Preformed acrylic bone cement spacer loaded with antibiotics

Use of two-stage procedure in 10 patients because of infected hips after total replacement

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ABSTRACT – In 10 patients having deep infection after total hip replacement, we used a two-stage revision procedure involving implantation of a preformed spacer with a cylindrical rod coated with acrylic cement containing antibiotics (Spacer-G). This device, which remained in situ for an average of 5 months, permitted healing of the infection in 8 cases and reimplantation of a new prosthesis (mean follow-up 35 months). During treatment, 1 dislocation occurred. The spacer maintained the gap between both bone segments and allowed a certain degree of joint mobility. Use of Spacer-G improved the quality of life of the patients during treatment and accelerated recovery of function after reimplantation.

In chronic infections of a total hip replacement the implant must be removed to obtain healing (Coventry 1975, Garvin and Hanssen 1995, Tsukayama et al. 1996, Hanssen and Rand 1998). Reimplantation of a prosthesis can be done at the same time, i.e., a one-stage revision procedure (Carlsson et al. 1978, Buchholz et al. 1981, 1984, Raut et al. 1995, Callaghan et al. 1999), or be delayed, i.e., two-stage revision procedure (Colyer and Capello 1994, Garvin et al. 1994, Ivarsson et al. 1994, Younger et al. 1998). The decision is usually based on personal preferences, which are often affected by the microbiological findings.

In many cases, two-stage revision involves reimplantation after 4–8 weeks, during which a temporary antibiotic (AB)-loaded polymethylmethacrylate (PMMA) spacer is inserted with the aims of avoiding periarticular soft tissue shortening and keeping a correct limb position and sterilizing the infected areas (Marks et al. 1976, Elson et al. 1977, Steinbrink 1990). We evaluated a preformed PMMA spacer which allows weightbearing and some joint mobility while ensuring constant known antibiotic release.

Figure 1. The spacer.

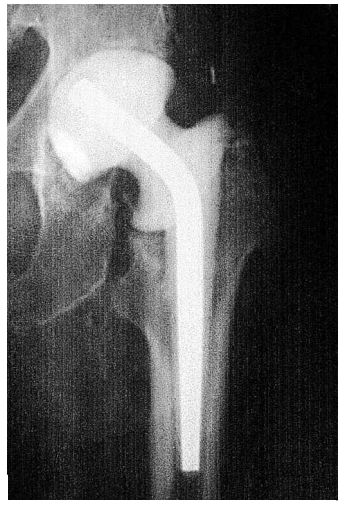

Figure 2. Spacer-G inserted: the antibiotic-loaded PMMA device fits the host bone adequately.

Characteristics of treated patients

A	B	C	D	E	F	G	H	I	J	K	L	M
1	F	66	OA	Escherichia coli	123	65	23	21	<3	<3	0	–
2	M	64	OA	none detected	197	59	31	23	15	8	3	–
3	M	74	OA	none detected	134	71	28	16	18	<3	0	acetabular bone graft
4	F	75	NF	Group B β–hemolytic Streptococcus	160	56	39	19	33	5	3	–
5	M	74	OA	Staphylococcus epidermidis	112	86	43	35	44	4	3	–
6	M	58	OA	Pseudomona aeruginosa	156	62	20	17	28	6	2	–
7	F	69	OA	Staphylococcus aureus	273	61	49	–	99	40	–	spacer dislocation not reimplanted
8	M	76	OA	none detected	204	91	32	30	98	5	4	acetabular bone graft
9	M	79	NF	Mycobacterium tuberculosis	114	36	59	–	22	102	–	not reimplanted
10	M	83	OA	none detected	89	26	22	20	37	<3	2	–

A Case
B Gender
C Age (years)
D Diagnosis
OA osteoarthrosis
NF neck fracture
E Type of bacteria
F Time on spacer (days)
G ESR before spacer
H ESR before reimplantation
I ESR at follow-up
J CRP before spacer
K CRP before reimplantation
L CRP at follow-up
M Complications and notes

Patients and method

"Spacer-G" is manufactured by Tecres S.p.A. (Sommacampagna, Verona, Italy) (Figure 1). It has a central load-bearing hollow cylindrical rod made of AISI 316L stainless steel, and having a maximal diameter of 10 mm. This is entirely covered by antibiotic-loaded "Cemex" bone cement. It weighs 180 g, has a surface area of 165 cm^2 and is currently available in three sizes with head diameters of 46, 54 and 60 mm; we used the intermediate size.

From September 1996 to January 1999 we treated 10 patients (age 58–83 years, 7 men) with an infected total hip arthroplasty. The previous prostheses had been implanted minimum 2 months and maximum 168 months before. In 6 cases, the infecting organism was identified before revision surgery: Staphylococcus epidermidis, Staphylococcus aureus, Group B ß-hemolytic Streptococcus, Pseudomonas aeruginosa, Escherichia coli and Mycobacterium tuberculosis in 1 case each (Table).

7 patients showed little, if any, periprosthetic osteolysis—type I using Paprosky et al.'s method (1994). 3 patients had a type IIA bone defect, presenting with generalized enlargement of the acetabulum and showing superomedial migration of the cup and metaphyseal femoral bone loss.

In the first 4 patients, the spacer PMMA was loaded with 1.9 g gentamicin sulfate. In the next 6 patients, the spacer PMMA was loaded with a 1.8% concentration of gentamicin sulfate to which 2 g of vancomycin (2.5% concentration) had been added during manufacturing. In vitro pharmacological tests show effective release of these antibiotics from the spacer (Wahlig et al. 1980, 1984, Salvati et al. 1986, Baker and Greenham 1988, Kuechle et al. 1991, Penner et al. 1996, Bertazzoni Minelli et al. 1999a, b).

Surgery was performed via a lateral approach: after removal of all implanted devices, debridement of the periprosthetic infected tissue, and insertion of the spacer in the femoral canal, we obtained an easy and stable reduction in all patients (Figure 2).

Postoperative rehabilitation included active and passive joint mobilization and muscle strengthening exercises. Weightbearing with crutches was permitted in 8 cases, in whom the spacer showed adequate mechanical stability. They became pain-free and could flex their hip up to 70 °C.

The erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) were followed at regular intervals (Sanzén and Carlsson 1989).

All the patients underwent a definitive prosthetic reimplantation using various models, as indicated. Implant fixation was obtained in all cases with

acrylic cement containing gentamicin (Cemex-Genta, Tecres S.p.A.), in the acetabular and femoral components, even in those requiring a homologous bone graft.

In all patients, several samples of periprosthetic tissues were taken during second-stage surgery for bacteriological examination. They were given 400 mg Teicoplanin every day for 4 weeks followed by 1.5 g Ciprofloxacin for 4 weeks.

The patients were then followed according to a protocol including clinical assessment, plain radiographs and laboratory parameters.

Results

The spacer remained in situ for 5 (3–9) months.

In 8 patients, ESR and CRP levels fell substantially (Table). Failure of this occur in the other 2 patients was regarded as a contraindication to prosthetic reimplantation. The surgical procedure was therefore limited to removal of the spacer. In these cases, the infective organisms were Mycobacterium tuberculosis and multiresistant Staphylococcus aureus. In the other cases, samples for bacteriological examination, taken in the operating room, were negative.

In 1 case, the spacer became dislocated after 7 days, because the diameter of the head was too small. The dislocation was treated by closed reduction and immobilization, using a pelvi-condylar plaster cast for 1 month.

The 8 patients were evaluated mean 3 (2–4) years after reimplantation of the prosthesis and showed no signs of recurrence of the infection. Hip flexion ranged from 90° to 110°. Radiographs showed no radiolucent lines or focal osteolysis or migration of the prosthesis components.

Discussion

Today, the two-stage revision procedure, initially limited to removal of the infected prosthesis with local administration of antibiotics using continuous irrigation, is usually done with temporary variously-shaped spacers of bone cement and antibiotics prepared in the operating room (Zilkens et al. 1990, Abendschein 1992, Duncan and Beauchamp 1993, Leunig et al. 1998, Younger et al. 1998).

A well-shaped spacer helps to reduce bone damage while the device is in situ, preserves better local conditions for the second-stage reimplantation and facilitates sitting and standing positions, thereby permitting some degree of mobility. A few surgeons encourage patients fitted with such devices to undertake assisted weightbearing, but the risk of mechanical failure or overload wear of the acetabulum should not be disregarded. Indeed, in our experience, weight bearing is not primarily affected by the mechanical resistance of the spacer, but the residual bone quality after the first implant. Therefore, this factor should help the surgeon select definition of the most suitable method of rehabilitation for avoiding further damage or even acetabular protrusion of the spacer.

Although gentamicin is effective treatment for most organisms causing periprosthetic infection, the recent development of Gram-positive cocci resistant to aminoglycosides means that drugs active against methicillin-resistant bacteria should also be used (Duncan and Masri 1994). The release of other antibiotics from acrylic bone cement, such as vancomycin, is now well documented (Kuechle et al. 1991, Penner et al. 1996). Therefore, routine use of vancomycin-loaded acrylic cement should be considered when epidemiologic data show a high incidence (> 50%) of methicillin-resistant strains (Borrè et al. 1992).

In our experience, "Spacer-G" maintained a correct gap between both bone segments. It permitted some degree of mobility, which improved the patients' quality of life during the postoperative period, and helped their functional recovery after prosthetic reimplantation.

One of our spacers dislocated early because it had too small a head, as also reported by Leunig et al. (1998). This shows the need for models of various sizes.

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