Original Article

High early failure rate for a new unicondylar knee system

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Background: This single-center retrospective study evaluated early failure rates for an unicompartmental knee arthroplasty (UKA) system with an anti-allergic surface.

Methods: We studied 87 consecutive joints received an UKA at a single center between 2017 and 2020. All patients received a fully cemented anti-allergic Univation-Aesculap partial knee replacement implant with a corundum blasting surface. All joints had precise indication of unicompartmental arthroplasty according to the current criteria of this procedure. The current series was restricted to patients undergoing medial cemented UKA. Medial compartment osteoarthritis was the main indication.

Results: We found early failure (aseptic loosening) was documented in 20 of the 87 joints (23%). The time to failure ranged from 7 weeks to 3 years, for an estimated 33% (15–46%) cumulative hazard rate for implant loosening over three years. No cases of periprosthetic joint infection were found. On average, the patients began complaining about first symptoms during the third month after surgery. In most cases (66.66%), the cement remained fixed to the bone.

Conclusions: Based on these early results, the manufacturer of this implant stopped all further distribution. Continued efforts should be made to understand the clinical and radiographic outcomes of alternative and anti-allergic surface coatings in knee arthroplasty.

Keywords: Unicompartmental knee arthroplasty (UKA); loosening; early failure; aseptic revision

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Introduction

Unicompartmental knee arthroplasty (UKA) is a procedure recognized worldwide for the treatment of unicompartmental femoro-tibial degeneration (1-3). It has been shown to be a satisfactory and less invasive alternative to TKA in selected patients (4,5). It is particularly attractive as an alternative to osteotomy or total knee arthroplasty (TKA), especially in middle-aged females (6).

Hypersensitivity to metallic implants remains relatively unpredictable and poorly understood, as well as a controversial topic among joint replacement surgeons (7,8). Coated implants have thus been developed to minimize the incidence of this complication (9).

In Germany over the last few decades an incidence of metal allergy of up to 20%—especially to nickel,

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Figure 1 Tibial and femoral components removed with no cement remaining.

cobalt and chromium—has been reported (10). This has prompted manufacturers to find ways to reduce allergic reactions in attempts to prolong implant survival. A new, hypoallergenic prosthesis, the Aesculap Univation (Aesculap®, Tuttlingen, Germany) with a corundum-blasting surface, has been used at the senior author's institution since 2017. The basis for the design and surface coating of this prosthesis was to develop a low-friction system with anti-allergic coating to reduce the incidence of immune reactions, with theoretically prolonged survival. The corundum surface used in this new system is not a novel concept in itself. Previous authors published their results using ceramic surfaces and the prospects for their use in restorative bone and joint surgery since the 1980's (11,12).

Here, we report our short-term experience with a new contemporary anti-allergic unicompartmental knee arthroplasty system which was specifically designed to address the issue of metal allergy. Given prior good results achieved using the anti-allergic Columbus Total Knee System for TKA, we started using this new UKA system believing that we would achieve similar favorable results. Our specific study objectives were (I) to estimate the rate of early failure with this new implant; and (II) to compare demographic features, morphometric, and clinical characteristics of patients experiencing versus not experience early prosthesis failure in terms of baseline demographic, morphometric, and clinical characteristics. We present the following article in accordance with the STROBE reporting checklist (available at https://aoj.amegroups.com/article/view/10.21037/aoj-22-18/rc).

Methods

Institutional board review approval

Our study obtained authorization from the Ethics Committee of our Hospital (Helios Klinik Berlin-Buch) for Human Research to carry out this study (No. 253/2021HKBB). A consent form was signed by each patient. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

Univation Aesculap UKA system

The Univation UKA is similar in its design to the Coated Columbus Knee System TKA (Aesculap®, Tuttlingen, Germany). To reduce ion release, the manufacturers added a multilayer coating system (Advanced Surface, AS) consisting of one thin adhesive chromium layer, five alternating intermediate layers composed of chromium nitride-chromium carbonitride (CrN-CrCN), and a final shielding layer of zirconium nitride (ZrN). This seven-layer coating system is applied to the surface of CoCrMo knee implants using a physical vapor deposition (PVD) method to achieve a total thickness of 4 µm (9). Therefore, there was no design change in the previous unicompartmental prosthesis. The manufacturer added the corundum surface to the previously developed unicompartment implant.

The current series was restricted to patients undergoing medial cemented UKA. Our indications for UKA were isolated unicompartmental OA or osteonecrosis; coronal deformity <15°; fixed flexion deformity <15°; intact anterior cruciate ligament and peripheral ligaments of the knee, as well as absence of inflammatory arthropathy. All patients had bone on bone changes in the medial compartment (13). In our study, there were no indications for UKA in the lateral compartment, as described by other surgeons (14,15). all procedures were performed using a similar technique. A fixed bearing cemented UKA prosthesis was used in all cases.

Between May 2017 and February 2020, 87 medial UKA procedures were performed in 82 patients. All patients had medial compartment disease caused by osteoarthritis, with no instances of osteonecrosis. In all cases, we used a cemented Univation hypoallergenic Aesculap® UKA. All procedures were performed at our institution by one of five experienced, fellowship-trained adult joint reconstruction surgeons (*Figure 1*).

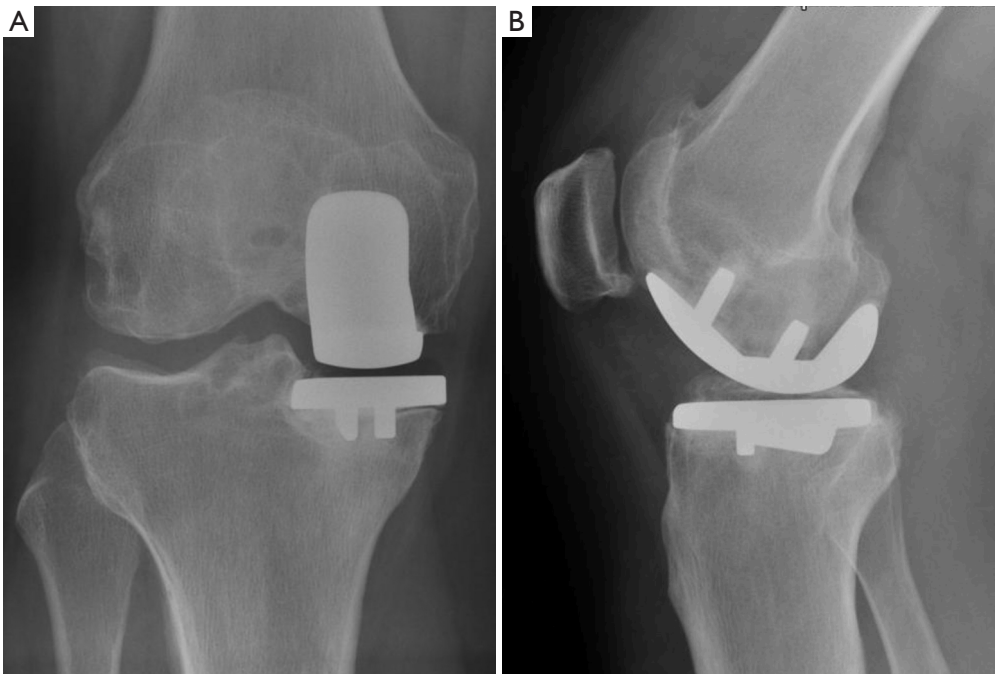

Figure 2 Tibial prosthetic interface radiolucency. (A) AP radiograph. (B) Lateral radiograph. AP, anteroposterior.

Imaging protocol

At our institution, standard radiographs are used routinely for patient diagnosis, surgical planning, and post-operative follow-up. These include antero-posterior, lateral, axial, panoramic and axial weight-bearing views. MediCAD® software is used to assist with planning every prosthesis implant procedure. All exams are recorded in our system. All cases were discussed at dedicated clinical meetings attended by at least three of the senior surgeons who performed the surgeries, as well as Radiology reports were reviewed by the Head of that Department. Thus, there was a consensus on the diagnoses (*Figure 2*).

Initial surgery

Preoperative templating was performed on all patients by the operating surgeon. During surgery, the patient was placed in a supine position and administered intravenous prophylactic antibiotics and tranexamic acid to reduce bleeding. A tourniquet was applied and inflated just before cementing. A medial parapatellar approach was performed in all cases.

Tibial cementation and insertion of the tibial component was performed prior to insertion of the femoral component in all cases. Third-generation cementing was consistently applied. Special care was taken to ensure a clean surgical field, including pulsatile jet lavage, followed by careful drying of all bone surfaces prior to cement application. Cement was applied under pressurized conditions. In all cases, pre-manufactured, antibiotic loaded PMMA bone cement (i.e., polymethylmethacrylate Palacos Gentamicin; Heraus Medical, Wehrheim, Germany) was used.

Given published results documenting safe weight-bearing and mobilization within one day in appropriately-selected patients (16), full weight bearing mobilization was permitted on the first post-operative day.

Revision surgery

Prior to revision, all patients underwent knee joint aspiration to rule out infection. Following published guidelines derived from the 2018 International Consensus Meeting on Musculoskeletal Infections (17,18), all appropriate methods to diagnose prosthetic joint infection were undertaken, both to guide treatment and to identify infection as a possible cause of early prosthesis joint loosening. During revision surgery, microbiology samples again were collected, per standard surgical protocol (*Figures 3-5*).

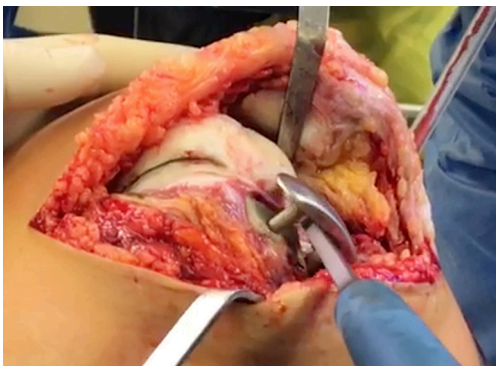

Figure 3 Intra-operative images at the time of revision surgery. Femoral gross loosening, easily removed.

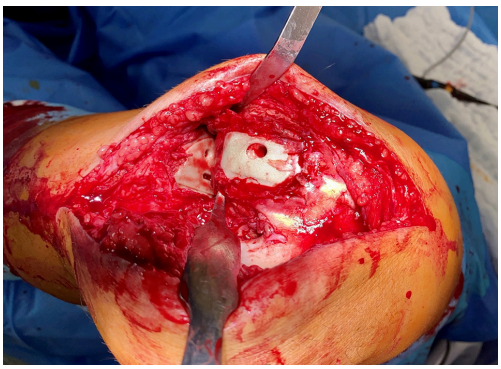

Figure 4 Intra-operative images at the time of revision surgery, exhibiting tibial and femoral with remaining cement.

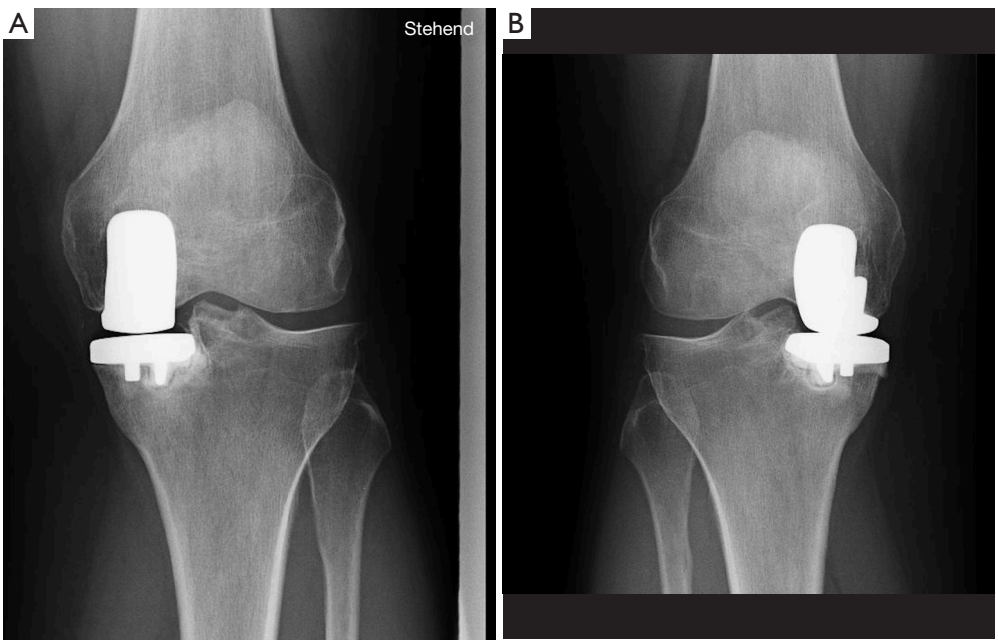

Figure 5 X-rays from a bilateral case. Both sides presented loosening with radiolucency at Tibia site. (A) AP radiograph from the left knee. (B) AP radiograph from the right knee. AP, anteroposterior.

Statistical analysis

In this paper, all continuous variables are reported as means with standard deviations (SD) ranges, while all categorical variables are reported as mean percentages, with 95% confidence intervals and ranges. Bivariate inter-group comparisons (between patients with versus without prosthesis failure) of continuous variables were conducted using Students *t* or non-parametric (log rank) tests, as indicated, while comparisons of categorical variables were conducted using Pearson χ^2 analysis or Fisher's exact test, as indicated. Survival analysis was performed to estimate the cumulative hazard of prosthesis failure through three years. All inferential tests were two-tailed with $P \leq 0.05$ set as the a-priori criterion for statistical significance. Statistical analysis was performed using statistical software R version 4.1.0. Packages used for survival analyses were survival version 3.2.11 and survminer version 0.4.9.

Results

Over the period of observation, UKA was performed on 87

Table 1 Patient characteristics

Characteristic	87 subjects, n (%)
Gender	
Male	37 (43%)
Female	50 (57%)
Age, years	61 (11)
BMI, mean ± standard deviation	29.8 (3.9)
Smoker	20 (25%)
Unknown	7
Joint side	
Left	47 (54%)
Right	40 (46%)
Post-op outcome	
Success	67 (77%)
Failure	20 (23%)

BMI, body mass index.

Table 2 Cumulative hazard of prosthetic aseptic loosening within three years of follow-up

Characteristic	3-year prosthetic loosening	P value
Overall	33% (15–47%)	
Gender		>0.9
Male	36% (3.3–58%)	
Female	33% (8.7–50%)	
Smoker		0.3
No	25% (10–37%)	
Yes	63% (0–91%)	
Joint		>0.9
Left	28% (10–43%)	
Right	39% (0.9–62%)	

For P values, groups were compared using the Log-rank test.

joints in 82 patients. Demographic data is shown in *Table 1*.

Twenty of the 87 implants (23%) failed, eight in males and 12 in females. The average age of the patients who experienced early prosthesis failure was 59.3 years (range 41–84 years) and the mean BMI was 29.8% (range 21.2–40.8). Two of these 20 patients were smokers. The earliest onset of symptoms was three months post-operatively.

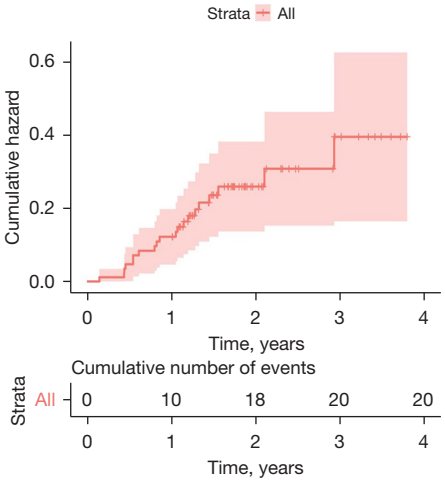

Figure 6 Cumulative hazard ratio of prosthetic loosening.

All 20 patients presented complaining of severe pain and swelling, and of progressively reduced range of motion in the affected knee.

The mean time between UKA surgery and the diagnosis of prosthesis loosening diagnose was 13 months (5–29 months). The cumulative three-year failure rate was 33% (95% CI: 15–46%). After one year under observation, the rate of prosthesis failure was 12%, increasing to 23% within two years. The follow-up was three years (*Table 2*). Comparing patients who experienced prosthetic joint failure against those who did not, there were no significant differences in age, sex, height, weight, BMI, preoperative or postoperative AP angle, the amount of correction obtained, posterior tibial slope obtained, or the angle of the femoral component in the sagittal plane (*Figures 6,7*).

Discussion

Unicompartmental knee replacement surgery has produced encouraging results using various implant designs and techniques in recent decades. Implant survival rates of over 90% have been reported at up to 10 to 15 years after surgery (19-21). Given the increased interest of patients in Germany and generally increasing discussion regarding anti-allergic implants, we started using an antiallergic UKA system in 2017. The first ceramic implant for unicondylar tibial surface replacement was reported 50 years ago and resulted in limited wear between the ceramic and cartilaginous surfaces (22). Undercuts generated is a highly efficient way to augment mechanical adhesion to a Co-Cr-

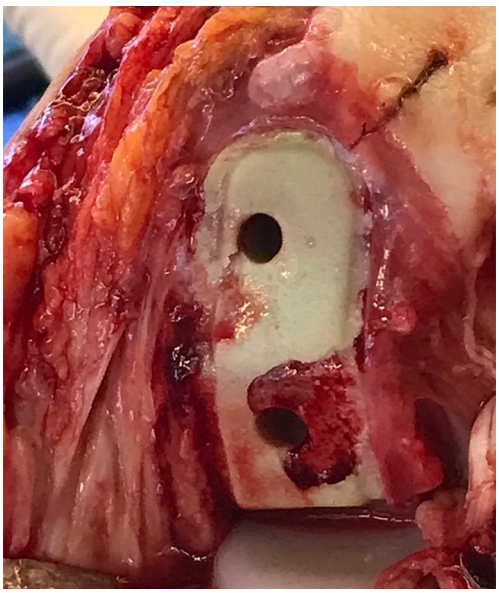

Figure 7 Femoral surface site exhibiting the cement remained well-fixed to the bone surface.

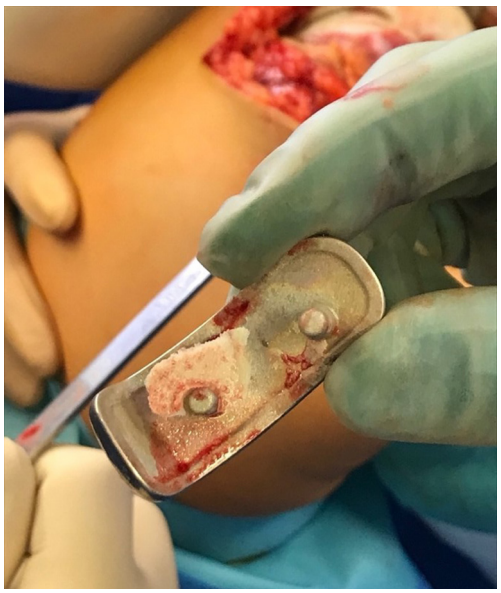

Figure 8 Femoral component after removal, demonstrating debonding of the cement from the prosthesis.

Mo surface; however, this is not possible on a ceramic surface, due to the brittleness of ceramics. Lack of bone cement retention promotes micromotion of the prostheses which, in turn, predictably leads to early aseptic loosening (23).

Following recognition of this high rate of prosthesis failure (projected as 33% over the first three years), we immediately stopped using the implant. We also sent an official warning to the manufacturer of this implant. Consequently, all further distribution of the anti-allergic UKA system was promptly discontinued in Germany to this day.

So far, the main cause of this extremely high rate of early aseptic loosening is not yet clear. A comparable total knee system using the same coating and produced by the same company has shown stable and satisfactory results (24). Some authors describe allergic reactions to the constituent metal used for the metallic components of the prostheses. Apostolopoulos *et al.* (25) described severe evidence of metallosis within the periprosthetic soft tissues of a 67-year-old female patient. In this patient, the tibial component was found to be loose, and the polyethylene bearing dislocated posteriorly. The same authors performed revision surgery for UKA failure due to allergic reactions to a TKA using an oxinium implant, identifying a positive reaction to a nickel lymphocyte proliferation skin allergy test (26). A similar case was reported by Bergschmidt *et al.* (27), involving a 58-year-old female patient with type IV hypersensitivity against both the nickel-II-sulfate and palladium chloride used during a TKA.

Law *et al.* (8) performed a retrospective review of a cohort of patients with self-reported metal allergy who underwent primary TKA employing an alternative ion-impregnated titanium implant. After a 4.6 years of follow-up, their results were encouraging, suggesting a potential implant option for patients with self-reported metal sensitivity. It is precisely this type of allergic reaction that we try to avoid with the newly-conceived hypoallergenic systems. Most of our 20 patients who experienced prosthetic joint failure were discovered to have synovial membrane thickening with hyperemia, an exudate, and synovium interposed between the cement and prosthesis surfaces at the time of revision. However, the patients' skin showed no signs of allergy such as petechiae, dermatitis, or pruritis. For this reason, our impression is that the early loosening we observed was not an allergic reaction.

Similar to Mariani *et al.* (28), we were unable to identify any factors that were statistically associated with early loosening of the femoral component. There was no statistical association between early loosening of the femoral component and age, sex, height, weight, BMI, preoperative or postoperative AP angle, the amount of correction obtained, posterior tibial slope obtained, or the angle of the femoral component in the sagittal plane.

In our cohort, loosening of the contact surface between the metal components and cement mantle—which

remained fixed in most cases—was the most prevalent factor (*Figures 7,8*). The quality of cementation was similar to what we have observed over decades during other TKA and THA our team has performed. As such, we do not feel that the high rate of loosening we observed was due to technical deficiencies, since we have never experienced such levels of failure with our other total joint surgeries.

The modes of UKA failure most commonly reported over the first and second decades post implantation have been polyethylene wear, progressive arthritis, and component loosening (29), none of which we observed in our series. Campbell *et al.* (30) reported the failure of biconcave unicompartmental polyethylene developed for mobile-bearing UKA, including four polyethylene fractures in the central area. The system they used was thereafter removed from the market. Arastu *et al.* (31) also noted failure with mobile bearings, reporting a 21% rate of required revision for the LCS Preservation mobile-bearings prostheses within 22 months of implantation. The high failure rate identified in this study led to them ceasing to use this implant. Citak *et al.* (32) and Epinette *et al.* (33) reported similar results, with more than 50% of revisions failing in both series within the first five years after UKA implantation. We did not attempt to model past three years; but it certainly is conceivable that our patients would have experienced at least a 50% failure rate over two additional years of implant wear.

Other surgeons have experienced the failure of ceramic-coated implants manufactured by the same company (Aesculap) that manufactures the Universion UKA. Lionberger *et al.* (34) also observed an alarming rate of cement debonding with tibial implants. As with our cases, these authors reported how easily the implant could be lifted out of its cement bed, leaving a perfect implant imprint indicating the previous fixation point.

In the National Joint Registry (NJR) of England and Wales, reasons for UKA revision include infection (6% of cases), loosening/lysis (30%), component/polyethylene wear (2%), intractable pain (23%), and progressive osteoarthritis (4%), among others. In their last three-year period report, out of 33,676 primary UKA, unicondylar knee surgery involved using a mobile bearing in 62.5% (35).

In their twenty-year report, the New Zealand Joint Registry identified 1,038 revisions among 12,627 registered UKA (8%). The mean time between UKA and revision was 2,080 days, with a minimum of 4 days. In the first year, 13.9% of revisions were caused by pain, 9.3% by femoral component loosening, and 17.7% by tibial component loosening (36).

Reporting on the results of a 25-center study, Epinette *et al.* noted that 19% of the UKA revisions occurred within the first year and 48.5% within the first five years. Loosening was the main reason for failure (45%), followed by osteoarthritis progression (15%) and wear (12%) (33).

The results that most closely resemble our own were reported by Mariani *et al.* (28), who diagnosed early failure in 39 UKAs, 15 (38%) from 9 to 12 months postoperatively. All patients in their series had received a DePuy Preservation prosthesis (DePuy, Warsaw, In) with an all-poly tibial component.

Our study has several limitations, foremost among them the lack of a control group. Second, at the beginning of the study, we were not expecting such a substantial percentage of early failure with this new device. Thus, we faced the dilemma of deciding which patient and procedural parameters were most important after our series had begun. Third, our evaluation was limited to macroscopic reasons for UKA loosening, without exploring potential microscopic explanations. For the latter, we addressed our concerns to the manufacturer of this prosthesis, assuming that they will be compelled to perform their own evaluations before reintroducing this or any similar prosthesis into the market.

Conclusions

In our series of 87 procedures using an anti-allergic UKA system, we observed an unexpectedly and unacceptably high rate of early loosening, projected to reach roughly one in three cases within three years. Though no cause for this high rate of prosthesis failure was identified, it is our belief that the answer lies in the loss of bonding at the implant-cement-bone interface. Until the reason is found, and the device modified to correct for this shortcoming, we have stopped using and the manufacturer has ceased distributing this implant.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://aoj.

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Data Sharing Statement: Available at https://aoj.amegroups.com/article/view/10.21037/aoj-22-18/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://aoj.amegroups.com/article/view/10.21037/aoj-22-18/coif). DK serves as an unpaid editorial board member of *Annals of Joint* from April 2022 to March 2024. The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Our study obtained authorization from the Ethics Committee of our Hospital (Helios Klinik Berlin-Buch) for Human Research to carry out this study (No. 253/2021HKBB). A consent form was signed by each patient. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

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