High Rates of Aseptic Loosening After Revision Total Knee Arthroplasty for Periprosthetic Joint Infection

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Background: With increasing life expectancy, the demand for knee replacement is continuously rising. Despite the use of antibiotic prophylaxis and improved aseptic surgical techniques, periprosthetic joint infection (PJI) still occurs in 1% to 5% of patients after primary arthroplasty. An open question is the influence of PJI and resulting surgical procedures on the occurrence of long-term complications such as aseptic loosening. Patients needing multiple revision surgeries are especially at risk for decreases in bone mass and damage to the medullary cavity. Thus, we theorized that prior surgeries on the affected knee increase the risk of aseptic loosening in patients with PJI.

Methods: We retrospectively analyzed the cases of 100 patients who underwent total knee replacement exchange surgery as a result of PJI. In addition to clinical, paraclinical, and radiographic examination, we assessed comorbidities and the number of prior surgeries.

Results: Prosthetic survival was drastically decreased after PJI-related revision arthroplasty: during the first 7.3 years after reimplantation, 22% and 16% of all patients had aseptic loosening and recurrent PJI, respectively. The prevalence of aseptic loosening was 27.8% for female and 15.2% for male patients. A significant association between increasing patients’ American Society of Anesthesiologists (ASA) classification and prosthetic failure rates was found, as was a strong correlation between number of prior surgeries and aseptic loosening.

Conclusions: In this study, we found notable rates of aseptic loosening and recurrent PJI following PJI-related revision arthroplasty. The difference in the rate of aseptic loosening among male and female patients supports theories of the role of bone metabolism in the development of aseptic loosening. The economic and clinical burdens of prosthetic failure make it paramount to gain a better understanding of bone metabolism in PJI. Additional research should address the need to optimize treatment strategies to increase prosthetic survival.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

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bone mass and damage to the medullary cavity. We theorized that prior surgeries on the affected knee for any reason increase the risk of aseptic loosening in patients with PJI.

Preoperative risk factors can be screened for using clinical scoring systems such as the American Society of Anesthesiologists (ASA) classification and the Charlson Comorbidity Index (CCI). Both have been shown to correlate with postoperative complication and mortality rates for various conditions. However, previous research focused either on the association with short-term complications or on long-term complications after primary knee arthroplasty. It remains unclear whether ASA classification and CCI can be used as predictors of prosthetic survival in revision arthroplasty.

In this study, we retrospectively analyzed the cases of 100 patients who underwent revision total knee arthroplasty due to PJI to assess the prevalence of aseptic loosening and recurrent PJI and to analyze the utility of ASA classification and CCI in identifying patients with an increased risk of prosthetic failure.

Materials and Methods

Patients

This study was approved by the local ethics board and was performed in accordance with the Declaration of Helsinki. We retrospectively analyzed the cases of all patients who had undergone total knee replacement exchange surgery due to chronic PJI between January 2012 and January 2018. As a supra-regional university medical center, we often get complicated cases with prior PJI referred to our department. Cases involving PJI after primary and revision arthroplasty were included in this study. Patients were treated in our specialized department using a centralized and interdisciplinary treatment approach. In total, we analyzed the cases of 100 patients. Inclusion criteria were a previously implanted total knee replacement and diagnosed PJI that was successfully treated at discharge. PJI was defined according to the Euroean Bone and Joint Infection Society (EBJIS) criteria: (1) prevalence of a sinus tract or purulence around a component; (2) >2,000 leukocytes/μL or >70% granulocytes in the synovial fluid; (3) histological confirmation of intraoperatively obtained tissue classified as Krenn and Morawietz type II or III; or (4) microbiological growth in synovial fluid, ≥2 tissue samples (highly virulent organisms or in patients being treated with antibiotics: 1 positive sample), or sonication fluid (>50 colony-forming units per mL). Successful treatment at discharge was defined using modified Delphi criteria: (1) wound-healing without fistula, drainage, pain, or recurrent infection; and (2) without PJI-related death due to sepsis.

Patients who met ≥1 of the following criteria were excluded from this study: (1) treatment with debridement, antibiotics, and implant retention (DAIR) or non-temporary arthrodesis; (2) no implantation of subsequent components after implant removal; (3) primary knee replacement due to infection; (4) primary knee replacement or reimplantation due to trauma without any pretraumatic signs of aseptic loosening; (5) incomplete postoperative clinical or radiographic examination; or (6) <6 months of postoperative follow-up. There were no further exclusions.

In addition to clinical, paraclinical, and radiographic parameters, we assessed comorbidities and the number of prior surgeries on the affected knee. Patient comorbidity was assessed using preoperative ASA classification and age-adjusted CCI.

Surgical Technique

Two- or multiple-stage exchange surgery is widely accepted as standard treatment for PJI and was performed as previously described. Briefly, after removal of the affected prosthesis, thorough debridement, and irrigation, patients received a temporary, antibiotic-loaded cement spacer between stages. Reimplantation of a modular or nonmodular, cemented, rotating-hinge prosthesis was performed at least 6 weeks after removal when no clinical or paraclinical signs of infection were found. The vast majority (95%) of patients received a stemmed rotating-hinge or full-hinged prosthesis. In detail, the Endo-Model (LINK) stemmed rotating-hinge prosthesis was used in 55 cases, the RT-PLUS (Smith & Nephew) stemmed rotating-hinge prosthesis was used in 32 cases, the Enduro (Aesculap) stemmed rotating-hinge prosthesis was used in 1 case, and the Endo-Model (LINK) stemmed full-hinged prosthesis was used in 7 cases. In the remaining 5 cases, the TC3 stemmed condylar constrained knee (CCK)-type prosthesis (DePuy Synthes, Johnson & Johnson) was used. All surgeries were performed by high-volume surgeons specializing in the treatment of PJI and revision total knee arthroplasty. Patients received antimicrobial therapy for up to 6 weeks after reimplantation. Antimicrobial agents were chosen on the basis of bacterial susceptibility and the recommendations of Zimmerli et al. and in consultation with our microbiologists.

Radiographic Analysis

Radiographic parameters were assessed to determine implant positioning using standing long-leg radiographs and anteroposterior and true lateral (30° of flexion) radiographs of the affected knee. Centricity Enterprise Web (v8.0.1400.511; GE Healthcare) was used for all measurements. Aseptic loosening was determined radiographically by assessing circumferential radiolucency at the bone-cement interface surrounding the prosthesis stem completely, prosthetic subsidence, change in the position of the stem or cement, or fractures in the cement mantle. The diagnosis of aseptic loosening was based on radiographic criteria and patient-reported clinical symptoms of pain and instability.

Follow-up

To screen for complications after revision arthroplasty, we regularly invited patients to our outpatient department. Within the first postoperative year, patients were invited for radiographic and clinical follow-up every 3 months. After 1 year, the follow-up was offered annually. Besides aseptic loosening and recurrent PJI, complications of revision arthroplasty include, among others, instability, pain, patellar,...
maltracking, arthrofibrosis, and limited range of motion. For this study, prosthetic survival was defined as the absence of aseptic loosening and recurrent PJI. Prosthetic loosening was diagnosed using radiographic examination, as described above, while taking into account clinical symptoms. Recurrent PJI was diagnosed using EBJIS and modified Delphi criteria.14,16

Statistics
Data were analyzed using Excel (version 16.30; Microsoft). Survival curves were used to plot prosthetic survival. All data are presented as the mean or the median with the range. Statistical analysis was performed using 1-way analysis of variance. An unpaired Student t test for samples of unequal variances was used to calculate significance (p < 0.05).

Results

Patients
Patient characteristics are outlined in Table I. Of the 100 patients included in our analysis, 46 were male and 54 were female. The median duration of follow-up was 37 months (range, 6 to 88 months). While 21 patients had experienced at least 1 PJI prior to PJI treatment at our clinic in the analyzed time frame, 70 patients were being treated for their first PJI. For 9 patients, the occurrence of a previous PJI was unknown. The mean body mass index (BMI) was 31.0 kg/m² (range, 20.0 to 54.2 kg/m²). Ninety-five percent of the 100 patients had >1 comorbidity. The average CCI was 3.7 (range, 0 to 14). Staphylococcus epidermidis, S. aureus, and Cutibacterium acnes were the most common pathogens, comprising 60.0% of all cases. Pathogens found for all patients and each prosthesis-outcome group are shown in Table II. We found no significant differences among the prosthesis-outcome groups in terms of the pathogens identified.

Eighty-five patients underwent 2-stage exchange surgery, and 15 patients underwent multiple-stage exchange surgery.

Prevalence of Postoperative Aseptic Loosening and Recurrent PJI
While prosthetic survival was 98.0% at year 1, it dropped to 74.0% within 5 years and to 62.0% within 7.3 years after revision arthroplasty (Fig. 1-A). Sixteen percent of all patients had at least 1 more PJI in the 7.3 years of follow-up (Fig. 1-B); approximately half of those patients were infected with the same pathogen as before. For the first 5 years, recurrent PJI showed slightly higher occurrences, but thereafter, aseptic loosening was the more common complication (Fig. 1-B). Strikingly, 22.0% of all patients were diagnosed with aseptic loosening within 7.3 years of follow-up.

We observed a statistical trend of women being more at risk of developing aseptic loosening: 27.8% of all female patients had aseptic loosening compared with 15.2% of all male patients.

| TABLE I Patient Characteristics (N = 100) |
|------------------------------------------|
| **No. (%) of** | **Mean (Range)** |
| **Patients** | **** |
| **Descriptive** | **** |
| Age (yr) | 68.6 (34.0-85.1) |
| Male | 46 (46.0) |
| Female | 54 (54.0) |
| Right knee | 54 (54.0) |
| Left knee | 46 (46.0) |
| >1 comorbidity | 95 (95.0) |
| **Clinical characteristics** | **** |
| Body mass index (kg/m²) | 31.0 (20.0-54.2) |
| CCI | 3.7 (0-14) |
| ASA classification | 6 (6.0) |
| 1 | 6 (6.0) |
| 2 | 43 (43.0) |
| 3 | 51 (51.0) |

| TABLE II Pathogens Found in Patients at Time of PJI |
|-----------------------------------------------|
| **All Patients (N = 100)** | **Prosthetic Survival (N = 62)** | **Aseptic Loosening (N = 22)** | **Recurrent PJI (N = 16)** |
| **No.** | **%** | **No.** | **%** | **No.** | **%** | **P Value** | **No.** | **%** | **P Value** |
| Coagulase-negative Staphylococci | 54 | 54.0 | 37 | 59.7 | 11 | 50.0 | 0.879 | 6 | 37.5 | 0.259 |
| Staphylococcus aureus | 16 | 16.0 | 9 | 14.5 | 2 | 9.1 | 0.659 | 5 | 31.3 | 0.175 |
| Cutibacterium acnes | 15 | 15.0 | 10 | 16.1 | 2 | 9.1 | 0.559 | 3 | 18.8 | 0.851 |
| Streptococci | 6 | 6.0 | 3 | 4.8 | 0 | 0.0 | 0.332 | 3 | 18.8 | 0.080 |
| Gram-negative bacteria | 3 | 3.0 | 2 | 3.2 | 1 | 4.5 | 0.700 | 0 | 0.0 | 0.467 |
| Other | 16 | 16.0 | 11 | 17.7 | 4 | 18.2 | 0.798 | 1 | 6.3 | 0.283 |
| None | 21 | 21.0 | 11 | 17.7 | 6 | 27.3 | 0.268 | 4 | 25.0 | 0.587 |
| Monomicrobial | 58 | 58.0 | 35 | 56.5 | 14 | 63.6 | 0.705 | 9 | 56.3 | 0.992 |
| Polymicrobial | 21 | 21.0 | 16 | 25.8 | 2 | 9.1 | 0.146 | 3 | 18.8 | 0.610 |
| Culture-negative | 21 | 21.0 | 11 | 17.7 | 6 | 27.3 | 0.393 | 4 | 25.0 | 0.555 |
Diagnosed recurrent PJI or aseptic loosening was considered failure of the prosthesis. While only 2.0% of all patients had failure of the prosthesis at year 1, the failure rate was drastically elevated to 26.0% within 5 years. Prosthetic survival continued to decline until the end of our study and was 62.0% at 7.3 years.

Comparison of prosthetic failure due to recurrent PJI (dashed line) and aseptic loosening (solid line). In the first 5 years, the prevalence of recurrent PJI was higher than the prevalence of aseptic loosening. At 7.3 years, 16.0% of all patients had experienced recurrent PJI. In comparison, 22.0% were diagnosed with aseptic loosening.

Images of a 63-year-old patient who had recurrent PJI with multiple revision surgeries. The patient experienced recurrent PJI after having received a hinged knee prosthesis during revision arthroplasty due to PJI 2 years prior. First-stage revision arthroplasty: prosthesis removal and temporal arthrodesis using a spacer and antibiotic-loaded cement. Second-stage revision arthroplasty: reimplantation of a hinged knee prosthesis 6 weeks later. Clinical and radiographic signs of aseptic loosening (arrows) of the tibial component after 2 years. After clinical, pathological, and microbiological exclusion of infection, the patient’s tibial component was changed to a cementless prosthesis. Good clinical, functional, and radiographic outcomes in the 1-year follow-up examination.
Figure 2 shows images of a representative patient who experienced aseptic loosening after multiple revision procedures with cemented components. In this case, after clinical, pathological, and microbiological exclusion of infection, the patient’s tibial component was changed to a cementless prosthesis.

Clinical Scores
The prevalence of aseptic and septic long-term complications was significantly increased among patients with higher preoperative ASA classification ($p = 0.020$) (Fig. 3). While no patient classified as ASA 1 had aseptic loosening, 1 patient in that group had recurrent PJI. Of the 43 patients classified as ASA 2, six patients had aseptic loosening and 4 had recurrent PJI. The prevalence of long-term complications was highest in the group classified as ASA 3. In contrast, CCI correlated only moderately with the prevalence of aseptic loosening ($r = 0.40$) and recurrent PJI ($r = 0.44$).

Preoperative Knee Surgery
To assess the impact of the number of surgeries on the affected knee and prosthetic survival, we evaluated the correlation between prevalence of aseptic and septic complications and number of prior surgeries. Prevalence of aseptic loosening correlated strongly ($r = 0.91$) with number of prior surgeries on the affected knee. Prevalence of recurrent PJI did not correlate ($r = 0.23$) with number of prior surgeries. The linear trend line is shown as a dashed line.

Discussion
In this study, we used clinical, paraclinical, and radiographic examinations to study the prevalence of the long-term
complications aseptic loosening and recurrent PJI among patients with prior PJI who had undergone subsequent revision surgery. Additionally, we retrospectively analyzed the utility of ASA classification and CCI to identify patients with an increased risk of prosthetic failure. The long-term arthroplasty failure rate was drastically elevated after revision surgery due to PJI.

Strikingly, we found that the prosthetic failure rate after PJI-related revision surgery was 22.0% for aseptic loosening in the first 7.3 years after revision surgery. In contrast, the prevalence of aseptic loosening in the first 6.5 years after primary arthroplasty previously was found to be 1% to 5%\(^{14}\). Similar to our results, Suárez et al. reported a prevalence of 19% for aseptic loosening after indication-independent revision knee arthroplasty\(^{7}\). An open question is the role of surgical techniques and the impact of PJI on the bone metabolism in the development of aseptic loosening.

Previous studies suggested that the occurrence of aseptic loosening hinges on the biological properties of the bone\(^{8}\). Wear particles from cement, metal, and polyethylene play a decisive role in the development of aseptic loosening by impacting the bone metabolism\(^{27-28}\). While PJI leads to an inflammatory response\(^{9}\), the effects of PJI on postoperative bone metabolism remain largely unclear. The observed differences in the prevalence of aseptic loosening between male and female patients supports theories surrounding the role of bone metabolism in the development of aseptic loosening, as sex-specific differences in bone metabolism have been demonstrated previously\(^{10}\). The economic and clinical burden makes it paramount to gain a better understanding of bone metabolism in PJI.

Additionally, we demonstrated that ASA classification was associated with the prevalence of aseptic loosening and recurrent PJI. Similar to our findings, previous studies postulating a correlation of ASA scores with bone metabolism and clinical outcome demonstrated increased short and long-term complications after primary arthroplasty\(^{30,31}\). However, we found only a moderate correlation between CCI and the development of aseptic loosening and recurrent PJI. Strong discrepancies between CCI and ASA scores have been described previously and may explain the differences in the strengths of their predictive values found in our study\(^{32}\).

There is an obvious need to optimize treatment strategies to increase prosthetic survival. Currently, the use of antibiotic-loaded cement and 1-, 2-, or multiple-stage revision surgery is recommended. PJI-related revision arthroplasty consists of the removal of the infected prosthesis, debridement, irrigation, and reimplantation of a new prosthesis into the cleaned bone bed\(^{11}\). In cases in which multiple revisions are needed, every subsequent surgery decreases remaining bone mass\(^{8}\), thus reducing the spongy bone surface area needed for cement penetration and successful long-term fixation. Our data indicate a correlation between long-term prosthetic failure due to aseptic loosening and the number of prior surgeries, including prior PJI revision surgery. An adequate bone-cement interface with interdigitation between cement and spongy bone is mandatory for prosthetic survival\(^{12}\). To avoid a loss of bone mass with every revision surgery, arthroplasty with cementless components could offer a way forward in complicated cases\(^{33}\). In patients with little remaining cancellous bone due to multiple revision surgeries, cementless prostheses can be anchored in the cortical bone\(^{34}\). Complication and prosthetic survival rates were found to be significantly improved for patients receiving cementless arthroplasty for lower limb salvage surgery\(^{35}\). Additionally, a review comparing cementless and cemented fixation in primary arthroplasty found no significant differences in long-term outcomes\(^{36}\). However, it has yet to be debated whether the absence of antibiotic-loaded cement may increase the risk of recurrent PJI. Antimicrobial nanoparticle prosthetic coatings might offer a suitable alternative\(^{37-39}\). Furthermore, because longer stems are needed for cementless prostheses, the intraoperative risk of periprosthetic fractures and the rates of perforation of the tibia or femur are increased\(^{40-42}\). Additionally, increased shear forces caused by longer stems and a high level of constraint should be discussed as a plausible mechanism leading to aseptic loosening. In support of this theory, almost all patients in our study received implants with a high level of constraint. On the basis of our results, implants with the least possible levels of constraint may be preferable for septic revision arthroplasty. In contrast, Hossain et al. reported midterm satisfaction to be highest among patients who received rotating-hinge implants in revision arthroplasty\(^{43}\). In cases involving extended bone loss, cones and sleeves allowing stable metaphyseal prosthetic fixation can reduce shear forces and thus potentially decrease prosthetic failure rates\(^{44}\). Additional research is needed to address the impact of the prosthetic design on post-revision prosthetic failure and to evaluate whether revision arthroplasty with cementless or non-constrained implants can be deemed a preferred treatment strategy.

Limitations of the current study include the heterogeneity of the analyzed population, differences in the type of revision implant used, and the short follow-up duration in a few cases. Although longer minimum follow-up for recurrent PJI is generally agreed upon, we chose a minimum follow-up duration of 6 months to ensure that we did not miss any patients with early signs of aseptic loosening. While too-short minimum follow-up times might skew the data toward lower prosthetic failure rates, exclusion of these patients overstates these rates. An additional limitation is that, in some cases, partial prosthetic loosening can be difficult to diagnose. Previous reports suggested that the number of affected patients is higher than originally assumed\(^{45}\). Conversely, it has been suggested that, in some patients, loosening is in fact not aseptic but due to occult infection\(^{46,47}\). Both factors potentially influence prosthetic failure rates presented in our study.

In this study, 16% of all patients had recurrent PJI in the first 7.3 years after revision arthroplasty. After primary arthroplasty, the risk of PJI has been reported to be only 1% to 5%\(^{12,48}\). In accordance with our results, previous research on septic long-term complications found an increased risk of recurrent PJI of 5% to 15%\(^{36,49}\). In approximately half of the cases with recurrent PJI, the pathogen found was the same as that previously diagnosed for the initial PJI. The role of incomplete pathogen elimination in such cases is the subject of ongoing debate\(^{50}\). In cases with different pathogens in the sense of a new infection, PJI recurrence may happen intraoperatively during revision surgery.
or may be hematogenous. It is unknown whether changes in the vascularization of the soft tissue surrounding the knee potentially compromise effective immune system responses. The regenerative capacities of various tissues have been linked to local immune system activity. Conversely, in the current study, no correlation between the number of prior surgeries and the prevalence of recurrent PJI was found. As prior surgeries also include those performed for reasons other than infection, it can be speculated that PJI-related inflammation has a substantial impact on the bone and soft tissue of the knee.

In conclusion, the prevalence of aseptic loosening and recurrent PJI was drastically elevated in patients after PJI-related revision arthroplasty: within 7.3 years of follow-up, 22.0% of all patients had aseptic loosening and 16.0% had recurrent PJI.

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