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Migration of the femoral stem after impaction bone grafting

FIRST RESULTS OF AN ONGOING, RANDOMISED STUDY OF THE EXETER AND ELITE PLUS FEMORAL STEMS USING RADIOSTEREOMETRIC ANALYSIS

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We report the initial results of an ongoing randomised, prospective study on migration of the Exeter and Elite Plus femoral stems after impaction allografting, as measured by radiostereometry.

Clinically, the impaction technique gave good results for both stems. The mean subsidence in the first year was 1.30 mm and 0.20 mm for the Exeter and the Elite Plus stems, respectively. In the second year, the Exeter stem continued to subside further by a mean of 0.42 mm, while the Elite Plus stem did not do so. Subsidence of the Exeter stem correlated with deficiency of bone stock as graded on the Gustilo and Pasternak scale. This correlation was not found for the Elite Plus stem. None of the other parameters which were studied predisposed to subsidence. There was no significant association between the amount of subsidence and the radiological appearance of the graft for either stem. Our findings do not support the theory that radial compression, due to subsidence of the Exeter stem, is the essential stimulus for remodelling in impaction allografting.

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Impaction allografting is one of the techniques which is used to address deficiency of femoral bone stock in revision total hip surgery. Gie et al[1] were the first to describe this technique, using the double-tapered polished Exeter stem. Because of its design, it generates radial compressive forces as it subsides within the cement mantle and these were considered to be the critical factor for remodelling of the graft into viable bone.[1,2] Early reports on impaction grafting showed favourable radiological and good clinical results.[1,3] Recent articles, however, have raised concern about the incidence and amount of subsidence of double-tapered polished stems when used with impaction grafting.[4-7] Marked subsidence has been associated with fracture of the cement mantle[6] and early failure.[8-10]

Impaction grafting has been increasingly used with other designs of femoral stem. Some are known to subside less than the Exeter stem in primary total hip arthroplasty.[11] These may also be more stable with impaction grafting and this may be an advantage in severely deficient femora in which marked subsidence of the Exeter stem has been seen. It is not known, however, whether less subsidence is associated with less remodelling of the graft.

We therefore initiated a randomised, prospective study to evaluate the influence of subsidence on the remodelling process. Using radiostereometry (RSA), we studied the patterns of movement of the Exeter stem (Stryker Howmedica Osteonics, Amersfoort, The Netherlands) and of the matt-surfaced flanged collared Elite Plus stem (Johnson & Johnson, Haarlem, The Netherlands) which is designed not to subside when used with impaction grafting. We also studied the influence of various factors on subsidence, particularly deficiency of bone stock. RSA is a reliable method of assessing migration and prosthetic design[12,13] and has been advocated for the evaluation of new prostheses and surgical techniques.[11] We present the results of this ongoing, prospective randomised study of the first 22 patients of whom 14 had had follow-up for two years.

Patients and Methods

Between 1998 and 2000, 24 consecutive patients underwent cemented revision total hip arthroplasty with impaction bone grafting of the femur. All agreed to participate in the study and were assigned at random, using sealed envelopes, to receive either an Exeter or an Elite Plus stem. The tantalum markers could not be imaged adequately in one patient, and one suffered a traumatic femoral fracture distal to the prosthesis. Thus, 22 patients, 11 with each stem, remained for RSA analysis. There were 12 women and ten men with a mean age of 69 years (30 to 83) and a mean weight of 76 kg (54 to 110) at the time of surgery. The

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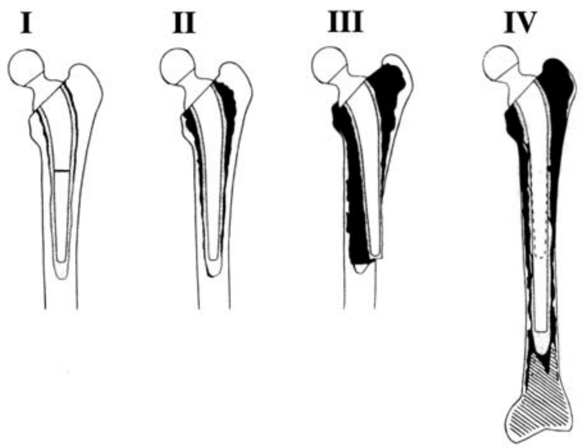

Fig. 1

Diagram showing the Endo-Klinik classification of femoral defects as follows: type I, radiolucent zone confined to the upper half of the cement mantle with clinical signs of loosening; type II, radiolucent zone around the cement mantle and endosteal erosion of the upper femur leading to widening of the medullary cavity; type III, widening of the medullary cavity by expansion of the upper femur with proximal bone loss and perforation; and type IV, gross destruction of the upper and middle thirds of the femur with damage to the distal third and loss of support.

indication for revision was aseptic loosening with severe femoral defects precluding a cemented revision procedure for all patients except one, who had a Girdlestone excision arthroplasty after the removal of an infected prosthesis in 1979. For 17 patients this was the first revision procedure, and for five it was the second. The original diagnoses were primary osteoarthritis in 13 patients, post-traumatic avascular necrosis of the femoral head in three, hip dysplasia in three, fracture of the neck of the femur treated by hemiarthroplasty in two, and necrosis of the femoral head secondary to steroids in one.

Before operation, deficiency of the bone stock was scored radiologically on the Endo-Klinik scale[14] as type I (two hips), type II (ten), type III (eight) and type IV (two) (Fig. 1). During the operation and before impaction, the defects were scored on the scale of Gustilo and Pasternak[15] as type I (two hips), type II (ten) and type III (ten) (Fig. 2). After randomisation there were no significant differences between the two groups with regard to age, weight and bone deficiency on both classifications, the preoperative Harris hip, RAND and Brooker scores, leg-length discrepancy or the Trendelenburg sign.

Operative technique. One surgeon (FCvB) performed all operations using the technique described by Gie et al.[16] A lateral approach with trochanteric osteotomy was used. After removal of the prosthesis, all cement, debris and fibrous membrane, an acrylic plug was placed at least 2 cm distal to the most distal defect. When the plug had to be placed beyond the isthmus, a screw or Kirschner wire was placed transversely to prevent its distal migration. A bone mill was used to produce bone chips of about 5 mm from fresh-frozen femoral heads. No defatting of the graft by rinsing was done. The femur was reinforced with mesh and cerclage wires in three patients, and the calcar was reconstructed with mesh and cerclage wires in 11. Bone chips were inserted and impacted into the femur with either the Elite Plus or the Exeter X-change instrumentation. An Elite Plus or an Exeter stem with a 28 mm head was introduced with erythromycin and colistin-soaked Simplex cement (Stryker Howmedica Osteonics). The greater trochanter was reattached using the technique described by Wroblewski and Shelley.[17] Tantalum markers of 0.8 mm were injected into the femoral cortex, three distal to the level of the trochanteric osteotomy, three into the lesser trochanter and two into the lateral femoral cortex distal to the prosthesis. The first six Elite Plus stems were marked during the operation by the cementing of two tantalum markers onto the shoulder region of the stem and two onto the tip, while the other five Elite Plus and all Exeter stems had been premarked by the manufacturer.

Postoperatively, the patients remained on bed rest for three weeks. Antibiotics (cephamandol nafate) were given during and after the operation for two days and anticoagulants for three months. After three weeks, non-

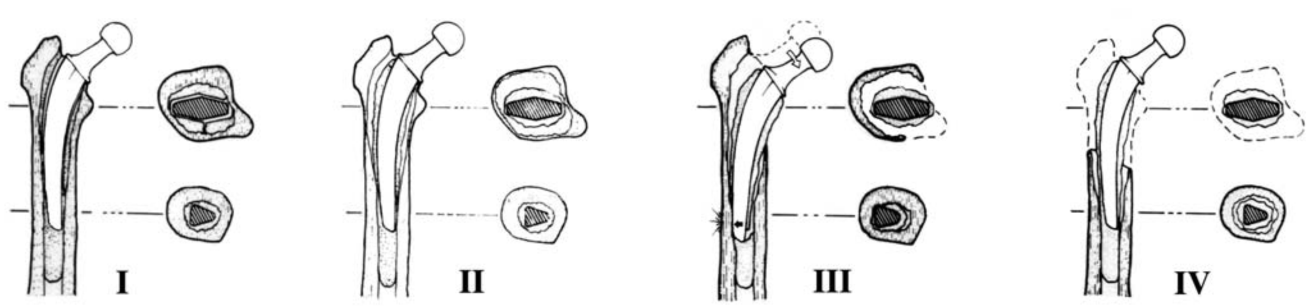

Fig. 2

Diagram showing the Gustilo and Paternak classification[15] of femoral defects as follows: type I, cement-prosthesis interface failure with <50% thinning of proximal cortices and the circumferential wall intact; type II, cement-prosthesis interface failure with >50% thinning of proximal cortices, enlargement of the canal and circumferential wall intact; type III, posteromedial bone loss; and type IV, proximal circumferential bone loss.

weight-bearing mobilisation started and gradually proceeded to full weight-bearing at six months.

Radiostereometric analysis. RSA examinations were performed at one, six and 12 weeks, six months and one year after operation for all stems and at two years for six Elite Plus and eight Exeter stems, using the uniplanar technique with the patient supine.[12] The radiographs were covered by grids in order to avoid fogging from the simultaneous exposure. The relative positions of the markers were sent to a Pentium PC by scanning the radiographs manually with a CCD camera attached to the moving arm of a high-precision measurement table. A software package (WinRSA) was used for the mathematical computations (software and measurement table: Tilly Medical Products, Lund, Sweden). We calculated the translations of the heads and of the tips of the prostheses. Subsidence of the tips was taken as 'true' subsidence, since it is least influenced by rotations.

In order to assess reproducibility we repeated the RSA examination after ten minutes on one occasion during follow-up for all patients.[13] No migration of the stems should be seen between these films and any migration which was detected represented noise in our system. Limits below which 99% of all errors of measurement fall were calculated as advocated by Ranstam, Ryd and Onsten.[18] These values were 0.18 mm (tip) and 0.31 mm (head) for transverse migration, 0.18 mm (tip) and 0.17 mm (head) for subsidence, and 0.38 mm (tip) and 0.46 mm (head) for anteroposterior migration. These values can be used as cut-off points for individual measurements. To quantify the agreement between the double examinations, intraclass correlation coefficients (ICC) were calculated. These were 0.95 (tip) and 0.96 (head) for transverse migration, 0.98 (tip) and 0.99 (head) for subsidence, and 0.59 (tip) and 0.97 (head) for anteroposterior migration. These high values indicate excellent agreement between the examinations.

Radiological evaluation. Standard anteroposterior radiographs were taken before and after operation. We assessed the bone graft in the seven zones of Gruen, McNeice and Amstutz[19] according to the guidelines of Gie et al,[1] while distinguishing between four basic appearances as advocated by Linder.[20] Heterotopic ossification was graded according to Brooker et al.[21]

Clinical evaluation. Harris hip scores[22] and SF-36 health-related quality-of-life scores[23] were measured before and one year after operation. The SF-36 outcome measure consists of 36 questions in eight fields: general health, mental health, vitality, physical function, social function, pain, physical impairment and emotional impairment. Van der Zee and Sanderman[24] translated the test into Dutch and tested its validity and reliability. Any complications, leg-length discrepancy and the presence of the Trendelenburg sign were also recorded.

Table I. Mean migration (mm; range) of the Exeter and the Elite Plus stems*

	Exeter		Elite Plus	
	Tip	**Head**	**Tip**	**Head**
Medial				
1-year	0.0 (-0.20 to 0.21)	0.29 (-0.48 to 1.58)	-0.12 (-0.40 to 0.31)	1.10 (0.36 to 3.88)
2-year	0.10 (-0.15 to 0.35)	0.50 (-0.46 to 1.16)	-0.05 (-0.36 to 0.32)	1.03 (0.34 to 1.82)
Distal migration				
1-year	1.30 (0.77 to 2.22)	1.51 (0.88 to 2.39)	0.20 (0.03 to 0.36)	0.76 (0.21 to 3.24)
2-year	1.72 (0.96 to 2.97)	1.99 (1.16 to 3.21)	0.22 (0.11 to 0.36)	0.74 (0.43 to 0.99)
Anterior				
1-year	0.28 (-0.13 to 0.42)	-0.19 (-1.50 to 1.33)	0.11 (-0.22 to 0.86)	-1.90 (-0.21 to –4.99)
2-year	0.30 (0.15 to 1.43)	0.02 (-0.98 to 2.86)	0.02 (-0.03 to 0.22)	-2.05 (-0.82 to –5.91)

*one-year values based on 11 Exeter and 11 Elite Plus stems, two-year values based on 8 Exeter and 6 Elite Plus stems

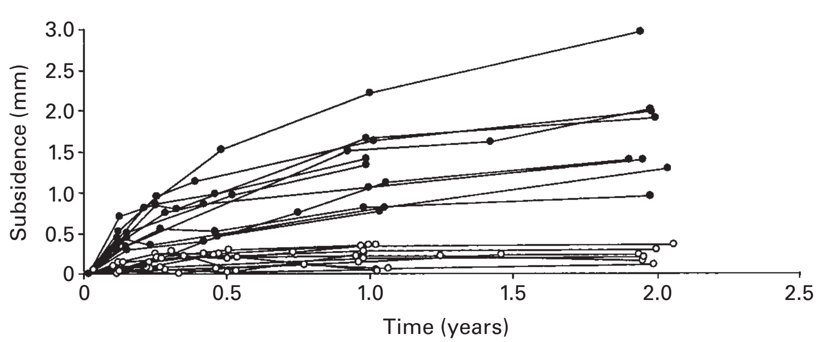

Fig. 3

Graph showing subsidence per patient of the Exeter and the Elite Plus prostheses (● Exeter; ○ Elite Plus).

Statistical evaluation. Continuous or ordinal data were compared between groups using the Mann-Whitney U test and within groups using the Wilcoxon test. The relationship between continuous variables was assessed using Pearson's correlation coefficient. Percentages were compared between and within groups by the chi-squared and McNemar tests, respectively.

Results

RSA analysis. The mean subsidence of the Exeter stem was significantly greater at one ($p = 0.0001$) and two years ($p = 0.002$) than that of the Elite Plus stem (Table I). During the second year, the mean subsidence of the Exeter stem was 0.42 mm ($p = 0.008$) while the Elite Plus stem showed no significant subsidence ($p = 0.22$; Fig. 3). At one year, the mean subsidence of the femoral head was significantly greater than that of the tip (Exeter, $p = 0.033$ and Elite Plus, $p = 0.003$), a finding which can be explained by varus alignment or by rotation around the transverse axis. Varus alignment is suggested by the fact that all the femoral heads except one migrated medially relative to the tip. One Exeter femoral head migrated laterally relative to the tip and this was the only prosthesis in which the tip subsided more than the head. Because of the geometry of the stems, valgus alignment of less than approximately 15° will tend to 'elongate' the stem. At one year, medial migration of the head was significantly greater ($p = 0.013$) for the Elite Plus than for the Exeter femoral head. In the second year, it increased slightly for both prostheses although not significantly (Exeter, $p = 0.11$ and Elite Plus, $p = 0.16$).

All Elite Plus femoral heads had migrated posteriorly at one year. The Exeter heads migrated significantly less posteriorly ($p = 0.002$). Eight Exeter heads had migrated posteriorly by a mean of 0.55 mm (0.19 to 1.50), and three anteriorly by 0.26, 0.70 and 1.33 mm. In the second year, anteroposterior migration of the Exeter and of the Elite Plus femoral heads did not change significantly ($p = 0.95$ and $p = 0.31$).

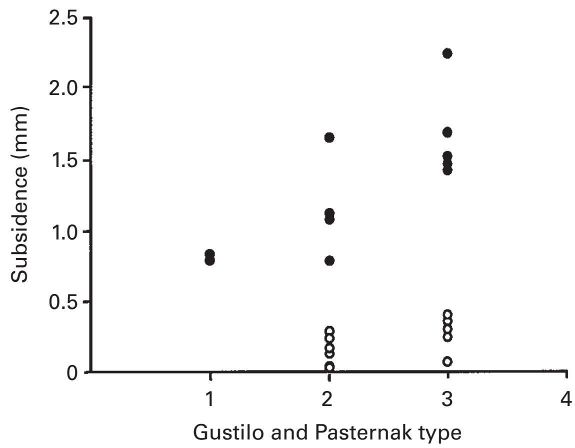

Fig. 4

Graph showing subsidence values at one year plotted against the type of defect on the Gustilo and Pasternak classification[15] (● Exeter; ○ Elite Plus).

Subsidence at one and two years did not correlate with age, weight, clinical pre- or postoperative leg-length discrepancy, the amount of bone graft which was used, or the Endoklinik scale, in either group (all p values >0.23). Subsidence did, however, correlate with femoral deficiency on the Gustilo and Pasternak scale only for the Exeter stem (Fig. 4). At one and two years, the correlations for these stems were, respectively, $r = 0.76$, $p = 0.007$ and $r = 0.80$, $p = 0.02$.

Radiological results. Complete radiological evaluation of the graft was not always possible, especially for the 14 hips in which metal meshes had been used. Graft packing on the postoperative films was excellent in all patients. At one year, we were able to evaluate 83% (146/176) of the zones of Gruen et al[19] (Fig. 5a). Cortical repair was seen in 23% (34/146) of the visible zones. Trabecular incorporation was

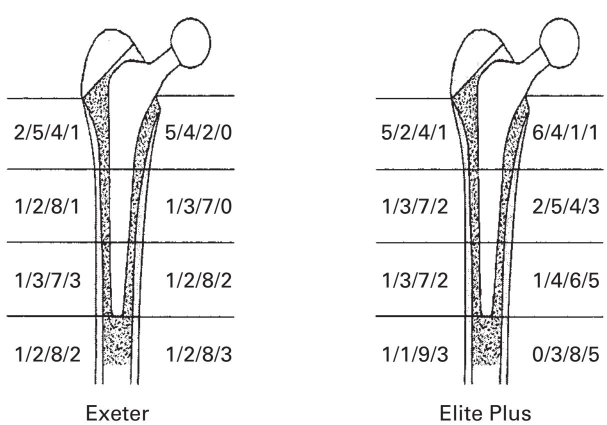

Fig. 5a

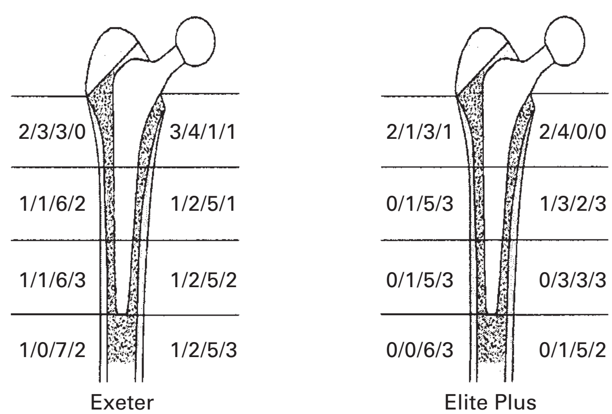

Fig. 5b

Change in appearance of the graft a) at one and b) at two years after operation compared with immediately after operation (not visible/trabecular incorporation/trabecular remodelling/cortical repair).

Table II. Harris hip scores and SF-36 scores per category. The mean values are presented as well as the p values of the changes of the one-year scores compared with baseline within both groups

		SF-36							
	HHS	General health	Mental health	Physical function	Social function	Pain	Role, emotional	Role, physical	Vitality
Exeter									
Preop	47	66	62	36	58	39	77	14	48
1-year postop	84	64	69	58	71	82	67	42	60
p-value	0.003	0.7	0.3	0.02	0.03	0.008	0.3	0.05	0.07
2-year postop	90	55	65	63	66	81	53	30	58
Elite									
Preop	53	67	76	35	60	41	48	28	58
1-year postop	85	79	82	73	89	88	87	70	72
p-value	0.003	0.05	0.6	0.01	0.01	0.005	0.2	0.03	0.2
2-years postop	88	70	82	61	68	84	93	65	64

seen in 33% (48/146) and trabecular remodelling in the remaining 67% (98/146). The mean percentage of zones with remodelling was 69 and 65 for the Exeter and the Elite stems, respectively (p = 0.43). The bone-graft interface had faded in 94% (137/146) of the visible zones, and was sharp in the remaining 6% (9/146).

At two years, we were able to evaluate 86% (96/112) of the zones of Gruen et al[19] (Fig 5b). Cortical repair was seen in 33% (32/96) of the visible zones. Trabecular incorporation was seen in 30% (29/96) and trabecular remodelling in the remaining 70% (67/96). The mean percentage of zones with remodelling was 72 and 67 for the Exeter and the Elite stems, respectively (p = 0.78). The bone-graft interface had faded in 99% (95/96) of the visible zones, and was sharp in the remaining 1% (1/96). During the second year, four zones around Elite Plus stems and five zones around Exeter stems changed from incorporation to remodelling.

No significant relationships could be detected between the radiological appearance of the graft at one or two years and the amount of subsidence, or with migration in any direction of the femoral head, for either stem.

At one year, bony union of the greater trochanter was seen in 16 patients and fibrous union in five. One trochanteric fragment had completely avulsed. The cerclage wires had broken in seven patients. No change occurred between one and two years.

Before operation, heterotopic ossification was absent in 11, was grade I in six, grade II in two and grade III in three hips. One year after operation it was absent in 12, grade I in six, and grade II in four; no hip was in grade III. No change occurred between one and two years. The scale of Brooker et al[21] was similar at one and two years in both groups (p = 1.0 and p = 0.545).

No debonding of the stem-cement interface, no fractures of the cement and no radiolucencies were seen in either group. In the Exeter group one stem had been placed in varus (8°) and one in valgus (5°). Remarkably, this was not the stem which showed evidence of valgus deviation.

Clinical results At one year, the mean Harris hip score had improved significantly within each group (Elite Plus, p = 0.003 and Exeter, p = 0.003) (Table II). The improvements did not differ significantly between the groups (p = 0.66). The Harris hip scores did not change significantly between one and two years (Elite Plus, p = 0.85; Exeter, p = 0.66). The SF-36 scores for pain and physical and social functioning improved significantly in both groups and did not change significantly between one and two years.

All patients except one were able to walk at least one kilometre without symptoms one year after the operation. One patient could not walk more than 10 metres because of severe cardiopulmonary symptoms. At two years, they remained able to walk at least one kilometre without symptoms.

Of the 16 patients with a positive Trendelenburg sign before operation, 13 could elevate the pelvis for more than ten seconds one year after the operation. Six patients had a negative Trendelenburg sign before as well as after the operation. No change in abductor function occurred between one and two years. Of the five patients with fibrous union of the site of the osteotomy only one had a positive Trendelenburg sign. The patient with an avulsed trochanteric fragment had an obvious positive Trendelenburg sign.

The mean leg-length discrepancy improved from 2 cm (0 to 5.5) to 0.7 cm (0 to 2.5) and was similar for both stems (p = 0.95).

A mean amount of 97 g (41 to 170) of bone was impacted during the operation. The amount of bone did not correlate with the deficiency in bone stock on either classification and was similar in both groups (p = 0.37).

Complications. There were systemic complications in seven patients; five cases of infection of the urinary tract, one of delirium and one of myocardial infarction. One patient was readmitted with local haemorrhage six weeks after the operation. The bone graft in the proximal femur showed trabecular incorporation without signs of loosening of the stem in the patient whose femur had been plated because of a traumatic fracture.

No hip has dislocated and none required further surgery.

Discussion

Stability of the stem in revision total hip surgery can be achieved by impacting particles of graft into the proximal femur.[25,26] Remodelling of the graft gives secondary stability. This is a heterogeneous process, characterised histologically by fibrous ingrowth, resorption of the dead graft, inactivity, deposition of bone and trabecular remodelling.[20,27-29] It is thought that radial compression of the graft and host bone resulting from subsidence of the tapered stem, is the essential stimulus for this process,[1,2] but adverse effects of subsidence of this type of stem with impaction grafting have been described recently. Masterson et al[6] reported subsidence of more than 10 mm in 20% of stems and Meding et al[7] reported a mean subsidence of 10.1 mm in 38% of stems. Another study reported early symptomatic subsidence of more than 10 mm necessitating a further revision in 10% of stems.[4] Subsidence of stems by more than a certain amount has been associated with thigh pain,[4] aseptic loosening,[30] dislocation,[6] and an increased requirement for revision.[8,9,31] In a previous study, we reported good results using the Exeter stem even with severely defective femora.[5] However, 33% showed subsidence of more than 5 mm and 19% more than 15 mm. Because of the adverse effects of subsidence, a non-subsiding stem may be preferable when using impaction grafting. In our study, the mean subsidence in the first postoperative year of the Elite Plus stem was 0.20 mm, while that of the Exeter stem was 1.30 mm. Moreover, in the second year the Elite plus stem did not subside significantly, while the Exeter stem continued to subside, albeit at a slower rate.

No relationship could be detected between the amount of subsidence and the radiological appearance of the proximal femur for either stem. Although the graft around both stems was loaded, no additional effect on the remodelling process was seen with the subsidence of the Exeter stem. These findings do not support the theory that radial compression due to subsidence of the Exeter stem, is the essential stimulus for remodelling. Osteoinductive properties of the graft, via growth factors, and osteoconductive properties, via the matrix, probably play an equally important role in the remodelling process as does loading.[32] It should be noted, however, that the radiological evaluation of the bone graft is not only very arbitrary,[29,33] but also that the correlation with histological changes is unclear.[20]

All the stems except one showed evidence of varus deviation, the Elite Plus stem significantly more than the Exeter stem. Posterior migration of the Elite Plus femoral head was significantly greater than that of the Exeter head. Theoretically, posterior migration of the femoral head can be explained by rotation around the transverse or longitudinal axes. Rotational stresses on the stem are considerable.[34] Therefore, the difference in posterior migration between the two types of stem is probably caused by rotation around the longitudinal axis. Because of its rounded shape, the Elite Plus stem could be more susceptible to these forces.

The pattern of distal, medial and posterior migration of the femoral head is similar to that reported in three other published RSA studies on impaction grafting,[35-37] and an additional three studies on primary stems.[11,38] Quantitative comparison of the amount of migration in these studies, however, is precluded by differences in the patient population, operative technique, postoperative mobilisation protocols and the time interval before the initial examination.[37]

We found a strong correlation between the Gustilo and Pasternak[15] scale and subsidence of the Exeter stem at one and two years. This was not found for the Elite Plus stem. The polished double-tapered Exeter stem may be more susceptible to deficiencies in the proximal femur because of its expansive character with subsidence. No other influence on subsidence could be identified.

In both stems improvement of the Harris hip and social scores was seen as well as disappearance of the Trendelenburg sign and leg-length discrepancy. There are no studies on the long-term results of the impaction technique, but Leopold et al[33] reported survival of 92% at six years for a precoated, collared stem, with aseptic loosening as the endpoint. These initial results show that impaction grafting with both the Exeter and the Elite Plus stem gives good clinical and radiological results. The latter may have the advantage of less subsidence, which was not found to be influenced by the degree of deficiency of bone stock.

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