Impaction grafting of the acetabulum with a mixture of frozen, ground irradiated bone graft and porous synthetic bone substitute (Apapore 60)

I. McNamara,
S. Deshpande,
M. Porteous

From Department of Orthopaedics, West Suffolk Hospital, Bury St Edmunds, England

The clinical and radiological results of 50 consecutive acetabular reconstructions in 48 patients using impaction grafting have been retrospectively reviewed. A 1:1 mixture of frozen, ground irradiated bone graft and Apapore 60, a synthetic bone graft substitute, was used in all cases. There were 13 complex primary and 37 revision procedures with a mean follow-up of five years (3.4 to 7.6). The clinical survival rate was 100%, with improvements in the mean Harris Hip Scores for pain and function. Radiologically, 30 acetabular grafts showed evidence of incorporation, ten had radiolucent lines and two acetabular components migrated initially before stabilising.

Acetabular reconstruction in both primary and revision surgery using a 1:1 mixture of frozen, ground, irriadiated bone and Apapore 60 appears to be a reliable method of managing acetabular defects. Longer follow-up will be required to establish whether this technique is as effective as using fresh-frozen allograft.

I. McNamara, MA(Cantab), BM, BCh(Oxon), MRCP, MRCS, Specialist Registrar
West Suffolk Hospital, NHS Trust, Hardwick Lane, Bury St Edmunds, Suffolk IP33 2QZ, UK.
and
The Orthopaedic Research Unit Addenbrooke's Hospital, Hills Road, Cambridge CB2 0QQ, UK.

S. Deshpande, MS(Orth), MRCS(Edin), FCPS, Consultant Orthopaedic Surgeon
M. Porteous, MBBS, FRCS(Orth), Consultant Trauma and Orthopaedic Surgeon
West Suffolk Hospital NHS Trust, Hardwick Lane, Bury St Edmunds, Suffolk IP33 2QZ, UK.

Correspondence should be sent to Mr I. McNamara; e-mail: imcnamara@doctors.org.uk

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The management of loss of acetabular bone stock at revision total hip replacement (THR) is a major challenge. Impaction grafting using fresh-frozen morsellised allograft has been shown to be effective in long-term studies, but carries with it problems of cost, supply and potential infection.[1-5] There is increasing evidence for the use of frozen, irradiated allograft bone in acetabular revision with all but one study having less than five years of follow-up.[6-10] Problems associated with the biomechanical variability of donated bone remain, due to the mode of its preparation and its biological variability.[11-19]

One method of addressing these concerns is augmentation or replacement with synthetic bone graft substitutes. These have advantageous biomechanical properties in terms of their stiffness and the stability which they confer.[20] Although they appear to be useful in animal models, no long-term clinical follow-up has been performed.[20-26]

The synthetic bone substitute used in this study was Apapore 60 (ApaTech Ltd, Elstree, United Kingdom), a phase-pure hydroxyapatite (HA) with 60% porosity. It has both a micro- (< 20 μm) and a macro- (> 50 μm) porosity. The combination of the pure-phase HA and this porous structure may improve osteoconductivity and hence encourage bone ingrowth and remodelling.[27-31]

We have evaluated the clinical and radiological results of using a mixture of ground, frozen, irradiated bone graft and Apapore 60 in patients undergoing acetabular impaction grafting.

Patients and Methods

We have used acetabular impaction grafting for revision and complex primary acetabular reconstruction since the mid-1990s. Before January 2002 all cases which had associated loss of acetabular bone had been managed with impaction grafting using only fresh-frozen morsellised bone graft. In January 2002, owing to difficulties in supply of the bone from the regional bone bank, a change in practice was instituted using a 1:1 mixture of frozen, ground irradiated bone graft and Apapore 60.

A total of five consultant surgeons performed the reconstructions, with the majority (47 of 53) being performed by the senior author (MP). All the bone graft was obtained from the National Blood and Tissue Services and had undergone irradiation using 25 kGy, and was packaged frozen and ready ground. The particles of bone provided were not graded, but we estimated the size as 1 mm to 3 mm in diameter. The particle size of the Apapore 60 was at 5 mm to 10 mm.

A total of 53 patients underwent acetabular reconstruction. One patient was excluded as

Table I. Patient characteristics and pre- and post-operative surgical information for primary and revision acetabular surgery

	Primary surgery	Revision surgery
Number of patients	13	35
Number of hips	13	37
Gender		
Male:Female	4:9	19:16
Left:Right	9:4	19:18
Mean BMI* kg/m^2 (range)	25 (17 to 42)	27.5 (22 to 31)
Mean age in years (range)	74 (48 to 88)	75 (59 to 90)
Indications for surgery		
Osteoarthritis	13	
Aseptic loosening		31
Second-stage revision for infection		4
Erosion following hemiarthroplasty		2
Mean follow-up in months (range)	63.6 (47.5 to 86.4)	56.9 (41.0 to 91.4)
Mean pre-operative HHS† (range)		
Pain	9 (0 to 20)	17 (0 to 44)
Function	20 (15 to 31)	19 (3 to 36)
Mean post-operative HHS (range)		
Pain	38 (20 to 44)	41 (40 to 44)
Function	32 (10 to 47)	32 (16 to 47)

* BMI, body mass index
† HHS, Harris hip score

she had no pre-operative questionnaire, having presented with a peri-prosthetic fracture and then subsequently died before the one-year follow-up. A further four patients were excluded as they had died from unrelated causes during the first post-operative year. There were no other losses to follow-up. Two patients had bilateral surgery, and thus a total of 48 patients and 50 hips were available for analysis. The mean follow-up for all patients was 60.3 months (41.0 to 91.4; 95% confidence interval (CI) 56.5 to 64.1). The patient's details are presented in Table I.

All patients assessed at the time of surgery as requiring impaction grafting of the acetabulum for bone loss were included. Pre-operative anteroposterior (AP) pelvic radiographs and the findings at the time of surgery were used to classify the acetabular defects, according to the system of the American Academy of Orthopaedic Surgeons (AAOS) Committee on the hip.[32]

All the data were collected prospectively on our hip arthroplasty database (Orthowave, ARIA Sarl, Lille, France).

Surgical technique. A posterior approach to the hip was used in all cases. In the case of primary reconstruction the femoral head was resected and the acetabulum was reamed to remove all remaining cartilage before any segmental defects were closed.

In cases of revision surgery the old implants and debris were removed and multiple samples of interface tissue were sent for microbiological culture to exclude infection. In both primary and revision surgery, segmental defects were reconstructed using mesh and screws prior to grafting. Any remaining sclerotic areas were perforated with multiple 5 mm drill holes and the bone bed cleaned with saline pulsed lavage. The allograft chips had been stored at -80°C and were thawed at room temperature. For preparation, a 1:1 mixture (by weight) of the frozen, ground irradiated bone graft and Apapore 60, was mixed with 20 ml of the patients' blood. The resultant composite was impacted in layers, each comprising approximately 15 ml of graft into the acetabular cavity using X-change acetabular impaction grafting instruments (Stryker Howmedica Osteonics, Limerick, Ireland).

The last trial prosthesis that was used was at least 2 mm larger than the proposed acetabular component in order to allow for an adequate cement mantle. Polymethylmethacrylate bone cement (Palacos R+G, Heraeus, Wehrheim, Germany) was inserted into the cavity and pressurised using the Exeter acetabular pressuriser (Stryker Howmedica Osteonics). After pressurisation, a polyethylene acetabular component of the surgeon's preference, with an inner diameter of 26 mm, was inserted and held until the cement had polymerised.

Post-operative regime. The post-operative treatment was based on the findings at operation and the stability of the components. Most patients remained partially weight-bearing for six weeks.

Table II. Operative findings and surgical procedure, including use of implants, for primary and revision acetabular reconstruction

	Primary surgery	Revision surgery
Acetabular defect type (AAOS* classification)[30]		
I	4	13
II	4	11
III	5	13
Volume of graft (units bone + Apapore 60)	2 (1 to 4.5)	4 (2 to 10)
Implants used:		
Acetabulum		
Mesh reconstruction	9	22
Ring reconstruction	1	3
Corin	7	28
Ogee	6	9
Femur		
Exeter stem (Stryker)	13	9
Revitan stem (Zimmer)		12
Cannulock (Orthodynamics)		4
Conelock (Biomet)		2
Dall cables (Stryker)		12
Post-operative radiologic findings		
Graft incorporation	10	20
Migration	0	2
Radiolucency	2	9
Failure	0	1
Unable to assess	1	1

* AAOS, american academy of orthopaedic surgeons

Follow-up. All patients had a plain AP pelvic and lateral plain radiograph prior to discharge. They were reviewed at six weeks, and then annually. All patients completed the pain and function parts of the Harris Hip Score (HHS)[33] pre-operatively and annually thereafter.

Radiological follow-up. Serial AP and lateral radiographs were assessed to determine the extent and timing of the incorporation of the graft, the presence of radiolucent lines, localised resorption, or migration of the acetabular component. Trabecular remodelling was defined as a change in graft pattern, with the trabeculae running from the surface of the graft to the cement.[34] Graft incorporation was defined as any change in the appearance of the post-operative radiograph short of fulfilling the criteria for remodelling.[35] The progression of radiolucent lines with time was assessed. Zones of radiolucency were assessed according to the zones of DeLee and Charnley,[36] with a radiolucent line measuring 2 mm in width considered to be a positive finding. Subsidence was determined on the AP radiograph by measuring the distance between the metallic wear marker in the polyethylene component and the 'teardrop' on the radiograph. Scaling of the measurements and correction for magnification on the radiographs was achieved by calibrating the measuring line on the software to the 26 mm femoral head. All radiological analyses were performed by three authors (IM, SD, MP) working together to reach a consensus.

Clinical failure was defined as revision or intention to revise. Radiological failure was defined by a progressive circumferential radiolucent line or migration of the acetabular component of > 5 mm in any direction relative to the inter-teardrop line, as seen on AP pelvic radiographs.

Survival analysis was performed using the life table method and CIs based on the effective number at risk using Rothman's equation.[37,38] The effective number at risk is equal to the harmonic mean of the number at risk in each year, which is itself calculated as the number of patients at the beginning of each year, less the number of patients withdrawn. Hence a starting value of 55 hips was used to calculate the CI.

Results

No patients have required re-operation of either the femoral or the acetabular components. Their operative details are presented in Table II.

Primary acetabular reconstructions. Of the 13 primary reconstructions performed, the mean follow-up was for 63.6 months (47.5 to 86.4; 95% CI 55.9 to 71.3). No complications were recorded, and no patient had radiological or clinical failure. Two patients had radiolucent lines on the radiographs at one year post-operatively. The first had a 2.5 mm wide radiolucent line in zones II and III, the other an 0.5 mm line in zone I alone. In neither patient was there

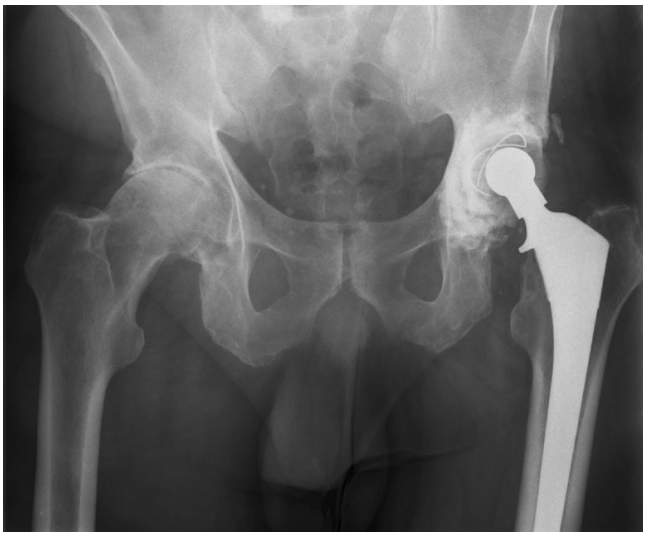

Fig. 1

Immediate post-operative radiograph of a reconstructed acetabulum with no subsidence or radiolucent lines.

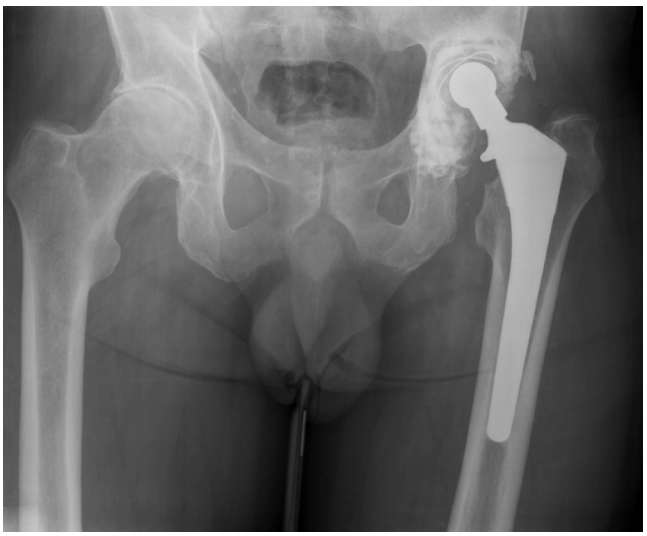

Fig. 2

A radiograph at 1-year follow-up of the same patient as in Figure 1, demonstrating subsidence of the acetabular component and the presence of radiolucent lines.

any progression of the radiolucent lines. The HHS for pain and function changed from 20 to 40 and from 19 to 35 for the first patient; and from 10 to 40 and 18 to 45 for the second patient from pre-operative to the first post-operative review at one year. There was evidence of graft incorporation in ten hips but the radiodense nature of the hydroxyapatite made the presence of trabeculae impossible to establish. One acetabulum could not be assessed because of overlying metalwork.

Revision acetabular reconstructions. In all, 37 acetabular revisions were performed, in eight of which the femoral component was not revised (Table II). The mean follow-up was for 56.9 months (41.0 to 91.4; 95% CI 52.6 to 61.2). Complications included one superficial infection treated with antibiotics, one deep infection managed by suppressive antibiotics, and one post-operative cardiac arrhythmia which was treated on the coronary care unit with no long-term sequelae.

One acetabular component migrated 8 mm medially. The patient was asymptomatic and all migration occurred within the first year. Subsequent annual radiographs demonstrated that the acetabular component had stabilised, but that a 2.5 mm radiolucent line had developed in zones 1 and 2 (Figs 1 and 2). The HHS for this patient changed from 20 to 44 and 27 to 30 for pain and function, respectively. One other acetabular component migrated by 3 mm during the first year and there was a 1.5 mm radiolucent line in zones 1 and 2 at the first year post-operative radiograph. Subsequent yearly radiographs have demonstrated no further migration or progression of the radiolucent lines. The HHS for the second patient changed from 0 to 10 and 27 to 24 for pain and function, respectively from pre-operative to the post-operative review at one year. In total, seven other patients had radiolucent lines of < 2 mm, three of which were in zone 1, and three in zone 3, and one patient had lines in zones 1 and 2. No patients had lines in all three zones. Incorporation of the graft occurred in 20 patients (20 hips). It was not possible to assess this in one patient owing to the metalwork obscuring the graft.

Survival analysis is presented in Table III and Figure 3.

Discussion

Our results using a mixture of frozen, ground irradiated bone and a bone-graft substitute are comparable with published data at the same interval for frozen irradiated bone alone.[6,7]

A number of authors have published favourable results using morsellised fresh-frozen allograft for acetabular impaction grafting.[39-44] However, there are concerns about the potential for transmission of disease from donor to recipient, and bacterial contamination, which can occur with fatal consequences.[4,45-47] Anxiety about the transmission of infection has led to irradiation of the bone allograft as a means of sterilisation. The typical gamma irradiation dose for bone used in impaction grafting is 25 kGy, which effectively reduces the bacterial load but may not inactivate HIV.[48]

Although most clinical studies examining the use of morsellised bone in impaction grafting for the acetabulum have demonstrated similar results for irradiated and non-irradiated graft,[7-9,49] concerns still exist that irradiation might affect the mechanical properties of the graft and its long-term biological incorporation.[49-53]

It has been demonstrated that a dose of 25 kGy does not greatly affect the mechanical properties of the bone, but increasing the dose has a detrimental, non-linear effect on the strength of the bone.[50,54-57] Irradiation has also been

Table III. Life table for clinical acetabular survival. The 95% confidence intervals were calculated by Rothman's method[38]

Years since operation	Number of hips at start	Clinical failure	Withdrawn	Lost to follow-up	Number at risk	Annual failure rate (%)	Annual success rate (%)	Survival rate (%)
0 to 1	55	0	5	0	52.5	*0*	*100*	*100*
1 to 2	50	0	0	0	50	*0*	*100*	*100*
2 to 3	50	0	0	0	50	*0*	*100*	*100*
3 to 4	38	0	0	0	38	*0*	*100*	*100*
4 to 5	24	0	0	0	24	*0*	*100*	*100*
5 to 6	11	0	0	0	11	*0*	*100*	*100*
6 to 7	5	0	0	0	5	*0*	*100*	*100*
7 to 8	3	0	0	0	3	*0*	*100*	*100*

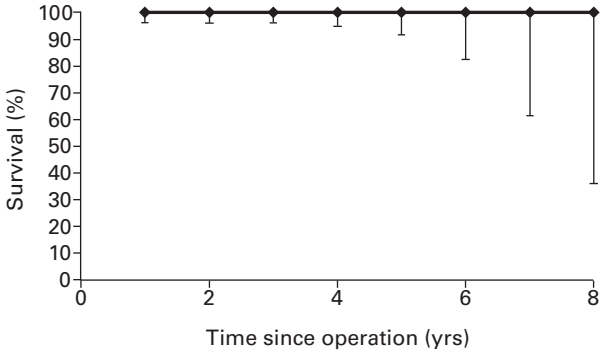

Fig. 3

Survival curve for acetabular components following impaction grafting. Error bars indicate 95% confidence intervals.

shown to impair the osteoconductive capacity of bone graft. This is thought to be due to oxidation of the lipids present in the marrow, rendering them cytotoxic to cultures of osteoblasts.[52] Where irradiated allograft bone has been grafted into animal models, a dose-dependent effect of the radiation on a reduction in bone incorporation is generally observed.[58-60]

Washing morsellised graft has been shown to remove fat, an effect that is greater for smaller particle sizes[61] and hence may diminish the problems related to oxidised lipids. This is supported by the observation that washed irradiated allograft implanted into a goat model has the same rate of incorporation as rinsed non-irradiated bone.[62] Washing may therefore be as important in the preparation of irradiated graft as the dose of radiation itself. Of note, Mehendale et al[49] described 50 patients who had undergone acetabular revision using unwashed irradiated bone, which had been irradiated with either 25 kGy or 50 kGy at a mean of 45 months. Good clinical results were described, but although 40% of patients had incorporation of bone, only 6% had evidence of remodelling.[49] This is the only report in the literature commenting on washing irradiated graft, other than our own series, where the bone used had been washed and decontaminated by the central tissue bank using hydrogen peroxide and ethanol.

The optimum size of chip for impaction grafting is still not known. In their initial clinical series, Slooff et al[63] used large, hand-prepared crouton-sized pieces of graft for impaction grafting in the acetabulum. Later, investigators using biomechanical studies demonstrated that large bone chips of between 8 mm and 10 mm confer greater stability to an acetabular model with a cemented component than a graft composed of smaller chips.[64-67] Further experimental work has revealed the importance of particle size and distribution for early mechanical stability of the bone-graft bed.[68]

The ground irradiated bone chips used in this study were much smaller at 1 mm to 3 mm diameter than recommended by others.[64-68] This might have been expected to result in a poor outcome, with marked migration of the acetabular component, but the addition of the larger, 5 mm to 10 mm particles of Apapore 60 produced a better-graded particle size than would have been achieved with the ground bone alone, especially as the impaction process fractures the Apapore 60 particles. It is likely that this resulted in improved distribution of particle size and enhanced stability of the graft bed.

In vitro studies have demonstrated improved implant stability in models using ceramic substitutes compared to morsellised bone graft alone,[15,26,69-71] but there are fewer clinical studies. One such report used impacted HA particles into which an acetabular component was cemented,[25] and another used impacted HA particles into which an uncemented acetabular component was introduced.[72] Blom et al[73] recently reported their results from acetabular reconstruction of contained defects using a biphasic 50% porosity bioceramic in a 1:1 mixture with femoral head allograft, with good results in 43 patients at a mean follow-up of two years. Both cemented and uncemented acetabular components were used, with no migration. However, radiolucent lines were observed at the component-graft interface in ten of 34 patients who had received an uncemented component, and one of nine patients with a cemented implant.[73] Less satisfactory results have been reported using an A-W glass ceramic as a bone-graft substitute.[74]

The HHS was adopted as an outcome measure to enable comparison with other series. It has been shown to have

good reliability and validity compared to other scores, although some domains, particularly the range of movement, have been reported to demonstrate ceiling effects.[75] Only the patient-reported outcomes were obtained, which have been shown to provide excellent concordance with the surgeon-assessed HHS.[76] In our series there was an improvement in both the pain and function portions of the HHS.

The radiological evaluation of graft incorporation was difficult to assess. Apapore 60 is more radiodense than bone graft and obscures any trabecular pattern that may be present. In addition, phase-pure HA undergoes reabsorption by giant cell reaction, a process that is very slow and may be incomplete. Due to the longer term presence of the HA in the graft, the usual method of assessing remodelling proposed by Conn et al,[34] where remodelling is defined as isodensity of the graft and host bone, cannot be used. The best that can be shown is the gradual incorporation of the dense Apapore granules.

No patient required revision for clinical symptoms, and in the two in whom there was radiological evidence of acetabular migration, this occurred early and then stabilised. We suspect that it was a reflection of inadequate impaction of the graft at the time of surgery. A number of patients developed radiolucent lines, all of which occurred early and have not progressed. Their significance is unclear, and the patients remain under review.

There are a number of shortcomings in this study. At present the mean follow-up is limited to 60 months. Although the AAOS classification has been reported to have poor inter- and intra-observer reliability with plain radiographs,[77] we used it to classify the bone defects both radiologically and intra-operatively. Nevertheless, no formal inter- or intra-observer evaluation of reliability was performed when assessing remodelling on the post-operative radiographs. We describe a heterogeneous series of complex primary and revision cases. We recognise that the biological environments of the two groups were different. Autogenous graft from the femoral head was not used in the complex primary acetabular reconstructions owing to concerns about the adequacy and quality of the graft prepared in a theatre setting and in four hips the femoral head after resection was considered too small to provide adequate graft.

Acetabular reconstruction in both primary and revision surgery using a 1:1 mixture by weight of frozen, ground irradiated bone and Apapore 60 appears to be a viable method for managing acetabular defects. This approach goes some way to addressing the problems of bone supply and disease transmission, as well as theoretically improving the mechanical properties of the impacted bed. The use of plain radiographs to assess incorporation remains difficult. Although the medium-term clinical results appear promising, longer follow-up will be required to establish whether this technique is as effective as using fresh-frozen allograft.

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