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Complications associated with 133 static, antibiotic-laden spacers after TKA

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Abstract
Purpose Periprosthetic infection after total knee arthroplasty (TKA) is a devastating complication, with a two-stage revision currently the 'gold standard' treatment for chronic infections. There is, however, a lack of information about mechanical complications during this treatment. The purpose of this study was to determine: (1) the rate and type of mechanical complications encountered during a two-stage exchange revision for periprosthetic infection of the knee and (2) possible factors of influence.
Methods Between 2000 and 2011, 133 patients received an antibiotic-laden cement spacer as part of a two-stage protocol. The overall frequency and types of complication were recorded (fissure/fracture of the tibia or femur, spacer fracture, subluxation of the patella, peroneus affection, wound healing disorder and mobilization under anaesthesia based on a constricted ROM). Also analysed were potential influencing factors (BMI, ASA classification, length of the interval with the enclosed spacer, revision needed after explantation, revision needed after reimplantation, complications after primary TKA, service life of the primary prosthesis) in terms of the overall outcome (possibility of reimplantation, complications during the two-stage protocol).
Results The mean age at the time of the first stage operation was 70.1 ± 9.9 years. Overall, 20 of 133 patients suffered one of the complications mentioned above (15 %). Fracture/fissure of the tibia occurred in nine cases (6.8 %) and fracture/fissure of the femur in three (2.3 %). There were also three mobilizations under anaesthesia after TKA reimplantation, two affections of the peroneus nerve, one spacer fracture, one subluxation of the patella and one wound healing disorder. The influencing factors on the overall outcome were revision after reimplantation (reinfection, $p = 0.002$), revision after explantation (reinfection, $p = 0.044$), prior aseptic revision after primary TKA (reimplantation, $p = 0.019$), and prior two-stage revision (reimplantation, $p = 0.002$).
Conclusion A two-stage revision arthroplasty using a static cement spacer is an effective therapy for infected TKAs. The complication rate of 15 % (including restricted ROM after reimplantation) is acceptable. Influencing factors (revision needed after reimplantation, revision needed after explantation) can be demonstrated and should be avoided during the two-stage protocol.

Keywords Spacer · Two-stage revision · TKA · Septic revision · Aseptic revision

Introduction

Periprosthetic infection after total knee arthroplasty (TKA) is a devastating complication. Although various treatment options exist for infections after TKA, a two-stage protocol with the temporary insertion of an antibiotic-laden cement spacer is currently the gold standard [1–4, 6, 7, 12–15, 17, 19, 23, 25].

Different types of spacer have been used to treat chronically infected TKAs: block spacers as static spacers (handmade with or without mould), articulated spacers (also handmade or preformed), and re-sterilized prostheses (technique by Hofmann). The principal functions of an antibiotic-laden cement spacer are to: maintain the tension

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of the surrounding soft tissue (in particular the patella and quadriceps tendon, joint capsule), the continuous local release of antibiotics; obviate bone loss; and prevent haematoma formation [5, 9, 21].

Authors have particularly reported a high incidence (up to 57 %) of spacer-specific problems during two-stage revisions [20]. Overall, the literature shows a lack of data concerning complications with spacers. And spacer-specific problems up to 57 % seem high.

Our patient collective is reported in this study. Almost every patient was treated in an external clinic (multiple prior surgeries) prior to assignment to our specialized hospital.

In the literature, a high amount of mechanical complications is reported with static spacers, some studies suggest a better outcome and lower complication rate with articulating spacers. In the literature, the influence of mechanical complications is not been reported yet to overall outcomes as reinfection or reimplantation rate. The aim of this study was to determine: (1) the frequency of mechanical complication associated with static, antibiotic-laden cement spacers, (2) the frequency of other intraoperative and post-operative complications, (3) possible factors of influence, and (4) if a mechanical complication influences the reinfection and reimplantation rate.

Materials and methods

Between 2000 and 2011, a two-stage protocol was performed on 133 patients with a periprosthetic infection after TKA. Spacers were implanted as static, antibiotic-laden placeholders. Partial weight bearing (20 kg) was allowed. All of the spacers were handmade with an endoskeleton (Steinmann pin with a 5 mm diameter or spine rods). In 37 spacers, Vancomycin was added to Gentamycin.

After the first stage treatment (spacer implantation), parenteral antibiotics were administered for an average of 2 weeks before being oralized for an additional 4 weeks (antibiotics depending on germ susceptibility). After normalization of the inflammation parameters (WBC, CRP), but no earlier than 6 weeks after spacer implantation, the antibiotics were discontinued. After another week without antibiotics, the first of three aspirations of the knee joint (at a gap of 1 week apart) was carried out. If all three aspirates (cultured for 14 days each) remained culture negative, reimplantation was scheduled at about 12 weeks after explantation.

The overall frequency of mechanical complications was recorded (fracture/fissure of the tibia/femur, spacer fracture, and subluxation of the patella). Other intraoperative and post-operative complications (mobilization under anaesthesia based on low ROM <85° flexion, affection of the peroneus nerve) were detected.

The study was approved by the institutional review board (Ethikkommission, University of Ulm, IRB number 413/12).

Statistical analysis

Descriptive statistics (means, standard deviation) were performed for complication rates and demographic analyses. Potential influencing factors were analysed: Length of the interval with enclosed spacer and ASA classification compared to complications (±) were analysed by Mann–Whitney test (mean, standard deviation, $p < 0.05$), BMI compared to complications (±) was analysed by Chi-square test (mean, standard deviation, $p < 0.05$). The influence of mechanical complications to reimplantation and reinfection rate was analysed by Fisher's exact test (n, percentage, $p < 0.05$). A p value of <0.05 was considered to be statistically significant. A post hoc power calculation showed 100 % power with $n = 133$ and an alpha error of 0.05 based on an incidence of 12 % (complications rate) reported by Johnson et al. [10]. All statistical analyses were performed using IBM SPSS Statistics software version 21 (Armonk, NY: IBM Corp.).

Results

The mean age at the time of the first stage operation was 70.1 ± 9.9 years. A total of 69 male and 64 female patients underwent TKA explantation and spacer insertion.

Of 133 patients who had a spacer implantation, 96 (72.2 %) underwent TKA reimplantation, 32 (24.1 %) had an arthrodesis due to devastating bone loss, persistent infection or insufficient femoral pulley, and five (3.8 %) died during the two-stage protocol.

Overall, 14 of 133 patients (10.5 %) suffered of a mechanical complication. Fissures of the tibia formed the majority, with nine cases (6.8 %), followed by fissures of the femur in three cases (2.3 %). One spacer fractured (0.8 %) and one subluxation of the patella occurred (0.8 %) during the interval between explantation and reimplantation. Other post-operative complications appeared in five patients (3.7 %): temporary affection of the peroneal nerve in two cases (1.5 %) and three cases of restricted ROM (<85° flexion) with manipulation under anaesthesia (2.3 %).

Possible influencing factors were not found. The time of enclosed spacer does not influence complication rate (12.9 ± 6 vs. 12.3 ± 4.2 weeks, n.s.), neither does ASA classification (n.s.), nor BMI (29.6 ± 5.2 vs. 28.9 ± 5.9, n.s.).

Mechanical complications do not statistically significantly influence the rate of reimplantation or reinfection (Tables 1, 2).

Table 1 The rate of reinfection is shown with or without mechanical complication within 128 patients (five patients excluded due to death during two-stage procedure)

	Reinfection		Total
	No	Yes	
Complication			
No	102 (79.7 %)	13 (10.2 %)	115 (89.8 %)
Yes	10 (7.8 %)	3 (2.3 %)	13 (10.2 %)
Total	112 (87.5 %)	16 (12.5 %)	p value = n.s.

No statistical significant differences were found by the Fisher exact test

Table 2 The rate of reimplantation is shown with or without mechanical complication during two-stage procedure in 128 patients

	Reimplantation		Total
	No	Yes	
Complication			
No	26 (20.3 %)	89 (69.5 %)	115 (89.8 %)
Yes	6 (4.7 %)	7 (5.5 %)	13 (10.2 %)
Total	32 (25 %)	96 (75 %)	p value = n.s.

Five patients died during two-stage procedure. The Fisher exact test does not show any significant differences

Discussion

The most important findings of this study were that mechanical complications with static spacers are rare (0.8 %), and the previously reported large incidence (up to 57 %) of spacer-specific problems in the two-stage revision process cannot be confirmed [20]. Post-operative complications occurred in 2.3 % of all patients. In light of the prerequisites of periprosthetic infection, this has to be regarded as an excellent outcome.

The two-stage protocol has proved to be the most successful method of treating chronically infected TKAs. Different types of spacer have been advocated for treating such infections. Static spacers have assumed to inferior outcomes and more complications than articulating spacers.

Mechanical complications with a static spacer in the interval between explantation and reimplantation during a two-stage protocol were rare in our study (0.8 %). In the literature, Castelli et al. [4] reported such complications with articulating spacers in two of 50 patients (4 %); Kim et al. [11] reported the absence of mechanical complications during a two-stage protocol in a small cohort using a modified articulating spacer in infected TKAs; Van Thiel et al. [22] had one mechanical complication (fracture of the spacer) in 60 patients (1.7 %) using an articulating, mould spacer, and Johnson et al. [10] reported a mechanical complication rate of about 12 % in a group with articulating spacers versus 0 % with static spacers. Overall, only a few studies have detected mechanical complications with spacers during a two-stage protocol. For many years, two-stage revisions have been carried out with static spacers and have been associated with less satisfactory knee motion [24]. However, although better post-operative ROM is associated with mobile spacers, the differences have not been found to be statistically significant [10, 16] and mechanical complications occurred in fewer cases in the group of static spacers. In our cohort, only 2.3 % showed a restricted ROM in the need for manipulation under anaesthesia.

In the current study, operative complications during explantation or reimplantation occurred in 12 cases (9 %). Of these, tibial fissures during explantation ($n = 3$) and reimplantation ($n = 6$) were the most frequent. In other research, Pietsch et al. [14] reported about one fracture of the tibia in 33 patients (3 %), while Silvestre et al. [18] reported intraoperative complications in four of 43 patients (9.3 %) in the form of partial avulsions of the patellar tendon, which were repaired with heavy sutures or staples.

Post-operative complications were monitored in 3 % of patients in the current study, meaning that there were three (2.3 %) cases of a restricted range of motion (flexion <85°). Kim et al. [11] reported one such patient (80° after a second stage operation) within a cohort of 20 (5 %) when using an articulating spacer. In their study, Pietsch et al. [14] revealed post-operative flexion ranging from 70° to 140°, but information on how many patients did not achieve a post-operative flexion of 90° is not provided. Van Thiel et al. [22] also reported improved flexion after a two-stage protocol (mean 101.3° ± 18.9°), but no explicit statement was made as to how many patients suffered from a restricted ROM of <80° of flexion after the second stage operation. The same is true of the study of Hwang et al. [8]: the post-operative ROM increased to 105° (range 65°–125°), but there was no statement on how many patients maintained a restricted flexion of <80°.

Finally, we detected a fairly high arthrodesis rate. This is a result of the selected patient collective, which is admitted to our hospital. Every enrolled patient had a long medical history concerning periprosthetic infection and underwent a few prior surgeries. Oftentimes, patients present insufficient general condition so that spacer interposition is used to eradicate periprosthetic infection, followed by final arthrodesis.

However, this research has a number of limitations. First, it is a retrospective study on a patient cohort collected over more than 10 years. Second, the study did not assess clinical outcome scores, although an indirect parameter of clinical outcome was analysed (manipulation under anaesthesia).

At the clinical routine of a two-stage procedure, the use of static, antibiotic-laden spacer shows a minimal rate of mechanical complications. The treatment with the lowest complication rate should be chosen in the circumstances of a two-stage procedure with high mortality [1], long treatment period and patients' psychological stress.

Conclusion

The most important finding of this study is that static, antibiotic-laden cement spacers used in two-stage revisions in infected TKAs produce minor mechanical complication rates (0.8 %) compared to articulating spacers in comparable studies (1.7–12 %).

The same applies to restricted ROM (flexion <80°) after the second stage, which occurred in 2.3 % of cases.

Accordingly, the use of static spacers during a two-stage revision in infected TKAs remains the gold standard treatment.

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