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Changements de prothèse en 1 temps versus en 2 temps au cours des infections de prothèses de genou

One-stage versus two-stage prosthesis replacement for prosthetic knee infections

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Contribution of authors

CR performed functional assessments and data collection, and wrote the article.

TM designed the study protocol and contributed to the result analysis.

HD contributed to the statistical analysis and reviewed the article.

CdS contributed to writing the article.

MD reviewed the article.

TF contributed to the result analysis and reviewed the article.

TF contributed to the result analysis and reviewed the article.

Mots clés : prothèse totale de genou, remplacement de prothèse, infection de prothèse de genou

Keywords: total knee prosthesis, prosthesis replacement, prosthetic knee infection

Résumé

Introduction. L'infection de prothèse articulaire de genou (IPG) est une complication sévère. Les critères de traitement par changement de prothèse en 1 ou en 2 temps restent discutés. Le changement en 1 temps est une option qui pourrait permettre un contrôle satisfaisant de l'infection ainsi qu'une amélioration des résultats fonctionnels.

Matériels et méthodes. Étude rétrospective entre le 1^{er} janvier 2009 et le 31 décembre 2014. Les objectifs de l'étude étaient de comparer l'évolution de l'infection et les résultats fonctionnels entre les changements en 1 ou 2 temps. Les résultats fonctionnels étaient évalués à l'aide du score IKS, du score KOOS et du score de qualité de vie SF-12.

Résultats. 41 patients ont eu un changement en 2 temps et 21 patients ont eu un changement en 1 temps. La durée moyenne de suivi après la chirurgie était de 22 mois. Une guérison de l'infection était obtenue chez 78 % des patients avec changement en 2 temps et 90 % des patients avec changement en 1 temps ($p=0,3$). Les amplitudes articulaires en flexion étaient significativement meilleures pour le groupe 1 temps que pour le groupe 2 temps ($p=0,04$). Les résultats du score IKS et du score KOOS étaient meilleurs chez les patients avec changement en 1 temps. Il n'y avait pas de différence pour le score SF-12.

Conclusion. Les changements en 1 temps pour IPG sont associés à une fréquence de guérison semblable à celle des changements en 2 temps et à un meilleur résultat fonctionnel pour le genou.

Abstract

Introduction. Periprosthetic knee infection is a severe complication. Confirmed criteria are lacking to choose between one-stage or two-stage prosthesis replacement to treat the infection. The one-stage replacement could lead to a satisfactory control of the infection and to better functional results.

Method. Retrospective study conducted between January 1, 2009 and December 31, 2014. The objectives of this study were to compare the infection outcome and functional results between the one-stage and two-stage replacement procedures. Functional results were evaluated using the IKS score, KOOS score, and SF-12 quality of life score.

Results. Forty-one patients underwent a two-stage replacement procedure and 21 patients a one-stage replacement. The average follow-up was 22 months after surgery. The infection was cured in 78% of patients who underwent a two-stage replacement and 90% of patients who underwent a one-stage replacement ($p=0.3$). The flexion range of motion was significantly better in the one-stage group than in the two-stage group ($p=0.04$). Results of the IKS score and of the KOOS score were better in the one-stage group. No difference was observed for the SF-12 score.

Conclusion. The one-stage replacement procedure for periprosthetic knee infection was associated with a similar healing frequency as the two-stage replacement procedure, and with better knee function.

Introduction

Periprosthetic infection following implantation of a knee prosthesis is a severe complication requiring multidisciplinary management. It is a rare complication (1.3% to 5% of arthroplasties) [1,2], even though responsible for a high morbidity with a poor functional prognosis. The curative treatment of chronic infections requires implant replacement with a one-stage or two-stage procedure and a targeted antibiotic therapy [3–5]. No specific criteria are detailed in the literature for choosing the prosthesis replacement modalities for chronic periprosthetic knee infections. The reference surgical treatment is still disputed. The one-stage replacement procedure could be associated with an adequate control of the infection and with improved functional results compared with the two-stage replacement procedure. The one-stage replacement procedure is indeed associated with earlier physiotherapy as no immobilization period is required. However, literature data is discordant on the benefit of one-stage replacement. Few comparative studies have been performed to assess one-stage versus two-stage replacement procedures [6–8]. None of these studies demonstrated the superiority of the one-stage replacement procedure in terms of articular range of motion and only Haddad *et al.* [6] reported better functional results with one-stage replacement. Such functional improvement is, however, only valid if it does not prevent the infection cure. We aimed to compare infection outcome and functional results in patients who underwent one-stage versus two-stage prosthetic knee replacement for infection.

Material and method

Study population

We performed a monocenter and retrospective cohort study of patients who underwent prosthetic knee replacement because of sepsis between January 1, 2009 and December 31, 2014. Inclusion criteria were adult patients aged above 18 years presenting with a chronic infection of a total knee prosthesis treated more than one month after infection onset with a one-stage or two-stage prosthesis replacement, and followed for at least one year after the procedure.

Criteria for the infection diagnosis were those of the Infectious Diseases Society of America (IDSA) [4] and of the French Infectious Diseases Society (SPILF) [9]: presence of a fistula or pus in contact with the prosthesis or identification in culture media of an infectious agent from a preoperative sample or from intraoperative samples (positive specimen with a virulent microorganism or at least two positive specimens for the same bacterium of the skin flora).

The type of procedure was decided by the multidisciplinary team including an orthopedic surgeon, an infectious disease specialist, and a microbiologist. A two-stage replacement procedure was preferred in the following cases: *(i)* unknown causative agent before the procedure, *(ii)* bacterial resistance profile preventing the use of molecules with a good bone diffusion and/or with a good bioavailability and/or with an activity against biofilm-associated bacteria, *(iii)* skin involvement or fistula preventing high-quality closure, *(iv)* substantial amount of pus associated with a risk of contamination of the new prosthesis, and *(v)* substantial bone defects requiring reconstruction with bone transplant. These multidisciplinary meetings are part of the national system of reference centers for bone and joint infections implemented in France in 2008 by the Ministry of Health. We performed this study at the University Hospital of Bordeaux, a 3,000-bed facility acting as the coordinating reference center for bone and joint infections in Southwest France.

Data was collected from the patients' medical records. We recorded risk factors for infections, as defined by the French National Authority for Health (French acronym HAS): ASA score, diabetes, obesity with a body mass index >40 , rheumatoid arthritis, duration of surgery >2.5 hours, active smoker, postoperative hematoma, time between fracture and surgery, cirrhosis, preoperative anticoagulation therapy with INR >1.5 [10]. Patient data was analyzed as two groups according to the prosthesis replacement modalities, i.e. one-stage or two-stage replacement. Patients included in the one-stage group started physiotherapy immediately after surgery. For patients included in the two-stage group, the number of physiotherapy sessions performed in-between both stages of the procedure was limited as the aim was only for patients to be able to change positions on their own. Articular range of motion exercises started after prosthesis replacement.

All patients were managed by a multidisciplinary team with a standardized follow-up by the infectious disease specialists at 6 weeks, 4 months, 6 months, and one year post-surgery. The following examinations were performed at each assessment: clinical examination (temperature, pain, articular range of motion), biological examination (complete blood count, CRP serum level), and radiological examination (frontal and lateral knee radiography). All included patients were then asked to come back after the longest possible follow-up time, to perform a functional assessment. Functional scores were the SF-12 quality of life score (Short Form-12), the Knee injury and Osteoarthritis Outcome Score (KOOS), and the International Knee Society (IKS) score [11–13].

KOOS is a knee-specific quality of life score used to analyze the impact of the knee on the patient's quality of life. It consists of five subscales, each assessed out of 100 points: pain, other symptoms, function in daily living, function in sport and recreation, and knee-related

quality of life. An overall score is not recommended with this scoring system. This is a self-administered questionnaire by the patient.

The IKS score is made of two components (subjective and objective clinical data) and of three subscales: expectations, satisfaction, and functional activities. The objective component is assessed over 100 points and includes assessment of knee alignment, flexed knee range of motion, and pain. The “expectations” subscale is assessed over 15 points. The “satisfaction” subscale is assessed over 40 points and focuses on pain, knee function in daily living and in sport and recreation. The “functional activities” subscale is assessed over 100 points and focuses on knee function in daily living and in sport and recreation. The subjective component of the questionnaire is self-administered.

The psychosocial assessment is based on overall quality of life scores. These scores assess the patient’s quality of life in terms of overall health and are thus not just focusing on the knee. This is what the SF-12 score aims to assess. This score is divided into two parts: a physical score and a psychological one aimed to assess daily living activities.

The primary endpoint was the infection cure rate, defined as the absence of clinical, biological, and radiological recurrence sign at one year of follow-up. The secondary endpoint was the functional result as assessed after an optimal follow-up time after the last procedure.

Statistical analysis

The statistical analysis was performed using the Graphpad Prism™ software (La Jolla, CA, USA). Qualitative data was analyzed as frequencies and percentages in each group. Quantitative variables were presented as means and standard deviations. Qualitative variables were compared using the Chi-square test or Fisher’s exact test for lower sample

sizes. For quantitative variables, the comparison of means for independent samples was performed using Student's *t* test. An ANOVA test was performed when more than two means were compared. We set the significance threshold between two variables at $p<0.05$.

Results

Sample description

A total of 71 patients were managed at the hospital between January 2009 and December 2014 for a total knee prosthesis infection requiring prosthesis replacement. Nine patients were not included in the study because of insufficient follow-up. A total of 62 patients were thus included: 21 patients in the one-stage replacement group and 41 in the two-stage replacement group (Figure 1). Population description is detailed in Table 1. Thirty-five of the 62 patients were men (56%) and the mean age was 70.7 years (standard deviation [SD]=9.0). Thirty-three per cent of patients included in the one-stage replacement group and 53% of patients in the two-stage replacement group presented with risk factors for infection, as defined by the HAS ($p=0.13$). No difference was observed between both groups in the number of conservative procedures in between prosthesis implantation and prosthesis replacement ($p=0.23$). Reasons leading to choosing the two-stage replacement procedure for the 41 patients concerned were: no bacterial identification before the procedure ($n=13$), bacterial resistance profile ($n=3$), presence of a cutaneous infection ($n=5$) or a fistula ($n=8$), presence of periprosthetic pus ($n=4$) or bone defects requiring reconstruction with a bone transplant ($n=6$), and subacute presentation with hemodynamic failure ($n=2$).

Staphylococcus aureus and coagulase-negative staphylococci were most frequently identified (Table 1). Among patients presenting with a coagulase-negative *Staphylococcus*

infection, four of the seven patients included in the one-stage replacement group and seven of the 15 patients of the two-stage replacement group were infected with a methicillin-resistant bacterium. Among patients infected with *Staphylococcus aureus*, none of the four patients included in the one-stage replacement group and two of the 13 patients of the two-stage replacement group were infected with a methicillin-resistant bacterium. The mean time between both stages of the procedure in the two-stage replacement group was 4.1 months (SD=1.9; range, 1-14 months). This mean time was higher than three months for 19 patients (46%), after which time the second prosthesis procedure is more difficult to perform [14]. Following the first stage of the procedure, patients received an antibiotic therapy for 6 to 8 weeks and most patients (39/41) had at least 14 days off antibiotics before the second-stage procedure. Samples were collected from all patients during prosthesis replacement and 85% of patients (35/41) had sterile bacteriological results during the second-stage replacement procedure.

The mean follow-up duration for the 62 patients following prosthesis replacement was 22 months. Six patients had to undergo flap surgery. All six patients belonged to the two-stage replacement group. Three of them experienced an infection relapse: two had to be amputated and one received a long-term oral suppressive antibiotic therapy.

Infection outcome

The infection cure rate was 82% (51/62 patients): 90% in the one-stage replacement group (19/21 patients) and 78% in the two-stage replacement group (32/41 patients), without any significant difference. Management of relapses was based on long-term suppressive antibiotic therapies (n=5), amputations (n=2), and revision surgeries for joint lavage (n=2).

Two patients died from a septic shock following relapse of the periprosthetic infection.

Functional outcome

Prostheses implanted during the replacement procedure were posterior-stabilized prostheses (n=3), varus-valgus constrained prostheses (n=39), and rotating hinge prostheses (n=20).

The mean time between the last procedure and measurement of functional scores was 48.2 months (SD=20.5), with 46.4 months (SD=23.1) and 49.4 months (SD=19) for the one-stage and two-stage replacement groups, respectively, without any statistically significant difference ($p=0.63$). Mean ranges of motion for flexion at 48 months were 116.7°, 97.0°, and 92.9° for patients with posterior-stabilized prostheses, varus-valgus constrained prostheses, and rotating hinge prostheses, respectively ($p=0.21$). Means for flexion were 101.6° and 86.1° in the one-stage replacement group and two-stage replacement groups, respectively ($p=0.04$) (Figure 2). Means for knee extension were -0.2° and -1.8° in the one-stage and two-stage replacement groups, respectively ($p=0.13$). In the two-stage replacement group, means for flexion were 89.5° for patients with a dynamic spacer (29 patients) and 81.2° for those with a static spacer (12 patients) ($p=0.45$).

Included patients were newly contacted for long-term functional score measurement using the SF-12, KOOS, and IKS scores. Response rate was 72.6% with 17 patients of the one-stage replacement group and 28 patients of the two-stage replacement group. No patient had experienced an infection relapse in the meantime. Results of these functional scores are reported in Table 2 and Figure 3. Significant differences were observed between both groups for the symptoms ($p=0.04$) and daily living ($p=0.03$) components of the KOOS score and for the objective score ($p=0.001$), satisfaction ($p=0.04$), and functional activities ($p=0.048$) components of the IKS score. As for the other components of these tests, mean results were

higher in the one-stage replacement group even though the difference was not statistically significant.

Discussion

On the basis of literature data, prosthesis replacement is the reference procedure for a prosthetic knee infection [3,14,15]. The infection cure rate ranges from 53% to 100% depending on studies [7,16–22]. The infection cure rate observed in our study with the one-stage replacement procedure (90%) was not statistically different than that of patients undergoing the two-stage replacement procedure (78%). However, we observed better results for some categories of functional scores in patients undergoing the one-stage replacement procedure.

Few studies compared the infection outcome between one-stage and two-stage prosthetic knee replacement. Results from Bauer *et al.*'s [7] and Haddad *et al.*'s studies [6], and from Kunutsor *et al.*'s meta-analysis [23] are similar to our results, with no significant difference observed in terms of infection cure. Jämsen *et al.* [15] reported better infection cure rates in the two-stage replacement group. The variety of results reported in the literature could be explained by the absence of randomized studies and by the poor standardization of criteria contributing to the choice of treatment. Zimmerli *et al.* [24] suggested criteria in favor of the one-stage replacement procedure: preoperative identification of the causative infectious agent, absence of difficult-to-treat infectious agent, good quality of skin and soft tissues, patient's general status, and no need for bone reconstruction. Our study strategy complied with these criteria. The six patients who underwent flap surgery were managed with a two-stage replacement procedure.

We observed better articular range of motion results following one-stage replacement. A 15.5° difference was observed in terms of knee flexion, i.e. 101.6° and 86.1° in the one-stage and two-stage replacement groups, respectively ($p=0.04$). This type of flexion benefit has a significant direct impact on patients. Indeed, more than 90° knee flexion allows patients to sit down and climb the stairs. This is also an important factor for the dressing up routine. However, we did not observe any difference in terms of knee extension with deficits of -0.2° in the one-stage replacement group and -1.8° in the two-stage replacement group. These results differ from those of Bauer *et al.*'s [7] and Jämsen *et al.*'s [15], who reported similar flexion results in both groups. The absence of extension difference observed in our study may be explained by the postoperative temporary immobilization of the extended knee with a splint. This temporary immobilization seems to improve healing, to limit flexum onset, and to stabilize the knee in between both stages of the procedure [25].

The present study also suggests the functional superiority of the one-stage replacement procedure with significant differences in terms of symptoms and daily living components of the KOOS score and in terms of objective score, satisfaction, and functional activities components of the IKS score. Haddad *et al.* [6] also reported a functional difference at two years of follow-up using the previous version of the IKS score (KSS score, Knee Society Score), with a better performance for one-stage replacement. Singer *et al.* [26] and Buechel *et al.* [27] also reported good functional results with the one-stage replacement procedure, but both of these studies were non-comparative (i.e., one-stage versus two-stage). In the present study, components of the functional scores without any significant differences were the “expectations” component of the IKS score, the “pain”, “sport and recreation”, and “quality of life” components of the KOOS score, although results were always better in the

one-stage replacement group. We cannot rule out that the lack of statistical power, related to our limited sample size, may explain the absence of difference. Overall functional results tend to indicate quality of life improvement for patients undergoing a one-stage replacement procedure. Several studies indeed reported a correlation between quality of life and results of KOOS and IKS functional scores [28]. However, the SF-12 score may have lacked sensitivity in detecting any effect of the type of surgical procedure chosen, and it may have been too generic to show any difference in such a specific context. The KOOS and IKS scores were indeed developed to assess knee joint, unlike the SF-12 score.

Our study had several limitations, such as its monocenter and retrospective nature. The limited sample size did not allow for a subgroup analysis of rare situations. We also could not perform a detailed analysis by microbial species. The mean time between both stages of the procedure observed in our study was quite long (four months), which could have impaired functional results in the two-stage replacement group. Due to the retrospective nature of the study, we also did not perform any assessment of articular range of motion nor any functional score measurement before the procedure. The observed functional differences may thus be due to the pre-surgical context, which could have had a potential impact on the treatment choice. However, characteristics of the one-stage and two-stage replacement groups were similar in terms of age, risk factors for infection, infection duration, and number of procedures before prosthesis replacement. We thus believe that the one-stage replacement procedure may have contributed to the observed functional improvement, as compared with the two-stage replacement procedure. The absence of practice modifications in our facility during the study period (2009-2014), mainly in terms of criteria for either choosing the one-stage or the two-stage replacement procedure, seems to

increase the reliability of our results. Our study suggests that the one-stage prosthetic knee replacement procedure is associated with a similar infection cure rate than the two-stage prosthetic knee replacement procedure, and with a better knee function when the procedure is performed by a trained team. The one-stage replacement procedure seems to reduce functional sequelae related to total prosthetic knee sepsis. Further studies are required to explore the benefit of the one-stage replacement procedure in clinical situations where the two-stage replacement procedure is usually performed, such as for infections caused by resistant bacteria or by bacteria unidentified before surgery.

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Figure 1. Flow chart

Figure 1. Diagramme de flux

Figure 2. Résultats des amplitudes articulaires de genou en flexion selon les changements en un ou deux temps opératoires (n = 62 patients), * $p = 0,04$

Figure 2. Results of knee flexion range of motion according to one-stage or two-stage replacement procedures (n=62 patients), * $p=0.04$

Figure 3. Résultats des scores fonctionnels

Figure 3. Functional score results

Tableau 1. Description de la population**Table 1.** Population description

	Total (n=62)	One-stage replacement procedure (n=21)	Two-stage replacement procedure (n=41)	p value
Age, mean (SD*), years	70.7 (9.0)	72.6 (9.2)	69.5 (9.1)	0.21
Male sex, n (%)	35 (56)	13 (61)	22 (53)	0.53
Time between prosthesis implantation and infection diagnosis, mean (SD*), months	43.5 (46)	54 (61)	38 (36)	0.21
Infection risk factors as per the HAS, n (%)	29 (46)	7 (33)	22 (53)	0.13
Presence of a fistula, n (%)	10 (16.1)	2 (9.0)	8 (19.5)	0.47
Culture results, n (%)				
<i>Staphylococcus aureus</i>	17 (27.4)	4 (19.0)	13 (31.7)	
Coagulase-negative staphylococci	24 (34.0)	14 (31.0)	15 (36.5)	
Streptococci	6 (9.6)	5 (23.8)	1 (2.4)	
Gram-negative bacilli	6 (9.6)	2 (9.5)	4 (9.7)	
Other bacteria	4 (6.4)	0 (0)	4 (9.7)	
Sterile	7 (11.3)	3 (14.3)	4 (9.7)	
Flap surgery, n (%)	6 (10)	0 (0)	6 (14)	na [#]
Follow-up duration after infection treatment, mean (SD*), month	22 (13)	23 (12)	22 (8.4)	0.8
Infection cure rate, n (%)	51 (82)	19 (90)	32 (78)	0.3

*SD: standard deviation, #na: non-applicable

Tableau 2. Résultats des scores fonctionnels en fonction du type de chirurgie**Table 2.** Functional scores by type of procedure

	One-stage replacement procedure (n=17)	Two-stage replacement procedure (n=28)	<i>p</i> value
IKS [*]			
Objective score	87.9	78.6	0.001
Satisfaction	22.3	17.21	0.04
Expectations	7.88	7.32	0.5
Functional activities	51.05	39.75	0.048
KOOS [#]			
Symptoms	73.52	57.52	0.04
Pain	68.23	57.45	0.09
Daily living	61.87	48.20	0.03
Sport and recreation	10.00	8.75	0.70
Quality of life	41.18	27.90	0.09
SF-12 [§]			
Psychological	43.11	38.08	0.09
Physical	39.10	34.41	0.10

^{*}IKS: International Knee Society; [#]KOOS: Knee injury and Osteoarthritis Outcome Score; [§]SF-12: Short form-12 questionnaire