THE JOURNAL OF BONE & JOINT SURGERY

■ HIP

The extent of the bone defect affects the outcome of femoral reconstruction in revision surgery with impacted bone grafting

A FIVE- TO 17-YEAR FOLLOW-UP STUDY

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We report the results of 79 patients (81 hips) who underwent impaction grafting at revision hip replacement using the Exeter femoral stem. Their mean age was 64 years (31 to 83). According to the Endoklinik classification, 20 hips had a type 2 bone defect, 40 had type 3, and 21 had type 4. The mean follow-up for unrevised stems was 10.4 years (5 to 17).

There were 12 re-operations due to intra- and post-operative fractures, infection (one hip) and aseptic loosening (one hip). All re-operations affected type 3 (6 hips) and 4 (6 hips) bone defects. The survival rate for re-operation for any cause was 100% for type 2, 81.2% (95% confidence interval (CI) 67.1 to 95.3) for type 3, and 70.8% (95% CI 51.1 to 90.5) for type 4 defects at 14 years. The survival rate with further revision for aseptic loosening as the end point was 98.6% (95% CI 95.8 to 100). The final clinical score was higher for patients with type 2 bone defects than type 4 regarding pain, function and range of movement. Limp was most frequent in the type 4 group ($p < 0.001$). The mean subsidence of the stem was 2.3 mm (SD 3.7) for hips with a type 2 defect, 4.3 mm (SD 7.2) for type 3 and 9.6 mm (SD 10.8) for type 4 ($p = 0.022$).

The impacted bone grafting technique has good clinical results in femoral revision. However, major bone defects affect clinical outcome and also result in more operative complications.

Good clinical results have been reported using a cementless extensively porous-coated stem in femoral revision surgery in patients with an endosteal canal with a diameter of less than 18 mm[1-3] but severe stress shielding in the proximal femur has been a major concern for long-term outcome.[4] Impacted bone grafting and cement have been used to reconstitute deficient bone stock in the proximal femur in revision total hip replacement (THR) with good results,[5-14] and even with acceptable results in patients with massive femoral defects.[15,16] New bone formation has been reported in histological[17-20] and positron emission tomography studies.[21] The infrequency of the call for this technically demanding procedure has resulted in early failures of impacted bone grafting with frequent complications such as femoral fractures and stem subsidences of more than 5 mm.[11,22-24]

Most series with impacted bone grafting in femoral revision surgery have not considered differences in survival between grades of bone defect. Accordingly, we have examined whether the intra-operative bone defect can affect the survival and fate of femoral reconstruction with impacted bone grafting. We investigated: 1) whether reconstructions performed using this technique and a cemented stem have a satisfactory medium-term outcome and whether the outcome can be related to the size of the bone defect; 2) the relationship between any complications of the technique and different degrees of bone defect; and 3) whether the radiological findings can also be related to the bone defects.

Patients and Methods

Between 1993 and 2005, 79 consecutive patients (81 hips) underwent femoral impacted bone grafting during revision THR prior to cementing of an Exeter stem (Stryker, Howmedica International, Staines, United Kingdom). The impacted bone grafting technique was introduced in our institution in 1993. The criteria for impacted bone grafting were: age < 70 years or in older patients the presence of moderate to severe proximal cortical bone loss, especially if the width of the endosteal canal exceeded 18 mm. Although no patient has been excluded from the survivorship analysis, a minimum five-year clinical and radiological follow-up of unrevised stems was required for inclusion in the study. No hips were lost to follow-up and no patients died from causes unrelated to the operation before five years.

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doi:10.1302/0301-620X.93B11.27321 $2.00

J Bone Joint Surg Br 2011;93-B:1457–64.
Received 8 April 2011; Accepted after revision 12 July 2011

Table I. Patient data and bone defects[25]

	Bone defect				
	Grade 2	**Grade 3**	**Grade 4**	**Total**	**p-value***
Mean age (years) (range)	66.3 (43 to 79)	64.9 (31 to 82)	60.0 (32 to 83)	64.0 (31 to 83)	0.177
Male:female	8:12	15:25	10:11	33:48	0.745†
Right:left	12:8	23:17	12:9	47:34	0.979†
Original diagnosis					
Osteoarthritis	14	26	8	48	
Developmental dysplasia of the hip	2	6	2	10	
Rheumatoid arthritis	1	1	5	7	
Avascular necrosis	2	1	3	6	
Hip fracture	1	3	2	6	
Developmental arthritis	-	1	1	2	
Other	-	2	-	2	
Cause of revision					
Aseptic loosening	19	36	15	70	0.057†
Septic loosening (resection-arthroplasty)	1	4	3	8	
Pre-operative peri-prosthetic fracture	-	-	3	3	
Revision number					
First	16	29	10	55	0.232†
Second	3	8	8	19	
Third or more	1	3	3	7	

* Mann-Whitney U test, unless otherwise stated
† Pearson chi-squared test

There were 48 women and 33 men and with a mean age of 64 years (31 to 83). The mean time between the initial THR and the revision surgery was 11 years (1 to 16). The diagnosis at the time of the primary THR was osteoarthritis in most cases. A variety of cemented (45) and cementless (36) THRs were revised in this series. The cause of revision was aseptic loosening in 70 hips (86.4%), septic loosening in eight (9.9%) and periprosthetic fracture in three (3.7%). The impacted bone grafting revision was the first revision in 55 hips (67.9%). Femoral bone status was classified during the operation according to the Endoklinik classification[25] and included 20 Type 2, 40 Type 3 and 21 Type 4 hips. Each revised stem was individually assessed; eight (9.9%) only underwent femoral revision and 73 (90.1%) underwent revision of both components. The mean follow-up for unrevised stems was 10.4 years (5 to 17). Patient data regarding the bone defects are detailed in Table I.

We used a posterolateral approach in all hips. Because of the difficulty of removing the cement or osseointegrated cementless stems in problematic cases, we began using an extended trochanteric osteotomy with increasing frequency to reduce the risk of cortical perforations (eight hips). The stem and all cement, debris and fibrous membrane were removed from the femoral canal before excising the membrane and sending it for histological and bacteriological study. Before introducing the morcellised allograft and cement, segmental defects in the cortex or calcar were reconstructed with metallic meshes and cerclage wires designed to retain the allografts (X-Change; Stryker, Howmedica International). In nine hips, only prophylactic cables were placed around a thin calcar or cortical bone and to prevent fracture during impaction. A Dall-Miles plate (Stryker, Howmedica International) was also added in five hips to reinforce the cortical bone, especially in cases with a pre-operative periprosthetic fracture. The femoral canal was occluded distally by an acrylic plug placed 3 cm distal to the most distal area of bone lysis. Using a bone mill (LereBone Mill; Johnson & Johnson, DePuy, Warsaw, Indiana), unwashed cancellous chips 2 mm to 5 mm in diameter were prepared from fresh-frozen femoral heads, obtained from microbiologically screened donors who had previously undergone primary THR. The graft was vigorously impacted with a trial prosthesis from X-Change instruments according to the Exeter technique.[5,7] A collarless double-taper polished Exeter stem was introduced with antibiotic-loaded cement (Palacos with gentamicin; Merck, Darmstadt, Germany), which was injected in a retrograde manner and pressurised with a proximal seal. A standard-length stem has been used in most cases (69 hips, 85.2%). A long stem has been used since 1998 in cases with severe distal bone loss to bypass the deficiency and reduce the risk of periprosthetic fracture (12 hips). Operative data regarding the bone defect are detailed in Table II.

The post-operative management in our early patients included bed rest for 14 days.[5] Beginning in 1997, patients spent five days in bed with the leg in abduction, and then, depending on the quality of the bone and the nature of the reconstruction, partial weight-bearing started at six weeks

Table II. Operative data and bone defects[25]

	Bone defect				
	Grade 2	Grade 3	Grade 4	Total	p-value*
Surgical approach					
Posterior	18	34	21	73	0.175
Extended trochanteric osteotomy	2	6	-	8	
Metallic meshes and Dall-Miles plates used during surgery					
No mesh	18	27	8	53	0.011
Calcar mesh	1	5	3	9	
Diaphyseal mesh	1	3	3	7	
Calcar and diaphyseal meshes	-	5	2	7	
Plate and diaphyseal mesh	-	-	5	5	
Number of femoral heads per allograft used during surgery					
One femoral head	3	1	-	4	0.001
Two femoral heads	13	31	8	52	
Three femoral heads	4	8	13	25	
Exeter stem used during surgery					
Standard stem	19	35	15	69	0.268
Long-stem	1	5	6	12	

* Pearson chi-squared test

with a gradual return to full weight-bearing after three months. Antibiotic prophylaxis (1 g cefazolin every six hours) was discontinued at 48 hours. Subcutaneous heparin was used as a routine thromboprophylaxis until the patients were fully mobile.

Clinical and radiological assessment. Clinical evaluation including pain, function, and range of movement was assessed using the Merle D'Aubigné and Postel score (range 1 to 6 in each domain)[26] at six weeks, 12 weeks, six months, one year, and annually thereafter. Levels 5 and 6 are considered a good clinical result and levels 4 and lower, a poor result. Clinical failure was defined as the requirement for further revision or removal of the femoral component for any reason, pain (level 4 or worse), or both. Thigh pain was considered evidence of failure, and groin and buttock pain were recorded as signs of acetabular loosening.[27]

Standard anteroposterior (AP) and lateral radiographs of the pelvis were undertaken for all patients immediately after surgery and at every follow-up examination. All post-operative and follow-up radiographs were made at our institution following the same protocol.[28] Measurements were made by a single author (EGR) who had not been involved in the surgery. The position of the stem was defined as neutral, valgus (lateral deviation of ≥ 3 mm) or varus (medial deviation of ≥ 3 mm). Grades of initial packing and cement filling were classified according to Gie et al[5] as excellent, good, fair, poor and defective. We also graded the later appearance of the grafts according to Gie et al[5] as no change, progress of radiolucent lines (RLLs), localised resorption, cortical repair and trabecular remodelling. Radiographs of hips with cancellous graft adjacent to cement were difficult to interpret, so these headings were empirical only.[5] Subsidence of the stem was measured according to the method of Fowler et al,[29] using the tip of the greater trochanter as the reference point. Subsidence was classified as minimum (< 5 mm), medium (between 5 mm and 10 mm), and massive (> 10 mm). Radiological failure was defined as a circumferential RLLs in all seven Gruen zones[30] on the AP view.[10] All measurements were corrected for magnification using the known dimensions of the femoral head.

Operative fractures were categorised radiologically according to Farfalli, Buttaro and Piccaluga[31] as: fractures of the greater trochanter, proximal vertical cracks; metaphyseal fractures; intra-operatively diagnosed complete diaphyseal fractures or incidental perforations. Diaphyseal fractures and stem perforations that were not diagnosed pre-operatively but identified post-operatively were included in the radiological analysis.

Statistical analysis. Qualitative data are expressed as counts and percentages and quantitative data by mean and standard deviation (SD) or range. Kaplan-Meier survivorship analysis, with 95% confidence intervals (CI), was used to estimate the cumulative probability of not having a further revision for any reason in the entire series of 81 hips in relation to different defect grades.[32] Kaplan-Meier survivorship analysis was also used to estimate the cumulative probability of not having a further revision of the for aseptic loosening, in 76 hips after excluding five stems revised for intra-operative complications. Differences in survival

Fig. 1a

Fig. 1b

Fig. 1c

Fig. 1d

Radiographs of a 44-year-old man a) at presentation with a loose cementless total hip prosthesis performed for arthritis secondary to an acetabular fracture, b) anteroposterior radiograph of the same hip one year after revision, c) anteroposterior and d) lateral radiographs 17 years post-operatively, showing a stable stem and trabecular remodelling.

Table III. The Merle D'Aubigné and Postel[26] clinical results by bone defect[25] (mean values (SD))

	Bone defect				
	Grade 2	**Grade 3**	**Grade 4**	**Total**	**p-value***
Pre-operative score					
Pain	2.6 (0.51)	2.5 (0.51)	2.4 (0.67)	2.5 (0.05)	0.573
Function	2.3 (0.44)	2.2 (0.42)	2.2 (0.40)	2.2 (0.42)	0.267
Range of movement	2.2 (0.41)	2.1 (0.36)	1.9 (0.22)	2.1 (0.35)	0.054
Post-operative score					
Pain	5.9 (0.22)	5.9 (0.49)	5.3 (1.3)	5.8 (0.79)	0.004
Function	5.7 (0.44)	5.7 (0.59)	4.9 (1.37)	5.5 (0.91)	0.005
Range of movement	5.4 (0.75)	5.5 (0.67)	4.5 (1.17)	5.2 (0.95)	< 0.001
Patients using crutches	-	1	7	8	< 0.001†
Patients with limp	2	5	15	22	< 0.001†
Length discrepancy (mm)	0.4 (0.62)	0.5 (0.88)	1.3 (0.91)	0.7 (0.91)	< 0.001

* Mann-Whitney U test, unless otherwise stated
† Pearson chi-squared test

were determined using the log-rank test. Qualitative data were compared with use of the chi-squared test and quantitative data were compared with use of the Kruskal-Wallis test. The level of significance was p-value < 0.05. Statistical analysis was performed using the statistical package SAS 9.1 (SAS Institute Inc., Cary, North Carolina).

Results

The final Merle D'Aubigné and Postel clinical score was higher for type 2 bone defects than type 4 regarding pain, function and range of movement. At the most recent follow-up evaluation 75 hips (92.6%) were pain-free or had mild pain (Fig. 1), three (3.7%) moderate pain and three (3.7%) severe pain and limitation. The number of patients requiring the use of crutches or who limped and the extent of leg-length discrepancy were higher in type 4 than the other groups (Table III). With the number of available hips no significant differences were found in post-operative pain, function and range of movement (p = 0.541, 0.750 and 0.402, respectively, Mann-Whitney U test). Failures included six post-operative femoral fractures, three non-diagnosed stem perforations, one non-diagnosed intra-operative femoral fracture adjacent to the tip of the stem, one hip with aseptic loosening and one deep infection (Table IV). All 12 patients requiring re-operation for any cause had type 3 or type 4 bone defects. No patient with a type 2 defect required re-operation. At 14 years, the Kaplan-Meier analysis for cumulative probability of not having a re-operation for any cause for the whole series was 81.8% (95% CI 72.2 to 91.5). In relation to different grades of bone defect, at 14 years, the cumulative probability of not having a re-operation for any cause was 100% for

Table IV. Intra-operative complications and bone defects[25]

	Bone defect				
	Grade 2	Grade 3	Grade 4	Total	p-value*
Greater trochanter fracture	4	10	2	16	0.353
Proximal vertical cracks	1	2	4	7	0.143
Metaphyseal fracture	1	2	5	8	0.045
Diaphyseal fracture or stem perforation	-	2	6	8	0.003
Non-diagnosed intra-operative fracture	-	-	1	1	0.595
Non-diagnosed stem perforation	-	1	2	1	0.232

* Pearson chi-squared test

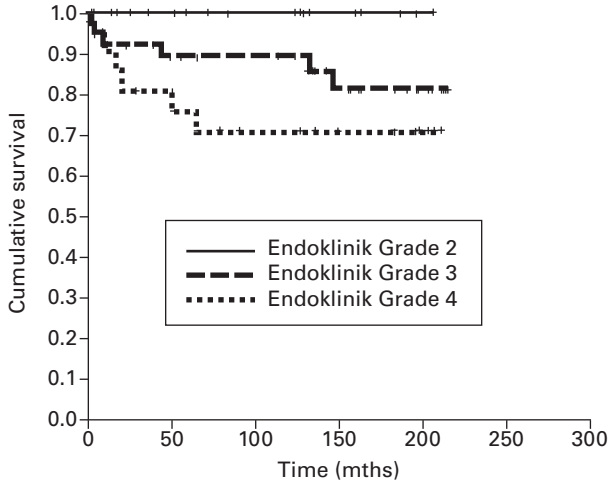

Fig. 2

Kaplan-Meier survivorship curves showing the cumulative probability of not having a re-operation for any reason for each classification of bone defects.

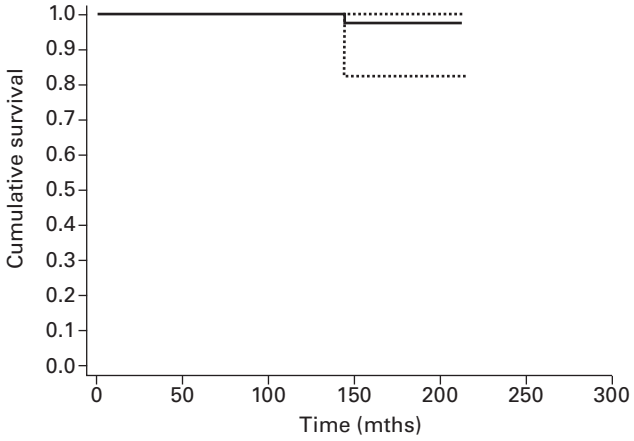

Fig. 3

Kaplan-Meier survivorship curves with 95% confidence intervals showing the cumulative probability of not having a revision of the femoral stem for aseptic loosening.

Table V. Radiological findings showing the graft status by bone defect[25]

	Bone defect				
	Grade 2	Grade 3	Grade 4	Total	p-value
Initial graft packing					
Excellent	11	18	5	34	0.054*
Good	8	16	10	34	
Fair	1	1	3	5	
Poor or defective	-	5	3	8	
Later appearance of the grafts[5]					
No change	1	1	2	4	†
Progress of radiolucent lines	-	1	1	2	
Localised resorption	1	3	2	6	
Cortical repair	1	5	5	11	
Trabecular remodelling	16	29	11	56	
Not evaluated (due to diaphyseal mesh)	-	-	2	2	

* Kruskal-Wallis test
† analysis was not performed due to the small number of cases

type 2, 81.2% (95% CI 67.1 to 95.3) for type 3, and 70.8% (95% CI 51.1 to 90.5) for type 4 (p = 0.0751, log-rank test) (Fig. 2). If we excluded the five revised stems for surgical complications from the whole series, the cumulative probability of not having a further revision for aseptic loosening was 98.6% (95% CI 95.8 to 100) (Fig. 3).

Technique-related complications. Metaphyseal and diaphyseal femoral fractures were more frequent in patients with type 4 defects. All intra-operative fractures occurred during the removal of cement at the beginning of the use of this technique. These were all treated by cerclage wires. In one patient an unrecognised femoral fracture occurred at the level of the tip of the stem; it was treated non-operatively and healed with some varus malalignment. Although the stem was stable with bone graft remodelling, the stem was revised at 63 months post-operation because of discomfort at the level of the femoral deformity. The three hips with an incidental femoral perforation detected post-operatively were revised. There were six post-operative femoral fractures sustained in a fall (7.4%), three occurred at the tip of the stem and all had poor or defective initial graft packing, and in three the fracture was distal to the tip of the prosthesis (Vancouver type C fractures[33]). No fracture was associated with loosening of the stem; all were treated successfully with open reduction and plate fixation without femoral revision and all healed in less than six months.

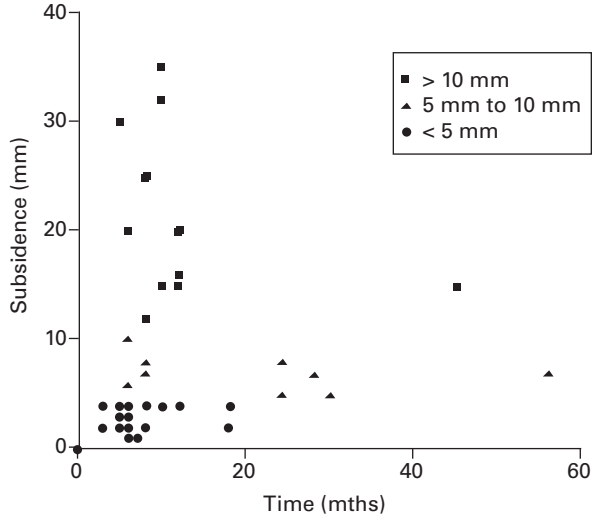

Fig. 4

Scatter-plot showing the post-operative duration for the appearance of stem subsidence (< 5 mm; 5 mm to 10 mm; and > 10 mm).

There were 62 stems positioned in neutral, three in varus and 16 in valgus. Although radiological interpretation was not always easy as the viability of the impacted graft adjacent to the cement and its capacity for remodelling were unclear, RLLs were very infrequent but were present in nine hips. In two hips (the hip with aseptic loosening and the infected hip) the lines were progressive and circumferential. The initial graft packing was excellent or good in 64 hips (79%) and was better in type 2 defect hips than in the other types. Graft remodelling was difficult to assess as metallic mesh often obscured these interfaces. However, trabecular incorporation was seen in 56 hips (69%). Cortical healing was found in 11 hips in which cortical bone had been compromised at the time of impaction grafting. Localised resorption was found in six hips. No definite change or a difficulty in interpreting the appearances, such as when obscured by mesh or cement, was noted in six hips (Table V). The mean subsidence of the stem was 2.3 mm (SD 3.7) for hips with a type 2 defect, 4.3 mm (SD 7.2) for type 3 and 9.6 mm (SD 10.8) for type 4 ($p = 0.022$, Kruskal-Wallis test). A total of 57 stems (70.4%) had migrated < 5 mm, 12 (14.8%) had migrated between 5 mm and 10 mm and 12 (14.8%) had migrated > 10 mm. Massive migration was more frequent in hips with a type 4 defect. Migration < 5 mm was seen within the first six months after the operation (mean 3.2 months, SD 4.3), while migration between 5 mm and 10 mm was seen at 17.5 months (SD 15.5) and > 10 mm migration at a mean of 19.8 months (SD 27.3) after surgery ($p < 0.001$, Kruskal-Wallis test). The mean time of appearance of the stem subsidence for the whole series was 7.8 months (SD 14.1) (Fig. 4). Despite the migration, these patients were asymptomatic with remodelling of the grafts.

Discussion

Whilst impacted bone grafting and cement have been used successfully in femoral revision surgery[5-10,13,14] it is essential that the graft is fully contained within the medullary canal. Histological studies have shown that allografts are largely replaced by viable cortical bone with bone remodelling and at least partial restoration of bone stock after revision surgery.[17,19,20,34] The tight packing of bone graft and cement may help to stabilise the entire composite in conjunction with radial compressive loads of appropriate magnitude produced by a polished and tapered stem while offering the potential to restore bone stock around the arthroplasty.[19] The key to success with this procedure is intra-operative stability of the stem, especially in torsion.[5] However, different authors report that femoral impacted bone grafting is technically demanding and time-consuming with frequent complications such as femoral fractures and stem subsidence,[35,36] although aseptic loosening has been notably uncommon.[7,9,10,37]

As in other series,[5-14] our results show a good clinical result and a good radiological fixation in most hips. No significant differences were found between the number of previous revisions and the final clinical outcome in this series. Pain, function and range of movement were better in type 2 than in type 4 defects and no type 2 hip required re-operation. Despite good results reported using lateral cortical strut grafts,[38] these were not used in this series. Different authors support the view that metal meshes do not affect the viability of the bone grafts.[5,10,34,39] Bolder et al[39] in an animal study in goats, report that wire mesh allowed more revascularisation than a strut in impaction grafting. Biopsies obtained from two patients at 24 and 33 months after the revision with impacted bone graftings contained by metal mesh at the calcar showed reparative changes after revascularisation similar to the findings reported in allograft contained by cortical host bone.[34]

With impacted bone grafting, complications are relatively frequent, including trochanteric-related problems, femoral canal perforations or intra-operative fractures during removal of the cement. In our series, there were no complications in patients with type 2 bone defects. Vigorous packing of the graft is essential to ensure stability of the stem but carries the risk of intra-operative fracture.[8,10,23] Although a number of both intra- and post-operative complications have been described, many have been shown to be of little or no consequence to the long-term results[31,40] and aseptic loosening is notably uncommon.[7,10,37] Intra-operative fractures and incidental perforations are frequent complications during the initial experiences with impacted bone grafting and are associated with removal of the cement rather than the reconstructive technique, so this complication is usually technique-related and should be avoidable with adequate pre-operative planning.[30,41] In contrast, post-operative femoral fractures are less likely to be related to the technique and more to the poor quality of the bone. There is an increased risk of periprosthetic

fractures in patients who had an incidental perforation during surgery and in those with severe bone defects.[31] Fractures usually occur distal to a standard-length stem in an area of weakened bone that has been left inadequately supported.[37] No fracture was associated with loosening of the stem, but all were treated successfully with open reduction and plate fixation without femoral revision. Two strategies have been adopted to reduce the incidence of femoral fractures: the use of cortical struts[8,31] and of longer stems.[7,37] However placement of cortical onlay requires extensive stripping of the femur, may adversely affect the blood supply to bone, and thus may affect revascularisation of the graft.[42] Although an Exeter standard-length stem has been used in most cases, since 1998 a long stem has been used in cases with a severe distal bone loss to bypass the bone deficiency and avoid a periprosthetic fracture.[37,43]

The appearance of the graft is difficult to interpret radiologically. We found evidence of trabecular remodelling in 56 hips (69%) and cortical healing in 11 hips where there had previously been some cortical compromise. Graft remodelling has been confirmed in most series.[5,9,10,12] There has been no focal femoral lysis. In an *in vitro* study it was found that BMP-7 is released from fresh-frozen femoral head cancellous bone in proportion to the strain applied to the bone.[44] It has been suggested that the impaction process itself may contribute to the biological process of remodelling and bony incorporation. Allograft remodelling has previously been reported[17-20] and angiogenesis and new bone formation around the femoral component after impacted bone grafting have also been found in positron emission tomography studies.[21] Concern has been expressed about subsidence of the stem in femoral impacted bone grafting[5,23,45,46] but it does not seem to correlate with clinical results.[5] Gokhale et al[45] report that most subsidence occurs during the first three months after surgery and that age, femoral canal diameter, stem design and density of the graft at the tip of the stem all affected subsidence. The small but continued subsidence reported by Wraighte and Howard[11] may represent creep occurring within the cement. However, Eldridge et al[22] reported massive early subsidence in 11% of patients and consider it predictive of early failure. Wraighte and Howard[11] reported that the pre-operative bone defect had a significant correlation with long-term subsidence. The major factor in controlling subsidence has been stated to be good surgical technique, with the use of larger bone chips in capacious canals, tighter compaction of these chips, and in cases with severe bone loss, the use of longer stems.[7] Most of the subsiding stems in our series were inserted during the first years of our experience or were in hips with type 3 or 4 bone defects and poor cement packing.

There were several limitations to our study. The primary limitation is the relatively small cohort available due to the infrequency of the procedure. We performed no analysis of inter- and intra-observer variability for the radiological measurements. The investigating surgeon studied the radiographs and entered the data on the day of assessment in the clinic. Additionally manual radiological measurement of the subsidence of the stem is less accurate than other methods used in different series such as computer assisted technologies.[35,47,48] We lacked a control group of patients with similar ages and femoral defects who were operated on with other techniques with which to compare our observations. Finally, we also lack biopsies and autopsy retrieval of femora reconstructed with this technique to confirm the bone graft remodelling and new bone formation.

We conclude, however, from our experience that the impacted bone grafting technique with the X-change femoral revision system and the Exeter stem provides good clinical results. The benefits of predictable relief from pain support the continued use of this technique because of its potential to restore bone stock. However, major bone defects affect the outcome and also result in more operative complications. Careful attention to the technical details and the use of long-stemmed prostheses may help reduce the incidence of complications.

Supplementary material

Tables showing the data of hips requiring re-operation for any cause and the radiological subsidence of the stem by bone defect are available with the electronic version of this article on our website at www.jbjs.org.uk

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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