



# Acceptable mid- to long-term survival rates and functional outcomes following a single design rotating hinge total knee arthroplasty

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## Abstract

**Purpose** This study first analyzes implant survival of this single design modular rotating hinge knee and identifies potential risk factors for failure and evaluates joint function using the postoperative WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) score, active flexion and extension deficit.

**Methods** 131 prostheses implanted for failure of prior total knee arthroplasty ( $n = 120$ ) or complex primary procedures ( $n = 11$ ) using a single modular implant (MUTARS—modular universal tumor and revision system GenuX, Implantcast, Buxtehude, Germany) between 2006 and 2014 including 73 patients treated for periprosthetic joint infection with a two-stage revision protocol were retrospectively identified. Implant survival was assessed using the Kaplan–Meier method; potential risk factors were identified using the log-rank test, as well as non-parametric analysis. Postoperative function was assessed using the WOMAC and measurement of range of motion.

**Results** After a median follow-up of 62 months, 37 implants required implant revision (28%). Five-year survival was 69.7% [95% CI (confidence interval) 60.9–78.5] with periprosthetic (re-) infection being the main cause for failure (15%), followed by aseptic loosening (9%). In cases of periprosthetic infection, infection-free survival was 83% at 5 years (95% CI 74–92) with twelve patients suffering reinfection (16%). While body mass index ( $p = 0.75$ ), age ( $p = 0.16$ ) or indication for rotating hinge knee arthroplasty ( $p = 0.25$ ) had no influence on survival, Charlson comorbidity score (CCI) ( $p = 0.07$ ) and number of previous revision surgeries ( $p = 0.05$ ) correlated with implant failure. There was trend ( $p = 0.1$ ) for improved survival in fully cemented implants. Mean postoperative WOMAC was 127 (range 55–191), 11 patients (15%) had limited knee extension.

**Conclusions** Rotating hinge total knee arthroplasty using a single modular implant shows acceptable survival rates and function compared to previous studies with (re-)infection being the most relevant mode of failure. Patients with a high CCI and multiple previous surgeries are at increased risk for failure.

**Level of evidence** Retrospective cohort study, III.

**Keywords** Revision knee arthroplasty · TKA · PJI · Periprosthetic joint infection · Total knee arthroplasty · Rotating hinge knee

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## Abbreviations

BMI	Body mass index
CCI	Charlson comorbidity index
CI	Confidence interval
IQR	Interquartile range 25–75%
MSIS	Musculoskeletal infection society
MUTARS	Modular universal tumor and revision system
PJI	Periprosthetic joint infection
PMMA	Polymethylmethacrylate
RHK	Rotating hinge knee
TKA	Total knee arthroplasty
WOMAC	Western Ontario and McMaster universities osteoarthritis index

## Introduction

Surgeons performing revision TKA are commonly facing bone loss and ligament instability that regularly requires the use of more constraint prosthesis designs to achieve adequate joint stability [3, 22, 27]. For this purpose hinged knee prostheses have been developed. The first designs using a fixed hinge only achieved low short term survivorship rates up to 60% [1, 14] which led to the development of rotating hinge knee implants (RHK) incorporating significant improvements in design and technology used, particularly its ability to rotate, therefore, reducing the forces transmitted to the bone-cement interface and providing for a greater congruency of the articulating surfaces [1, 11, 20, 21, 27].

While traditionally these implant designs were reserved for oncologic reconstructions [20], current designs offer the advantage of modular components and stems, complex hybrid or cemented fixation and the use of augments to reconstruct massive bone defects that are often encountered [3, 8]. Therefore, rotating hinge designs are not only used in megaprosthesis reconstructions [12], but regularly in non-megaprosthesis revision arthroplasty or complex primary procedures with instability or severe deformity [3, 8, 11, 24–27].

While there are comprehensive studies reporting implant survivorship of modern, third generation rotating hinge designs to be 52–85% at 5 years [3, 27] to 71–92% at 10 years [3, 13], generalizability of these data can be difficult because differences in implant systems used need to be considered as a confounding factor [18].

The study's purpose was to investigate implant survival rates of this single-design RHK and identify patient- and surgery-related risk factors for failure and for reinfection in patients treated for PJI, as well as to evaluate joint function through postoperative WOMAC score, active flexion ability, and extension deficit.

## Methods

Approval of the institutional review board was obtained prior to this investigation (local ethical committee ref. no. 2018-123-f-S). A specific source of funding was not required in this study. It was conducted according to the principles of the World Medical Association Declaration of Helsinki.

The authors' institution's database was retrospectively reviewed and a total of 131 patients who underwent total knee revision arthroplasty ( $n = 120$ ) or complex primary joint replacement ( $n = 11$ ) using a single rotating hinge modular knee revision system (MUTARS—modular universal tumor and revision system GenuX, Implantcast GmbH, Buxtehude, Germany) between 2006 and 2014 were identified. Patients with a minimum follow-up period of 24 months were included. Patients who died or developed complications within 24 months following implantation were included as well. Follow-up was derived from the last contact with our institution with seven patients being lost to follow-up and excluded from the study population. Patients who received other (rotating hinge) knee implants, megaprosthesis reconstructions or patients who had reconstructions following primary or metastatic tumor resection were excluded. Functional assessment was performed using the Western Ontario and McMaster Universities Osteoarthritis index [4] that measures pain, stiffness and limitation of function in daily activities as well as measurement of knee range of motion derived from the last clinical examination for all patients with retained implants at latest follow-up. Patients' previous medical history was analyzed and the Charlson comorbidity index [2] was calculated.

Primary endpoint was defined as prosthetic failure requiring revision and exchange of implant components attached to the host bone (stems, femoral shield, tibial plateau). Secondary endpoints were death, revision with only polyethylene or modular hinge mechanisms exchange and reinfection-free survival for patients treated for periprosthetic joint infection.

Diagnosis of failure and loosening was based on clinical and radiological findings as proposed by the Knee Society's evaluation system with three views that defines zones around the tibial and femoral components identifying radiolucent lines and their progression in these areas [7]. Joint aspiration was performed in all knees prior to revision surgery and infection was diagnosed using the criteria of the Musculoskeletal Infection Society (MSIS) that assesses fistula, positive cultures as well as different serum and synovial markers [21]. Treatment success after staged revision in cases of periprosthetic joint infection was defined based on the Delphi consensus criteria [5, 28] listing reinfection or persistent infection, unhealed wounds or sinus tracts, unplanned surgical intervention for infection and PJI related mortality as reasons for failure.

In cases of revision TKA, previous revision surgeries were analyzed and counted. For septic revision surgeries all previous surgeries for PJI were counted including debridement and component exchanges, one-stage revisions and two-stage revisions with the latter being counted as one exchange.

### Surgical procedures and implant features

Surgeries were performed by a senior orthopedic surgeon with special expertise in revision arthroplasty. During the course of the study four different senior surgeons performed the surgeries. A standard medial parapatellar approach was performed in all patients. In case of revision surgery existing components were carefully removed and a thorough debridement was performed removing bradytrophic tissue in cases of infection in all compartments of the knee. In all revisions, a minimum of 3 to 5 microbiological samples were taken and cultured for a minimum of 7–14 days. Intraoperative antibiotics (2nd generation cephalosporin) were withheld until samples were obtained. The implant system used offers multiple reconstruction options with stems, offset adapters and wedges to reconstruct the joint line anatomically. The general approach regarding the use of cement was to perform a “hybrid” fixation cementing the femoral shield and the tibial plateau with a cementless stem whenever possible, but as shown in Table 1 stems were cemented when diminished bone quality was encountered or if only a short stem anchorage due to ipsilateral hardware or diaphyseal deformity was achievable. In planned aseptic revisions gentamicin and clindamycin polymethylmethacrylate (PMMA) bonecement was used (Copal G+C, Heraeus medical, Wehrheim,

Germany) and in cases of resistant bacteria in septic revisions gentamicin and vancomycin PMMA (Copal G+V, Heraeus medical, Wehrheim, Germany) was used. All cases of infection underwent at least 2 weeks of tailored intravenous antibiotics then continuing oral antibiotics for a total of at least 6 weeks in between stages. Antibiotic suppression was not used. Patients’ characteristics are presented in Tables 1 and 2.

### Statistical analysis

Data collection and statistical analysis were performed using Excel (Microsoft Corporation, Redmont, Washington, USA) and SPSS Statistics for Windows Version 25 (IBM Corporation, Armonk, NY, USA). All patient records were anonymized prior to analysis.

Descriptive statistics were used to analyze distribution of data, means and ranges were calculated for parametric data; medians and interquartile ranges (IQR) for non-parametric data. Survival analysis was performed using the Kaplan–Meier method [16], differences in survival and influencing factors were assessed using the log-rank test [19]. 95% confidence intervals (CI) were calculated. Contingency tables were analyzed using the  $\chi^2$ -test. Non-parametric analyses were performed using the Mann–Whitney *U* test. Statistical significance was defined as  $p \leq 0.05$ . A sample size calculation was not performed given the retrospective nature of the study and the fact that the implant system analyzed is no longer used in our department and has been replaced limiting the number of patients available (Fig. 1).

## Results

### Implant survivorship

The cumulative implant survival rate with implant removal for any cause as the primary endpoint was 91.3% after 2 years (95% CI 86.4–96.2), 69.7% after 5 years (95% CI 60.9–78.5) (Fig. 2).

**Table 1** Patient demographics, indication for surgery and fixation

Variable	<i>N</i>	%
Male	64	49
Diabetic	40	31
Primary RHK	11	8
Revision RHK	120	92
Indication for revision		
Osteoarthritis with gross instability	9	7
Fracture	3	2
Aseptic loosening	22	17
Instability	24	18
Exchange for PJI	73	56
Mode of fixation		
Hybrid fixation	92	70
One stem cemented	10	8
Both stems cemented	29	22

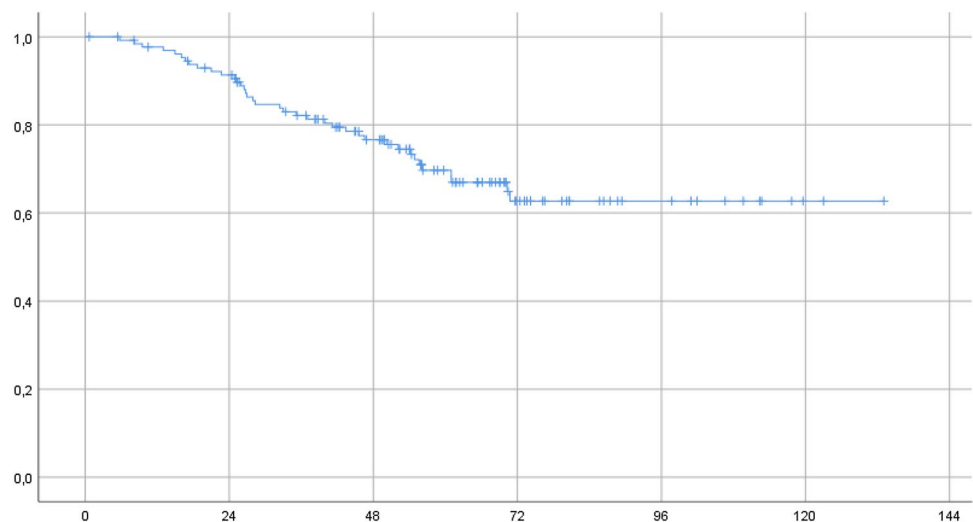
RHK rotating hinge knee, PJI periprosthetic joint infection

**Table 2** Patient demographics and surgical details

Variable	Median	Interquartile range 25–75%
Age at surgery in years	72	60–77
BMI in kg/m <sup>2</sup>	29	27–34
Number of previous exchanges	2	1–3
Septic exchanges	1	0–1
Aseptic exchanges	1	0–1
Follow-up period in months	62	48–78
Charlson comorbidity index	4	2–5

RHK rotating hinge knee, BMI body mass index

**Fig. 1** Kaplan–Meier curve showing cumulative implant survival in months



At the latest follow-up evaluation, 37 implants had to be removed (28%). Reasons for implant removal were periprosthetic joint infection in 20 cases (15%), aseptic loosening in 12 cases (9%), non-reconstructable extensor mechanism deficiency requiring arthrodesis in 3 cases (2%) and periprosthetic fracture in 2 cases (2%). Implant failure occurred after a median of 28 months (IQR 21–47). Postoperative complications that could be treated without implant revision included five hematomas (3.8%), three periprosthetic fractures that were revised with plating (2.2%) and three patella tendon deficiencies (2.2%) that underwent tendon augmentation surgery.

11 patients died during the follow-up period of unrelated cause to our knowledge after a median of 25 months (IQR 15 to 59) although two of these patients underwent revision surgery during the follow-up period. One of these patients was revised due to periprosthetic femoral fracture 6 months after reimplantation in two-stage revision for PJI and the

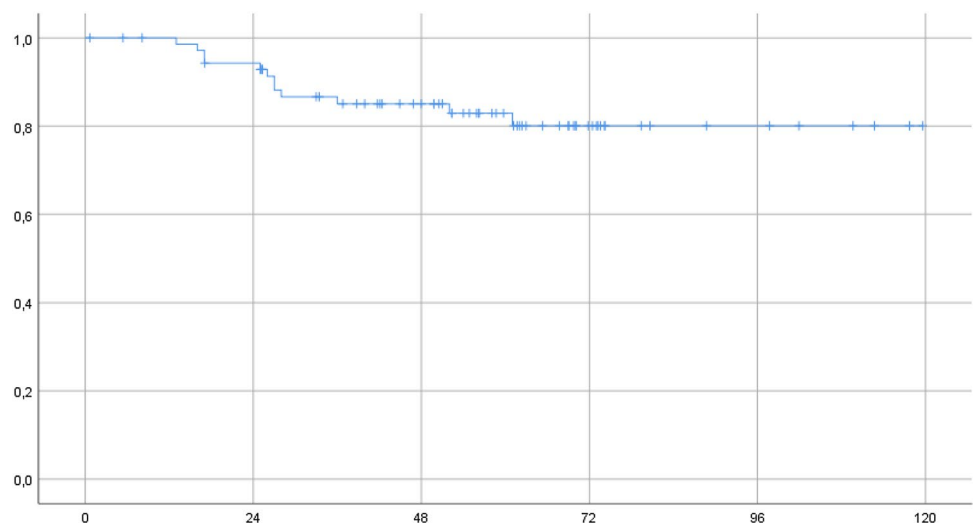
other patient due to low-grade reinfection 23 months after successful reimplantation in two-stage revision for PJI.

The total number of previous surgeries was found to be significantly associated with implant failure ( $p = 0.047$ ). Patients that required TKA revision had a median of 2 (IQR 1.5–4) previous surgeries compared to a median of 2 (IQR 1–3) in patients with retained prosthesis. Further factors are shown in Table 3. Furthermore, there was a trend for a higher median Charlson comorbidity index in patients in whom the implant needed to be removed (3 vs. 4,  $p = 0.07$ ).

### Aseptic loosening

The cumulative incidence of aseptic loosening was 11% at last follow-up (95% CI 5–17) with all cases of aseptic loosening occurring within 4.7 years postoperative. Isolated loosening of either the tibial or femoral component was found in five patients each, with two patients having

**Fig. 2** Kaplan–Meier curve showing infection-free cumulative survival for patients treated for PJI in months



**Table 3** Factors influencing implant survival

Variable	<i>N</i> patients <sup>a</sup>	5-year implant survival in %	95% CI	<i>p</i> (log-rank)
Age				n.s.
> 70	78	73	59–83	
< 70	53	65	50–78	
Diabetic				n.s.
Yes	40	68	50–83	
No	91	71	61–81	
Obesity with BMI > 30				n.s.
Yes	60	66	52–80	
No	54	69	56–82	
Primary or revision TKA				n.s.
Primary	11	81	56–100	
Revision	120	69	58–78	
Previous septic exchanges				n.s.
Yes	61	62	57–76	
No	55	73	59–86	
Previous aseptic exchanges				n.s.
Yes	61	61	47–73	
No	55	76	62–88	
Cemented stems				n.s.
Hybrid fixation	92	66	56–76	
Both cemented	29	86	72–99	
Treatment for PJI				n.s.
Yes	73	68	57–81	
No	58	72	59–85	
Indication for RHK in revision TKA				n.s.
PJI	73	68	57–81	
Aseptic loosening	22	70	50–90	
Instability	24	81	55–97	
Periprosthetic fracture	3	0	n/a	

<sup>a</sup>Missing to 131: missing values for BMI. *RHK* rotating hinge knee, *PJI* periprosthetic joint infection, *BMI* body mass index

loosening of the entire prosthesis. In regard to factors that correlate with aseptic loosening, patient aged over 70 years had a reduced probability of revision for aseptic loosening (6 vs. 18%,  $p = 0.058$ ) as well as fully cemented implants (0 vs. 14%,  $p = 0.06$ ).

### Periprosthetic reinfection

A total of twelve patients that were treated for PJI suffered reinfection (16%). The infection-free survival was 83% at 5-years (95% CI 74–92). We were not able to identify significant risk factors for reinfection (Table 4), furthermore differences in the Charlson comorbidity index were not associated with reinfection (n.s.).

### Functional outcome

In 71 patients functional scores were retrospectively available. The mean WOMAC was 127 (range 55–191). While on the one hand the median active flexion was 90° (IQR 90–100), a deficit in active extension (median 5°, IQR 5–10) was noted in 11 patients (15%), although there was no significant difference in postoperative clinical scores in these patients ( $p = 0.58$ ). There was no correlation between functional outcome and age (n.s.), BMI (n.s.), indication for RHK implantation in revision cases (n.s.) or mode of implant fixation (n.s.).

Patients who underwent primary TKA using a rotating hinge implant reported a postoperative WOMAC of a median of 103 (IQR 71–131), while in comparison a trend

**Table 4** Factors influencing infection-free survival in patients treated for PJI

Variable	N patients <sup>a</sup>	5-year infection-free survival in %	95% CI	p (log-rank)
Age				n.s.
> 70	26	73	59–83	
< 70	47	65	50–78	
Diabetic				n.s.
Yes	19	83	65–100	
No	54	83	72–94	
Obesity with BMI > 30				n.s.
Yes	35	78	64–92	
No	29	84	70–98	
Previous septic exchanges				n.s.
Yes	50	84	74–94	
No	19	83	65–100	
Previous aseptic exchanges				n.s.
Yes	37	84	71–97	
No	32	82	68–96	
Cemented stems				n.s.
Hybrid	50	80	69–91	
Both	29	87	70–100	

<sup>a</sup>Missing to 73: missing values for BMI, no previous revision surgeries or only one cemented stem. *RHK* rotating hinge knee, *PJI* periprosthetic joint infection, *BMI* body mass index

( $p=0.08$ ) for a reduced postoperative functional outcome in patients with revision TKA with a median WOMAC of 129 (IQR 100–162) could be identified.

## Discussion

The most important finding in this study is that the implant system used leads to an acceptable 5-year implant survivorship of 69.7% with an infection-free survival of 83% of cases that were treated for PJI. The numbers of previous implant revision surgeries as well as a high comorbidity score were associated with a higher probability of implant failure.

The survivorship of rotating hinge design total knee replacements for non-oncologic indications and the impact of patient- and surgery-related factors is still unclear with reported survival rates greatly varying. No study has analyzed the survivorship of this implant system. A limitation to the existing literature is heterogeneity of implants used in studies that report on RHK.

The overall implant survivorship in the present study was found to be 69.7% at 5 years which is comparable to a study by Farid et al. [8] of 141 single design RHK(OSS model, Biomet, Warsaw, Indiana, USA) who report a 5-year survival of 73% with a comparably high percentage of infection cases(42%) although the authors depict a knee system in their study that would qualify as a megaprosthesis in our definition and can't be compared to the design included in

this study. Though the indication for revision surgery was not found to be a significant risk factor for failure in any comparably large study [8, 13, 26], it is discussed that due to the necessity of soft tissue debridement and possibly associated requirement for flap coverage a stable rotating hinge design provides the most durable mode of reconstruction [8, 13] in cases of PJI. This is supported by superior functional results in patients with moderate bone defects that underwent revision TKA utilizing a rotating hinge design following infection compared to other unlinked constraint implants [26].

Mid- to long-term eradication of infection was achieved in 84% of all patients treated for PJI in the present study. In a two-stage revision protocol this is also comparable to the study by Farid et al. [8] who report a reinfection rate of 18% with an overall rate of infection of 15% which is the same as in this study. While these results are favorable in comparison to a study by Smith [27] who report an overall infection rate of 23.7% for their RHK cohort although a reinfection rate is not provided. However, the rate of infection in a large study by Hossain [13] including 74 RHK with 32% of all TKA revision performed for periprosthetic joint infection was only 2.7% in the entire group. A separate rate of reinfection was not provided, but given only two cases of infection in the entire cohort, it most likely is quite low as well. It is to be noted that overall implant survival at 10 years was over 90% for RHK designs in this study and superior to other less constraint prostheses used in the cited study. One

possible explanation for limited survivorship might be the high number of previous surgeries in the present study that were found to be a significant risk factor for failure. In this context one has to acknowledge a certain selection bias for patients with PJI and failed prior surgery with debridement and component exchange that were referred for staged revision. Previous surgeries lead to reduced local tissue quality creating a poor environment especially in cases of PJI [3, 9, 22] with some authors suspecting that many aseptic revisions are actually undetected periprosthetic infections that might explain a higher percentage of septic failures [8]. Additionally, particularly in cases of PJI [22] patient related risk factors must be considered as they pose as a predictor of failure. While BMI was not associated with implant failure in this study, the CCI was significantly higher which is in line with previous data on septic knee revision [22].

While periprosthetic infection appears to be the main reason for failure in current TKA [17], aseptic loosening in contemporary rotating hinge design appears to be less common [27] with rates of aseptic loosening of 4.5% after 10 years [3] and 2.7% after a mean of 67 months [13] reported. The rate of aseptic loosening in the present study is higher, but also in line with other previous studies [8]. While this can be partially attributed to the number of previous surgeries, one must discuss implant fixation [6]. While Cottino et al. [3] found a trend for improved survival after using uncemented porous metal cones in revision TKA to improve metaphyseal component anchorage, the authors acknowledge a bias that these cones were used in the most difficult cases and no analysis of outcome with respect to defect size was performed. The use of augments and cones was not analyzed in the present study because of heterogeneity in implant choice and only 8 cases available, although cones and sleeves generally play a vital role especially in tibial bone loss and have certainly broadened the armamentarium facing substantial bone loss [15].

Furthermore, implant fixation in RHK designs is greatly dependent on the use of either cemented or uncemented stems [6, 10] with full cementation showing a trend for improved implant survival although rarely used exclusively in older patients. The general approach is the use of an uncemented stems with diaphyseal anchorage combined with offset couplers to restore alignment and facilitate revision surgery facing the still considerable re-revision rate of these implants that would require extensive removal of cement in cases of infection [9, 10, 22]. In contrast, comparably sized studies on RHK designs that report much lower rates of aseptic loosening than the present study relied on cemented stem fixation [3, 13], while Farid et al. [8] who also employed full cementation only in cases of reduced bone quality, reports a rate of loosening comparable to the results presented. However, in the literature there is no consensus on which mode of stem fixation should be used [6,

10] and generalizability of registry studies [23] and other series [29] that favor hybrid fixation is difficult due to heterogeneous implant designs without hinged knees and multiple different indications for revision. For future studies, details on metaphyseal bone defects, use of augments, length of stems and mode of fixation should be recorded and compared.

While this is a single center, single design implant study first reporting outcome of this implant with a high percentage of patients treated for periprosthetic joint infection and a median follow-up period of over 5 years, there are limitations to this study: it is limited by its retrospective design with possible recall and selection bias with some patients being lost to follow-up and complications that were treated at an outside hospital not being available for analysis. Additionally, a comprehensive discussion of fixation methods and possible use of augments is hindered by the lack of a uniform bone defect classification. While functional results are acceptable compared to the literature, the lack of preoperative patient reported outcome scores makes the assessment of an improvement impossible. As periprosthetic joint infection is a main cause of concern in revision arthroplasty with treatment and diagnostics constantly evolving, there is a limitation in comparing treatment of historic cases of infection given the diagnostic and therapeutic options nowadays.

It would be desirable for future studies to compare different designs of RHK with large numbers also including condyle replacing implants and distal femoral replacements to see whether there are differences in survival.

Based on the present study's results patients who undergo TKA using a rotating hinge implant can be counseled more comprehensively regarding the functional and clinical results of these implants and complications that can be expected.

## Conclusion

This single design RHK in revision total knee arthroplasty provides acceptable mid- to long-term results compared to the literature although one must be aware of high rates of failure, particularly infection. The number of previous surgeries as well as comorbidity might be associated with increased failure rates, while fully cemented implants showed improved survival.

**Authors' contributions** CT review of literature, conception and design, acquisition of data, analysis and interpretation of data, statistical analysis, drafting of the manuscript; TSB review of literature, conception and design, acquisition of data, analysis and interpretation of data, statistical analysis, drafting of the manuscript; GG conception and design, critical revision of the manuscript; BT acquisition of data, analysis and interpretation of data, critical revision of the manuscript; BM critical revision of the manuscript; JR critical revision of the manuscript; DA critical revision of the manuscript; JS critical revision of the manuscript; RD conception and design, acquisition of data, analysis

and interpretation of data, drafting of the manuscript, administrative, technical and material support, critical revision of the manuscript. All authors read and approved the final manuscript.

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### Compliance with ethical standards

**Conflict of interest** One author has received travel expenses by Implantcast GmbH, Buxtehude, Germany outside the submitted work.

**Ethical approval** Approval of the institutional review board was obtained prior to this investigation (local ethical committee ref. no. 2018-123-f-S).

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