so-called "premium" implants justifies the increased cost over standard implants that have performed well remains unknown and, in a more general sense, provides an important part of the rationale behind large joint registries.

We sought to determine whether higher-cost premium hip and knee implants were superior to standard knee and hip implants in terms of implant survival in our community total joint registry. Thus, the primary objective of this study was to assess the difference, if any, in the cumulative revision rate of premium and standard TKA and THA implants. Secondary aims were to analyze the effect of different variables such as age, gender, and diagnosis on the survival of the two implant categories. Finally, we examined any potential differences in patient length of stay and discharge disposition between the implant categories.

Patients and Methods

The HealthEast Joint Registry (HEJR) is a community-based total joint registry in the St Paul, MN, metropolitan area that provides information on more than 21,500 hip and knee arthroplasties performed since September 1, 1991. More than 40 community surgeons operating at five hospitals contribute complete registry data on all total joint operations performed. Details on the data collection methods and the application of statistical analyses for this registry have been previously reported [10].

For this study, we included primary TKAs that had a porous femur and cemented tibia, cemented femur and cemented tibia, or a cemented femur and cemented all-polyethylene tibia (n = 10,326). Cementless designs where both porous femoral and tibial components were utilized were excluded based on their small number. Premium TKA components were defined as mobile-bearing designs, high-flexion designs, those including oxidized-zirconium femoral components or newer moderately-crosslinked polyethylene inserts, or some combination of these designs (n = 2806). All TKAs from 1991 through 2000 were excluded, since the premium design inclusions above were not available before 2001 (n = 4043), and an additional 15 TKAs utilizing highly constrained or hinged designs were also excluded. This left a total of 6268 TKAs (3462 standard TKAs and 2806 premium TKAs) for analysis. All THAs that utilized cementless femoral and acetabular components with any bearing surface combination were considered for inclusion (n = 2973). Premium THAs included ceramic-on-ceramic, ceramic-on-polyethylene, or metal-on-metal designs (n = 1311). Again, all THAs from 1991 through 2001 were excluded since the premium design inclusions above were not available before 2002 (n = 792), and an additional two THAs that used non-highly-crosslinked liners were also excluded. This left a total of 2179 THAs (868 standard THAs and 1311 premium THAs) for analysis.

Of the 6268 TKAs, 64% were female, the average age was 66.4 years, and the minimum followup was 0 years (average, 3.4 years; range, 0.0–8.0 years). Of the 2179 THAs, 52% were female, the average age was 62.7 years, and the minimum followup was 0 years (average, 2.8 years; range, 0.0–7.0 years). We used revision of the index arthroplasty as the end point and defined revision as the removal, exchange, or addition of any prosthetic component. Other variables assessed were age, gender, year of index procedure, cost of primary implant, length of stay in hospital for index procedure (LOS), primary diagnosis, discharge disposition after index procedure, head size (for THAs only), and reason for revision.

Premium and standard implants were compared univariately using the Wilcoxon rank sum test for continuous variables (age, cost of primary implant, and LOS) and the Pearson's chi-square test for categorical variables (gender, year of index procedure, primary diagnosis, discharge disposition, and reason for revision). We also performed subgroup analyses comparing premium TKAs with moderately-crosslinked polyethylene inserts, mobile-bearing/oxinium femoral component designs, and high-flexion designs to the standard TKAs separately. Cumulative revision rates (CRRs) were compared for the premium and standard implants using the Kaplan-Meier method to calculate the CRR and the log-rank test to compare those rates. Relative risk of revision was computed using Cox regression models and all variables of interest (except reason for revision) were considered for potential confounding. A confounder was defined as a variable that changed the main effect estimate by greater than 10%. Only age met those criteria for the TKA analysis, and age, cost of implant, and year of index procedure met those criteria for the THA analysis.

Results

We found no difference in the CRR between premium and standard TKAs at 7 years (Fig. 1). When compared to standard TKAs, the premium TKAs were on average younger patients, had a higher implant cost, and were more often implanted from 2005 to 2008 (Table 1). There were no differences in gender or revision reason between the standard and premium TKAs. Finally, there was no difference in either the crude relative risk of revision (p = .94) or the age-adjusted relative rate of revision (p = .75) when comparing premium to standard TKAs.

In the subgroup analysis within the premium TKA group, we found no differences (p = 0.51–0.67) in CRRs between the premium subgroups and the standard TKAs. There were also no differences (p = 0.42–0.81) in the crude or adjusted relative risk of revision for any of the premium subgroups and the standard TKAs.

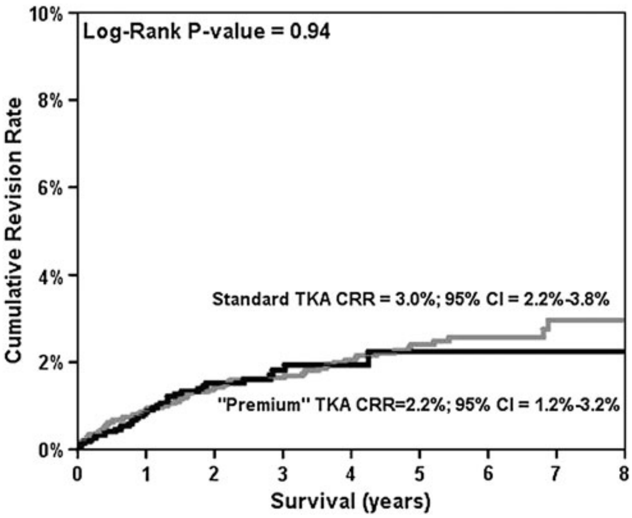

Fig. 1 A graph shows the CRR by type of implant for TKA. There was no difference (p = 0.94) in the CRR between premium and standard TKAs at 7 years (2.2% versus 3.0%). CI = confidence interval.

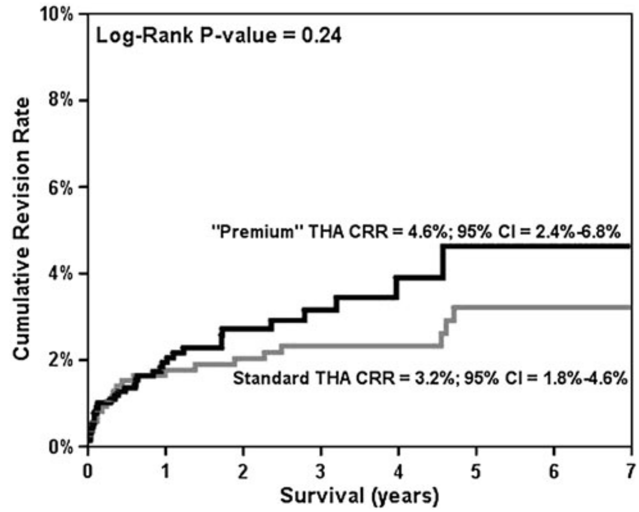

Fig. 2 A graph shows the CRR by type of implant for THA. There was no difference (p = 0.24) in the CRR between premium and standard THAs at 7 years (4.6% versus 3.2%). CI = confidence interval.

Table 1. Univariate comparison of premium and standard TKAs

Variable	Premium TKA (n = 2806)	Standard TKA (n = 3462)	P value
Age (years)*	63.3 (10.2)	69.0 (10.4)	< 0.001
Cost of implant* (US dollars)	$4245.47 ($959.44)	$3210.21 ($795.89)	< 0.001
Length of stay (days)*	3.24 (0.98)	3.86 (1.32)	< 0.001
Gender (number of TKAs)			0.62
Male	1010 (36%)	1225 (35%)	
Female	1796 (64%)	2237 (65%)	
Year of index procedure (number of TKAs)			< 0.001
2001–2004	400 (14%)	2007 (58%)	
2005–2008	2406 (86%)	1455 (42%)	
Primary diagnosis (number of TKAs)			0.002
Osteoarthritis	2769 (98.7%)	3386 (97.8%)	
Rheumatoid arthritis	20 (0.7%)	22 (0.6%)	
Other	17 (0.6%)	54 (1.6%)	
Discharge disposition (number of TKAs)			< 0.001
Home	627 (22%)	553 (16%)	
Home care	1623 (58%)	1552 (45%)	
Skilled nursing facility/other	556 (20%)	1357 (39%)	
Revision reason (number of TKAs)			
	33 (1.2%)	66 (1.9%)	0.49
Aseptic loosening	6 (21%)	10 (15%)	
Infection	7 (18%)	10 (15%)	
Instability	7 (21%)	24 (36%)	
Other	13 (39%)	22 (33%)	

* Values are expressed as mean, with SD in parentheses.

Table 2. Univariate comparison of premium and standard THAs

Variable	Premium THA (n = 1311)	Standard THA (n = 868)	P value
Age (years)*	59.5 (11.6)	67.4 (10.7)	< 0.001
Cost of implant*	$6002.74 ($790.71)	$5191.80 ($676.24)	< 0.001
Length of stay (days)*	3.30 (1.29)	3.67 (1.30)	< 0.001
Age group (number of THAs)			< 0.001
< 60 years	691 (53%)	203 (23%)	
60–69 years	361 (28%)	243 (28%)	
≥ 70 years	259 (20%)	422 (49%)	
Gender (number of THAs)			0.18
Male	640 (49%)	398 (46%)	
Female	671 (51%)	470 (54%)	
Year of index procedure (number of THAs)			< 0.001
2002–2004	212 (16%)	450 (52%)	
2005–2008	1099 (84%)	418 (48%)	
Primary diagnosis (number of THAs)			< 0.001
Osteoarthritis	534 (74%)	975 (62%)	
Aseptic necrosis	275 (21%)	300 (35%)	
Other	61 (5%)	34 (4%)	
Head size (number of THAs)			< 0.001
≤ 32 mm	349 (31%)	559 (64%)	
> 32 mm	775 (69%)	309 (36%)	
Discharge disposition (number of THAs)			< 0.001
Home	327 (25%)	198 (23%)	
Home care	716 (55%)	372 (43%)	
Skilled nursing facility/other	268 (20%)	298 (34%)	
Revision reason (number of THAs)			0.007
Dislocation	7 (22%)	13 (68%)	
Periprosthetic fracture	5 (16%)	2 (11%)	
Failure of bone ingrowth	8 (25%)	3 (16%)	
Other	12 (37%)	1 (5%)	

* Values are expressed as mean, with SD in parentheses.

There was no difference in the CRR between premium and standard THAs at 6 years (Fig. 2). When compared to standard THAs, the premium THAs were on average younger patients, had a higher implant cost, and were more often implanted from 2005 to 2008. They also had a head size of greater than 32 mm more often (69% versus 36%) and were less often revised for dislocation (Table 2). There was no difference in gender between premium and standard THAs. Finally, there was no difference in either the crude (p = .24) or the age-adjusted relative risk of revision (p = .72) when comparing premium to standard THAs.

Discussion

The rising cost of health care in the United States and increasing constraints on economic resources have led to an increased emphasis on healthcare economic evaluation. Primary and revision TJA accounts for a higher percentage of Medicare spending than any other inpatient procedure [3]. With the number of such procedures expected to increase [16, 19], TJA continues to attract the attention of the Center for Medicare and Medicaid services. Since implant expense is a major portion of the total cost of the procedure [16–19, 25, 34] and increasing use of premium implants is one of the drivers [9], we sought to determine whether such implants could be demonstrated to have superior value in early- to midterm followup.

Our study has the obvious limitations inherent to the use of any joint registry. First, the use of survival analysis with an end point of revision surgery does not identify the proportion of the patients who might have had clinical failure or poor functional results, as is usually the case with cost-effectiveness studies [5]. Similarly, it cannot identify patients who may somehow benefit from superior functional results achieved with a premium implant. Second, there is a possibility that some patients might have had their revision surgery performed elsewhere, but we have previously reported a greater than 94% "capture rate" in our registry, and this limitation would presumably affect both premium and standard implant recipients in a similar distribution [10]. Third, the length of followup is short but was limited by the relatively recent introduction of some of the designs reviewed, and our registry will continue to capture these data prospectively over the longer term. The strength of the study lies in the community nature of the registry, with more than 40 surgeons participating, none of whom is an implant designer-developer or industry consultant. As a result, we would presume surgeon implant choices were unaffected by such direct relationships.

There is an essential conflict between surgeons and payors around the issue of implant choice, since a surgeon's primary perspective is to select the "best" implant to achieve a superior outcome and meet the patient's expectations, regardless of the cost of the implant [16, 17, 34]. Most surgeons would choose a more costly implant with "better" clinical results versus an inexpensive implant with "acceptable" results [34]. Patients overwhelmingly want their surgeon to choose their implant and want quality to be the overriding consideration in that choice [34]. Unfortunately, the lack of timely evidence that new innovations in TJA will result in superior outcomes and the certain knowledge that not all innovations improve outcome make such choices difficult [19].

Previously published reports demonstrate no obvious superiority of the premium implants over the standard lower-cost implants reviewed in this paper (Table 3). Reports of high-flexion knees [2, 23, 27], mobile-bearing knees [6, 24], oxidized-zirconium femoral components [22, 35], and moderately crosslinked polyethylene inserts [29, 31, 32] have not been consistently associated with either improved function or survival when compared to standard lower-cost

Table 3. Selected prior studies of TKA design survival

Authors	Study design	Implant characteristics	Time frame	Survival
Bettinson et al. [2]	Prospective RCT	All-polyethylene tibia (APT) vs. metal-backed tibia (MBT)	10 years	94.5% (APT) 96% (MBT)
Gioe et al. [11]	Prospective, community joint registry	APT	14.3 years	99.4%
Gioe et al. [12]	Prospective RCT	APT vs. MBT	10 years	91.6% (APT) 88.9% (MBT)
Hooper et al. [20]	Prospective	Mobile bearing	12 years	92%
Huang et al. [21]	Retrospective	Mobile bearing	15 years	88.1%

Table 4. Selected prior studies of THA design survival

Authors	Study design	Implant characteristics	Time frame	Survival
Dorr et al. [7]	Prospective	MOM	7 years	98.2%
Grubl et al. [13]	Cross sectional study at 10 yrs	MOM	10 years	98.6%
Hamadouche et al. [14]	Prospective	COC	20 years	85.6% (cementless acetabular cups)
				87.3% (cementless femoral stem)
Hasegawa et al. [15]	Retrospective	COC	10 years	75% (acetabulum)
				86% (femur)
Lusty et al. [26]	Retrospective	COC	7 years	99%
Migaud et al. [28]	Prospective, matched control	MOM	5 years	100%
		COP		97%
Murphy et al. [30]	Prospective	COC	9 years	96%
Urban et al. [36]	Retrospective	COP	5 years	95%
			10 years	95%
			15 years	89%
			20 years	79%
Zijlstra et al. [38]	Prospective RCT	MOM	5 years	97%
		MOP		99%

COC = ceramic-on-ceramic; COP = ceramic-on-polyethylene; MOM = metal- on-metal; MOP = metal-on-poly.

designs. All-polyethylene tibial components have demonstrated similar or better mid- to long-term results than metal-backed tibial component designs at lower cost [1, 11, 12, 33]. Similarly, the results for the premium metal-on-metal and ceramic hip designs reviewed here have also been mixed, with improved wear characteristics balanced by concerns over metal ion concentrations, delayed hypersensitivity reactions, ceramic articulation squeaking, and fracture [7, 8, 13–15, 26, 28, 30, 36–38] (Table 4).

In a time frame of 6 to 7 years of survival data, premium TKA and THA implants in our registry did not demonstrate better survival than standard implants. The fact that patients receiving premium implants were more frequently discharged home and had shorter hospital LOS undoubtedly reflects their younger age and evolving rehabilitation and surgeon protocols during the same time frame. There were fewer THA patients revised for dislocation in the premium group, but this was not significant after adjusting for age grouping (< 60 years, 60–69 years, ≥ 70 years) and head size (< 32 mm versus ≥ 32 mm). Premium TKA implants as a percentage of total TKA implants in the HEJR rose to 62% during the years 2005 to 2008 and premium THA implants increased to 72% of the total during the same time period.

We believe surgeons should make implant choices with the patient's best interest in mind. However, surgeons cannot watch from the sidelines during the intensifying debate over national healthcare reform. Evidence-based medicine on implant performance, including registry studies, randomized trials, and cost-effectiveness analysis, will permit us to make informed choices for our patients. Cost-awareness programs for surgeons are excellent first steps in managing implant costs [16, 34], and to date surgeons still play the primary role in determining the implant chosen. All innovation does not represent improvement, and higher cost does not necessarily equate to higher quality. Numerous studies point to the substantial percentage of early revision indications in TJA that are design-independent, such as infection and instability [4, 34]. Surgeons must continue to play a key role in deciding what represents rational cost-effective care or that role may be assumed by others.

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