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ORIGINAL PAPER

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Pre-formed articulating knee spacer in two-stage revision for the infected total knee arthroplasty

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Abstract We performed a prospective study to assess safety and effectiveness of a pre-formed articulating spacer made of gentamicin-impregnated acrylic cement in the management of infected total knee arthroplasty. Twenty-one consecutive patients with unilateral deep infection were treated by two-stage revision in two centres. Two patients were excluded, and 19 patients remained available for assessment. The mean implantation time of the spacer was 12 weeks. The rehabilitation programme between stages consisted in early range of motion exercises and partial weight bearing. Mean follow-up after removal of the spacer and insertion of the final prosthesis was 24 (range, 12–43) months. No patient had recurrence of infection at the latest follow-up. The mean Knee Society functional score during spacer management was rated 75 points and was rated 84 points at the latest follow-up. No device-related complication was observed.

Résumé Nous avons étudié prospectivement la sécurité et l'efficacité d'un espaceur articulé pré-formé fait en ciment acrylique imprégné de gentamicine dans la gestion de l'arthroplastie totale infectée du genou. Vingt et un malades consécutifs avec une infection profonde monolatérale ont été traités dans deux centres, avec une révision en deux temps. Deux malades ont été exclus, et 19 malades sont restés disponibles pour l'estimation. Le temps d'implantation moyen de l'espaceur était de 12 semaines. La rééducation entre les deux étapes a consisté en un travail précoce de la mobilité et un appui partiel. Le suivi moyen après réimplantation prothétique était de 24 mois (12 à 43 mois). Aucun malade n'avait de récidive de l'infection au dernier recul. Le score fonctionnel moyen (Knee Society) pendant le port de l'espaceur a été estimé à 75 points et à 84 points au dernier recul. Aucune complication liée à l'espaceur n'a été observée.

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Introduction

The most feared complication after total knee arthroplasty (TKA) is deep infection [11, 19, 21]. The treatment often results in prolonged hospital stay, a period of marked limitation of mobility for the patient and the prospect of a major reconstructive procedure with a compromised outcome. It is been widely accepted that the most reliable outcome for the treatment of late chronic infection is obtained by a two-stage exchange technique involving implant removal followed by a 6-week course of systemic antibiotics and delayed exchange arthroplasty [12, 17, 20]. The major disadvantage of this method is the period between stages, which is often associated with pain, difficult mobility and knee instability [4, 6]. Furthermore, re-implantation is often difficult because of scar formation, shortening of the extensor mechanism and retraction of the joint capsule and ligaments. To overcome these difficulties, temporary joint spacers have been introduced. Antibiotic-loaded bone–cement spacers in a two-stage re-implantation technique allow early joint and patient mobilisation, shorter hospital stay and potentially a reduced rate of re-infection [5, 9].

The aim of this prospective, two-centre clinical study was to verify safety and effectiveness of an innovative, pre-formed articulating knee spacer in a two-stage technique for the management of infected TKA.

Materials and methods

The spacer (Spacer-K, Tecres, Verona, Italy) is pre-formed in the factory with ultra-congruent condylar knee prosthe-

sis design made of gentamicin-impregnated acrylic cement (2.5% w/w) and produced in three sizes (Fig. 1). The device is comprised of two independent elements: a flat base (tibial component), upon which the femoral component articulates. The two components must be fixed with bone cement to the bone. The three sizes contain, respectively, 0.8, 1.1 and 1.8 g of active gentamicin. The mechanical and pharmacological properties are adequate for the intended use of the device (partial weight bearing, 180 days of maximum implantation). The device has been mechanically tested following the International Standards Organisation (ISO) and American Society for Testing and Materials (ASTM) standards used for definitive prostheses. The in vitro release has been tested according to the European Pharmacopoeia (agar-well diffusion test).

Twenty-one consecutive patients with infected TKAs requiring two-stage exchange were treated with the Spacer-K at two centres between March 2000 and June 2003. Mean patient age was 67 (range, 58–89) years; there were 12 women and nine men. In all patients a joint aspiration for microbiological examination was performed prior to revision surgery. Diagnosis of infection was confirmed on the basis of positive cultures of pre-operative aspirates and intra-operative tissue specimens and increased C-reactive protein levels. The first stage of treatment was removal of the infected prosthesis, debridement of infected and devitalised tissues, extensive pulsating lavage with saline solution and insertion of the articulating spacer. The spacer was fixed using gentamicin-loaded acrylic cement (Cemex System Genta, Tecres) (Figs. 1 and 2). Infection was caused by *Coagulase neg. Staphylococcus* (10 cases), *Staphylococcus aureus* (3), *Staphylococcus epidermidis* (2) others (3). In 3 patients the causitive microorganisms could not be identified. All knees had anatomical and functional integrity of the extensor apparatus and adequate mediolateral stability. Eleven knees were rated type I, and eight were rated type II bone loss according to Engh's criteria [3]. Two knees were rated type III. The rehabilitation programme during the between-stages period consisted of early active range of motion exercises and partial weight bearing. The Knee Society score (KSS) was used for functional and clinical rating during the between-stages period and at follow-up after second-stage surgery. Patients were asked for subjective judgement of their quality of life during stages. The spacer was left in place until clinical healing of the soft tissues and normalisation of the laboratory parameters (white cells count, C-reactive protein), and a minimum of 6-week intravenous systemic antibiotic therapy. Antibiotic management was performed under the guidance of the infectious-diseases specialist. A joint aspiration for microbiological investigation was carried out 1 week after interruption of the antibiotic therapy. The second stage of exchange surgery consisted of removal of the spacer, microbiological investigation of peri-prosthetic tissue, debridement, pulsating lavage with saline solution and implantation of a new prosthesis using antibiotic-loaded cement. Intravenous systemic antibiotic therapy was continued until the end of the sixth post-operative week.

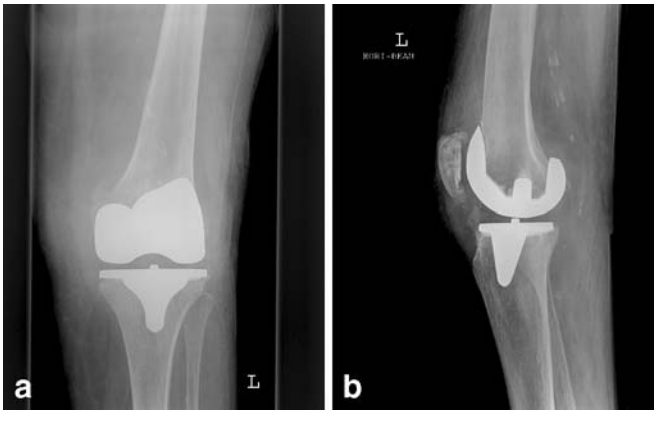

Fig. 1 **a**, **b** Pre-operative radiographs (AP and lateral) of a 75-year-old woman with total knee replacement (TKR) deep infection 2 years after the index operation

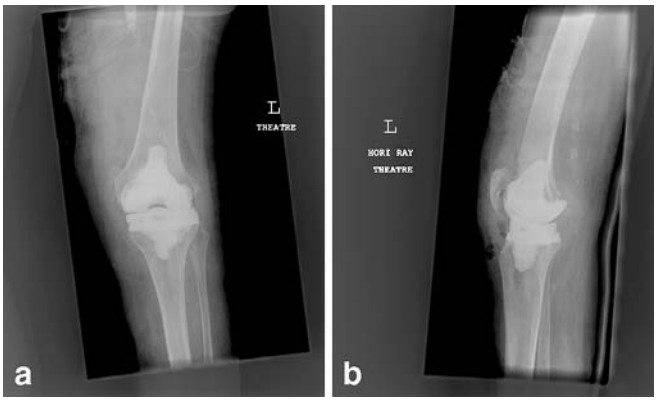

Fig. 2 **a**, **b** Post-operative radiographs (AP and lateral) after removal of the prosthesis, debridement, wash out, and insertion of the Spacer-K fixed with gentamicin-loaded cement

Results

Mean spacer implantation time was 12 (range, 7–28) weeks. No microorganisms grew on any of the cultures of the last aspiration, except one. In this patient removal of the spacer and insertion of a moulded cement block with vancomycin was necessary following the development of methicillin-resistant *S. aureus* isolated between stages. This patient was excluded from the study. One elderly patient refused re-operation; she had an almost unrestricted knee function without symptoms at the 1-year follow-up, and the radiographs showed no signs of wear or fracture of the spacer. This patient was also excluded from the study. Thus, 19 patients remained for clinical and radiological assessment. The mean pre-operative range of motion (59°, range 5°–90°) was almost unchanged during the inter-stage period with the articulating spacer (77°, range 10°–100°), and improved after insertion of the final prosthesis (94°, range 0°–120°) (Table 1). Neither breakage nor clinically relevant wear of the spacer were detected, nor were

Table 1 Demographic data of 21 patients with deep infection of total knee replacement (TKR) treated with two-stage revision surgery using an articulating spacer

	21 knees (21 patients)
Gender (females/males)	12/9
Age (years)	67 (range, 58–89)
Follow-up (months)	24 (range, 12–43)
Implantation time of spacer (weeks)	12 (range, 7–28)
Range of motion of knee (degrees)	Pre-operatively: 59° (range, 5°–90°) Between stages: 77° (range, 10°–100°) At follow-up after 2nd stage: 94° (range, 0°–120°)

complications related to the spacer. Removal of the spacer was uneventful in all patients; the amount of bone stock loss was unchanged between stages. The spacer showed no macroscopic signs of wear or breakage (Table 1).

Mean follow-up after removal of the spacer and insertion of the new prosthesis was 24 (range, 12–43) months. No patient had recurrence of infection at the latest follow-up (Fig. 3). The mean KSS during spacer management was rated 74 (range, 50–83) points and was rated 81 (range, 30–92) points at the latest follow-up. The mean KSS functional score (KSS-F) during spacer management was rated 75 (range, 41–86) points and was rated 84 (range, 13–97) points at the latest follow-up. One unsatisfactory outcome, with a KSS score of 30 and KSS-F score of 10 was observed in a patient with associated medical problems. Patients judged the quality of life during the in-between period as excellent (n=3), good (n=13), and poor (n=3). Daily outdoor walking distance with partial weight bearing was more than 1 k in seven patients and was less than 1 k in 12 patients. There were no radiological signs of loosening or osteolysis at the latest follow-up.

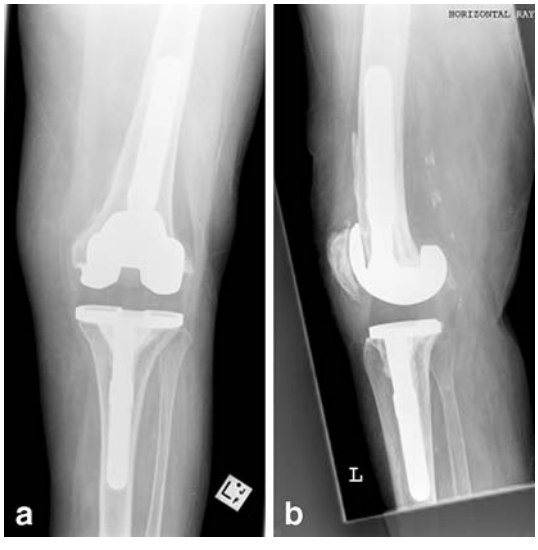

Fig. 3 **a**, **b** Two-year follow-up radiographs (AP and lateral) after insertion of the final prosthesis. The joint is free of infection, the prosthesis appears stable, the Knee Society score (KSS) was rated 90 points and the KSS function score was rated 85

Discussion

Total knee replacement is one of the most common and successful procedures in orthopaedic surgery [1, 13, 14]. However, despite meticulous prophylactic protocols, infection remains a devastating complication. The incidence ranges from 0.5% to 5%, with an increase risk in revision surgery or in patients with risk factors such as rheumatoid arthritis on steroid treatment, diabetes or compromised immune status [15, 16]. The proper management of this complication is still controversial, with various therapeutic options currently used ranging from antibiotic therapy only, repeated joint lavage, debridement preserving the prosthetic implant, resection arthroplasty, one-stage or two-stage re-implantation and arthrodesis or amputation [8]. The choice of treatment depends upon many variables, such as severity and resistance of infection and microorganism and general health status of the patients. The best results in terms of eradication of the disease and functional recovery have been obtained with either one- or two-stage re-implantation. One-stage surgery has been found to be most effective in specialised centres [4]. On the other hand, two-stage re-implantation can be used successfully in ordinary settings, with a freedom from infection rate ranging from 81% to 100%. In the two-stage technique, the use of an antibiotic-impregnated cement spacer maintains the articular space, prevents retraction of the collateral ligaments and guarantees a local release of antibiotic [18, 20]. The joint rigidity frequently observed in patients treated with spacer blocks has stimulated some authors to propose the use of an articulated spacer [5, 7, 9, 10, 17]. McPherson [9] advocated the use of a cement spacer moulded intra-operatively. Duncan and Beauchamp [2] have developed a custom made articulated spacer, called Prostalac. The first version of the device consisted of an intra-operative moulding of the femoral and tibial components using acrylic bone cement and appropriate antibiotics. The Prostalac system has undergone a subsequent evolution with two thin metal articulating strips on the femoral component. The tibial part has two thin plates of polyethylene and a post in acrylic cement articulated to the metallic femoral cam for posterior stability. Unfortunately, cement spacers moulded in the operating theatre do not have reproducible mechanical characteristics, and there is a potential risk of fracture of the components [12]. Hofmann [7] used the removed and re-sterilised femoral component in association with a new polyethylene component fixed with antibiotic-impregnated cement as a spacer. Scott [17] used a spacer prosthesis in combination with antibiotic-impregnated cement chains. A major drawback of the spacer prosthesis is the presence of hardware, which could theoretically favour bacterial adhesion.

In a previous study, we introduced the new pre-formed articulating Spacer-K with the characteristics of an ultra-congruent condylar knee prosthesis. Dynamic mechanical

tests of the spacer showed adequate structural stability to withstand at least 6 months of clinical use and antibiotic elution tests confirmed high release of gentamicin from the Spacer-K [12].

One of the limitations of the present study is the short follow-up after insertion of the revision prosthesis. On the other hand, the aim of the investigation was to identify problems related to the inter-stages management with the new device and not the long-term outcomes of the two-stage revision technique. Another limitation is the absence of a control group managed either with a static spacer or an intra-operative moulded spacer. Such a study would require a consistent sample size, a difficult task with this kind of pathology.

In conclusion, the advantages of spacer articulation are perceived to be improved function between stages, avoidance of bone loss due to unstable static bone cement block, easier second-stage surgery and subsequent recovery and rehabilitation. The articulating Spacer-K is a safe and effective device for the management of the infected TKA caused by gentamicin-sensitive microorganisms. Early mobilisation does not compromise the rate of eradication of infection.

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