Acetabular bone reconstruction in revision arthroplasty

A COMPARISON OF FREEZE-DRIED, IRRADIATED AND CHEMICALLY-TREATED ALLOGRAFT VITALISED WITH AUTOLOGOUS MARROW *VERSUS* FROZEN NON-IRRADIATED ALLOGRAFT

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Deficiencies of acetabular bone stock at revision hip replacement were reconstructed with two different types of allograft using impaction bone grafting and a Burch-Schneider reinforcement ring. We compared a standard frozen non-irradiated bone bank allograft (group A) with a freeze-dried irradiated bone allograft, vitalised with autologous marrow (group B). We studied 78 patients (79 hips), of whom 87% (69 hips) had type III acetabular defects according to the American Academy of Orthopaedic Surgeons classification at a mean of 31.4 months (14 to 51) after surgery. At the latest follow-up, the mean Harris hip score was 69.9 points (13.5 to 97.1) in group A and 71.0 points (11.5 to 96.5) in group B. Each hip showed evidence of trabeculation and incorporation of the allograft with no acetabular loosening.

These results suggest that the use of an acetabular reinforcement ring and a living composite of sterile allograft and autologous marrow appears to be a method of reconstructing acetabular deficiencies which gives comparable results to current forms of treatment.

Primary total hip replacement is being undertaken in patients who are younger, living longer and have higher demands. There is also a real risk that they will need two or more revision procedures in their lifetime.

Substantial bone loss, especially of pelvic bone, is one of the most challenging problems faced by the surgeon who performs revision surgery.¹⁻⁴ Restoration of bone stock is required to stabilise the components and facilitates further revision.⁵ The selection of suitable bone graft is based on the size of the defect, its location, the biology of the defect site, and whether structural support is required.⁶ The use of impaction bone grafting is well established. High rates of success have been reported when morcellised graft is used in combination with uncemented,⁷⁻⁹ and cemented acetabular components,¹⁰⁻¹³ or with¹⁴⁻¹⁸ or without¹⁰⁻¹³ a reinforcement ring.¹⁴⁻¹⁸

Autograft has been shown to be better than allograft in restoring bone stock because of its osteoconductive, osteoinductive and osteogenic properties.^{19,20} However, because autograft is of poorer quality in elderly patients and postmenopausal women, allograft is used extensively not least because of its ready availability and lack of donor site morbidity.²¹⁻²³ However, allograft does have a number of disadvantages. There is a risk of transmitting pathogens,^{24,25} and of an adverse

immune response.^{26,27} In addition, the method of processing, preservation, sterilisation and storing of allograft bone may influence its biophysical properties.²⁸⁻³¹ Hence, morcellised allograft, albeit commonly used, serves mainly as an osteoconductive matrix because of its lack of osteogenic cells and reduced osteoinductive factors.⁵

The safety of allograft therefore remains a major concern. The European Union has issued standards to maximise the quality and safety of allograft,^{32,33} but these have created difficulties in bone bank management and insurance that have yet to be resolved.

This study was undertaken to evaluate the clinical and radiological results of using a safe, freeze-dried, irradiated allograft-autologous marrow composite with a Burch-Schneider reinforcement ring (Zimmer GmbH, Munsingen, Switzerland) to manage severe acetabular deficiency in revision hip replacement. We used a matched cohort of patients in which frozen non-irradiated bone graft had been used as a control group.

Patients and Methods

Between 1 January 2003 and 31 December 2005, 103 patients (104 hips) were treated for aseptic loosening of the acetabular component with an associated bony defect. Patients were

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Fig. 1

Bar chart showing the distribution of follow-up after revision surgery of all 78 patients (79 hips) in the two groups.

followed up for a minimum of 14 months, during which three patients died, 15 had moved away and could not be contacted, and seven were confined to bed or required nursing care, so that no measurement of functional outcome was possible. The remaining 78 patients (79 hips) were assessed clinically and radiologically at a mean of 31.4 months (14 to 51) post-operatively (Fig. 1). The loss of pelvic bone stock was determined from pre-operative radiographs and intra-operative assessment and was classified using the system devised by the American Academy of Orthopaedic Surgeons.³⁴ Type I defects were present in eight hips (10.1%), type II defects in two (2.5%) and a type III defect in 69 (87.3%) (Table I).

In July 2004 the bone bank was closed to prepare it for compliance with European Union Directive 2004/23/EC.³² Before this, bone defects had been filled with frozen non-irradiated banked allograft (group A (40 patients, 41 hips); Table I). After July 2004 defects were treated with freeze-dried, irradiated and chemically-treated allograft (group B (38 patients, 38 hips); Table I). Patients were not randomised to a particular group: the allograft type used was determined by the date of surgery.

Operative technique and rehabilitation program. The lateral transgluteal approach was used in all patients. The failed acetabular component was removed, and the acetabulum debrided, fully exposing any defect. For group A, frozen non-irradiated allogeneic cancellous bone from donor femoral heads stored at -80°C ³⁵ was thawed, washed, and morcellised (chip size approximately 1 cm^3). Cancellous bone from up to two femoral heads was used in each case depending on the size of the defect. This was pressed into the acetabular defects and carefully impacted. A Burch-Schneider reinforcement ring (Zimmer GmbH) was then implanted. The inferior flange of the metal ring was

impacted into the ischium and the superior flange fixed to the ilium with cancellous bone screws. A polyethylene cup was then cemented into the metal ring in the appropriate position.

For group B, freeze-dried irradiated and chemically-treated allografts (Greffon Phoenix; TBF, Mions, France) were used. These were obtained from femoral heads harvested during hip replacement and prepared by TBF Banque de Tissus (TBF), a bone bank approved by the Agence Française de Sécurité Sanitaire des Produits de Santé.³⁶ These allografts comply with the European Union Directive 2004/23/EC.³² At the time of revision arthroplasty, bone graft was prepared using the method we have previously reported.³⁷ Briefly, the allograft block was rehydrated using bone marrow aspirated from the iliac crest or tibial metaphysis through a Jamshidi needle (Cardinal Health, Baesweiler, Germany). The marrow was injected into the allograft several times until the bone block was saturated. The allograft-autologous marrow composite was morcellised (size approximately 1 cm^3). Up to two femoral heads were used depending on the size of the defect. The chips were pressed into the acetabular defects and were carefully impacted. A Burch-Schneider reinforcement ring was implanted using the same technique as described for group A.

Post-operatively, each patient rested in bed for one week. Intensive physiotherapy was started on the first post-operative day. The patients were advised to avoid flexion of the operated hip beyond 90° and forced internal rotation. Weight-bearing was restricted to 20 kg for at least six weeks. Clinical and radiological follow-up took place at three months, six months and one year post-operatively, and annually thereafter.

Clinical follow-up examination. Clinical outcome was assessed using the guidelines described by Johnston et al,³⁸ the Harris hip score,³⁹ and the patient's subjective impression (very satisfied, satisfied, or dissatisfied), similar to other studies.⁴⁰ Physical examination included an assessment of the range of movement of the hip and leg lengths. Pre-operative data were compared with the outcomes at follow-up.

Radiological evaluation. All 78 patients had a detailed radiological examination. The acetabular index, horizontal migration and vertical migration were measured on the immediate post-operative and latest follow-up anteroposterior radiographs according to the methods described by Peters, Curtain and Samuelson.⁴¹ The host-allograft and allograft-implant interface were examined for the presence of radiolucent lines. The allograft was deemed to be either incorporated or not incorporated on the basis of the appearance of trabecular remodelling within the grafted area. Trabecular remodelling was assumed to have occurred when the graft density and architecture were same as those of the surrounding native bone.⁴²⁻⁴⁴ Acetabular loosening was established if the sum of acetabular migration in the horizontal and vertical planes was $\geq 5\text{ mm}$, if the

Table I. Study groups

	Group A	Group B
Number of patients	40	38
Number of hips	41	38
Gender		
Male:Female	16:24	16:22
Mean age in years at primary hip arthroplasty (range)	59.1 (24 to 79)	54.9 (24 to 69)
Revision hip arthroplasty		
Mean age in years (range)	72.5 (47 to 90)	69.9 (46 to 83)
Mean BMI* in kg/m ² (range)	27.8 (20.5 to 42.5)	26.5 (18.7 to 38.7)
Side		
Left:Right	21:20	24:14
Indication for revision surgery (%)		
Aseptic cup loosening	34 (82.9)	32 (84.2)
Aseptic cup and stem loosening	7 (17.1)	6 (15.8)
Previous revisions (same side) (%)		
None	35 (85.4)	30 (79.0)
Aseptic cup replacement	3 (7.3)	6 (15.7)
Aseptic cup and stem replacement	3 (7.3)	2 (5.3)
Acetabular defect type ³⁴ (%)		
I	4 (9.8)	4 (10.5)
II	0 (0)	2 (5.3)
III	37 (90.2)	32 (84.2)
IV	0	0
V	0	0
Follow-up in mths (range)	37.8 (23 to 51)	24.6 (14 to 35)

* BMI, body mass index

change in the acetabular index was $\geq 5^\circ$, or if there was a progressive radiolucent line > 1 mm in all zones, as described by DeLee and Charnley.⁴⁵ All radiological analyses were performed by two authors (BGO, UO). Only if both authors agreed on the presence of trabeculation in each grafted zone was trabeculation recorded. Heterotopic ossification was classified according to Brooker et al.⁴⁶

Statistical analysis. For intra-group analysis, paired observations (e.g. range of movement) were analysed before and after treatment using the paired *t*-test and Wilcoxon's rank sum test. For inter-group analysis, Student's *t*-test and the Mann-Whitney U test were used. A *p*-value ≤ 0.05 was considered to be significant.

Results

There were no significant differences between the groups in terms of demographics, disease pattern or pre-operative clinical findings. The follow-up time was the only exception to this ($p < 0.001$) (Table I).

Clinical. At the latest follow-up, 20 patients (50%) in group A were very satisfied with their surgery, 18 (45%) were satisfied, and two (5%) dissatisfied. In group B, 17 patients

(44%) were very satisfied, 20 (53%) were satisfied, and one (3%) was dissatisfied. In terms of pain, 22 patients (55%) in group A were free from pain, nine (22.5%) had slight pain, two (5%) had moderate pain and seven (17.5%) severe pain. In group B, 19 patients (50%) had no pain, seven (18.4%) slight pain, seven (18.4%) moderate pain and five (13.2%) severe pain. Statistical analysis showed no significant differences between the two groups.

The range of movement of the operated hip had improved significantly ($p < 0.005$) in all patients in both groups, with the exception of extension in both groups and internal rotation in group B. The mean increase in limb length was 0.2 cm (0 to 2.0) in group A and 0.3 cm (0 to 2.5) in group B. At the latest follow-up examination the mean Harris hip score³⁹ was 69.9 points (13.5 to 97.1) in group A and 71.0 points (11.5 to 96.5) in group B. In group A, 16% (six) of the 38 patients available had an excellent score (90 to 100 points), 26% (10 patients) a good score (80 to 89 points), 16% (six patients) a fair score (70 to 79 points) and 42% (16 patients) a poor score (less than 70 points). In group B, 14% (five patients) had an excellent score, 19% (seven patients) a good score, 31%

Table II. Migration of acetabular implants

	Group A		Group B	
	Hips	Mean (range)	Hips	Mean (range)
Horizontal migration (mm)	41	1.1 (0 to 5)	38	2.1 (0 to 13)
Vertical migration (mm)	41	2.2 (0 to 10)	38	2.4 (0 to 11)
Horizontal migration ≥ 5 mm (%)	2 (4.9)	5	5 (13.2)	7.2 (5 to 13)
Vertical migration ≥ 5 mm (%)	4 (9.8)	6.5 (5 to 10)	3 (7.9)	7.7 (5 to 11)
Acetabular index				
Post-operative ($^{\circ}$)	41	39 (24 to 52)	38	35 (22 to 49)
Follow-up ($^{\circ}$)	41	38 (23 to 51)	38	34 (22 to 49)

Fig. 2a

Fig. 2b

Fig. 2c

Anteroposterior radiographs a) of the right hip of a 77-year-old man, taken 17 years after a total hip replacement, showing aseptic loosening of the acetabular component and a type III combined acetabular bone defect, b) three months after acetabular revision using morcellised frozen, non-irradiated bone-bank graft, a Burch-Schneider reinforcement ring, and a cup inserted into the ring with cement, and c) at four-year follow-up examination showing the position of the components to be unchanged, and trabeculation in the area in which the graft was implanted.

(12 patients) a fair score and 36% (14 patients) a poor score. Statistical analysis showed no significant differences between the two groups.

Radiological. Horizontal migration of the acetabular components by ≥ 5 mm occurred in two hips in group A and in five hips in group B (Table II). Vertical migration by ≥ 5 mm occurred in four hips in group A and three in group B. Tilting of the reinforcement ring of $> 5^{\circ}$ was found in three hips in each group (group A: 7.3%; group B: 7.9%). With regard to migration of the acetabular component in all 79 hips, no significant differences in intra- and inter-group analysis between the immediate post-operative and latest follow-up were detected with respect to horizontal or vertical migration; however, inter-group analysis of the immediate post-operative acetabular index ($p = 0.022$) and the acetabular index at latest follow-up did demonstrate a significant difference ($p = 0.014$).

At the latest follow-up, the allograft had become incorporated without signs of loosening of the acetabular components in all 79 hips. Also, in the six patients in whom the

reinforcement ring had initially tilted by $> 5^{\circ}$, trabeculation and integration of the graft was seen in each of the three acetabular zones defined by DeLee and Charnley.⁴⁵ No radiolucent lines were seen at the host-allograft interface or the graft-implant interface. Radiologically, the morphology of the graft appeared to match that of the surrounding native bone. This was interpreted as trabecular remodelling (Figs 2 and 3).

There was no radiologically-detectable heterotopic ossification in 51.2% (21 hips) of the hips in group A or in 44.7% (17 hips) of those in group B. In group A grade I ossification was seen in 36.6% (15 hips) of hips, grade II in 0% (0 hips) and grade III in 12.2% (five hips). In group B this was 34.2% (13 hips), 5.3% (two hips) and 5.8% (six hips) for grades I, II and III, respectively. Grade IV ossification was not found in either group.

Complications. No peri-operative complications were seen in either group. There were, however, three post-operative medical complications: one urinary tract infection (group A), one deep-vein thrombosis (group B), and one pulmo-

Fig. 3a

Fig. 3b

Fig. 3c

Radiographs of a) the left hip of a 69-year-old man 18 years after a total hip replacement with a loose screw cup component and a type III combined pelvic bone defect, b) at three months' follow-up showing reconstruction using a freeze-dried irradiated bone allograft-autologous marrow composite, a Burch-Schneider reinforcement ring and a component inserted into the ring with cement, and c) two years after revision hip arthroplasty showing good reconstitution of the bone stock, with no radiolucent lines around the cup. The allograft is incorporated.

nary embolism (group B) despite treatment with low-dose heparin. Local post-operative complications included three haematomas in each group, which were surgically drained. Post-operative dislocation of the hip and subcutaneous or deep infections were not seen.

Discussion

There are an increasing number of failed hip replacements associated with massive defects in the acetabular bone stock. The perfect graft for restoration of these defects has not yet been found. Concerns exist about the currently used frozen, non-irradiated bone-bank graft, particularly with regard to its microbiological and immunological safety. Consequently, its use has become subject to the restrictive European Union Directive 2004/23/EC.³² This study has shown that a sterile allograft-autologous marrow composite gives an identical clinical and radiological outcome.

The allograft used in impaction grafting is not vascularised; it is therefore unclear how successful incorporation is achieved.⁴⁷ Bone ingrowth can be encouraged by osteoinduction, osteoconduction and mechanical loading; however, irradiation of allograft may reduce its osteoinductive capacity.⁴⁸ A living composite, combining autologous marrow, a rich source of autologous osteoinductive cells and growth factors, with sterile allografts may have a number of biological advantages over the current use of allograft. Autologous marrow can easily be obtained from all patients and is rapid, cost-effective and applicable to a number of clinical orthopaedic conditions.

The use of bone marrow to augment allograft is not new. Since the 1960s the addition of autologous marrow to bone allograft or xenograft has become established as a method of stimulating osteoinduction.⁴⁹ Although the technique has yet to become standard clinical practice, autologous marrow is increasingly used in conjunction with synthetic grafts in spinal fusion⁵⁰ and maxillofacial reconstructive

surgery.⁵¹ A number of clinical studies have evaluated the separate use of bone marrow to augment osteogenesis, for example, for the treatment of tibial nonunions.^{52,53} One study has evaluated bone marrow in combination with morcellised allograft.⁵⁴ The addition of autologous marrow may also be advantageous when using freeze-dried, irradiated and chemically-treated allografts, as our study suggests.

Reconstruction of acetabular defects in revision hip surgery by impaction bone grafting has been used successfully since the pioneering work of groups in Nijmegen,⁵⁵ and Exeter.⁵⁶ Currently, the procedure is well-established and the use of morcellised cryopreserved allogeneic banked bone has been considered the gold standard.^{57,58} Recent series using irradiated allograft also show good results in the medium and long-term^{40,59} (Table III⁶⁰⁻⁶³). Irradiation of deep-frozen allografts ensures bacterial and fungal sterility. The recommended radiation dose for sterilisation of medical devices is 25 kGy. However, this dose is not virucidal for HIV,⁶⁴ hepatitis B and hepatitis C virus. The use of an additional chemical process (ethanol, chloroform, hydrogen peroxide) ensures viral inactivation. Prion inactivation can be achieved using different methods. The freeze-dried and irradiated allografts used in group B (Greffon Phoenix) were also treated with sodium hypochlorite (2% chlorine) for one hour, which is classified by the World Health Organisation as a highly effective method of inactivity to prions.⁶⁵ Therefore, the freeze-dried, irradiated and chemically-treated allograft used in group B complies with European Union Directive 2004/23/EC³² and meets the highest standards of quality, traceability and safety.

From a biomechanical perspective, irradiation causes an alteration in the bone matrix, leading to a reduction in strength.⁶⁶ Irradiation at ambient temperature denatures collagen, but this effect is negated at cold temperatures.⁶⁷ Furthermore, irradiating allograft also damages its remain-

Table III. Comparison of incorporation rates in acetabular revision of non-irradiated and irradiated allografts

Authors	Number of hips	Graft used	Implant used	Incorporation rate (%)	Mean follow-up (range)
Slooff et al ⁶⁰	88	Frozen non-irradiated allograft	Cemented cups	88	70 months
Winter et al ¹⁵	38	Frozen non-irradiated allograft	Burch-Schneider APC*	100	7.3 years (4.2 to 9.4)
Schreurs et al ⁶¹	62	Frozen non-irradiated allograft	Cemented cups	80 radiologically stable	16.5 years (15 to 20)
Current study (group A)	41	Frozen non-irradiated allograft	Burch-Schneider APC	100	37.8 months (23 to 51)
Buckley et al ⁴⁰	123	Frozen irradiated allograft	Cemented cups	88	60 months (24 to 145)
Hassaballa et al ⁶²	58	Freeze-dried irradiated allograft	Cemented cups	45	48 to 90 months
				6 remodelling	
Deakin and Bannister ⁵⁴	51	Washed, irradiated allograft with autologous marrow	Harris-Galante cups, ABG cups	96	44 months (6 to 132)
Caltran et al ⁶³	44	Freeze-dried, irradiated and chemically-treated allograft (Greffon Phoenix)	Cemented cups, Kerboul rings, Octopus APC	97	40 months (33 to 49)
Vargas and Caton ⁶⁹	17	Freeze-dried, irradiated and chemically-treated allograft (Greffon Phoenix)	Kerboul ring, steel meshes, cemented cups	94	7.8 years (5 to 11)
Current study (group B)	38	Freeze-dried irradiated and chemically-treated allograft (Greffon Phoenix) with autologous marrow	Burch-Schneider APC	100	24.6 months (14 to 35)

* anti-protrusion cage

ing osteoinductive capacity.^{42,68} Therefore, it appears that the potential advantage of increased sterility gained by the use of irradiated allograft may be bought at the price of impaired graft incorporation.^{30,31,69} However, this has not been borne out by clinical studies.⁷⁰ A comparison of the incorporation rates in acetabular revision of non-irradiated and irradiated allografts is shown in Table III. The rates range between 45% and 100%, depending on the type of allograft and its preparation. It is gratifying to see that newer preparations of allografts with their high safety standard and marrow-improved osteoinductive properties, show similar incorporation rates to those of frozen non-irradiated allograft.

Currently, radiological examination remains the standard method of evaluating graft incorporation.⁷¹ Our study showed equivalent graft incorporation rates for both groups, with a mean follow-up of 31.4 months (14 to 51). According to the literature,^{54,72-78} graft incorporation in human and animal studies is usually apparent six to eight months after revision. Deakin and Bannister⁵⁴ showed incorporation of impacted acetabular graft in 96% of patients by 12 months, with 90% showing radiological evidence of trabeculation on the first review radiograph, taken after three or six months. The authors therefore concluded that the rapid incorporation rate in more than 90% is comparable with that of fracture union, and is usually apparent after six months. Other studies, including some animal experiments, have shown that impacted morcellised fresh-frozen allograft bone chips are incorporated completely into a new bone structure within six months.⁷⁴⁻⁷⁶ Histological studies have shown that bone graft incorporation and remodelling is seen eight months after acetabular revision

surgery, and at 15 months remnants of the graft are extremely scarce.^{77,78} Therefore, a follow-up period of over 12 months seems appropriate for the assessment of graft incorporation. Our study showed incorporation of 100% in both groups and all had follow-up of more than 14 months. Thus, acetabular reconstruction with the composite is radiologically equivalent to the current treatment.

We noted six patients (7.6%) in whom the tilt of the reinforcement ring exceeded 5°. However, at the latest follow-up, the allograft had incorporated in all 79 hips with no signs of acetabular loosening. This incorporation rate may be related to the modest follow-up rate of 76%, as 25 patients (25 hips) were lost to follow-up. According to Britton et al,⁷⁹ patients lost to follow-up have worse outcomes than patients attending review, whereas patients who die during the follow-up period are similar to the surviving population. Therefore, a lower rate of graft incorporation and a higher rate of implant failure can be assumed. However, the short-term outcome shown in the present study, using a sterile allograft-autologous marrow composite, was radiologically encouraging, clinically satisfactory, and also comparable to current methods.

In summary, acetabular reconstruction using an acetabular reinforcement ring, a vital composite of sterile allograft, and autologous marrow for improved osteoinductivity appears to be a viable method of managing acetabular defects and is equally as good as the current standard. This approach applies current principles of tissue engineering by allograft vitalisation, offers biological advantages, and ensures a higher level of microbiological safety than the current standard. It may, therefore, be a valuable clinical tool that warrants further evaluation.

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