Iontophoreosed segmental allografts in revision arthroplasty for infection


From the Royal Perth Hospital, Perth, Western Australia

Revision arthroplasty after infection can often be complicated by both extensive bone loss and a relatively high rate of re-infection. Using allograft to address the bone loss in such patients is controversial because of the perceived risk of bacterial infection from the use of avascular graft material. We describe 12 two-stage revisions for infection in which segmental allografts were loaded with antibiotics using iontophoresis, a technique using an electrical potential to drive ionised antibiotics into cortical bone.

Iontophoresis produced high levels of antibiotic in the allograft, which eluted into the surrounding tissues. We postulate that this offers protection from infection in the high-risk peri-operative period. None of the 12 patients who had two-stage revision with iontophoresed allografts had further infection after a mean period of 47 months (14 to 78).

Many techniques have been used to treat infected arthroplasties including joint debridement, resection arthroplasty, arthrodesis and revision arthroplasty. All involve removal of the infected implant and thorough debridement of all necrotic tissue, foreign material and cement, often resulting in severely depleted bone stock. Bone deficiency after infection has traditionally been seen as a contraindication to the use of structural bone allograft, since the avascular allograft may be susceptible to re-infection. However, good results have been reported using morcellised allograft in two-stage revisions for infection in which impaction grafting is feasible. Between December 1997 and July 2003, 12 patients requiring structural allografts consented to receive iontophoresed grafts (Table I). There are, however, few reports of the use of structural allograft in revision of infected arthroplasty. The advantage of using such allografts under these circumstances includes the opportunity to retain soft tissues and to use conventional revision prostheses. Megaprostheses can be used as an alternative, but bone loss may be so severe that it may be impossible to stabilise the new implant. Furthermore, megaprostheses do not allow the biological re-attachment of tendons to bone, making any future surgery more difficult.

Tumour prostheses are expensive, particularly if modular in design, and have a rate of dislocation as high as 28% in the hip, primarily due to violation of the abductor mechanism. Because an allograft-prosthesis composite can heal to the host bone, the rotational stresses on the implant may be reduced once union has been established. Graft-prosthesis composites have been reported to have better long-term survival and better function than mega-prostheses.

Iontophoresis is a technique which employs an externally applied electric field to supplement allograft bone with antibiotics. It has been described in disciplines ranging from dermatology to ophthalmology, but its use in bone allograft is new. In the laboratory, iontophoresis has shown promising results, achieving levels of gentamicin of up to 187.1 mg/kg and of flucloxacinil of up to 31.9 mg/kg in sheep and in human allograft specimens. Iontophoresed allografts have been shown to elute antibiotics for periods of up to two weeks, and these antibiotics have remained biologically active. This is a preliminary clinical report on the use of iontophoresis to supplement massive allografts with antibiotics in two-stage revision arthroplasty for infection.

Patients and Methods

Between December 1997 and July 2003, 12 patients undergoing two-stage revision for infection with major uncontained bony defects requiring structural allografts consented to receive iontophoresed grafts (Table I). There were six men and six women with a mean age of 68 years (49 to 86). The operations were carried out by one of two experienced surgeons (including DJW) in laminar flow theatres using exhaust hoods.
Deep infections were due to Gram-positive organisms in seven patients and to a Gram-negative organism in one. In four, no organism was identified. However, two of these patients had draining sinuses and raised inflammatory markers, and two had abscesses with deep pus, one additionally presenting with erosive bone loss. In seven, the site of infection was an existing non-iontophoresed allograft (cases 2, 3, 4, 6, 7, 8 and 9). In one (case 11), the site of the infection was an iontophoresed allograft initially implanted for nonunion of a peri-prosthetic fracture.

All but one of the patients underwent two-stage revision with a polymethylmethacrylate (PMMA) gentamicin-loaded spacer for a mean period of 18 weeks (8 to 28) before the second-stage reconstruction. In one patient a Spacer-G (Zimmer, Warsaw, Indiana) was used, in three custom-made gentamicin-impregnated knee spacers and in seven custom-made hip spacers produced at the Royal Perth Hospital. In 11 patients more than one spacer was implanted over the course of their second stage. In one patient (case 4) second-stage reconstruction was undertaken 18 months after a Girdlestone resection procedure. The one Gram-negative bacillus isolated in this series was in a knee which became infected after a gunshot wound. This patient had an interval of six months between stages during which time he had a hospital-manufactured custom-made knee spacer in situ.

The decision to proceed to the second stage was based on the patients’ well-being and on their clinical picture, supported by the level of the erythrocyte sedimentation rate (ESR) and C-reactive protein in accordance with the recommendation of Ilyas and Morgan. Antibiotic therapy was generally administered according to the Massachusetts General Hospital protocol, but tailored to each patient’s requirements with the assistance of a consultant in infectious diseases.

Of the 12 allografts implanted, nine were proximal femoral, two were distal femoral and one proximal tibial. All were obtained from our local tissue bank. They were harvested under sterile conditions, placed in 1 l of normal saline containing 1 g of cephalosporin and stored at -70˚C until cleared for further processing. Processed grafts were finally sterilised using 25 kGy of gamma irradiation before storage at -70˚C.

At operation, after removal from its packaging, the allograft was thawed in warm sterile water. Any remaining soft tissue was removed and the intramedullary canal was handreamed and cleaned by pulsatile lavage. One end of the bone was then occluded with bone cement and any nutrient

### Table I. Details of the primary infection in the 12 patients

<table>
<thead>
<tr>
<th>Case</th>
<th>Age (yrs)</th>
<th>Gender</th>
<th>Primary surgery</th>
<th>Site of infection</th>
<th>Evidence of infection</th>
<th>Time between stages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>83</td>
<td>F</td>
<td>Left TKR for OA + 1 revision</td>
<td>Left TKR</td>
<td>Draining sinus, intra-operative deep pus. ESR 28, CRP 36</td>
<td>6 weeks custom-made knee spacer</td>
</tr>
<tr>
<td>2</td>
<td>81</td>
<td>M</td>
<td>Left THR for OA + 2 revisions</td>
<td>Left THR and non-iontophoresed allograft</td>
<td>Pain on mobilisation, sinus coagulase-negative Staph. aureus, frozen section strongly suggestive of infection. ESR 81, CRP 63</td>
<td>7 months custom-made hip spacer</td>
</tr>
<tr>
<td>3†</td>
<td>65</td>
<td>M</td>
<td>Right THR for OA + 2 revisions</td>
<td>Right THR and non-iontophoresed allograft</td>
<td>Extensive endosteal erosion, abscess and deep pus intra-operatively</td>
<td>5 months custom-made hip spacer</td>
</tr>
<tr>
<td>4</td>
<td>74</td>
<td>F</td>
<td>Excisional arthroplasty for OA + 4 revisions</td>
<td>Proximal femur and non-iontophoresed allograft</td>
<td>Deep tissue Staph. aureus</td>
<td>Girdlestone 18 months</td>
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<tr>
<td>5</td>
<td>67</td>
<td>F</td>
<td>Left THR</td>
<td>Left THR</td>
<td>Staph. epidermidis on 4 of 4 hip swabs, ESR 77, CRP 93, chronic pain</td>
<td>2 months custom-made hip spacer</td>
</tr>
<tr>
<td>6†</td>
<td>65</td>
<td>F</td>
<td>Right THR with bulk allograft after excision of chondrosarcoma right proximal femur</td>
<td>Non-iontophoresed right allograft</td>
<td>Fever, rigours, pain, nausea. White blood cell count indicated right thigh abscess, intra-operative pus</td>
<td>6 weeks custom-made hip spacer</td>
</tr>
<tr>
<td>7</td>
<td>56</td>
<td>M</td>
<td>Left THR for OA + 2 revisions</td>
<td>Left THR and non-iontophoresed strut grafts</td>
<td>Pain, difficulty weight-bearing, wound discharge. ESR 100, CRP 250, intra-operative pus</td>
<td>4 months custom-made hip spacer</td>
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<tr>
<td>8</td>
<td>51</td>
<td>M</td>
<td>Bilateral THR after sea-dive incident at 26 years of age + 2 revisions</td>
<td>Left THR and non-iontophoresed allograft</td>
<td>Acute presentation with pain, erythema, swelling, 2 weeks shivering and night sweats. Coagulase-negative Staph. aureus aspirate</td>
<td>10 weeks custom-made hip spacer</td>
</tr>
<tr>
<td>9</td>
<td>79</td>
<td>M</td>
<td>Left THR for OA + 2 revisions</td>
<td>Non-iontophoresed allograft</td>
<td>Deep intra-operative Echinococcus faecalis</td>
<td>4 months custom-made hip spacer</td>
</tr>
<tr>
<td>10</td>
<td>49</td>
<td>M</td>
<td>Debridement of gunshot wound Right knee</td>
<td>Gunshot wound right knee</td>
<td>Deep tissue Pseudomonas aeruginosa</td>
<td>6 months custom-made knee spacer</td>
</tr>
<tr>
<td>11</td>
<td>86</td>
<td>F</td>
<td>Right THR for OA + 4 revisions</td>
<td>Right THR and iontophoresed allograft</td>
<td>Copious pus intra-operatively, deep intra-operative Streptococcus mitis Abscess, Staph. epidermidis aspirate, ESR 88</td>
<td>11 weeks Zimmer &quot;Spacer-G&quot;§</td>
</tr>
<tr>
<td>12</td>
<td>64</td>
<td>F</td>
<td>Right TKR for OA + 9 revisions</td>
<td>Right TKR</td>
<td></td>
<td>3 months custom-made knee spacer</td>
</tr>
</tbody>
</table>

* TKR, total knee replacement; OA, osteoarthritis; THR, total hip replacement
† ESR, erythrocyte sedimentation rate; CRP, C-reactive protein
‡ patient allergic to penicillin; his graft was iontophoresed with gentamicin only
§ Zimmer, Warsaw, Indiana
foramina were sealed with bone wax. Once it had been demonstrated that the construct was watertight, the medullary cavity was filled with 4% gentamicin sulphate solution. The allograft was suspended in the iontophoresis chamber containing 1% flucloxacillin sodium solution and a cylindrical mesh electrode was placed around the graft within the chamber. A Kirschner (K-) wire of appropriate length was placed centrally into the lumen and an electrical potential of 90 V was applied between the cathode (mesh) and the anode (K-wire) across the cortex of the bone (Fig. 1). Gentamicin carries a positive charge and flucloxacillin a negative charge in solution. These two antibiotics were selected because of their synergistic bactericidal activity against the organisms commonly encountered in allograft surgery. The allografts were iontophoresed for 20 minutes since this had been determined from laboratory studies to be the optimum time for iontophoresis.\(^{37,38}\) At 20 minutes, the flow of current, and therefore the movement of antibiotic ions in solution, reached a plateau after a period of peak activity. Therefore continuing the iontophoresis for longer than 20 minutes was of limited value since most of the antibiotic in solution had been deposited in the bone by this time. One patient with a penicillin allergy had his allograft iontophoresed using gentamicin only.

Once iontophoresis was complete, the allografts were prepared for implantation in the usual way. They were used with a wide array of prostheses including hinged knee prostheses, custom-made femoral and tibial stem extensions, acetabular cages and constrained acetabular liners. Antibiotic-loaded cement was employed in some instances but gentamicin- or flucloxacillin-loaded cement was avoided. Perioperative antibiotic prophylaxis was used, with intravenous antibiotics administered upon induction and in the early post-operative period, followed by oral therapy for up to six weeks (Table II). At least one drain was placed alongside each allograft before closure of the wound. Samples of serum and fluid from the drain were taken at 2, 4, 8, 12, 24 and 48 hours post-operatively from seven patients from whom adequate samples were available and assayed for the concentration of antibiotic. Gentamicin was assayed using a competitive immunoassay on an ADVIA Centaur (Bayer Healthcare, Leverkusen, Germany). Flucloxacillin was assayed using high-performance liquid chromatography (Waters, Milford, Massachusetts).

Follow-up times were taken from the date of implantation of the iontophoresed allograft at the second stage of the revision. Clinical evaluations were performed pre-operatively and at 3, 6, and 12 months post-operatively, with annual review thereafter. The presence of post-operative allograft infection was determined on the basis of the clinical course, culture results and histology. Early deep post-operative infections were defined as those occurring within six months of surgery, according to the classification introduced by Coventry.\(^{43}\)

**Results**

No patient was lost to clinical or radiological evaluation at a mean follow-up of 47 months (14 to 78; Table II). Four patients died but their final review data were included in the study. One patient (case 6) whose primary surgery before infection had been the excision of a femoral chondrosarcoma, died from lung metastases 14 months after the second-stage procedure. Another (case 4) died from laryngeal cancer 56 months after the second stage, while the remaining two patients (cases 1 and 2) died from unrelated conditions aged 90 years (stroke) and 87 years (left ventricular failure secondary to ischaemic heart disease). None of the patients have become re-infected after implantation of their iontophoresed grafts at their latest follow-up, and all 12 allografts remain *in situ*, giving an allograft retention rate of 100%.

**Early complications.** There were no early complications related to the allograft. One patient (case 4) had recurrent dislocation of the hip and required open reduction and a hip spica for six weeks. Another dislocation (case 7) was success-
fully treated by an abduction brace. One patient (case 12) had dislocation and loosening of a rotating hinged knee prosthesis requiring removal of the loose anti-rotational screw and plating of the femoral allograft to her native femoral shaft. The peg and tibial insert were also exchanged.

**Late complications.** Nonunion in one patient (case 3) required bone grafting 26 months after operation. The patient subsequently developed a superficial infection which was successfully managed with antibiotics. The graft united to the host bone.

**Antibiotic levels.** The mean antibiotic levels at 2, 4, 8, 12, 24 and 48 hours assayed in the blood collected in the drains were above the minimum inhibitory concentration of *Staphylococcus aureus* for flucloxacillin (0.3 mg/l) and gentamicin (0.25 mg/l), while serum levels remained well below peak recommended serum levels for gentamicin (10 mg/l). The mean level of flucloxacillin in the drains was 17.67 mg/l at two hours (3.6 to 37, 3 patients) and 2.72 mg/l at 48 hours (1 to 6.2, 5 patients). Only one serum flucloxacillin assay was available at two hours with a level of 1 mg/l.

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**Table II. Details of the second stage of revision using an iontophoresed allograft**

<table>
<thead>
<tr>
<th>Case</th>
<th>Peri-operative antibiotic</th>
<th>Graft type</th>
<th>Duration of suppressive antibiotics after second-stage reconstruction</th>
<th>Patient risk type*</th>
<th>Duration of follow-up (mths)</th>
<th>Complications</th>
<th>Outcome†</th>
</tr>
</thead>
</table>
| 1    | Flucloxacillin, Gentamicin | Left proximal tibia | Dicloxacillin 5 days, Gentamicin 2 days | Clindamycin 3 weeks | Nil | 78 | Nil. Deceased: stroke  
Wheeled Zimmer frame |
| 2    | Ciprofloxacin             | Left proximal femur | Cephalothin 5 days, Vancomycin 9 days | Cephalothin 6 weeks, Clindamycin 1 week | Multiple revisions | 66 | Nil. Deceased: left ventricular failure secondary to ischaemic heart disease  
Walking stick |
| 3    | Vancomycin                | Right proximal femur | Clindamycin 4 days, Vancomycin 9 days | Clindamycin 6 weeks, Ciprofloxacin 8 days | NIDDM | 74 | Nonunion leading to grafting  
Elbow crutch |
| 4    | Cephalothin               | Right proximal femur | Cephalothin one week, Teicoplanin 3 weeks | Cephalothin 6 weeks | Multiple revisions | 56 | Deceased: laryngeal cancer. Partial sciatic palsy, two dislocations, open reduction  
Walking short distances with crutches and calliper |
| 5    | Vancomycin                | Left proximal femur | Vancomycin 3 weeks, Clindamycin 4 weeks, Fusidin 6 weeks | Multiple revisions | 63 | Nil | Walking without aid |
| 6    | Cephalothin               | Right femur | Cephalothin 7 days | Clindamycin 6 weeks, CXT after chondrosarcoma excision | Nil | 14 | Nil. Deceased: lung metastases  
Walking without aid |
| 7    | Cephalothin               | Left proximal femur | Teicoplanin 15 days, Ceftriaxone 15 days | Amoxycillin + Clavulanic acid 4 weeks, Doxycycline 8 days | Multiple revisions | 53 | Dislocation, abduction brace  
Walking without aid |
| 8    | Gentamicin, Doxycycline   | Left proximal femur | Teicoplanin 2 days, Gentamicin 5 days | Clindamycin 1 week, Ciprofloxacin 6 weeks | Multiple revisions | 49 | Nil | Walking without aid, pain-free |
| 9    | Cephalothin               | Left proximal femur | Cephalothin 3 days, Teicoplanin 5 days, Ciprofloxacin 5 days | Ciprofloxacin 6 weeks | Multiple revisions | 37 | Nil | Walking without aid, good ROM |
| 10   | Cephalothin               | Right distal femur | Cephalothin 3 days, Meropenem 3 weeks, Amikacin 2 weeks | Cephalixin 1 day | Multiple revisions | 40 | 0° to 45° ROM, good function |
| 11   | Gentamicin                | Right proximal femur | Cephalothin 2 days | Ciprofloxacin 3 weeks, Rifampicin 7 days | Multiple revisions | 24 | Nil | FWB with heel raise |
| 12   | Teicoplanin               | Right femur | Teicoplanin 11 days | Rifampicin 12 days | MRSA, multiple revisions | 14 | Dislocation, open reduction  
2 crutches |

* NIDDM, non-insulin-dependent diabetes; CXT, chemotherapy; MRSA, methicillin-resistant *Staphylococcus aureus*
† ROM, range of movement; FWB, full weight-bearing
and this was unchanged at 48 hours. The mean level of gentamicin in the drain was 55.32 mg/l at two hours (4.7 to 131, 4 patients) and 5.35 mg/l at 48 hours (4.5 to 6, 2 patients). The mean serum gentamicin level was 0.37 mg/l (0.2 to 0.5, 3 patients) at two hours and 0.33 mg/l (0.1 to 0.5, 3 patients) at 48 hours. These results are illustrated in Figure 2

**Discussion**

Massive allografts have been used in musculoskeletal surgery for decades with varying reports of success.\(^8,25,28-32,34,42,44-67\) Preservation of the soft-tissue envelope helps to stabilise the reconstruction\(^26,32\) and, in the hip, allows restoration of abductor function, providing a better functional outcome.\(^26\) In the knee, it allows the use of an implant less constrained than a hinged prosthesis, resulting in decreased forces at the implant-allograft and allograft-host interfaces.\(^62\) Reconstruction using allograft bone can result in loading of the host bone in a more physiological way,\(^65\) allowing a normal gradation of forces from the implant to the host bone.\(^61\)

The use of allograft in revision after sepsis represents a risk since it is avascular and therefore provides a favourable site for bacterial colonisation.\(^8\) If infection recurs, it inevitably requires removal of the allograft, usually with resection arthroplasty as the definitive procedure.\(^14,28,29\) There are few reports on the use of allograft bone in revision of a previously septic arthroplasty\(^14,19,25-32,68\) and only one of these series has more than 12 patients.\(^29\) (Table III). The reported rates of re-infection vary and the relatively few patients per series make it difficult to determine the true rate of infection in this population. Berry et al\(^29\) reported a rate of recurrence of 1 in 13 associated with massive allograft use, but the time to recurrence was not stated, while Loty et al\(^31\) reported one early recurrence (before six months) in nine septic revisions. Nestor et al\(^14\) used bulk femoral head allograft for structural support of porous prostheses in three septic revisions in a group of 34 patients and reported the recurrence of infection in one patient at 14 months. Ammon and Stockley\(^28\) recently reported a recurrence of infection in two of 12 massive allografts used for infective revision. They used customised antibiotic cement beads but not systemic antibiotics to treat their patients before re-implantation. They did not specify whether the infections recurred early or late. Likewise, Graham and Stockley\(^32\) recently reported a rate of recurrence of 1 in 5 after revision of septic total hip replacement using proximal femoral allografts, but did not specify the timing of the recurrence. Clatworthy et al\(^62\) reported one recurrence of infection in six patients treated by two-stage revision and structural allograft after infection of a total knee replacement. Several authors have found no recurrence of infection when using massive allograft for septic revision\(^25,27,30\) but all in the series had fewer than 12 patients. As the use of allograft bone in revision after infection becomes widespread, larger series will become available, allowing a more accurate determination of the rate of recurrent infection to be made.

In 1999, Hanssen and Osmon\(^69\) reported the incidence of peri-prosthetic infection caused by each bacterial species.
within their institution between 1969 and 1991. They found that the highest incidence for all micro-organisms occurred in the first three months post-operatively and then gradually decreased, levelling out at between 18 and 24 months after operation. They concluded that infections attributable to operative contamination or problems with wound-healing increased the incidence of infection in the early post-operative period. This was in agreement with the findings of several authors who noted that 75% of deep infections present within the first four months after operation. They found that the highest incidence for infection in 12 previously infected arthroplasties. However, infections present within the first four months after operation. They concluded that infections attributable to operative contamination or problems with wound-healing increased the incidence of infection in the early post-operative period, which ordinarily offer protection to bacteria, from the allograft, small crevices and holes in the bone, guard it from infection. As these antibiotics diffuse out of the graft itself could potentially safeguard it from infection. As these antibiotics diffuse out of the graft itself could potentially safeguard it from infection. As these antibiotics diffuse out of the graft itself could potentially safeguard it from infection. As these antibiotics diffuse out of the graft itself could potentially safeguard it from infection. As these antibiotics diffuse out of the graft itself could potentially safeguard it from infection. As these antibiotics diffuse out of the graft itself could potentially safeguard it from infection. 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In 2002, Gross et al in a review of the role of allografts in total hip replacement, stated that “The practice of restoring bone stock in revision arthroplasty of the hip is an accepted standard treatment for patients who are likely to face additional surgery during their lifetime, and it is imperative that technologies to facilitate the use of allograft tissue continue to be developed”. The early results of our small series of antibiotic-supplemented cortical allografts are promising. Iontophoresis can be applied to massive grafts used to replace uncontaminated or circumferential defects or to grafts which are processed into struts. It is intended that iontophoresis of allograft bone should be used as an adjunct to antibiotic-loaded bone cement and systemic antibiotics in aiding prophylaxis of early recurrent infection. Further clinical data are required in order to evaluate the efficacy of this method.

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References


