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Long term follow-up of a completely metal free total knee endoprosthesis in comparison to an identical metal counterpart

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Aseptic loosening is a feared and not yet fully-understood complication of total knee arthroplasty (TKA). Hypersensitivity reactions may be the underlying cause within some susceptible patients. Metal-free implants have been developed as a possible solution. The aim of this prospective, observational long-term study was the assessment of a completely metal-free ceramic knee replacement system compared to its identical metal counterpart 8 years after implantation, conducted as a follow-up of a previous report. A total of 88 patients (mean age 69 years) were enrolled in this prospective, observational long-term 8-year follow-up study. The "ceramic group" with a completely metal-free total knee replacement system was compared to the "conventional group" with an identical metal TKA system at the final follow-up. Clinical assessment included Knee Society Score (KSS), Oxford Knee Score (OKS), European Quality of Life 5 Dimensions 3 Level Version (EQ-5D-L), European Quality of Life 5 Dimension Visual Analogue Scale (EQ-VAS) and High Activity Arthroplasty Score (HAAS) as well as perioperative or postoperative complications and need for revision. The tibial/femoral positioning, signs of periprosthetic fissures/fractures or radiolucent lines were documented radiographically. All postoperative clinical scores in the ceramic group primarily improved from baseline to 4-year follow-up, but then decreased at the final 8-year follow-up. At the final follow-up, statistically non-significant differences were found in comparison of both groups for the KSS (ceramic: 166 ± 31, conventional: 162 ± 29; $p > 0.05$), OKS (ceramic: 37, conventional: 39; $p > 0.05$), EQ-VAS (ceramic: 77 ± 17, conventional: 72 ± 18; $p > 0.05$), and HAAS (ceramic: 8.29 ± 3.32, conventional: 9.28 ± 4.44; $p > 0.05$). A significant difference was found for EQ-5D-L (ceramic: 0.819 ± 0.284, conventional: 0.932 ± 0.126; $p \leq 0.05$). Progressive radiolucent lines have been found around the uncemented tibial stem (0.8 mm at initial diagnosis (mean 19 months); 1.3 mm at 4-year follow-up; 1.6 mm at 8-year follow-up) without any clinical signs of loosening. One revision surgery was performed after a traumatic polyethylene inlay-breakage. No allergic reactions could be detected. The used ceramic TKA system meets the functional performance standards of an established identical metal TKA system after an 8-year follow-up period, offering a safe option for patients with prior hypersensitivity reactions to metallic materials. Full cementation of ceramic components is recommended.

With rising life expectancy and higher activity levels of patients, more durable total knee arthroplasty (TKA) systems are being sought. In this context, there are growing concerns about aseptic loosening caused by metal hypersensitivity, which unfortunately still is a poorly understood phenomenon. Almost 20% of patients with properly aligned and well-fixed knee implants remain dissatisfied with the results, which in turn puts a great burden on both the surgeon and the patient[1].

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It is a well-known fact, that any metal being placed within a biological environment will undergo corrosion. The large metallic surfaces of TKAs are particularly prone to such corrosive processes, with subsequent release of metal ions into the human tissue[2]. An increased metal ion concentration in patients' blood plasma after TKA has been detected, which may cause common hypersensibility reactions[3]. Early failures of orthopedic implants due to mechanical loosening have recently been related to indirect activation of macrophages through metal ions after contacting host fluids[4].

Within the general population, the prevalence of cutaneous hypersensitivity to nickel is approximately 10–15%[4,5], and as high as 25% in patients with metal previously implanted[6,7]. However, the actual incidence of metal hypersensitivity to general metallic implants is less than 1%[8]. Up to 60% of all patients with failure of total joint arthroplasty express signs of metal allergy with positive allergologic test results, but the actual influence on the implant's service life remains unclear[7]. Signs of hypersensitivity to the previously implanted metallic joint replacement may be unexplainable postoperative pain, sustained swelling, decreased range of motion and bone resorption[1,6]. Cutaneous reactions like eczema or dermatitis are not always present[1,6].

In several patients with aseptic implant loosening and verified metal allergy, contact-induced local/general allergic reactions remained until removal of the orthopedic device[9]. Nickel constitutes the highest metal sensitivity within the population, and is usually included in orthopedic implants to grant necessary implant strength and durability[10]. Most common orthopedic implants consist of 316 L stainless steel (19% chromium, 14% nickel), cobalt-chromium-molybdenum (67% chromium, 30% cobalt, 2% molybdenum, 1% nickel), or titanium-alloy (91% titanium, 5% aluminum, 3.9% vanadium, 0.1% nickel)[11].

To avoid at least part of the problems in patients with known history of hypersensitivity reactions to metals, "hypersensitivity-friendly" metal-free implants and instruments have been developed[12,13]. Especially bio-ceramic materials have already shown promising in vitro and in vivo results with a comparable outcome to standard metal implants[14–16].

The aim of this prospective, observational long-term study was the assessment of a completely metal-free ceramic knee replacement system compared to its identical metal counterpart 8 years after implantation, conducted as a follow-up of a previous report by the current authors[17].

Materials and methods

Study population

This study was conducted as a prospective, observational long-term study over a follow-up period of 8 years. A total of 88 patients have been enrolled at the beginning.

Forty-two patients were enlisted into the "Ceramic group" and implanted with the completely metal-free Brehm Precision Knee System (BPK-S) Integration total knee replacement system® (Peter Brehm GmbH, Weisendorf, Germany) with a composite matrix material containing aluminum oxide (Al_2O_3) and zirconium oxide (ZrO_2) (Biolox®delta; CeramTec AG, Plochingen, Germany) for both the femoral and tibial components. A standard, fixed bearing ultra-high-molecular-weight polyethylene (UHMWPE) inlay was used to complete the wear couple.

Another 46 patients were enrolled into the "Conventional group" and implanted with the identical standard BPK-S total knee arthroplasty made of a cobalt-chrome alloy. The same UHMWPE inlay was used as implanted in the "Ceramic group".

For both groups, consecutive recruiting has been performed. Subjects from the conventional group were initially recruited for a primary control group, which could not be examined at the beginning due to a lack of financial resources.

Inclusion criteria were age > 18 years and < 85 years at the date of surgery, osteoarthritis or rheumatoid arthritis of the knee joint which required TKA after failing conservative treatment with consecutive severe limitations of activities of daily life (ADLs), credible anamnestic or via epicutaneous test suggested hypersensitivity reactions to metallic materials (for the "ceramic group")[1,7].

The Exclusion criteria were age < 18 or > 85 years, previous surgery causing measurable alterations of the lower extremity such as osteotomy or patellectomy, preoperative ROM of < 90° flexion, > 20° of fixed valgus or varus deformity, severe ligamentous instability, excessive extra-articular femoral or tibial hereditary or post-traumatic bony deformity (defined by the need for concomitant extra-articular osteotomy or an implant with varus-valgus constraint), revision TKA, previous intra-articular knee infection or osteomyelitis of the adjacent bones, metastatic cancer, major neurological or musculoskeletal disorders altering gait pattern or weight bearing, drug addiction, and pregnancy. All patients had to give their written consent to participate within this study, all methods were performed in accordance with the relevant guidelines and regulations. The study was approved by the ethics committee of the Territory of Upper Austria (Study-Nr. B-13–11) and registered in ClinicalTrials.gov (Identifier: NCT03097471).

Intra- and perioperative management

All cases were preoperatively planned via aid of a surgical planning software (MediCAD®, HECTEC GmbH, Landshut, Germany). Full-length a.p. standing radiographs were used according to the technique used by McGrory[18]. Resection lines were planned to acquire a mechanical axis of 0° deviation. For exact implant positioning, an extramedullary guided technique was used for the tibial component and an intramedullary system for the femoral component. Intraoperative ligament balancing guaranteed the proper rotational positioning of the femoral component. The instrumentation was of identical design for both implants, except for a complementary special plastic coating for the metal-free implant to strictly prevent any metal contacting the ceramic components. Standard polymethyl-methacrylat (PMMA) bone cement (Palacos®, Zimmer Biomet; Freiburg im Breisgau, Germany) was used to fixate the femoral and tibial components. The ceramic implants had to be

meticulously dried off before cementing. In both implants, the tibial post was spared during the cementation process, as it is viable according to the recommendation of the manufacturer. The cement mantle had to be below a thickness of 2 mm for the femoral component. The patients were mobilized under the tutelage of experienced physiotherapists starting on the first postoperative day according to a standardized procedure. They were allowed full weight bearing using two crutches. For prophylaxis of venous thrombosis, a light molecular weight heparin was administered on a daily basis for six weeks. A continuous passive motion (CPM) device was used to help the patients exercise their knee joint during their in-hospital stay until they reached 90 degrees of flexion, which was a main criterion for dismissal. Other criteria for hospital discharge were safe climbing of at least 1 flight of stairs and a compensated pain situation.

Clinical evaluation

The clinical outcome of the ceramic implant was evaluated preoperatively (baseline), as well as 12 months, 48 months and 96 months postoperatively using the Knee Society Score (KSS)[19], Oxford Knee Score (OKS)[20], European Quality of Life 5 Dimensions 3 Level Version (EQ-5D-L) and European Quality of Life 5 Dimension Visual Analogue Scale (EQ-VAS)[21]. The control group has been introduced only for the final follow-up, therefore no prior values have been acquired for the aforementioned parameters. For evaluation of sports activity level, the High Activity Arthroplasty Score (HAAS) was used at final follow-up in both groups[22]. Collected data also included occurrence of early/late revision surgery, medical device incidences, and any pre-/intra-/postoperative complications of any kind throughout the entire study period.

Radiological evaluation

As previously described, preoperative standardized X-rays of the respective knee joint (anteroposterior, lateral, full-length ap standing) were obtained for every patient in the ceramic group. Radiological follow-up, obtaining the same X-rays, occurred on the first postoperative day (except full-length a.p. standing), and at follow-up visits after 3 months, 6 months, 12 months, 24 months, 48 months and 96 months. All cases in the control group have undergone radiological follow-up as well, but not in the same strict intervals. The tibial/femoral component positioning was evaluated by two independent observers in the standard anteroposterior and lateral views according to the method of the Knee Society Roentgenographic evaluation[23], documenting the implant positioning and alignment, any periprosthetic fissures/fractures, as well as possible radiolucent lines or osteolysis.

Statistical analysis

Descriptive data are presented as mean and standard deviation for between-subject data. For within-subject data the median and range are reported additionally. Standard distribution testing was performed by means of the Shapiro–Wilk test. Due to the violation of normal distribution, within-subject differences of score values (KSS, OKS, EQ-5D-L, EQ- VAS and HAAS) and radiographic measurements, at the follow-up measurements were evaluated using the Friedman-Test. To determine the magnitude of effects found, Kendall's W was calculated for each Friedman-Test. In case of a significant results post-hoc Bonferroni corrected pairwise comparisons were conduncted using Wilcoxon Test.

For between-subject comparisons independent sample T-test (two-sided; robust against normal distribution violation) was used with adjustment of degrees of freedom (Welch). To determine the effect size of between-subject comparisons Cohens d was used. The level of significance for all conducted analyses was set to $p \leq 0.05$. All statistical analyses were undertaken using R (Version 2023.03.0 Build 386) and written as RMarkdown report.

Results

The "ceramic group" consisted of 42 cases with a mean age at surgery of 69 ± 8.38 years and 74 ± 7.73 years at the final follow-up. Thirty-six (86%) of these patients were female. The surplus of female cases in the ceramic group can be explained by the much higher prevalence of metal allergies in the female population[24,25]. The primary indications for total knee arthroplasty were osteoarthritis (96%) and rheumatoid arthritis (4%). Patients' median hospital stay was 11 days (Min = 7d, Max = 21d). The "conventional group" consisted of 46 cases with a mean age at surgery of 69 ± 8.64 and 75 ± 7.96 years at the time of the last follow-up. Twenty-six (57%) of these patients were female. The indication for total knee arthroplasty was osteoarthritis in all included cases. Average hospital stay was 11 days (Min = 6d, Max = 29d) as well. Patient age and hospital stay comparison did not reveal any statistical difference ($p = 0.337$; $p = 0.531$). One revision surgery had to be performed in the ceramic group because of a broken polyethylene inlay after a traumatic event, which occurred roughly six years after implantation. This patient has been excluded from further follow-up. Furthermore, one case of postoperative deep vein thrombosis was diagnosed in each group, which did not prevent further follow-up visits for study purposes. At the eight-year follow-up, no more complications have been registered.

At the final follow up, 31 patients were left to analyze in the ceramic group. The one mentioned patient was excluded due to revision surgery, 7 patients have died, and 3 patients were lost to follow-up. In the conventional group, 32 patients could be examined at the latest follow-up. Of the initial group, 10 patients died, and 4 were lost to follow up.

"Ceramic group"

All but one patient developed radiolucent lines around the tibial post of the prosthesis. The mean width of radiolucent lines at the tibial post at initial diagnosis was 0.8 ± 0.5mm and the average duration until primary diagnosis was 19 ± 21 months (Min = 3, Max = 93) after surgery. Over time, the radiolucencies progressed to a width of 1.3 ± 1 mm ($p = 0.004$) at the 4-year follow-up and 1.6 ± 1.1 mm ($p < 0.001$) at final follow-up after eight years. The effect size showed a moderate magnitude (Kendall-W 0.46). The exact development is depicted in Figs. 1 and 2.

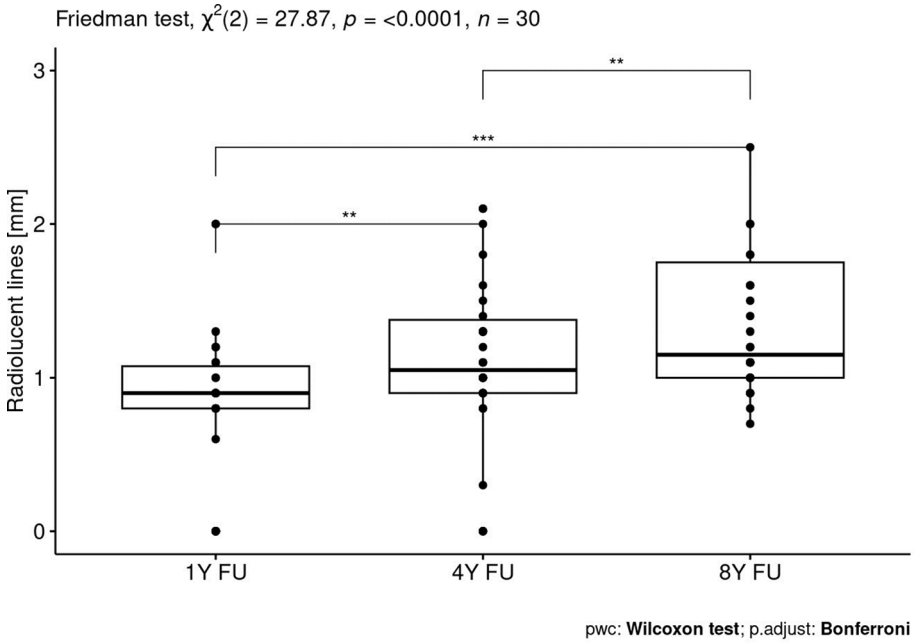

Fig. 1. Development of radiolucent lines after metal-free implant ("Ceramic group"). Significant progression from the 1-year follow-up (1Y FU) to 4-year (4Y FU) and 8-year follow-up (8Y FU).

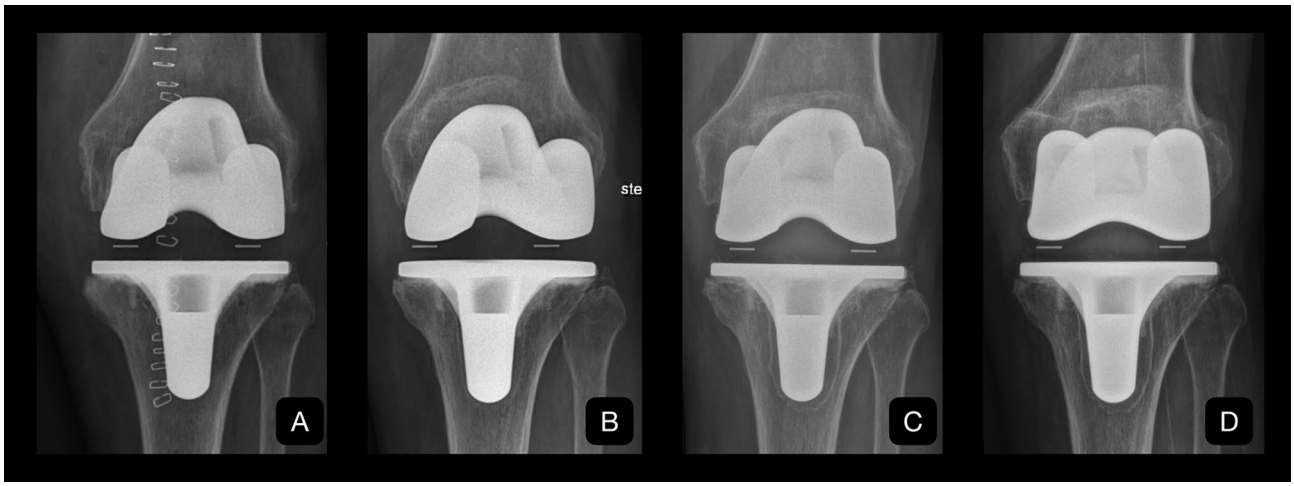

Fig. 2. Radiographs of radiolucent lines around the tibial post ("Ceramic group"). X-rays taken from a 59 year old patient, left knee. (**A**) postoperatively; (**B**) 1-year follow-up; (**C**) 4-year follow-up; (**D**) 8-year follow-up.

Each individual score improved significantly from baseline to 1 year postoperatively ($p \leq 0.001$). The functional scores Knee Society Score and Oxford Knee Score remained at the same level until the 4-year follow-up compared to one year after surgery ($p = 1$), but decreased significantly from four years to eight years after surgery ($p \leq 0.001$).

The EQ-5D-L and EQ-VAS developed divergently. The EQ-5D-L showed a significant decrease between the first and fourth year after surgery ($p = 0.007$) with no further differences compared to the eight postoperative year ($p = 1$). The EQ-VAS improved significantly from 1-year follow-up to 4-year follow-up ($p \leq 0.001$), but decreased from the 4-year follow-up to the final eight year examination ($p \leq 0.001$). To the eight year follow up, each score showed a significant decrease ($p \leq 0.001$), except for the EQ-5D-L, as already stated above. When comparing the baseline values to the final follow-up, the OKS ($p = 1$) decreased to the baseline level, whereas the KSS, the EQ-5D-L and EQ-VAS ($p \leq 0.001$) remained constantly better. For each of the intraindividual score comparisons, the effect size showed a large effect (Kendall-W: KSS: 0.77; OKS 0.71; EQ-5D-L: 0.5; EQ-VAS 0.8). Eight years after surgery, the High Activity Arthroplasty Score (HAAS) was assessed with a sample mean of 8.29 ± 3.32, where the maximally achieved score could have been 18.

The exact numbers of each individual score and its respective development during the follow-up period are depicted in Fig. 3 and Table 1.

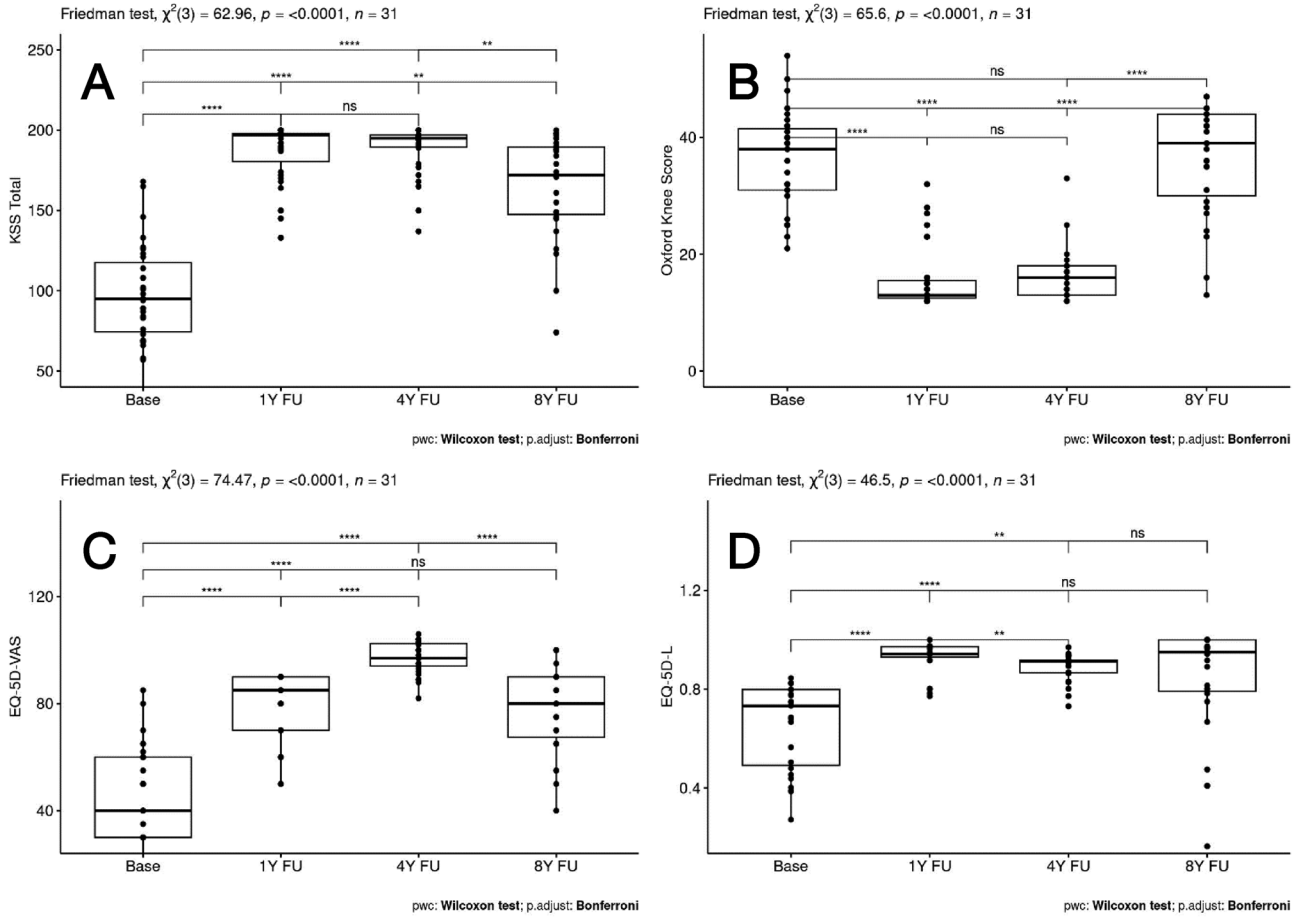

Fig. 3. Development of functional and quality of life score after metal-free implant ("Ceramic group"). (**A**): Knee Society Score KSS, (**B**): Oxford Knee Score, (**C**): EQ-VAS, (**D**): EQ-5D-L; 1Y FU = 1-year follow-up, 4Y FU = 4-years follow-up, 8Y FU = 8-years follow-up; * = statistically significant; ns = statistically non-significant;

Functional parameters—metal free implant ("Ceramic group")							
Score	**Baseline**	**1-year FU**	***p*-value (Base vs. 1Y)**	**4-year FU**	***p*-value (1Y vs. 4Y)**	**8-year FU**	***p*-value (4Y vs. 8Y)**
Knee Society Score	96 ± 32 (13–168)	187 ± 18 (133–200)	≤ 0.001	189 ± 15 (137–200)	0.692	166 ± 31 (74–200)	≤ 0.001
Oxford Knee score	36 ± 8 (21–54)	16 ± 5 (12–32)	≤ 0.001	16 ± 4 (12–33)	0.382	36 ± 9 (13–47)	≤ 0.001
EQ-5D-L	0.643 ± 0.205 (−0.018–0.845)	0.929 ± 0.064 (0.772–1)	≤ 0.001	0.890 ± 0.054 (0.731–0.97)	= 0.001	0.819 ± 0.284 (−0.18–1)	= 0.829
EQ-VAS	52 ± 11 (40–65)	80 ± 13 (50–90)	≤ 0.001	97 ± 6 (82–106)	≤ 0.001	77 ± 17 (40–100)	≤ 0.001

Table 1. Functional parameters during follow-up period after metal free implant ("Ceramic group"). The parameters are depicted as arithmetic mean and standard deviation. Minimum and maximum are stated in the brackets. The *p*-values represent the differences between the respective follow-ups.

"Ceramic group" vs. "conventional group"

As already stated above, the two groups did not differ in age or gender characteristics as well as in the duration of hospital stay. Due to the identical nature of implantation technique and implant system, comparability of the two groups is given. Comparing the two groups at 8-year follow-up, functional outcome parameters did not differ significantly, with the EQ-5D-L being an exception. The single exception was the EQ-5D-L with a small significant difference in favor of the convention implant. Table 2 gives an overview about exact numbers and *p*-values of the group comparison.

	Functional outcome at 8-year follow-up Ceramic vs. Conventional		
	Ceramic	Conventional	*p*-value
Knee Society Score	166 ± 31 (74–200)	162 ± 29 (110–200)	0.596
Oxford Knee score	37 ± 9 (13–47)	39 ± 7 (25–48)	0.41
EQ-5D-L	0.819 ± 0.284 (− 0.18–1)	0.932 ± 0.126 (0.49–1)	0.049
EQ-VAS	77 ± 17 (40–100)	72 ± 18 (40–100)	0.265
High Activity Arthroplasty Score	8.29 ± 3.32 (3–14)	9.28 ± 4.44 (2–17)	0.319

Table 2. Comparison of functional parameters at 8-year follow-up ("Ceramic group" vs. conventional group). The parameters are depicted as arithmetic mean and standard deviation. Minimum and maximum are stated in the brackets.

Discussion

Since the role of hypersensitivity reactions to metallic materials and possible consequent aseptic loosening is not yet finally determined in susceptible patients, a certain factor of insecurity remains for both patient and surgeon once complaints after TKA arise[26]. To our knowledge, this is the first long-term follow-up investigating the clinical outcome and safety of a completely metal-free TKA system.

A recent systematic review by Xiang et al., showing satisfactory mid- and long-term survival of ceramic femoral components in total knee arthroplasty, are somewhat comparable with conventional alloy components[27]. Another recent systematic review and meta-analysis by Banci et al. investigated nitride-based ceramic coatings in total knee arthroplasty[28]. The results showed comparable survival rates, complication rates, metal blood concentration and clinical outcome among the two groups after a 1-year follow-up[28]. These findings are compatible with our research, where ceramic components in TKA display highly similar outcomes compared to their metallic counterparts even after a follow-up period of 8 years.

A 13-year follow-up study of oxinium-zirconium femoral components compared to cobalt-chrome femoral components in patients' contralateral knee showed very similar results regarding functional scores and range-of-motion. No radiographic evidence of osteolysis or loosening around the ceramic femoral component was detected in CT scans. The Kaplan–Meier survivorship free from revision was 97% vs. 98%[29]. In our study group, radiolucent lines appeared in all but one patient after ceramic TKA around the tibial post, which we already documented in a previous paper[17]. Nevertheless we did not find any sign of clinical component loosening (e.g. pain, effusion or instability) in our patients. As described in our previous report, the missing cement mantle around the post could have led to this phenomenon[17]. Non-progressive partial radiolucent-lines have been described in 6 out of 38 patients (5 tibial, 1 femoral) with the same metal-free TKA system at 1-year follow-up by Meier et al., each being less than 1 mm in width and occurring at the bone-cement interface[12]. Guha et al. generally ascribe such radiolucent lines to a stress-shielding phenomenon or poor cement penetration due to sclerotic bone[30]. Whatever the underlying reason for our progressive radiolucent lines may be, they currently do not affect the clinical presentation, as no revision surgery due to loosening or pain had to be undertaken at 8-year follow-up. However, the progression will need to be examined closely within the next years to further guarantee efficacy and safety of this system, as well as to draw final conclusions concerning the survival rate and polyethylene wear of the ceramic TKA. Even if radiolucent lines do not always warrant revision surgery in "conventional" TKA designs as well[31], we still recommend to use full cementation around the entire implant-bone interface. Therefore further radiolucencies may be avoided and consequent uncertainties from patients as well as unwanted revision from alarmed colleagues can be prevented. In general, we had a surprisingly high implant survival rate. Nevertheless it should be stated, that a noticeable amount of patients died in course of the follow up, in both the conventional and ceramic group, so the actual long term implant survival rate may be affected due to this fact.

Finally, none of our patients developed an allergic reaction to the implant or exacerbation of existing hypersensitivities, therefore underlining the rationale of utilizing completely metal-free TKA in patients with known hypersensitivities. Regarding functional outcome, the above mentioned study demonstrated a similar Knee Society Score at 13-year follow-up with patients aged less than 55 at implantation, in comparison to our 8-year follow-up with a mean age of roughly 69 at the time of implantation[29]. Similar long-term clinical results were shown by Heesterbeck et al. at 11-year follow-up of 189 cases comparing fixed-bearing vs. mobile-bearing metallic TKAs, with a mean total KSS of 157[32]. Kim et al.[33] published a mean Knee Society Score of 172 at 11-year follow-up within 92 bilaterally implanted TKAs (high-flexion fixed-bearing vs. high-flexion mobile bearing) at a mean age of 72 years at final follow-up. Although our studied patients were older at final follow-up with a mean of roughly 79 years, a similar mean Knee Society Score could be found. The Oxford knee score, as another valid tool to asses general function after TKA, revealed similar results to current literature as well[34]. In addition, this case series represents one of the longest follow-up intervals, in which the Oxford knee score has been assessed.

Our results showed a highly satisfactory increase in clinical scores from baseline until the 4-year follow-up. However, the 8-year follow-up depicted a statistically significant decrease in Knee Society Score, Oxford Knee Score and EuroQol VAS. Nevertheless, most of the functional scores remained at a higher average than the respective baseline levels. Similar findings were published by Bercovy et al., arguing a slight functional decrease already at 4-year follow up within 152 TKAs with minimal ligament release due to increasing age[35]. The same can be seen in another case series by Williams et al.[34]. We can support this explanation, as our elderly patients presented many additional musculoskeletal ailments aside from the satisfactory function of the TKA. These further limitations could certainly affect the answers for respective clinical scores and lead to a non-knee specific reduction.

Since the elderly population is continuously increasing their activity level, we focused not only on "classic" pain-centered outcome scores, but took quality of life and even sports activity into account. Even if the average age of our subjects at final follow up was 79 years, the patients in both groups did reach a comparatively good sports performance in the HAAS score[36,37]. This emphazises the importance of these matters even in the elderly population, when the success of arthroplasty is evaluated in future research projects. Compared to current literature of conventional and anti-allergic TKA our quality of life results appear very similar[31,38]. We could see a barely significant difference between the conventional and ceramic TKA group at final follow-up, which can be attributed to the larger standard deviation, and in our opinion does not depict any specific clinical relevance. In total, the metal-free alternative shows acceptable long-term-results at the time of final follow-up, not only in comparison to current literature but also in direct comparison with a highly similar control group after implantation with an identical conventional counterpart.

The strengths of this study are its prospective design, the obtained long-term results, the introduction of a control group, the homogenous patient characteristics in both groups, the additional focus on patient related outcome measures and the strict inclusion and exclusion criteria.

The limitations include the comparatively small number of enrolled patients, which can be attributed to the initial recruitment in the pilot study as well as the rather small prevalence of a verified metal allergy within the general population. In the ceramic group the gender distribution is not evenly matched. As already stated above, metal allergy is mainly a female phenomenon, therefore an even recruiting was unlikely to be reached. Another restriction is the late introduction of the "conventional" control group at the final follow-up and the high drop-out rate. This can be attributed to the naturally high mortality rate of the geriatric subjects, and at least partially due to the COVID-19 pandemic.

Conclusion

In our series, the BPK-S ceramic TKA system meets the durability and functional performance standards of an established identical metal TKA system after an 8-year follow-up period, offering a safe option for patients with prior hypersensitivity reactions to metallic materials. We recommend full cementation of the entire ceramic-bone interface to avoid possible radiolucent lines, even if the clinical consequences still remain unclear. Further prospective long-term studies with larger case numbers are required to validate the results and to provide the possibility of establishing metal-free designs as standard options for total knee arthroplasty.

Data availability

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

Received: 18 January 2024; Accepted: 26 August 2024
Published online: 09 September 2024

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Author contributions

R.F., F.H.,T.H. and F.P. carried out clinical investigation, R.B. wrote the main manuscript text and R.B. prepared Figs. 1–3. All authors reviewed the manuscript. B.S.K. statistics, supervisison B.R. and K.T., conception K.T.

Competing interests

The authors declare no competing interests.

Additional information

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