Mid- to long-term results of irradiated allograft in acetabular reconstruction

A FOLLOW-UP REPORT

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Between 1990 and 2000, 123 hips in 110 patients were reconstructed for aseptic loosening using impaction bone grafting with frozen, irradiated, morsellised femoral heads and cemented acetabular components. This series was reported previously at a mean follow-up of five years. We have extended this follow-up and now describe the outcome of 86 hips in 74 patients at a mean of ten years. There have been 19 revisions, comprising nine for infection, seven for aseptic loosening and three for dislocation. In surviving acetabular reconstructions, union of the graft had occurred in 64 of 67 hips (95.5%).

Survival analysis for all indications at ten years was 83.3% (95% confidence interval (CI) 68 to 89) and 71.3% (95% CI 58 to 84) at 15 years.

Acetabular reconstruction using irradiated allograft and a cemented acetabular component is an effective method of reconstruction, providing results in the medium- to long-term comparable with those of reported series where non-irradiated freshly-frozen bone was used.

The demand for allograft bone has expanded rapidly in recent years because of the increasing number of revision joint replacements being performed.1 The associated loss of acetabular bone stock remains a challenge. Many techniques including impaction grafting,2-7 filling the defect with bone cement,8-10 use of large uncemented acetabular components,11-13 cages and support rings,14-17 have been described. Impaction grafting is seen as an attractive method as it can effectively restore bone stock. The clinical results in the mid-term of impaction grafting with fresh-frozen morsellised bone in acetabular reconstructions are acceptable.18-20 There are many published series of fresh-frozen allograft hip reconstructions, but few using irradiated allografts.18-23 An earlier mid-term review of irradiated allografts in acetabular reconstructions in our centre demonstrated good results, with 87.8% survival at five years in 123 hips.3

We undertook a further review of these 123 reconstructions using morsellised irradiated allograft at ten years to establish the mid- to long-term survival in our patients.

Patients and Methods

Morsellised femoral head allograft was first used in our unit in 1987 to restore acetabular bone stock in revision hip replacement. In 2003, our series of 123 hip reconstructions in 110 patients for whom the allograft bone had been sterilised with irradiation were clinically and radiologically reviewed at a mean follow-up of 60 months (24 to 145). This cohort of patients has been reviewed again at a mean follow-up of 123 months (60 to 197). Each operation was performed by one of four consultants (AJH, RMK, IS, RE). The initial diagnoses are shown in Table I, and the indications for revision are listed in Table II.

The mean age at revision with allograft was 64.3 years (26 to 97). There were 55 men and 55 women. Of this group, 86 hips (70%) in 74 patients were reviewed both clinically and radiologically. At the time of review, 28 patients (29 hips) had died and five patients (five hips) were lost to follow-up. From those patients who had died, 18 hips had been followed up to a mean of 66 months (12 to 145). A further three hips were unavailable for clinical review but had accurate survival data for the implant-allograft. These were included in the survival analysis at the time of their last review in the clinic (74, 78 and 80 months respectively).

Surgical technique. All hips undergoing revision within ten years of the primary procedure were aspirated to exclude infection. Revision was performed through a posterior or a trans-trochanteric approach. All patients received cefuroxime 750 mg eight-hourly for three doses post-operatively.
At the time of revision the acetabular defects were assessed and classified using the AAOS classification, as shown in Table III.

The allograft bone was from femoral heads obtained at primary joint replacement and had been processed with irradiation of 2.5 Mgy (equivalent to 25 kGy) and frozen at -70°C. After thawing, the allograft was prepared in theatre at the time of revision using large bone rongeurs to create cancellous chips between 0.5 cm³ and 1.0 cm³. Bone chips were created in sufficient volume to fill the defects. Between one and three femoral heads were used per patient. At the time of the operation in this series, allograft bone was not routinely washed prior to impaction. The technique has evolved over time, it is now our routine practice to wash the prepared morsels with pulsed saline lavage as this has been shown to give better results.

Small uncontained defects were contained using the X-change system of mesh and screws (Stryker-Howmedica-Osteonics, London, United Kingdom). The allograft was then firmly impacted with appropriately sized impactors to create a solid dry bony acetabular bed to which Palacos R cement (Schering-Plough Ltd, Welwyn Garden City, United Kingdom) was introduced with a cement gun and pressurised prior to placing the acetabular component.

Larger defects were reconstructed with a combination of impaction of allograft, an overlying support ring (Burch-Schneider Rings, Zimmer, Warsaw, Indiana) screwed to the pelvis, and an acetabular component cemented in place. The accessory implants used are shown in Table IV.

Patients were mobilised with partial weight-bearing commencing 48 hours after surgery, and elbow crutches were used for six to 12 weeks.

Assessment. Anteroposterior radiographs of the pelvis were evaluated for several parameters. The graft was assessed for union, lucency and component migration. Assessment was performed by two authors (NWE, SCB) reaching a consensus.

Union of the graft was assessed according to the criteria of Conn et al., with union being considered complete when the graft density returned to normal with obliteration of the graft host interface and restoration of a normal trabecular pattern as applied in other reports.

The presence, if any, of radiolucent lines at the bone-cement interface in the three acetabular zones described by DeLee and Charnley was also recorded. Loosening of the acetabular component was then defined according to the criteria described by Hodgkinson, Shelley and Wroblewski. Radiological migration of the acetabular component in relation to the inter-teardrop line was recorded in the initial post-operative radiograph. Radiological failure was defined as migration of the component by more than 5 mm or the development of circumferential progressive radiolucent lines. Clinical failure was defined as acetabular revision or the intention to revise.

Statistical analysis. All analyses were performed on SPSS statistical software v.14.0 (SPSS Inc., Chicago, Illinois) using a critical p-value of < 0.05 to define the level of significance. Kaplan-Meier survival analysis was calculated with 95% CI using implant failure defined as revision for any indication.

Results

Implant survival. There were 19 revisions in 19 patients for reasons of deep infection in nine, aseptic loosening in seven, and dislocation in three.

The survival rate of the allograft reconstructions with revision as the endpoint, using the Kaplan-Meier method was 83.3% (36 patients at risk, 95% CI 68 to 89) at ten years and 71.3% (four patients at risk, 95% CI 58 to 84) at 15 years (Fig. 1).
Further revisions. Of the nine hips that required revision for deep infection, the mean time to failure was 49 months (2 to 143). These patients all underwent a two-stage revision procedure. Of the seven hips requiring revision for aseptic loosening, the mean time to surgery was 96.9 months (23 to 137). The patient whose hip loosened by 23 months had associated resorption of the graft and migration of the component of 20 mm. At re-revision there was evidence of some bone graft incorporation, which lessened the requirement for further complex reconstruction, but we have no histological analyses available.

Radiological assessment. In surviving acetabular reconstructions, union of the graft had occurred in 64 of 67 hips (95.5%). Three allografts had not returned to normal radiodensity or had an absence of bony trabeculae crossing the graft-host interface (Fig. 2).

Radiolucent lines at the bone-cement interface were seen in 12 hips (17.9%), affecting a single DeLee and Charnley zone in nine patients and involving multiple zones in three patients, but none were considered loose according to the criteria of Hodgkinson et al. 31 Migration of the acetabular component in excess of 5 mm was seen in two surviving hips (3.0%), comprising 7 mm and 8 mm, respectively. These patients were asymptomatic with low demands, and despite features of radiological failure had not undergone revision surgery.

Discussion

In this study we examined the mid- to long-term survival of irradiated allograft bone for acetabular revision and demonstrated survival at ten years of 83.3% (95% CI, 68 to 89), with union of the graft in 64 of 67 surviving implants (95.5%). At medium- to long-term follow-up our results support the use of this technique of acetabular reconstruction, with little deterioration in the survival from 87.8% at five years. 33

Allograft can be processed in different ways. The mechanical or biological properties of freeze-dried, irradiated and fresh-frozen material may not be comparable. 22 However, a recent short-term comparison of freeze-dried, irradiated and chemically treated allograft vitalised with autologous marrow versus fresh-frozen non-irradiated allograft showed no significant difference in clinical or radiological outcomes at 31 months in 79 hips. 33

There have been good early results in the literature on the survival of hip reconstructions using fresh-frozen allograft at five-year follow-up ranging from 95.8% in 131 hips 18 to 96.4% in 60 hips 19 and 100% in 24 hips. 20 Thien et al 34 demonstrated good short-term survival with freeze-dried cancellous bone chips of 86% at seven years. Fresh-frozen allograft has also performed well in the long term, with survival of 79% at 15 years in 63 hips. 22 To date, no long-term results have been published for the use of irradiated morsellised allografts in acetabular reconstruction. Van Haaren et al 23 found survival of 72% at seven years in their series of 71 revisions using fresh-frozen allograft, but they had a higher incidence in their series of complex acetabular defects, 41 of 71 hips (57.8%) being AAOS III or IV, compared to our series, which had 33 of 123 hips (26.8%) classified as AAOS III or IV. Previous studies have shown that larger bone defects are associated with increasing risk of failure in revision surgery. 18,23,35,36 Kawanabe et al 37 reported a significantly higher failure rate in AAOS III and IV acetabular defects with impacted allograft compared to bulk graft in their series.

Fresh-frozen femoral heads which are not formally sterilised are currently the most frequently used form of graft, but concern remains over the risk of disease transmission although this has been reported as low. 37

The only documented sources of viral infection in recipients of bone graft have been from unprocessed fresh-frozen allografts. 38-41 Bacterial infections have also had a low incidence. Kwong, Ibrahim and Power 42 reported a rate of deep infection of 0.7% at one year in 144 allograft reconstructions using washing alone as preparation of fresh-frozen, non-irradiated bone.

In our series there were nine deep infections in 123 hips (7.3%) that occurred at a median of 37 months (2 and 144) post reconstruction which is higher than in other series which had 4.8% in 42 hips, 7 2.2% in 131 hips, 18 and 0% in 60 hips. 19 We cannot identify any specific features that contributed to the infections in our patients. Our unit acts as a centre for the management of infected joint replacements, which gives us a great awareness of this condition which may have contributed to establishing the presence of infection in the late failures.

In order to minimise any potential risk of disease transmission from the donor to the recipient, the allograft can be sterilised. Sterilisation can be performed using either γ irra-
radiation or ethylene oxide gas, but the latter has been shown to reduce bone incorporation, and in a series of hip reconstructions 62% of 21 hips demonstrated significant acetabular component migration.

A previous study has shown a loss of strength of cortical irradiated grafts compared to fresh-frozen bone, although this finding may not relate to cancellous allograft in clinical practice. Low-dose irradiation (25 kGy) of frozen unprocessed human cancellous bone has been shown to have no effect on its mechanical properties, but higher doses of 60 kGy were deleterious to its strength. In our series, low-dose irradiation was used (25 kGy), which is the current regimen employed by the NHS Blood and Transplant Tissue Services in processing fresh-frozen irradiated femoral heads.

Radiological assessment of graft consolidation has been described as difficult and perhaps unreliable. So far, we have no cadaver retrievals available to assess healing at the host-graft junction. In our series, three of 67 reconstructions (4.5%) showed incorporation of the graft to be incomplete as defined by the lack of trabeculae crossing the graft-host interface or a return of the graft to isodensity. However, these patients had no radiological signs of loosening or excessive component migration, and so, despite remaining symptomatic, revision has not been indicated.

Van Haaren et al, in their series of 71 hips, demonstrated that poor graft incorporation was associated with a need for further revision. Migration in excess of 5 mm has also been shown to be associated with failure.

In our series we have seen migration of greater than 5 mm in two hips (3.0%), which is similar to the rates reported in other series, but as these patients were asymptomatic revision surgery has not been undertaken and so they have not been counted as failures. They continue to be monitored. Our radiological results at long-term review do not seem to differ from series where fresh-frozen allograft has been used.

As the mean age of our patients was 64.3 years at revision, there was a loss of 28 patients (25.4%) due to death from unrelated causes during follow-up, but none of these patients had required further surgery.

Acetabular reconstruction using irradiated allograft and a cemented acetabular component is an effective, reliable technique with good results in the medium- to long-term, comparable to series using non-irradiated fresh-frozen bone.

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References
Rinsing morselized allografts


