Cement migration after THR

A COMPARISON OF CHARNLEY ELITE AND EXETER FEMORAL STEMS USING RSA

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Studies using roentgen stereophotogrammetric analysis (RSA) have shown that the femoral components of cemented total hip replacements (THR) migrate distally relative to the bone, but it is not clear whether this occurs at the cement-implant or the cement-bone interface or within the cement mantle. Our aim was to determine where this migration occurred, since this has important implications for the way in which implants function and fail.

Using RSA we compared for two years the migration of the tip of the stem with that of the cement restrictor for two different designs of THR, the Exeter and Charnley Elite. We have assumed that if the cement restrictor migrates, then at least part of the cement mantle also migrates.

Our results have shown that the Exeter migrates distally three times faster than the Charnley Elite and at different interfaces. With the Exeter migration was at the cement-implant interface whereas with the Charnley Elite there was migration at both the cement-bone and the cement-implant interfaces.

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Roentgen stereophotogrammetric analysis (RSA) can be used to measure accurately the movement of an implant relative to bone in three dimensions. All studies of the femoral components of cemented total hip replacements (THR) have shown that implants migrate relative to the bone.[1-4] With satisfactory implants migration is rapid initially and then slows.[5] In those which are going to fail early, rapid migration continues after the initial phase.[6] There is, however, little information about where this migration occurs. It may take place at the interface between the cement and bone or the cement and implant, or it may be the result of creep in the cement. The site of the migration is important since it influences the mechanism by which failure occurs.

It is generally believed that some femoral stems, such as the Charnley, do not sink within the cement mantle whereas others, such as the Exeter, do, but there have been no detailed studies of this migration. The Charnley THR has an excellent long-term survival rate.[7,8] The Charnley Elite was developed from the Charnley. It is, however, different from the original Charnley and has no published long-term results. It has a small collar, and in some cases a flange, to help to compress the cement and to prevent the implant migrating within it. The surface has a 'vaquasheen' finish, which is matt. There are clinical reports on the Exeter stem for up to 16 tears,[9] but no long-term published data on survival.[10] The Exeter has a smooth polished, collarless tapered stem which allows it to subside within the cement. Both implants are made of stainless steel.

If the early migration is low, the implant will probably be satisfactory in the long term. It is therefore generally believed that designs of implants which have high mean rates of migration are likely to give unsatisfactory long-term function. Kobayashi et al[11] have recommended that implants migrating more than 0.4 mm at two years should not be used because they are likely to have a high failure rate. This recommendation was based on studies of implants that have not been designed to migrate within the cement and may not be appropriate for implants such as the Exeter.

Our aim was to determine the migration of the implant and the cement mantle for the Exeter and Charnley Elite stems. This was achieved by measuring the migration of both the tip of the prosthesis and the radiopaque marker in the cement restrictor.

Patients and Methods

Using RSA we studied 26 patients with 26 THRs. Fourteen had a cemented Exeter femoral component (Howmedica International Ltd, London, UK). There were seven women and seven men with a mean age at operation of 66 years (57 to 77). Twelve had a Charnley Elite prosthesis (DePuy

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International Ltd, Leeds, UK). There were six women and six men with a mean age at operation of 69 years (55 to 78). All the patients had osteoarthritis. The Charnley Elite group was collected first followed by the Exeter patients. The operations were done by a number of different surgeons who used both implants. In all cases an anterolateral approach was used and CMW cement (DePuy International Ltd, Leeds, UK) was inserted with a gun. Cement restrictors and stem centralisers were used according to the manufacturers' guidelines. All arthroplasties were satisfactory at the time of the latest follow-up.

RSA system. Our current RSA system is an improved version of that described by Kiss et al.[3] We now use a more accurate calibration frame and digitising tablet. For analysis, improved algorithms and p-matrix rather than digital linear transformations are used.

At the time of operation, pairs of 0.8 mm tantalum marker balls were inserted into the bone in the greater trochanter, lesser trochanter and distal to the tip of the prosthesis. All the patients had cement restrictors in which radiopaque markers had been incorporated. We used Hardinge cement restrictors (DePuy International Ltd) for the Charnley Elite prosthesis and Exeter restrictors, in which 0.8 mm tantalum markers had been cemented, for the Exeter implant. Patients were mobilised fully weight-bearing as soon after the operation as possible.

For RSA, the patients stood weight-bearing within a calibration frame which contained accurately positioned radiopaque markers. The stereo X-rays were angled at 60° and were perpendicular to the X-ray films. The radiographs were taken consecutively to allow lead shutters to be placed in front of the unexposed film in order to prevent fogging. The first RSA examination was carried out at one to two weeks after operation when the patient was safe to stand with crutches. Subsequent examinations were undertaken at approximately 3, 6 and 12 months and then annually. Some examinations were missed or had radiographs that could not be analysed.

The system uses a digitising tablet with a nominal accuracy of 50 μm. The portion of the films to be digitised was imaged by a magnifying CCD camera, which is rigidly attached to the cursor of the digitiser. Its output was fed into the input of a video capture card (Screen Machine II, FAST Electronics Ltd, Germany) housed in a Pentium PC. From the images of the calibration markers on each radiograph, the position of the X-ray tubes and plates in space was calculated. The position of the marker balls in the bone was then determined. Using geometrical algorithms, based on those which we have previously described,[3] the positions of the head, shoulder and tip of the prosthesis were determined in space. These algorithms allow femoral stems to be studied without the need for markers attached to the prostheses. The position of the radiopaque marker in the cement restrictor was also assessed. To determine migration, two sets of pairs of stereo radiographs were analysed. A femoral axis system was defined by the marker balls in the femur and the femoral axes on the two sets of radiographs were then fitted. The positions of the balls were compared to determine if any had moved. If this had occurred the ball was ignored. An optimisation routine was used to match the remaining balls precisely. The relative movement of the component was then determined, assuming it to be a rigid body, and converted to an axis system defined by the implant.

For this study, the migration of the tip and the cement restrictor were determined in distal, medial and anterior directions. Mean migrations were calculated by comparing radiographs taken postoperatively with those taken at approximately 3, 6, 12 and 24 months after the operation. For statistical analysis we used the *t*-test, paired when appropriate. We have previously demonstrated, using Monte Carlo methods, that tests of this type are appropriate.[5]

Accuracy. In a previous study using our old calibration frame, we repeated the stereo radiographs in seven patients on two separate occasions to assess the accuracy of the system.[3] For ethical reasons we have not repeated this but we have reanalysed the radiographs with our new equipment. We express accuracy as two standard deviations of the differences between the positions of the implant. For the tip of the prosthesis, the accuracy was 0.35 mm proximally to distally, 0.28 mm medially to laterally, and 0.28 mm anteriorly to posteriorly. We expect the accuracy to be better with the improved calibration frame used in this study. In the study of accuracy, patients did not have radiopaque markers in the cement restrictor and we did not therefore know the accuracy of assessing these. Since the markers are well-defined, however, it is likely to be substantially better than for the tip.

Results

Exeter prosthesis. The tip of the Exeter prosthesis migrated rapidly distally during the first year by 1.06 mm ($p < 0.0001$, 95% confidence interval (CI) 0.77 to 1.36). After the first year its distal migration slowed and by the end of the second year it had migrated 1.20 mm ($p = 0.03$, 95% CI, 0.15 to 2.23). The cement restrictor did not move distally significantly over this period of time (Fig. 1). The distal migration of the tip was significantly larger than that of the cement restrictor ($p = 0.001$ at 3 months; $p = 0.001$ at 6 months; $p < 0.0001$ at 1 year; $p = 0.1$ at 2 years).

The tip of the Exeter prosthesis migrated medially reaching 0.4 mm ($p = 0.009$, 95% CI, 0.13 to 0.74) at one year (Fig. 2). The cement restrictor did not move significantly in this direction. There was no significant migration of either the tip or the cement restrictor in the anteroposterior direction (Fig. 3).

Charnley Elite prosthesis. The tip of the Charnley Elite prosthesis migrated distally rapidly for the first six months reaching 0.32 mm ($p = 0.03$, 95% CI, 0.06 to 0.59). After

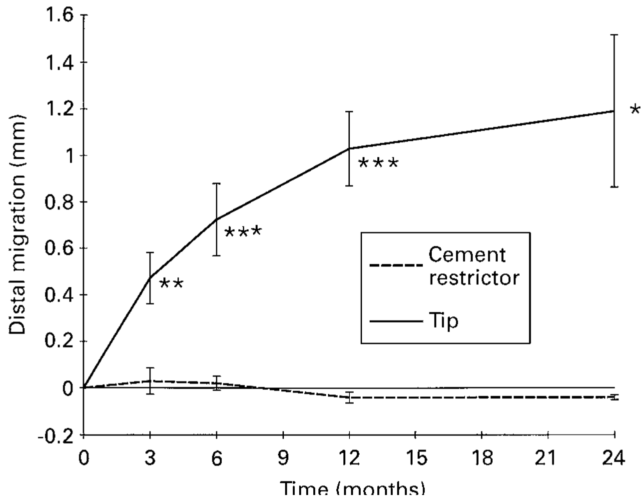

Fig. 1

Mean distal migration of the cement restrictor and tip of the Exeter prosthesis. Error bars give the SEM (*p < 0.05;**p < 0.01; ***p < 0.001).

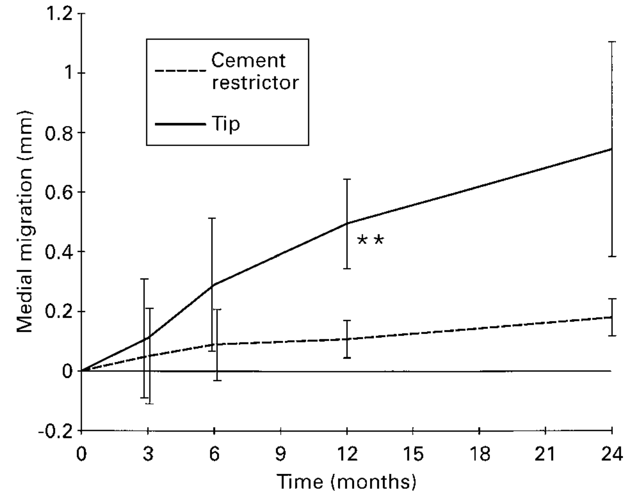

Fig. 2

Mean medial migration of the cement restrictor and tip of the Exeter prosthesis. Error bars give the SEM (**p < 0.01).

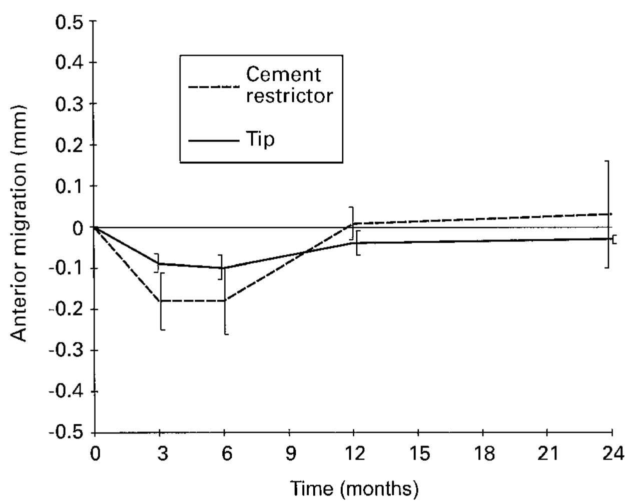

Fig. 3

Mean anterior migration of the cement restrictor and tip of the Exeter prosthesis. Error bars give the SEM.

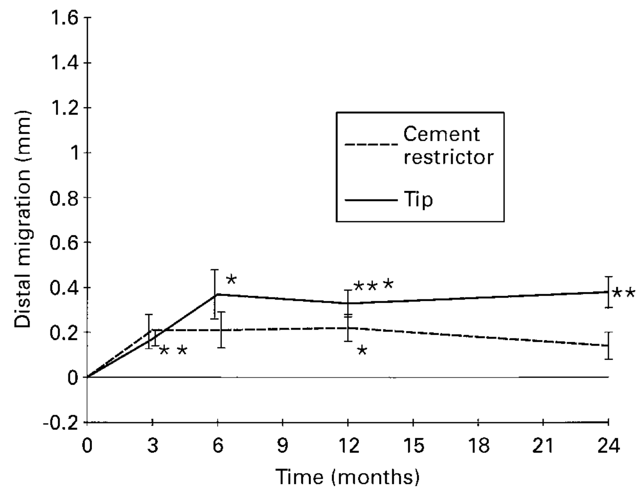

Fig. 4

Mean distal migration of the cement restrictor and tip of the Charnley prosthesis. Error bars give the SEM (*p < 0.05;**p < 0.01; ***p < 0.001).

that there was little further distal migration and by the end of the second year it had migrated 0.38 mm. The cement restrictor migrated at about the same rate as the tip for three months and then stabilised. At one year, the cement restrictor had migrated distally 0.19 mm (p = 0.01, 95% CI, 0.05 to 0.34) and the tip of the Charnley Elite prosthesis 0.32 mm (p = 0.0003, 95% CI, 0.19 to 0.46). The migration of the cement restrictor was significantly less than that of the tip of the prosthesis in the period studied (p = 0.1 at 6 months; p = 0.09 at 1 year; p = 0.015 at 2 years) (Fig. 4).

The tip of the Charnley Elite prosthesis migrated medially 0.5 mm (p = 0.016, 95% CI, 0.11 to 0.88) during the first year and by two years it had migrated 0.65 mm (p = 0.02, 95% CI 0.12 to 1.17) (Fig. 5). There was no significant movement of the cement restrictor medially, or of the tip or the cement restrictor in the anteroposterior direction (Fig. 6).

Discussion

We have studied the migration of radiopaque markers incorporated in the cement restrictor to assess the migration of the cement mantle. If the cement restrictor is not migrating it is reasonable to assume that there is no movement between the cement mantle and the bone. By contrast, if the cement restrictor does move, then either the whole cement mantle is moving relative to the bone or the cement mantle is fractured transversely and only part of it is moving.

Our study has shown that the pattern of migration of the cement mantle is different for the two implants. For the Exeter, there was significant migration of the implant yet there was no migration of the cement restrictor, suggesting that all migration occurred at the cement-implant interface. For the Charnley Elite, there was significant migration of

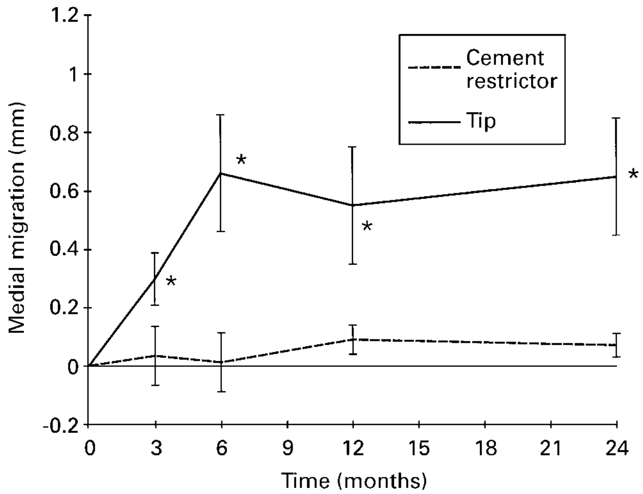

Fig. 5

Mean medial migration of the cement restrictor and tip of the Charnley prosthesis. Error bars give the SEM (*$p < 0.05$).

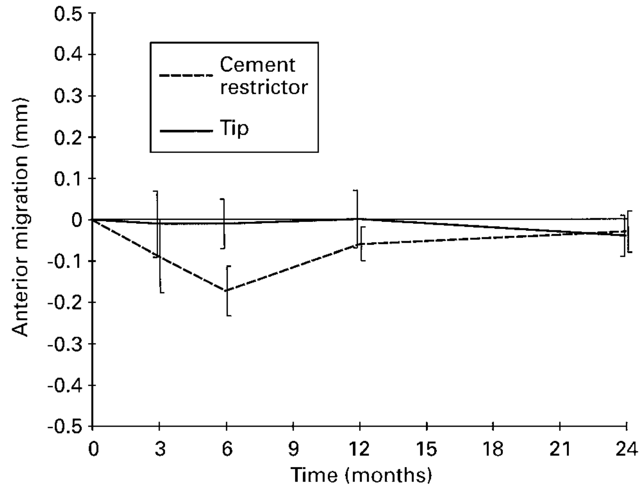

Fig. 6

Mean anterior migration of the cement restrictor and tip of the Charnley prosthesis. Error bars give the SEM.

both tip and cement restrictor, but the migration of the tip was significantly more than that of the cement restrictor. This suggests that for the Charnley Elite there was migration at both cement-bone and cement-implant interfaces. For both implants the migration slowed after the first year.

The site of early migration is important. Migration at the cement-bone interface, as occurred with the Charnley Elite, may interfere with fixation and lead to long-term failure. The consequence of migration at the cement-implant interface depends on the design of the implant. With a polished tapered device such as the Exeter, migration at the cement-implant interface is probably not harmful and may be advantageous[12] since it will expand the cement mantle and reinforce the cement-bone interface. By contrast, with devices such as the Charnley Elite which are not designed to sink within the cement mantle, such sinkage may not be ideal. Furthermore, if the implant has a rough surface, particles may be generated at the cement-implant interface.

The finding of medial migration of 0.5 mm at one year of the tip of the Charnley Elite and Exeter prostheses is important and is difficult to explain. Some finite-element models of THR suggest that the forces at the tip would tend to make the tip migrate laterally, rather than medially.[13,14] This questions the validity of these studies.

RSA studies are useful for predicting the outcome of a prosthesis in an individual and assessing a design of implant in a group of patients. Kobayashi et al[11] have suggested that a new design of prosthesis will have a high failure rate if its mean rate of migration for the first two years after implantation is more than 0.4 mm as assessed by uniplanar radiographs. This guideline is inappropriate since we have shown that the mean distal migration of the Exeter, which is an implant with good results, at two years is 1.2 mm, which is substantially more than 0.4 mm. If recommendations are to be made, then the algorithm will have to be more complex and take into account possible rapid migration between implant and cement. For implants not designed to migrate, 0.4 mm of distal migration in two years may be a reasonable cut-off since this is the mean migration for the Charnley Elite. We believe that RSA is essential to assess migration of this order. The accuracy of uniplanar systems, when assessed rigorously, is a few millimetres, which is not sufficient.[15] Furthermore, with RSA it is possible to assess migration in three dimensions.

We therefore recommend that new implants should be studied by RSA and their migration compared with that of established prostheses. The migration of the cement mantle should be assessed as well as the implant.

Conclusions

1. The site of migration of a cemented femoral component can be assessed using RSA with marker balls in the cement restrictor. It has implications in regard to how an implant functions and fails. Migration at the cement-bone interface may interfere with fixation. The significance of migration at the cement-implant interface depends on whether the implant is designed to subside within the cement mantle or not.
2. The Exeter femoral stem migrates on average 1 mm distally during the first year at the implant-cement interface. In addition, the tip migrates medially 0.4 mm during the first year.
3. The Charnley Elite stem migrates distally 0.3 mm during the first year. This migration occurs at both implant-cement and cement-bone interface. In addition, the tip of the prosthesis migrates medially 0.5 mm in the first year.

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