Original Research

Tibial Baseplate-Cement Interface Debonding in the ATTUNE Total Knee Arthroplasty System

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ARTICLE INFO

ABSTRACT

Background: Acrylic bone cement is the most common method of fixation for primary total knee arthroplasty (TKA). Several studies have described good short-term outcomes; however, there have been reports of early failures due to tibial baseplate debonding at the implant-cement interface of The ATTUNE Knee System (DePuy Synthes, West Chester, PA). We examined the causes and rates of revision in patients who underwent TKA with this system to identify factors associated with this mode of early failure.
Methods: A retrospective review of electronic health records between 2013 and 2018 identified all patients undergoing TKA with the ATTUNE Knee System with a minimum 2-year follow-up. Cause of revision, patient, implant, instrumentation, cement, and surgeon variables were collected. A descriptive analysis was used to identify characteristics of surgeon (fellowship-trained, surgical volume), implant (baseplate, bearing), and cement (brand, viscosity) that were associated with aseptic loosening.
Results: A total of 668 patients representing 742 knees were identified. Eighteen (2.4%) required a revision surgery. Aseptic loosening was the leading cause of revision surgery (n = 10, 55.6%). All failures due to aseptic loosening involved debonding of the tibial implant-cement interface. A multivariate analysis identified low-volume surgeons (9.0%, $P < .0001$) and 1 specific brand of high-viscosity cement (14.3%, $P < .0001$) as risk factors for aseptic loosening.
Conclusions: This study represents the largest nonregistry review of the original ATTUNE Knee System. Surgeon case volume and cement viscosity were factors associated with an increased rate of early failure due to tibial baseplate implant-cement interface debonding.
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Introduction

The volume of total knee arthroplasty (TKA) has dramatically increased over the last decade with 3 million surgeries projected to be performed annually by 2030 in the United States [1]. The most frequent reasons for failure of primary TKA have changed as implant designs, materials, and surgical techniques which have been refined. Early studies implicated polyethylene-wear-associated osteolysis as a major cause for revision, while more recent investigations have identified infection and instability as more frequent causes [2,3].

Acrylic bone cement is the most common method of fixation for TKA with low rates of early aseptic loosening [4,5]. Implant selection, cementing technique, and cement selection are all factors under surgeon control, which can affect risk of aseptic loosening. The original ATTUNE total knee system (DePuy Synthes, West Chester, PA) was introduced in 2012 with features aimed at addressing cement adhesion and aseptic loosening. The underside of the tibial baseplate was designed with a grit-blasted surface finish roughness of 2.5-3.5 Ra to better accommodate fixation of bone cement [6,7]. Early studies demonstrated good short-term outcomes [8,9]. However, there have been reports of early failures due to aseptic loosening of the tibial component, specifically at the implant-cement interface [4,10]. This system was subsequently

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redesigned in 2017 as seen in Figure 1, introducing a new tibial baseplate, which was reconfigured with an undercut cement pocket area and a greater surface roughness (3.0-6.5 Ra) to enhance cement bonding. Cement debonding of the tibial component during revision surgery was observed independently by 2 of the adult reconstruction fellowship-trained authors (D.K. and C.D.) prompting investigation of the cases and rates of failure (Fig. 2).

Currently, the majority of clinical data on the survivorship of this total knee system stem from registry data [6,12,13]. Previous studies have failed to establish causes for this mode of failure and were often limited by small sample sizes or brief follow-up [4,14–18]. The purpose of our study was to describe the causes and rates of early revision in patients undergoing primary TKA with the ATTUNE total knee system and to identify surgical factors associated with aseptic tibial loosening. We hypothesized that aseptic loosening would be the leading cause of early revision and failure rates, specifically debonding at the tibial implant-cement interface. We also hypothesized a low surgery volume would lead to an increased early revision rate.

Material and methods

Institutional review board approval was obtained for this retrospective study. The electronic health record of a large, rural integrated health system between March 1, 2013, and November 15, 2018, was queried to identify patients who underwent cemented primary TKA utilizing the ATTUNE total system (Fig. 2). The use of this TKA system as well as cement type in the primary setting was surgeon preference in all cases and not based on institutional standard or specific patient factor. Patients were included if they had at least 2-year clinical follow-up or revision surgery at an earlier timepoint. Patients were excluded if 2-year follow-up was not available. If patients had inadequate follow-up, they were contacted by phone utilizing an institutional review
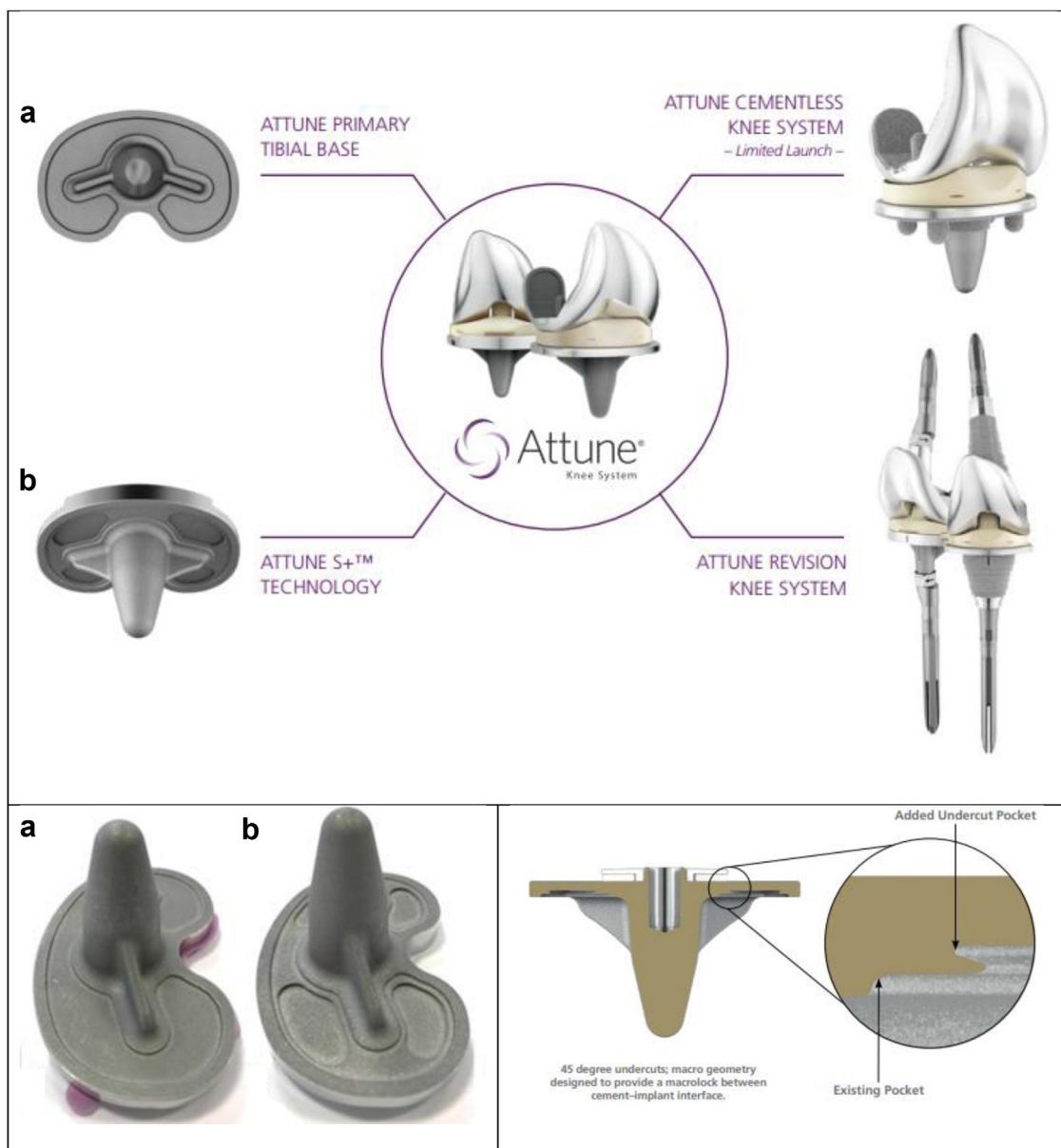

Figure 1. Images designated A demonstrate the 2012 original ATTUNE tibial base plate design compared to images labeled B of the 2017 new S+ design. The lower right panel depicts the described added undersurface "under pocket" features to provide a macrolock at cement-implant interface [11]. Specifically, the new S+ design was manufactured with greater surface roughness (3.0-6.5 Ra) to enhance cement bonding. The image is reproduced with permission from DePuy.
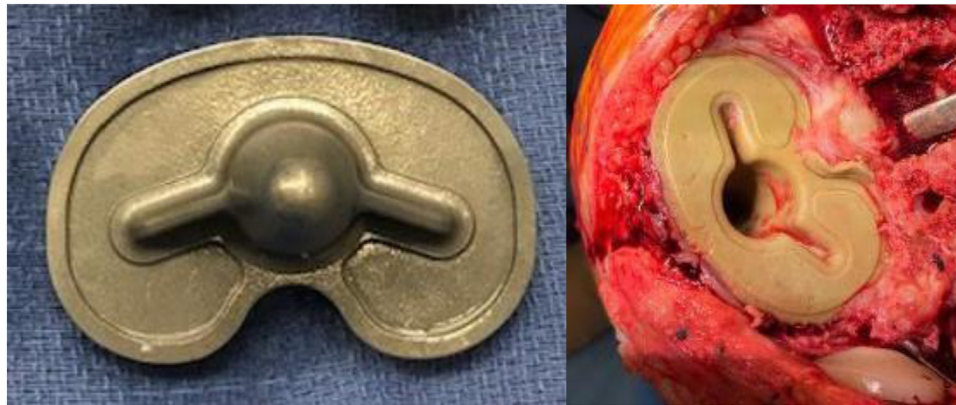
Figure 2. Example of the original ATTUNE tibial component retrieved during revision surgery. The undersurface of the component is shown demonstrating the surface completely devoid of cement adhesion. A corresponding intraoperative photograph depicting remaining cement mantle in tibia.

board-approved script of simple yes or no questions to specifically collect interval history of any information regarding detail on status and date of reoperation or revision. The phone call did not inquire about patient-reported outcomes or complaints and only asked about any surgery or procedure to the knee in question. Three attempts were made to reach the patient, and if unsuccessful, patients were excluded. Patient demographic characteristics, including age, body mass index (BMI), gender, employment status, tobacco use, and history of diabetes, were collected (Table 1).

Complications were identified using International Classification of Diseases (ICD-10: T84.*) diagnosis codes, and all cases were manually reviewed by coauthors (D.T. and B.F.) (ICD-10: international statistical classification of disease and related health problems: tenth revision, second edition, World Health Organization). Cause of revision was determined by review of the electronic health record including office visit documentation and operative reports. Surgeons were categorized based on TKA volume (high >50 vs low ≤50 cases per year) and completion of an adult reconstruction fellowship (yes or no) [19]. Cement was identified by manufacturer (DePuy Synthes, West Chester, PA; DJO Global, Vista, CA; Stryker, Kalamazoo, MI; and Zimmer Biomet, Warsaw, IN) and categorized into viscosity levels (high, medium, or low) based on the manufacturer classification. Only 1 of the 4 manufacturers (DePuy) was associated with 2 different cement viscosity types (medium and high); otherwise, DJO and Zimmer cements were of high viscosity, and Stryker was of low viscosity. Tibial baseplates were classified according to bearing type (fixed or rotating platform) and baseplate type.

Statistical analysis

We examined each of the 6 characteristics described above (surgeon volume, surgeon training, cement manufacturer, cement viscosity, bearing type, and baseplate type) individually and used chi-squared or Fisher's exact tests to compare percentages of cases

with revision and aseptic loosening within each. We then divided all cases into all 120 possible combinations of the 6 characteristics and descriptively examined which combinations of factors had the highest percentage of aseptic loosening. A statistical analysis was performed using the SAS software (SAS 9.4; SAS Institute, Cary, NC), with contrasts of $P < .05$ considered statistically significant.

Results

Of 836 cases identified, 742 (89%) met the inclusion criteria (Fig. 3). If patients had inadequate follow-up, they were contacted by phone to collect interval history pertaining to reoperation or revision data to establish the minimum follow-up. Ninety-two out of 836 (11%) were not able to be contacted to establish follow-up. None of these patients had a revision surgery within our system based on manual review of the electronic medical record. Overall, 18 patients underwent a revision surgery, resulting in a 2-year revision rate of 2.4% (95% confidence interval [CI] = 1.4% to 3.8%). Aseptic loosening was the leading cause of revision (n = 10, 55.6% of revisions) for a 2-year aseptic loosening revision rate of 1.3% (95% CI = 0.6% to 2.5%) (Table 2). All cases of aseptic loosening demonstrated debonding at the tibial implant-cement interface (Fig. 2). The mean time to revision was 22.6 months (range: 9.8-36.3 months).

Surgeries were performed by 8 surgeons using 5 different types of cement (Table 3). Taken individually, the 2 factors that were significantly associated with all-cause revision were cement manufacturer (17.1% DJO Surgical high-viscosity cement [HVC] vs

Table 1
Patient demographics.

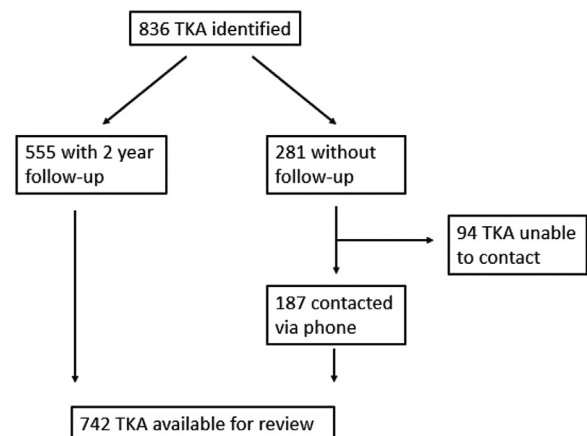| Patient demographics	All	Without revision	With revision
Age in years, mean (SD)	70.3 (9.8)	70.5 (9.6)	61.4 (11.0)
BMI, mean (SD)	33.0 (3.4)	33.0 (6.4)	35.3 (5.1)
Male, n (%)	260 (38.9)	254 (38.9)	8 (44.4)
White, n (%)	653 (97.8)	636 (97.4)	17 (94.4)
Employed, n (%)	116 (17.4)	109 (16.3)	7 (38.9)
Active tobacco use, n (%)	42 (6.3)	38 (5.8)	4 (22.2)
Diabetes, n (%)	153 (22.9)	150 (23.0)	3 (16.7)
Follow up in years, mean (SD)	3.5 (1.4)	3.5 (1.4)	3.2 (0.9)

Figure 3. Flow chart.

[Flow chart: 836 TKA identified → 555 with 2 year follow-up; and → 281 without follow-up → 94 TKA unable to contact; and → 187 contacted via phone → 742 TKA available for review]

Table 2
Causes of revision.

Cause of revision	n (%)
Aseptic loosening	10 (55.6)
Infection	3 (16.7)
Instability	2 (11.1)
Patella maltracking	1 (5.6)
Patella resurfacing	1 (5.6)
Fracture	1 (5.6)
Total	18

0.0%-2.2% for all others, $P = .0003$) and surgeon volume (10.5% low-volume surgeons vs 1.6% high-volume surgeons, $P = .0005$) (Table 4). These same 2 individual factors were also significantly associated with higher rates of revision due to aseptic loosening (14.3% DJO Surgical HVC vs 0.0%-1.1% in all others, $P < .0001$; 9% for low-volume surgeons vs 0.6% high-volume surgeons, $P < .0001$) (Table 5). Non–fellowship-trained surgeons demonstrated a marginally significant association with higher risk of aseptic loosening (2.1% vs 0.3% for fellowship-trained, $P = .05$). None of the aseptic loosening cases used low-viscosity cement (LVC) (Stryker), medium-viscosity cement (DePuy), the newer baseplate design, or the revision tibial baseplate design.

Of the 120 possible combinations of the 6 characteristics we examined, only 19 were observed as cases in the data, and of those, 9 combinations had 10 or more surgical cases in their subgroup. As summarized in Table 6, the group with the highest percentage of aseptic loosening was non–fellowship-trained surgeons using DJO Surgical HVC (n = 31, 5/31 cases, or 16.1% with aseptic loosening; 95% CI = 5.4% to 33.7%). All surgeons in this group had a low volume (<50 cases per year), and all cases used fixed-bearing tibial implants with the original ATTUNE baseplate design, making it impossible to further isolate risk factors in this group. The combination that led to the second-highest rate of aseptic loosening occurred with non–fellowship-trained surgeons using Zimmer HVC and the original tibial baseplate design (n = 51, 3/51 cases, or 5.9% with aseptic loosening; 95% CI = 1.2% to 16.2%). All implants in this group used a fixed-bearing baseplate, and the cases with low-volume surgeons in this group had a slightly lower percentage of aseptic loosening (1/19 cases, or 5.3%) compared to 2 of 32 cases or 6.3% for the high-volume surgeons. When comparing these 2 groups to the remainder of the cohort, chi-squared testing concluded that the rates of aseptic loosening in both groups were statistically significantly higher than those of the remainder of the population ($P < .01$).

Discussion

Aseptic loosening at the tibial implant-cement interface is an uncommon mode of early failure but has been reported when using the original ATTUNE total knee system [4]. This study represents the largest nonregistry review of this contemporary total knee implant with at least 2-year follow-up and is the first to present revision rates. Aseptic loosening was the most common cause for early revision, accounting for over half of early revisions. Interestingly, all cases demonstrated debonding at the tibial implant-cement interface (Fig. 2). Non–arthroplasty-fellowship-trained surgeons using DJO (medium viscosity) or Zimmer (high viscosity) cements were at the highest risk of aseptic loosening with tibial baseplate cement debonding.

Shortly after the release of this implant system, the manufacturer published its surgical technique guide, describing the design and surface finish on the underside of the tibial baseplate aimed at addressing aseptic loosening and based on internal research [7]. This design feature has given rise to conflicting outcome reports. Registry data showed low rates of overall revision, and several studies reported good short-term outcomes [12,20–23]. However, early aseptic loosening was described in several studies, and retrieval studies noted poor cement adhesion to the tibial baseplate [4,10,18,24,25]. The revision rate reported here (2.4%) is significantly higher than the 1.3% 4-year revision rate from the National Registry for England, Wales, Norther Ireland, and the Isle of Man, as well as the revision rates for the cruciate retaining option (0.5%) and posterior stabilized option (0.4%) from the 2016 Australian Orthopedic Association National Joints Replacement Registry [12,20]. All our cases involving aseptic loosening occurred with the original baseplate design and demonstrated debonding at the tibial implant-cement interface (Fig. 1). This mechanism of failure matches previous studies showing poor cement adhesion to the tibial baseplate with this implant design [4,10,24].

Numerous factors including BMI, bone quality, component alignment, implant design, and perhaps most importantly, surgical technique contribute to aseptic loosening following TKA [24]. One potential technique factor that has received recent attention is the viscosity of the cement used during prosthesis implantation. HVC appeals to arthroplasty surgeons due to its fast mixing and waiting phases with concomitant prolonged working and hardening phases compared to LVC [4,5,10]. However, prior investigations showed HVC to have less penetration into bone and weaker cement-implant shear strength in a bovine cancellous bone model and a cadaveric femur study 4/5. Recently, a previously rare mode of early aseptic loosening was reported in which the tibial component debonded at the implant-cement interface [4,5]. The use of HVC was implicated as a potential factor contributing to this failure mechanism, even though the vast majority of TKAs performed with HVC have performed well. In our study, DJO HVC was significantly associated with risk of revision and aseptic loosening. Additionally, no cases of aseptic loosening occurred with LVC. Previous studies have also demonstrated higher failure rates with HVC [19,26,27]. The case series by Hazelwood et al. reported on 9 early cases of

Table 3
Surgeon demographics and cement use.

Surgeon #	# Cases contributed	Fellowship trained	High volume	Cement brands used	Viscosities used
1	44	N	N	DJO Surgical, Zimmer	High
2	60	N	Y	DePuy	Medium, high
3	34	N	Y	Zimmer, Stryker, DePuy	Low, medium, high
4	23	N	Y	DePuy	Medium, high
5	307	Y	Y	Zimmer	High
6	192	N	Y	Stryker, Depuy	Low, medium
7	23	N	N	Zimmer, Stryker	Low, high
8	59	N	Y	DePuy	Medium, high

N, no; Y, yes.

Table 4

Numbers and percent of patients in each category of risk factor that required revision surgery (for any reason).

	N (%) with revision for any reason (n = 18)	P value
Cement brand, N (%)		.0003
DJO Surgical (n = 35)	6 (17.1%)	
DePuy (n = 265)	4 (1.5%)	
Stryker (n = 74)	0 (0%)	
Zimmer (n = 368)	8 (2.2%)	
Cement viscosity, N (%)		.12
Low (n = 74)	0 (0%)	
Medium (n = 182)	2 (1.1%)	
High (n = 483)	16 (3.3%)	
Surgeon fellowship trained, N (%)		.24
Yes (n = 307)	5 (1.6%)	
No (n = 435)	13 (3.0%)	
Surgeon with high volume, N (%)		.0005
Yes (n = 675)	11 (1.6%)	
No (n = 67)	7 (10.5%)	
Baseplate design, N (%)		.44
ATTUNE (n = 615)	17 (2.8%)	
ATTUNE S+ (n = 120)	1 (0.8%)	
ATTUNE Revision Tibia (n = 7)	0 (0%)	
Bearing type, N (%)		.66
Rotating platform (n = 63)	2 (3.2%)	
Fixed bearing (n = 679)	16 (2.4%)	

Table 5

Characteristics of patients who underwent revision surgery for aseptic loosening.

	Aseptic loosening (n = 10)	P value
Cement brand, N (%)		<.0001
DJO Surgical (n = 35)	5 (14.3%)	
DePuy (n = 265)	1 (0.4%)	
Stryker (n = 74)	0 (0%)	
Zimmer (n = 368)	4 (1.1%)	
Cement viscosity, N (%)		.07
Low (n = 74)	0 (0%)	
Medium (n = 182)	0 (0%)	
High (n = 486)	10 (2.1%)	
Surgeon fellowship trained, N (%)		.05
Yes (n = 307)	1 (0.3%)	
No (n = 435)	9 (2.1%)	
Surgeon with high volume, N (%)		<.0001
Yes (n = 675)	4 (0.6%)	
No (n = 67)	6 (9.0%)	
Baseplate design, N (%)		.44
ATTUNE (n = 615)	10 (1.6%)	
ATTUNE S+ (n = 120)	0 (0%)	
ATTUNE Revision Tibia (n = 7)	0 (0%)	
Bearing type, N (%)		.59
Rotating platform (n = 63)	1 (1.6%)	
Fixed bearing (n = 679)	9 (1.3%)	

aseptic loosening of the tibial component [26]. HVC was used in all 9 cases, and 7 loose components were from a similar implant knee system from the same manufacturer. HVC may be a contributing factor to loosening, but our review identified no cases of femoral component loosening, suggesting the unique repeated failure of the tibial component is feasibly related to tibial component design issues rather than surgeon technique.

Low-volume surgeons were found to be at a higher risk of revision for aseptic loosening. This association may be related to cementing technique. However, this hypothesis is not proven from our results and is not fully defined in the literature. A recent multicenter review of 4 academic hospitals found low-volume surgeons (<50 cases/year) to be a risk factor for implant malalignment in primary TKA [28]. However, a review of the 64,017 primary TKA cases from a Total Joint Replacement Registry demonstrated that surgeon volume (<10 cases/year, 10-49 cases/year, or ≥50 cases/year) and surgeon fellowship training were not associated with risk of aseptic revision [29]. Martin et al. presented a cadaveric study at the American Association of Hip and Knee Surgeons Annual Meeting 2021 after studying if motion during cementing significantly altered tibial implant fixation strength in 4 contemporary TKA designs [30]. They found that knee motion during cement polymerization is associated with significant decreases in tibial implant fixation strength in each implant design and recommended limiting motion while cementing the tibial implant to improve fixation strength [30]. The role of surgeon technique in implant failure remains unclear and is confounded in our review as 1 low-volume surgeon exclusively used HVC.

Recent literature has shown that the risk for revision TKA due to aseptic tibial component failure is almost 2 times greater in those with BMI ≥35 kg/m² and independent of age and coronal alignment [31]. The average BMI for our cohort was 34 kg/m², with 50% of the patients having a BMI ≥35 kg/m² consistent with other series [32–34]. Martin et al. presented a retrospective cohort of 216 patients revised for aseptic tibial loosening at the American Association of Hip and Knee Surgeons Annual Meeting 2021 in an attempt to determine if there is a difference in cement mantle thickness based on the failure interface [35]. In their study, 203 patients demonstrated radiographic failure at the implant-cement interface, and 13 patients demonstrated failure at the cement-bone interface.

The average cement mantle thickness for all anterior posterior and lateral zones was significantly greater for patients that had failure at the implant-cement interface vs for those with failure at the cement-bone interface (anterior posterior: 4.6 mm vs 1.4 mm [$P < .001$]; lateral 4.6 mm vs 1.9 mm [$P < .001$]) suggesting methods for decreasing tibial implant loosening should likely focus on improving the fixation at the implant-cement interface [35].

Aseptic loosening of the tibial component was the most common cause of early revision. Surgeon volume and cement viscosity were associated with an increased rate of failure. Aseptic failure was not seen in any case where the revision tibia and the newly designed tibial baseplate were used. We believe our findings demonstrate that cement debonding is a potential issue with the original design of the tibial component. The new tibial base plate, ATTUNE S+ was designed in 2017 to enhance tibial fixation. Four cement pockets were added for macro-mechanical fixation combined with a 45-degree undercut geometry to provide a macrolock at the cement-implant interface. Additionally, a microblast surface finish increased the surface roughness (3.0-6.5 Ra) compared to the original design (2.5-3.5 Ra) (Fig. 1). The new design of the tibial component appears to have resolved these issues although our series was not able to demonstrate statistically significant difference in performance between tibial components, likely due to a small sample size.

The results of this study should be interpreted in light of its strengths and weaknesses. Major strengths of this study are the large sample size and low loss to follow-up. There are several limitations of this study. It was conducted at a single health system with a relatively small number of surgeons with limited number of arthroplasty-fellowship-trained as well as low-volume surgeons for comparison. Excluding patients with less than 2 years of follow-up has the potential to misreport the reported data. The high rate of revision associated with 1 brand of cement, only used by 1 low-volume surgeon, introduces bias into the study. Additionally, we did not perform radiographic assessment to determine additional factors leading to cement-implant interface failure. As a retrospective, comparative, exploratory study testing multiple risk factors, caution should be taken when interpreting statistical significance of these findings, but the evidence suggests that further study of cement type and baseplate design could be warranted.

Table 6
All cases divided into 3 combination categories based on fellowship status and cement used vs all other cases.

	N, % of cases with aseptic loosening [95% CI]	P value
Category		<.01
Non-fellowship-trained, DJO cement (n = 31)	5 (16.1%) [5.4%, 33.7%]	
Non-fellowship-trained, Zimmer cement (n = 51)	3 (5.9%) [1.2%, 16.2%]	
All other cases (n = 660)	2 (0.3%) [0.04%, 1.1%]	

We echo the calls of other authors in the search of additional peer-reviewed clinical results on this total knee system. An update on the prospective clinical trials sponsored by the manufacturer (clinicaltrials.gov identifiers NCT01746524 and NCT01754363) will provide much-needed insight into the long-term success of this total knee system in large prospective trials.

Conclusions

This study represents the largest nonregistry review of the original ATTUNE total knee system. In this retrospective review at our institution, surgeon case volume and cement viscosity were factors associated with an increased rate of early failure due to tibial baseplate implant-cement interface debonding.

Conflicts of interest

Dr. Christopher Damsgaard has served as the principal investigator on project that received institutional research suppoer from Breg Inc. and his wife is an employee of Pfizer. Dr. Graham has served as the principal investigator on projects that received institutional research support from Pfizer Inc., Medtronic Inc., Astra Zeneca, and Purdue Pharma LP. All other authors declare no potential conflicts of interest.

For full disclosure statements, refer to https://doi.org/10.1016/j.artd.2022.06.012.

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