# Subsidence of the stem after impaction bone grafting for revision hip replacement using irradiated bone

**M. Hassaballa,**
**S. Mehendale,**
**S. Poniatowski,**
**G. Kalantzis,**
**E. Smith,**
**I. D. Learmonth**

*From University of Bristol, Bristol, England*

**Loss of bone stock is a major problem in revision surgery of the hip. Impaction bone grafting of the femur is frequently used when dealing with deficient bone stock. In this retrospective study a consecutive series of 68 patients (69 hips) who had revision of a hip replacement with femoral impaction grafting were reviewed. Irradiated bone allograft was used in all hips. Radiological measurement of subsidence of the stem, incorporation of the graft and remodelling was carried out and showed incorporation of the graft in 26 of 69 hips (38%). However, there was no evidence of trabecular remodelling. Moderate subsidence of 5 mm to 10 mm occurred in ten hips (14.5%), and massive subsidence of > 10 mm in five (7.2%).**

**The results of this study are less favourable than those of others describing studies of revision of the femoral stem using impaction bone grafting. The absence of the characteristic changes of graft remodelling noted in other series raises the question as to whether irradiated bone graft may be a significant factor influencing the post-operative outcome.**

Loss of bone stock is an important factor in determining the outcome of revision of a total hip replacement. Impaction bone grafting is a valuable option in the management of deficiency of bone.[1,2]

There is a risk of transmitting bacterial, fungal, viral, prion and protozoal microbiological disease through human allografts.[3,4] Donor selection and microbiological testing of donors and donations reduce the risk of such transmission. The bio-burden is reduced by aseptic collection, antibiotic soaks, and the use of ethylene dioxide or gamma irradiation to inactivate infectious agents.[5,7] Irradiation may have an adverse effect on the mechanical properties of bone.[8] However, Banks, Allen and Aldam[9] did not identify any significant difference in their series of patients between the use of irradiated or fresh-frozen allografts at a mean follow-up of four years.

Excellent results have been reported from the centres which first described impaction bone grafting,[10-12] but less favourable outcomes have been experienced in other centres.[13-16]

Frozen bone allografts, gamma irradiated with a minimum of 25 kGy or 50 kGy, have been used at the Avon Orthopaedic Centre since 1993. Eldridge et al[13] observed massive subsidence in a cohort of patients operated on at this centre before 1994. At that time, impaction bone grafting was recognised as a technique-dependent procedure and failures were ascribed to technical shortcomings associated with the learning curve. The bone grafts used were not scrutinised, nor were the results evaluated according to the nature or source of the graft. In this study we have assessed those patients who had revision hip surgery with femoral impaction grafting using irradiated bone graft after 1994.

## Materials and Methods

We clinically and radiologically reviewed 68 patients (69 hips) who had femoral impaction bone grafting using frozen irradiated allograft between 1994 and 2001 at the Avon Orthopaedic Centre, Bristol, United Kingdom (Table I). All operations were performed or supervised by the two senior authors (ES, IDL). Irradiated graft from the femoral was used in all patients. The bone was initially supplied from Blood Services South West in Bristol from 1992/1993, then from the Oxford Regional Blood Transfusion Centre and, more recently, following a national reorganisation in 2000, by the National Blood and Tissue Services.

Before 1997 the bone from the Blood Services South West was irradiated to 50 kGy. Allograft subsequently obtained from the Oxford Regional Blood Transfusion Centre and Bone Bank and from National Blood and Tissue Services was irradiated to 25 kGy. A total of 25 kGy is strong enough to kill most bacteria and viruses without damaging the structural properties of the graft.

■ M. Hassaballa, MCH Ortho, MD Ortho, Senior Fellow
■ S. Mehendale, FRCS, FRCS Ortho, Specialist Registrar
■ S. Poniatowski, BSc(Hons), National Tissue Bank Manager
■ G. Kalantzis, MBBCH, Senior House Officer
■ E. Smith, FRCS, Consultant Orthopaedic Surgeon
■ I. D. Learmonth, FRCS, Professor of Orthopaedic Surgery
Avon Orthopaedic Centre, Southmead Hospital, Westbury on Trym, Bristol BS10 9NB, United Kingdom

Correspondence should be sent to Mr M. Hassaballa; e-mail: mahassaballa@aol.com


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**Table I.** Number of hips/patients, gender, mean age and SD

| | Male | Female | Total |
|---|---|---|---|
| Number of hips/patients (%) | 37/36 (*52.94*) | 32/32 (*47.06*) | 69/68 |
| Mean age yrs (range) | 65 (39 to 88) | 63.2 (34 to 82) | 64.2 (12.6) |

**Table II.** The Endo-Klinik classification of femoral bone loss[17]

| Grade | Definition |
|---|---|
| I | Radiolucent lines confined to the upper half of the cement mantle; clinical signs of loosening |
| II | Generalised radiolucent zones and endosteal erosion of the upper femur leading to widening of the medullary cavity |
| III | Widening of the medullary cavity by expansion of the upper femur |
| IV | Gross destruction of the upper third of the femur with involvement of the middle third, precluding the insertion of even a long-stemmed prosthesis |

**Table III.** Inclusion and exclusion criteria

| Inclusion | Exclusion |
|---|---|
| First revision operation | Septic revisions |
| Aseptic revisions | Peri-prosthetic fractures |
| Femoral impaction bone grafting in accordance with the Exeter technique | Structural allografts |
| Cemented stems | Cementless prosthesis |
| | Incomplete notes and radiographs |

The patients' notes and radiographs of all 69 hips were reviewed. Operative notes and pre-operative radiographs were studied. Femoral bone loss was classified according to the Endo-Klinik classification[17] (Table II). Inclusion and exclusion criteria are shown in Table III.

Post-operative radiographs were taken on the third day after surgery and at three months, six months and yearly thereafter.

The hip was exposed either through an anterolateral approach (35 hips) or a posterior approach (34 hips) in accordance with the surgeon's preference.

The principles of the operative technique were described by Gie et al[18] using the Exeter impaction grafting system (Stryker, Newbury, United Kingdom). The femoral heads were stored at -20°C, allowed to thaw at operating room temperature (23°C) and sectioned prior to being milled. A Novogamus bone mill was used to provide a chip size of around 5 mm. The milled grafts were not defatted. Intra- and post-operative complications were recorded. The dose of radiation of the allografts used for 61 of the 69 hips was obtained from records at the National Blood and Tissue Services (London, United Kingdom). Palacos R (Schering-Plough, Welwyn Garden City, United Kingdom) was used in 63 hips and Simplex P (Stryker) in six hips. The Exeter (Stryker, United Kingdom) stem was used in 63 hips, the Elite/Elite plus (Depuy, Leeds, United Kingdom) in five and the CPS stem (Endoplus, Tuttlingen, Germany) was used in one. A customised set of cannulated broaches was used for the Elite/Elite system.

The serial post-operative radiographs were assessed for the timing, severity and progression of subsidence, evidence of loosening, trabecular remodelling, graft incorporation, cortical repair, alignment of the prosthesis, localised resorption and radiolucent lines. Serial radiographs were reviewed by two independent observers working together to assess loss of bone stock, signs of loosening, trabecular incorporation/remodelling and subsidence of the stem. A standardised anteroposterior radiograph of the pelvis showing both hips was used to calculate subsidence. The radiographs were taken with the tube at a distance of 100 cm. The beam was centred midway between the upper border of the anterior superior iliac spine and the upper border of the symphis pubis. Loosening, graft incorporation and trabeculation were assessed on both anteroposterior and lateral radiographs.

Subsidence was measured by drawing a line on the long axis of the femur. Two further lines were drawn perpendicular to this, one through the centre of rotation of the femoral head, the other to one of three points on the femur: the top of the greater trochanter, the medial neck cut, or the top of the lesser trochanter. The point on the femur that was most clear and consistent on the consecutive radiographs was selected. Subsidence was defined as minimal (< 5 mm), moderate (5 mm to 10 mm) or massive (> 10 mm).[13]

**Table IV.** Variables related to the development of subsidence. Results are presented as mean (SD) or numbers (%)

| Variable | Hips showing no subsidence (n = 14) | Hips showing subsidence (n = 55) | p-value* |
|---|---|---|---|
| Age at surgery (yrs) (range) | 59.1 (*35 to 75*) | 65.5 (*34 to 88*) | 0.09 |
| Female (%) | 6 (*42.9*) | 26 (*47.3*) | 0.77 |
| Left side of surgery (%) | 7 (*50*) | 26 (*47.3*) | 0.86 |
| Endo-Klinik class | | | |
| 1 | 2 (*14.3*) | 9 (*16.4*) | 0.86 |
| 2 | 5 (*35.7*) | 23 (*41.8*) | |
| 3 | 7 (*50*) | 23 (*41.8*) | |
| Consultant firm (%) | | | |
| First | 5 (*35.7*) | 30 (*55*) | 0.37 |
| Second | 9 (*64.3*) | 25 (*45.8*) | |
| Cement type (%) | | | |
| P | 10 (*71.4*) | 53 (*96.4*) | 0.013 |
| S | 4 (*28.6*) | 2 (*3.6*) | |
| Revision component (%) | | | |
| Exeter | 12 (*85.7*) | 51 (*92.7*) | 0.47 |
| Elite (Elite plus) | 2 (*14.3*) | 3 (*5.5*) | |
| CPS | - | 1 (*1.8*) | |
| Neutral alignment (%) | 11 (*78.6*) | 43 (*78.2*) | 0.98 |
| Follow-up (mths) (range) | 21.1 (12 to 89) | 30.3 (12 to 89) | 0.095 |
| One-year follow-up (%) | 9 (*64.3*) | 51 (*92.7*) | 0.005 |

* significant if $p < 0.05$

Trabecular remodelling was defined as a change in graft pattern, with the trabeculae running obliquely from the endosteal surface of the femur onto the cement. Graft incorporation was defined as any change in appearance on the post-operative radiograph short of fulfilling the criteria of remodelling.[19] Cortical repair was present when a thinned-out or eroded cortex regained normal cortical structure and thickness.[19]

The patient's notes from the last follow-up clinic were reviewed. The level of mobility and the presence or absence of pain were recorded.

The mean follow-up was 28.4 months (12 to 89). Table I shows the gender distribution and mean age of the patients.

**Statistical methods.** A logistic regression analysis was used to study the timing of appearance of subsidence. All input variables were fitted in a Cox regression model to assess their effect on subsidence. The 'subsidence progression rate' was used to correlate the level of subsidence in millimetres (mm) with the total period of follow-up. The differences in the level of increase of subsidence among all hips were analysed using analysis of variance (ANOVA). The level of significance was taken at $p < 0.05$.

## Results

On radiological evaluation 11 hips (16%) had relatively mild deficiency of bone stock (Endo-Klinik grade I), 28 (41%) grade II and 30 (43%) grade III. None showed grade IV deficiency.

No hips showed localised resorption. Cortical repair was present in 21 (30%) and evidence of trabecular incorporation was seen in 26 (38%), in 13 at six months and in 13 after one-year. There was no evidence of remodelling in any hip in the serial follow-up radiographs.

At the time of final follow-up, 14 hips (20%) showed no subsidence, whereas the remaining 55 (80%) exhibited a varying degree of subsidence at the bone cement interface (Table IV). When first recorded at three months post-operatively, subsidence was mild in 48 hips (70%), moderate in five (7%) (Fig. 1) and massive in two (3%) (Fig. 2). At final follow-up moderate subsidence (5 mm to 10 mm) occurred in ten cases and massive subsidence (14.5%) occurred in five cases (7.2%).

Variables with a p-value < 0.1 in simple analysis (Table V) were introduced into a logistic regression model, which showed that a higher Endo-Klinik class was the only independent predictor for the early appearance of subsidence during the first three months after surgery, compared with its appearance at one year or later after operation ($p = 0.042$). Stepwise regression analysis suggested that significant early subsidence and an advanced Endo-Klinik classification were independent predictors for progression of subsidence. There was a trend towards greater subsidence with a higher dose of graft irradiation, although this was not statistically significant. However, massive subsidence was only seen in patients who had received allografts irradiated to 50 kGy.

All the patients with massive subsidence had symptoms and were subsequently revised. Two complained of pain and three

Fig. 1a

Fig. 1b

Fig. 1c

Radiographs of case 2 showing moderate subsidence a) Pre-operatively, b) immediately after operation, and c) final subsidence. Subsidence was measured by drawing a line on the long axis of the femur. Two further lines were drawn perpendicular to it, one through the centre of rotation of the femoral head, the other to one of the three points on the femur; the top of the greater trochanter, the medial neck cut or the top of the lesser trochanter. The point on the femur was selected that was most clear and consistent on the consecutive radiographs.

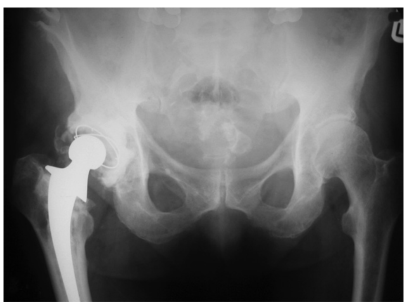

Fig. 2a

Fig. 2b

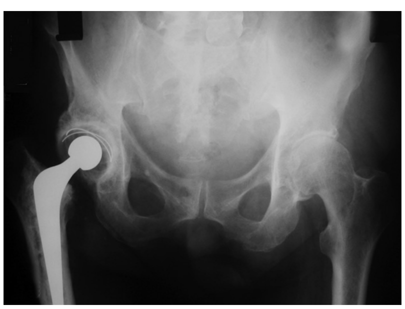

Fig. 2c

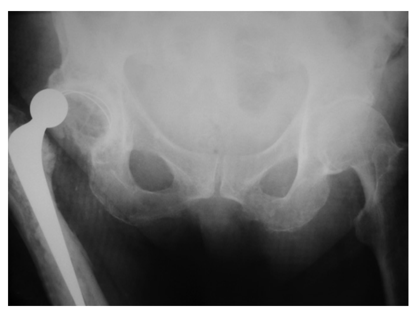

Fig. 2d

Radiographs showing massive subsidence. a) Pre-operatively, b) immediately after operation, c) one year after operation and d) final subsidence and dislocation.

of instability and symptoms of impingement. In the moderate subsidence group four patients had mild trochanteric pain; otherwise all the remaining hips were asymptomatic.

The dose of irradiation used to sterilise the allograft could be established in 61 of the 69 hips reviewed and was correlated with the measured level of subsidence of the stem. The results are shown in Table VI. Massive subsidence (Fig. 2) was encountered only in patients who had received allograft irriadiated to 50 kGy.

## Discussion

**Irradiation.** Bone banks are struggling to meet the demand for allograft in orthopaedic surgery. The danger of contaminated allograft taken from live donors at the time of surgery is well documented.[20] The use of fresh-frozen allograft bone carries with it the risk of transmission of disease. There have been a small number of cases reported in the United States where the human immunodeficiency virus (HIV) has been transmitted via allograft bone.[21] This

**Table V.** Variables related to the timing of initial subsidence appearance. Results are presented as mean (SD) or numbers

| Variable | Hips showing subsidence at 3 months (n = 43) | Hips showing subsidence at one year or later (n = 12) | p-value* |
|---|---|---|---|
| Age at surgery (yrs) (range) | 65.9 (34 to 88) | 63.8 (34 to 62) | 0.59 |
| Female (%) | 21 (*48.4*) | 5 (*41.7*) | 0.75 |
| Endo-Klinik class (%) | | | |
| 1 | 7 (*16.3*) | 2 (*16.7*) | |
| 2 | 14 (*32.5*) | 9 (*75*) | |
| 3 | 22 (*51.2*) | 1 (*8.3*) | 0.017 |
| Consultant (%) | | | |
| First | 18 (*41.9*) | 9 (*75*) | |
| Second | 25 (*58.1*) | 3 (*25*) | 0.042 |
| Cement type (%) | | | |
| P | 41 (*95.3*) | 12 (*100*) | |
| S | 2 (*4.7*) | - | 1 |
| Revision component (%) | | | |
| Exeter | 40 (*93*) | 11 (*91.7*) | |
| Elite (Elite plus) | 2 (*4.7*) | 1 (*8.3*) | |
| CPS | 1 (*2.3*) | - | 0.77 |
| Neutral alignment (%) | 35 (*81.4*) | 8 (*66.7*) | 0.43 |
| Follow-up (mths) (SD) | 29.9 (16.6) | 31.5 (22.5) | 0.79 |

* significant if $p < 0.05$

**Table VI.** Dose of allograft irradiation and their subsidence category in 61 of the 69 hips in which the irradiation dose was established

| | Subsidence | | | | |
|---|---|---|---|---|---|
| | Massive | Moderate | Mild | No | Total |
| 50 kGy | 4 | 6 | 17 | 8 | 35 |
| 25 kGy | 0 | 4 | 16 | 6 | 26 |
| Total | 4 | 10 | 33 | 14 | 61 |

virus is known to reside within the bone and remains active after gamma irradiation, although irradiation is one of the most popular methods of sterilising bone.[22-24] Several authors have described the radiosensitivity of HIV.[8,25-29]

Currently, the National Blood and Tissue Services uses gamma irradiation to a minimum of 25 kGy.[30] A total of 25 kGy (SD 5) is sufficient to reduce the surviving fraction of most bacteria to $10^{-9}$ but this is not adequate for HIV. However, studies have demonstrated that high doses of irradiation (50 kGy[31] or 60 kGy[8]) have a deleterious effect on the mechanical properties of bone, and sterilisation of all bone by irradiation to 25 kGy has been recommended.[18]

Some studies have suggested that, whereas the elastic modulus is unaffected, the ultimate stress, strain and toughness are significantly reduced as a result of sterilisation by irradiation.[8,32-34] Komender, Malczewska and Komender[35] showed a marked reduction in the strength of irriadiated bone as the dose increased from 30 kGy to 60 kGy.

**Radiological appearance.** There has been considerable interest in the radiological appearance of impaction bone grafting and its correlation to histology. Trabecular remodelling and cortical repair were found to be consistently associated with histological evidence of bone healing in the graft.[36] The radiological appearance of graft incorporation was associated with variable histology, ranging from a stable fibrous composite to an absence of any interface between graft and host bone.[36]

In this series, graft incorporation was found in 26 of 69 hips (38%), whereas cortical repair was seen in 21 (30%). Trabecular remodelling was not observed in any hip. These results contrast with the very high rate of remodelling reported in the series from Exeter, which showed cortical healing in 87%[33] and 89%.[37] The use of irradiated bone in the present series might account for this difference. Holt, Elson and Ibbotson[38] comparing the use of fresh-frozen and irradiated allograft bone for impaction bone grafting of the acetabulum, showed no significant difference in the clinical or radiological outcome using these different types of graft. Deakin and Bannister[39] have shown that the addition of autologous marrow significantly increases the radiological evidence of graft incorporation.

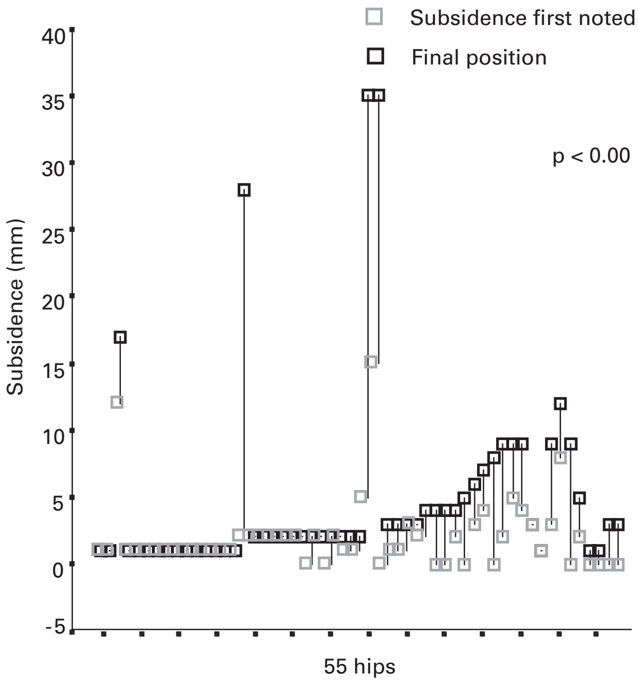


Fig. 3

Graph showing subsidence change during follow-up.

In this series, the majority of the hips that underwent moderate and massive subsidence used allograft bone which had received a higher dose of irradiation (Table VI).

**Subsidence.** The polished Exeter universal stem used in the majority of the hips in this series is a force-closed or taper-slip[40,41] design. Such a design has been shown to migrate axially within the cement mantle more than any other stem studied,[42] but there is no associated migration between cement and bone when the mantle remains intact.[43-45] When the subsidence is excessive the cement mantle is disrupted and predisposes to progressive subsidence and failure.

In this series, all five hips with massive subsidence were symptomatic and underwent a further revision. The symptoms ranged from pain to impingement and dislocation. Moderate subsidence occurred in ten hips within the first two years, but the stem stabilised thereafter. None of these patients were significantly symptomatic.

Four patients had trochanteric pain unrelated to the degree of subsidence. None of the patients who showed mild subsidence were symptomatic. Minimal subsidence is almost a prerequisite to epitomise the advantages in stress distribution and fixation offered by this type of stem.

We did not find any correlation between the type of stem design used and the subsidence, but this may be related to the limited number of other stems used.

Subsidence usually occurred in the first year after operation (Fig. 3). An advanced Endo-Klinik grade was found to be an independent predictor for the appearance of subsidence as early as the third month after operation. No additional hips showed signs of subsidence after the first year, and there was no progression of subsidence after the second year.

Simplex P cement was used in less than 10% of the patients reviewed. Only 33% of stems subsided when Simplex P cement was used, compared with 84% when Palacos R cement was used. The numbers were too small for statistical significance or further comment.

Recently, Halliday et al[10] suggested that the most important predictor for subsidence was the surgical technique, and that subsidence could be reduced by the use of larger bone chips in capacious canals, tighter compaction of these chips, and the use of longer stems. This is clearly a technique-dependent procedure, and numerous variables may influence the outcome.

In this series, one of the senior authors (ES) was trained in this technique at Exeter, and there was no significant difference in the operative technique between the two surgical firms. There was no statistically significant difference in the Endo-Klinik stage, the results, the degree of subsidence or the case mix of patients revised by either surgical team.

Four of the five patients who showed massive subsidence had a mean age of 75.8 years (68 to 88; SD 9), which was significantly older than the mean age for the whole group (63.5 years (34 to 88; SD 12.5)). This suggests that it may be prudent to avoid the use of impaction bone grafting in elderly patients, a view supported by Halliday et al,[10] who advocate its use in younger patients.

The bone chips used in this series were not defatted. Some authors believe that defatting may be significant as it can improve initial implant stability[46] and the grading of the bone graft,[47] thereby facilitating a more rapid incorporation. Similarly, defatting also reduced the immunogenic properties of the graft and hence the immunological response.[48]

This paper highlights the numerous variables that influence the outcome of impaction bone grafting, including the effects of irradiated bone graft, implant and patient variables. The degree of bone loss and the level of irradiation of the allograft appeared to be the two most important variables associated with a poor outcome.

Although a randomised controlled trial would be the ideal model to assess the influence of one specific variable on outcome, it would be difficult to match all the other potential variables in order to validate the outcome.

Impaction grafting remains a valuable option in restoring bone stock at revision hip surgery, but it is reasonable to be vigilant concerning the use of irradiated bone in these circumstances.

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