Original research

Unacceptable failure rate of a ceramic-coated posterior cruciate-substituting total knee arthroplasty

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ABSTRACT

Background: Aseptic loosening is one of the most elusive problems in total knee arthroplasty. We compared the failure rates of posterior cruciate-substituting total knee arthroplasty utilizing implants with hardened surface coating to a previous cohort of patients who underwent the procedure with traditional cruciate-retaining noncoated cobalt-chrome implants.
Methods: A retrospective study was conducted of 1099 total knee arthroplasties performed from 2009 to 2017. Two hundred forty-nine total knee arthroplasties performed from January 2015 to March 2017 under a single design were reviewed retrospectively and compared to the author's previous 850 total knee arthroplasties performed from January 2009 to December 2014 under a different design.
Results: This series demonstrated an alarming debonding of cement in the tibial implant. The resultant failure rate of 6% (*P* < .001) is higher than observed in 850 total knee arthroplasties in the previous 5 years and higher than those reported in the literature giving cause for concern regarding this implant.
Conclusions: Due to the observed excessive failure rate, the authors recommend exercising high levels of caution using this implant with hardened surface treatment until further testing can be ascertained as to the root cause of failure.

Introduction

With 600,000 total knee arthroplasties (TKAs) performed each year in the United States, providing excellence in performance and survivability is placed on the surgical community [1]. Success is derived, in part, by reporting successful as well as unsuccessful outcomes. Mean failure rates of primary TKAs in most national registries are 5%-6% at 10-year follow-up [2]. Given that most of these revisions are for infection, for which there is limited ability to effect an improvement, the remaining failures give rise to heightened scrutiny on prevention and improvement in techniques and designs that reduce the incidence of aseptic loosening [3].

The orthopedic community, therefore, is implored to recognize correctable causes of early failures and lessen the economic burden of revisions [4-6]. For instance, byproducts of wear have long been recognized as a cause of osteolysis and loosening and may also trigger allergic reactions [7,8]. As a response, some implant vendors have proposed that the long-term outcomes could be improved by improving implant wear characteristics through surface treatments with oxinium or zirconium. Aseptic loosening has been studied with traditional cobalt chrome implants and failure along the cement-implant interface is a known mode of failure [9-14]. However, there are no reports on coated implants where both the cemented and articulating surfaces are finished with a global surface treatment. Therefore, the aim of this study is to compare the failure rates of a cohort of patients who underwent posterior cruciate-substituting (PS) TKA utilizing implants with hardened surface coating to a previous cohort of patients who underwent the procedure with traditional noncoated cobalt-chrome implants. In this review, we present comparisons of early time to failure cases in a single surgeon's sequential experience with this implant. Additionally, we evaluate any disparity in physical characteristics, demographics, and pre-

existing risk profiles in those who failed vs those who did not to rule out other causative factors of increased failure.

Material and methods

Study design

This is a retrospective study comparing patients who had TKAs from 2009 to 2017 under the care of the primary senior author. The excessive failure rate of more than 6% prior to 1 year in a series of 249 patients (study group) prompted a comparison to 850 procedures performed from 2009 to 2014 (control group). In the study group, 53% of patients were female and 54% of knees replaced were right. The average age was 68 years (range 46-91). The average follow-up from the index procedure was 7.7 months (range 0.5-28.3) for the study cohort. Phenotype, sex, age, and demographic profiles in the study group were compared to assess differences between those who failed and those who did not (Table 1). There were no differences in Knee Society Scores, disease states such as AVN, rheumatoid arthritis, or connective tissue disorders nor on mechanical alignment tendencies which may otherwise bias one group over another (Table 2). The use of primary TKA implants was used identically in both series of patients. Patients with fixed deformities, previous hardware, or traumatic deformities were excluded as they received stemmed semiconstrained implants of a different variety.

The primary implant used in the study group was a Vega (Aesculap, Tuttlingen, Germany) between January 2015 and March 2017. The primary implant used in the control group was a Columbus (Aesculap) between January 2009 and December 2014. Failure in both cohorts was defined as symptoms that required reoperation, excluding infection. Only revisions were counted as failures. We obtained institutional review board approval for this retrospective review.

We sought follow-up on all patients by electronic and paper mail, and personal call back if mail attempts were unsuccessful. At the close of this expedited review, 174 of the 249 patients responded to inquiries and were seen. All patients who conveyed symptoms of dissatisfaction were reassessed, whether secondary to loosening, pain, or another complaint. These patients were sought out and seen earlier than usual due to the concerning failure trends. The patients from 2009 to 2014 were assessed with routine 3-week and 1-year radiographs as a standard practice, including standardized anteroposterior (AP), lateral, sunrise, and, where necessary, oblique views. Planar tangential tray and condylar views were taken to critically analyze any cement failures, if identified, such as lift-off and/or subsidence. Serial comparisons from previous visits were used to evaluate progressive changes in both loosening and stability of the prosthesis along bone interfaces and zones of bony resorption and correlated to symptomatic progression.

Criteria for loosening were based on the Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System, with >10 as a positive result [8]. We also used a quantitative percentage-based system (>25% linear) which included lateral or AP progression of fixation to further expand the role of failures and region of initial at-risk implant interface [15]. As a secondary outcome, we recorded the location of radiographic loosening on all patients in the 2015-2017 cohorts. Patients in both cohorts who

Table 1
Demographic comparison between the patients not receiving revisions and those who were revised.

Demographic	Nonrevised (234)	Revised (15)	P-value
%Female	53.4%	46.7%	.61
%Right laterality	53.8%	53.3%	.97
Age (±SD)	68.37	68.80	.85

SD, standard deviation.

Table 2
Comparison of alignment and Knee Society Scores preoperatively and postoperatively.

Control	Measure	Study
−7.8	Pre-TKA mechanical axis (°)	−7.9
64	Pre-TKA functional score	65
78.4	Pre-TKA clinical score	79
−1.8	Post-TKA mechanical axis (°)	−1.7
82	Post-TKA functional score	83
90	Post-TKA clinical score	92
3	ASA classification	3
119	Post-TKA ROM (°)	123
33	BMI (kg/m^2)	31

ASA, American Society of Anesthesiologists; BMI, body mass index; ROM, range of motion.
There is no significant difference between the 2 cohorts.

met all criteria for loosening and were symptomatic were offered a revision. If they declined a revision, they were then considered "at risk" and followed up with every 6 months as a standard practice.

Surgical technique

The surgical technique remained identical from 2009 to 2017. The implant used in the control group was a cruciate-retaining design. During the study phase, the PS was used primarily. All TKAs were done in a high-volume setting using the same protocols utilized in the preceding years. All surgeries were performed using Aesculap TKA SMART computer-assisted surgery software. An identical target value of 2° overall mechanical varus comprised of 1° femoral varus with 1° tibial varus was used. Additionally, 1°-2° femoral component flexion with 2°-4° tibial slope was added to the built-in 3° tibial slope of the implant (depending on the native tibial slope). Gap distances were balanced in both extension and flexion and the target values were 2 mm medial and 3-4 mm lateral.

The cementing techniques were also identical to preceding years, with Palacos (Zimmer Biomet, Warsaw, IN) high-viscosity antibiotic-incorporated cement applied to the tibial bony surfaces under low-pressure injections. The cement was vacuum mixed in single-use syringe tubes and application to the components took place between 1 and 5 minutes with final component assembly no later than 6 minutes after initial mix. Surface preparation using a gun injection to penetrate the trabecular surface was performed. Implants were dry and nonhandled to maximize cement adhesion. While the cement cured, the knee was placed in 60° of flexion with the final articulating surface in place while irrigation was performed and the first phases of closure were begun. By the time cement curing was completed, the first layer of capsular closure was complete. The knee never changed position during the curing process. Postoperative care and management included a traditional program of rehab on the day of surgery followed by discharge and weight-bearing activities as tolerated in the postoperative phase. The rehabilitation program was consistent from 2009 to 2017.

Statistical assessment

Statistical analysis included an assessment of failures for any reason, including infection. During this time, there were 2 infections for which there was no noted loosening of the implant. These were included in the total number of cases; however, they were not reported in the group of failures for mechanical reasons. Failures were recorded as reoperation was undertaken.

Statistical analysis

Failure rates were reported for each group along with 95% confidence intervals (CIs). The Fisher's exact test was used to

Table 3
Contingency table of TKA results.

Condition	2009-2014	2015-2017	Totals
Mechanically intact	848	234	1082
Mechanical failure	2	15	17
Totals	850	249	1099

compare failure rates between groups. The Fisher's exact test does not assume cell frequencies to be greater than or equal to 5 and thus was used because of the low number of failures observed from 2009 to 2014. An alpha value of 0.05 was used to determine statistical significance. We also statistically compared the differences between those who needed revisions vs those who did not in the 2015-2017 group. We used t-tests for continuous variables and chi-squared tests for categorical variables.

Results

An aseptic failure requiring a reoperation rate of 6% (95% CI 3.41-9.74) at an average of 7.7 months was observed over a cohort of 249 sequential TKAs (Table 3). There were 6 infections in the series and 1 traumatic revision, none of which were included in the statistical failures. From 2009 to 2014, the same single surgeon under the same surgical conditions performed 850 TKAs with a total of 2 aseptic loosenings requiring reoperation, with a failure rate 0.24% (95% CI 0.03-0.85). The Fisher's exact test revealed a statistically

significant higher failure rate for the 2015-2017 group compared to the 2009-2014 group ($P < .001$).

Prior to loosening, satisfaction in both groups appeared similar as reflected by equivalent Knee Society Scores. Although range of motion in the study group averaged 3° more than control, this was not statistically significant (Table 2).

From the standpoint of comparisons of the 2 groups, mean alignment in the control group was 1.21° varus (95% CI 0.98-1.44) and in the study group was 1.42° varus (95% CI 1.1-1.67) with no statistical difference between groups.

Of the revised failures, 12 (37%) were tibial, 8 (23%) were femoral, and 14 (40%) were combined tibial and femoral failures. Of the TKAs with concerning radiographs, 43% have gone on to revision. The most frequent and earliest area of loosening was seen on the lateral projection in the region of the posterior keel. The second area was lifting off on the AP projection of the lateral tibial component, followed by anterior flange resorption in more chronic cases [15]. Figure 1b shows the classic debonding of the tibial keel with early posterior subsidence characteristic of the bulk of loosening in this series. These patients required revision with a stemmed tibial implant (Fig. 2).

Discussion

Results from this study suggest that a higher failure rate occurred with coated implants than noncoated implants under similar surgical conditions. Our unacceptable failure rate of 6% at average follow-up of 7.7 months compares unfavorably to the
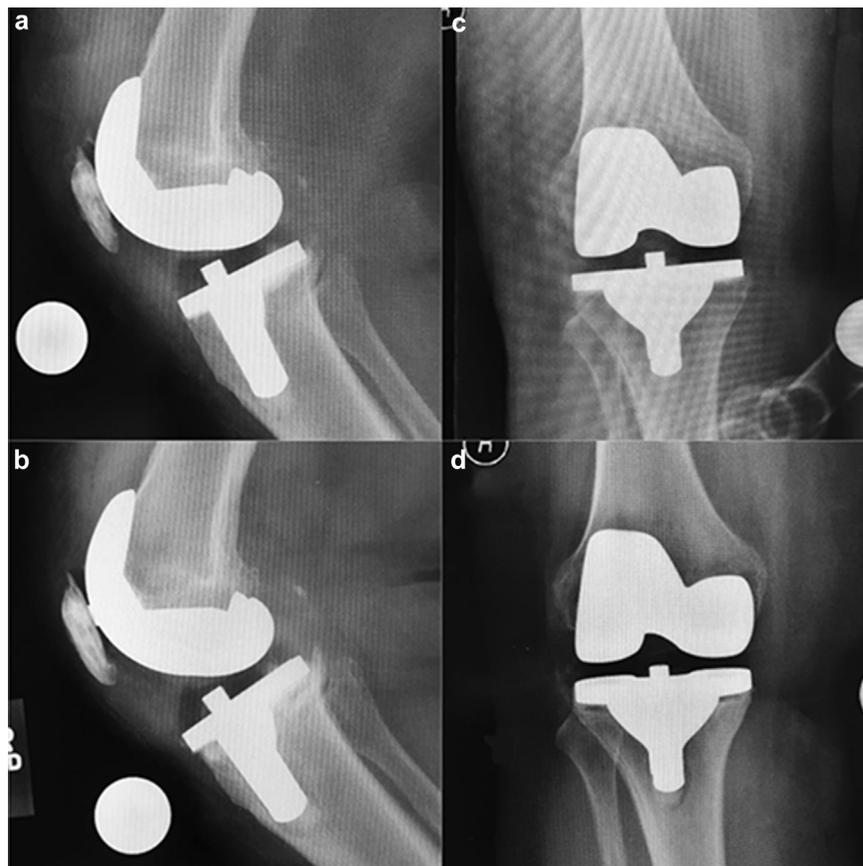

Figure 1. View 1 is a lateral view of the implant before (a) and after (b) radiographic failure at 7 months. View 2 is an anterior view of the implant before (c) and after (d) radiographic failure at 7 months.

Figure 2. Postrevision anteroposterior and lateral radiographs of the above patient using a hybrid cement and cementless stem, now 12 months since revision.

acceptable rates in the literature varying between 0.3% and 2% per use year [15-23] (Table 4). What is more troubling is graphically displayed by a Kaplan-Meier graph that shows failure far outpacing the expected rate (Fig. 3).

Due to the nature of counting failures as the revision surgeries were performed, the failure rate reported in this paper underestimates the eventual failure rate of the 2015-2017 cohort. At the time of this report, only revised failures are reported. Additionally, there are 35 (14%) patients with progressive radiolucencies not choosing to revise their knee at this time for a variety of reason; hence the failure rate at 5 years will likely be higher. Given the 6% failure over such a short time frame, the expected survival of the remaining cohort is in significant danger if the risk group fails in a linear pattern. This can be deceptive in that the failures are very recent and we do not have the luxury of waiting for more patients to fail.

We report this series of failures to highlight 2 important aspects with regard to coating and design of implants. First, there are many controlled studies that evaluate cement bonding to noncoated implants. However, there are none evaluating outcomes of coated implants in TKA. Cement, environment conditions of temperature and humidity in the operating room, and technique have previously been addressed as contributing factors to loosening and failure at the cement-bone interface [24,25]. The coating is a zirconium 7-layer advanced surface ceramic coating on all surfaces over a cobalt-chrome base metal. Although superior surface technology that minimizes potential allergic reactions and enhances wear characteristics is promising, the surgical community must consider more than just potential wear characteristics such as adhesion. Second, there are other noncoated implants currently on the market with early tibial tray failure that have gone through geometric surface modification to enhance cement adhesion that may need closer scrutinizing, although none have shown a sustained failure rate similar to this report [26].

Although most patients underwent revision to prevent this course of demise, 6 patients chose to delay revision. As a result, there were cases where the progression of the mechanical failures could be monitored for a year or more. What was reproducible was the apparent failure of the cement bonding to the tibial implant surface. Loosening did not appear to be occurring at the bone-cement interface, but rather the implant-cement interface. In most revisions, the tibial tray and/or femoral component were easily lifted out of its cement bed with a perfect implant imprint of

Table 4
Summary of published aseptic loosening incidence.

Article reference	Year	Total knees (n)	Knee type (n)	Knees at follow-up (y)	Revisions: total	Revisions: aseptic loosening	Rate (%): aseptic loosening	Survivorship
Ritter et al	1983- 1999	5649	PCS (5649)	4225 (5), 2531 (10), 1026 (15), 270 (20), 73 (25), 8 (30)	112	48	0.85	94.2% at 25 y 92.4% at 30 y
Abdel et al	1988- 1998	8117	PCR (5389) PCS (2728)	6855 (5), 4448 (10), 1309 (15) (total) 4615 (5), 3325 (10), 1257 (15) (PCR) 2240 (5), 1123 (10), 52 (15) (PCS)	507 (total) 320 (PCR) 187 (PCS)	206 (total) 118 (PCR) 88 (PCS)	2.54	89.8% at 15 y (PCR) 76.5% at 15 y (PCS)
Callaghan et al	1988-1991	75	PCR (75)	22 (20)	6	4	5.33	91% at 20 y
Kremers et al	1985-2005	16,584	Unspecified	16,584 (9.4)	1180	275	1.66	94% at 10 y 88% at 15 y
Jung et al[a]	2007-2008	187	PCS (187)	187 (2)	0	0	0	100% at 2 y
Long et al	1977-1992	107	PCS (106) Total condylar prosthesis (1)	107	25	13	12.15	70.1% at 30 y
						Weighted average	1.788287	

PCR, posterior cruciate retaining; PCS, poster cruciate stabilizing.

[a] Columbus PCS excluded from analysis, Scorpio PCS included.

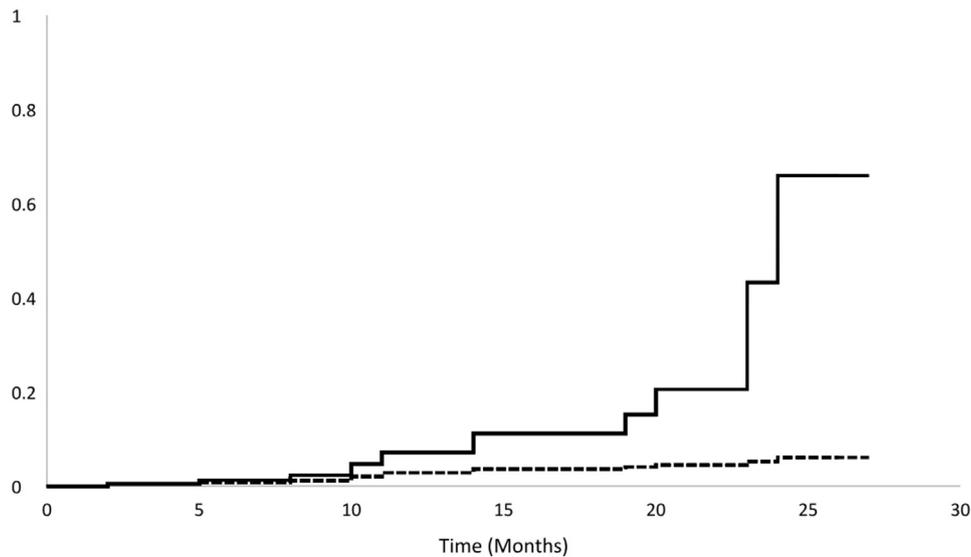## Kaplan-Meier Failure Estimate for Patients with Vega Replacement

Figure 3. The solid line represents the Kaplan-Meier failure estimates for patients who had the Vega (Aesculap, Tuttlingem, Germany) replacement (n = 249). The average follow-up time was 7.7 months. The dotted line represents a conservative failure estimate for patients with the Vega replacement procedure, based on the assumption that patients who did not contact the lead physician in the 26 months after their operation did not fail in this time frame.

the previous fixation point (Fig. 4). Likewise, in many instances, the femoral component would be easily revisable as it also was found to be debonded from the cement fixation on the femur.

There are weaknesses and limits to this study. Being a retrospective follow-up study, there is potential for confounding errors related to surgical techniques, cement time insertion, vendor product variability beyond our knowledge, and potential patient selection. However, the strict adherence to the same parameters for insertion techniques in utilizing computer-assisted surgery tends to normalize many of these variables that would otherwise be eliminated in a highly controlled prospective trial. Second, the series is a typical adult reconstructive practice utilizing sequential series in both cohorts without selection. There are differences between the method in which the 2009-2014 cohort and 2015-2017 cohort were followed, due to the retrospective nature of review. However, patients from the 2009 to 2014 cohort were seen in follow-up as a matter of standard procedure and the majority of patients were seen at least 2 years after surgery without aseptic loosening noted. It is possible that incidences of failure in both cohorts were missed

due to patients electing not to see the operating physician due to dissatisfaction or moving out of state, thereby artificially lowering the failure rates. The symptoms and radiographs in these loosened patients were so profound that the senior author became concerned for insidious failure of hardware. We have judiciously and critically looked at all potential pitfalls (or "pilot errors" on the part of the senior author) that may have created such a scenario without successful identification of another mode of failure.

Conclusions

Nowhere in recent literature can there be found such egregious failure rates on short-term follow-up such as in this group. The acceptable average of the recent publications found in Table 4 speaks to the gravity of the 6% failures at 7.7 months. This figure would be expected at 10 years.

This study provides preliminary evidence to suggest this implant is leading to higher failure rates. This paper is not intended to address root cause analysis but instead make surgeons aware of this implant with this treatment coating failing at an unacceptable level. The reader is encouraged to extrapolate or draw their own conclusion while alerting us as surgeons to be aware of future work necessary in instilling confidence in new designs as they become available. Future studies should further investigate failure rates for the new implant using more rigorous study designs.

Figure 4. TKA revision for aseptic tibial loosening. Implant easily removed without adherent cement. Imprint of tibial tray visible. Bone-cement interface intact with apparent implant-cement interface failure.

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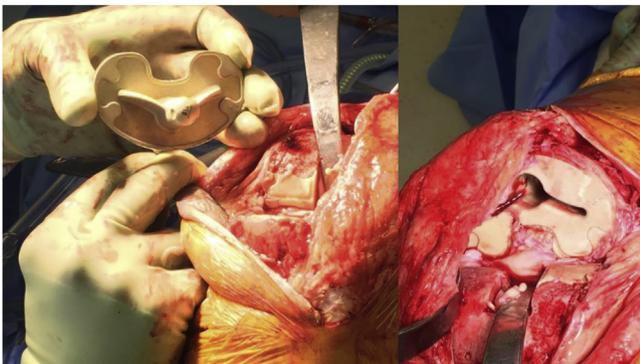
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