In vivo failure analysis of intramedullary cement restrictors in 100 hip arthroplasties

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Background We occasionally noticed excessive distal plug position in our clinical routine of cemented hip arthroplasties. We therefore performed an analysis of risk factors for migration of a biodegradable intramedullary gelatine plug.

Patients and methods The performance of a cement restrictor was studied in 100 consecutive cemented total hip arthroplasties implanted with third-generation cementing techniques. In a radiographic analysis anatomical parameters, cement mantle quality, and mechanisms and factors for restrictor failure were evaluated.

Results 40 restrictors showed inadequate performance: 5 cases of tilting, 22 cement leakages, 16 excessive migrations, 2 excessive migrations plus leakages, and 1 case of leakage plus tilting. Excessive migration (> 5 cm) was more common in large intramedullary canals ($p = 0.04$) and cement leakage was more common in patients with a proximally located isthmus ($p = 0.04$). Half of the hips showed a complete or almost complete filling of the intramedullary cavity, which was more often found in operations carried out by experienced surgeons.

Interpretation A more reliable plug design should be considered for patients with wide intramedullary canals and a high isthmus, to minimize the risk of plug migration and poor cement mantle quality.

For adequate cement interdigitation, the use of a distal intramedullary cement restrictor (plug) is essential in order to obtain high cement pressures (Markolf and Amstutz 1976, Bannister and Miles 1988, Bean et al. 1988). Plug performance should be consistent and reliable, but comparative clinical studies have shown high variability between different designs and materials (Thomsen et al. 1992, Bulstra et al. 1996, Visser et al. 2002). Even well-controlled biomechanical tests have confirmed that there is a high variability in plug performance with regard to stability and occlusion of the intramedullary cavity (Prendergast et al. 1999, Danter et al. 2000, Heisel et al. 2003).

In our clinical practice, we noted varying distal plug position. Despite the fact that there has been a long interest in cementing technique, to the best of our knowledge there has been no published study describing attempts to analyze risk factors for plug migration or failure of biodegradable intramedullary gelatine plugs.

Patients and methods

Cemented THA was performed in 100 consecutive patients (75 women). The preoperative diagnoses were osteoarthritis in 78 hips, femoral neck fracture in 10, osteonecrosis in 3, and there were miscellaneous diagnoses in 9. The straight, polished MS-30 stem (Zimmer, Muensingen, Swizerland) with a ceramic-on-polyethylene bearing (Aesculap, Tuttlingen, Germany) was implanted. Palacos Refobacin bone cement was used in all patients. 44 THAs were done by inexperienced orthopedic surgeons and 56 by experienced orthopedic surgeons (> 100 THAs/year). Modern cementing techniques including the use of a distal, biodegrad-

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Figure 1. Biodegradable intramedullary gelatine plug (IMSET; Aesculp, Tuttlingen, Germany). In its design and material properties, the plug is comparable to the Biostop G cement restrictor (DePuy Orthopaedics, Blackpool, England).

able intramedullary gelatine plug (IMSET; Aesculp, Tuttlingen, Germany) (Figure 1), cleansing of the femoral canal by the use of jet-lavage, and proximal pressurization with a femoral seal were used in all operations. In its design and material properties, the IMSET plug is comparable to the Biostop G cement restrictor (DePuy Orthopaedics, Blackpool, England). 18 intramedullary canals were blocked with IMSET plug size 8, 12 with size 10, 35 with size 12, 32 with size 14, 2 with size 16, and 1 with size 18. All surgeons aimed to place the cement restrictor 1 cm below the tip of the stem using the original intramedullary testing probes and measurement tools.

Radiographic analysis

The apex of the lesser trochanter was used as a fixed point for all measurements. Vertical femoral offset (D), distance between lesser trochanter and isthmus (C), diaphyseal width at isthmus (B), metaphyseal width 2 cm above lesser trochanter (A), and femoral diameter 10 cm below lesser trochanter were measured preoperatively on anteroposterior radiographs of the pelvis. Canal flare index (A/B) was calculated (Noble et al. 1988) (Figure 2). Vertical femoral offset was then re-measured on radiographs taken at the first postoperative follow-up evaluation. Distance between the lesser trochanter and the tip of the prosthesis and between the tip of the prosthesis and the cement restrictor were evaluated. All anteroposterior radiographs were measured in random order and coded regarding patient and operation information. All measurements were adjusted for magnification using femoral head diameter as a reference. In addition, the femoral diameter and vertical femoral offset of the contralateral side were measured on the preoperative radiograph and compared with those measured on the postoperative radiograph.

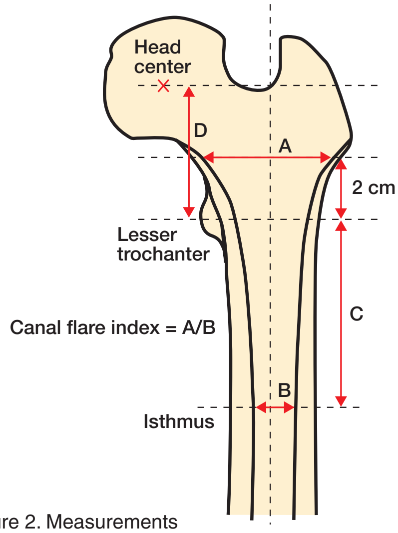

Figure 2. Measurements

Cement mantles were classified according to Mulroy and Harris (1996) as grade A (complete filling of the intramedullary cavity of the femoral diaphysis with cement), grade B (a slight radiolucent line at the cement-bone interface), grade C1 (a more extensive radiolucent line encompassing 50–99% of the cement-bone interface or voids in the cement), grade C2 (a thin mantle of cement measuring < 1 mm at any site or a defect in the mantle with direct prosthesis-bone contact), or grade D (a radiolucent line encompassing 100% of the cement-bone interface on any radiograph, or no cement distal to the tip of the stem, or multiple defects or large voids in the cement mantle). Radiolucent lines at the cement-bone and prosthesis-cement interfaces were recorded for Gruen zones 1–7.

Plug tilting and cement leakage distal to the plug were assessed and three groups of plug performance were defined. We defined migration as the difference between the plug position attempted intraoperatively (see above) and the plug position achieved, as measured postoperatively. The first group ("stability") was defined as plug position less than 2 cm below the stem tip, the second group ("moderate migration") as plug position from 2 to 5 cm below the stem tip, and the third group ("excessive migration" = failure) by plug position more than 5 cm from the stem tip.

Ethics

Measurements and assessments were performed on the basis of regular postoperative follow-up radiographs. No additional radiographic examinations were necessary. The treatment of the patients was in no way altered as a result of the investigation.

Statistics

Variables were analyzed and t-tests, analysis of variance (ANOVA), and chi-square tests were used for group comparisons as required for different types of data. Correlation was calculated using correlation coefficient or Kendall's tau. All tests were two-sided, and a p-value < 0.05 was considered significant. All analyses were done by a statistician using SPSS for Windows version 12.0.

Pre- and postoperative radiographic measurements, mean (range) in mm

	Preoperative measurements	Postoperative measurements
Vertical femoral offset (D)	58 (38–92)	63 (42–103)
Distance between lesser trochanter and isthmus (C)	108 (53–148)	
Diaphyseal width at isthmus (B)	12 (8–18)	
Metaphyseal width 2 cm above the lesser trochanter (A)	39 (27–67)	
Calculated canal flare index (A/B)	3.4 (2.2–5.0)	
Distance between lesser trochanter and tip of the prosthesis		82 (53–104)
Distance between tip of the prosthesis and cement restrictor		34 (0–105)

Results

The vertical offset increased by a mean of 5.0 mm after stem implantation. The calculation of the canal flare index revealed 30 stovepipe intramedullary canals, a normal shape in 68, and 2 champagne-flute canals (Table).

The mean position of the plugs was 34 (0–105) mm below the tip of the prosthesis, 10 (-35–143) mm below the isthmus, and 116 (79–185) mm below the lesser trochanter.

Tilting and leakage

There was cement leakage in 22 cases, with a greater risk in patients with larger-sized cement plugs (p = 0.02, 95% CI: 0.25–2.31) and a proximally located isthmus (p = 0.04, 95% CI: 0.36–13.92). The mean distance between lesser trochanter and isthmus was 102 (82–128) mm for leaking plugs and 109 (79–148) mm for plugs that did not leak.

In addition, in 5 cases the cement restrictors were tilted; there was a higher risk of tilting with decreased distance between prosthesis and plug (p = 0.02, 95% CI 3.0–28). The mean distance between prosthesis and plug was 15 (0–27) mm for tilted plugs and 35 (0–105) mm for plugs that were not tilted.

Neither leakage nor tilting adversely affected the quality of the cement mantle.

Distal plug position

There were 21 plugs in the "stability" group, 63 in the "moderate migration" group, and 16 in the "excessive migration" group. The tendency for distal plug position was higher in patients with a wide isthmus (p = 0.04, 95% CI: 0.07–1.8) and resulted in a higher risk of cement mantle defects (p = 0.02). The risk of excessive plug migration was 0.09 in patients with an isthmus diameter of less than 10 mm, 0.14 for a diameter between 10 and 13 mm, and the risk rose to 0.27 for isthmus diameters greater than 13 mm.

40 plugs showed inadequate performance (16 excessive migrations, 22 leakages, 5 tiltings, 2 excessive migrations plus leakage, and 1 leakage plus tilting).

Cement grading

We found a cement mantle quality of grade A in 20 patients, grade B in 33, C1 in 20, C2 in 26, and grade D in 1 patient (Figure 3). 62 cement mantles had no radiolucent lines, 26 had 1 defect zone, and 12 had 2 defect zones. Cement mantle defects for Gruen zones 1–7 are shown in Figure 4. We found better cement mantle quality (p = 0.01) and fewer radiolucent lines (p = 0.004) in operations carried out by experienced surgeons. There was no correlation between the experience of the surgeon and plug position or plug tilting.

The risk of occurrence of cement mantle defects was 0.63 in the "stability" group and 0.76 for

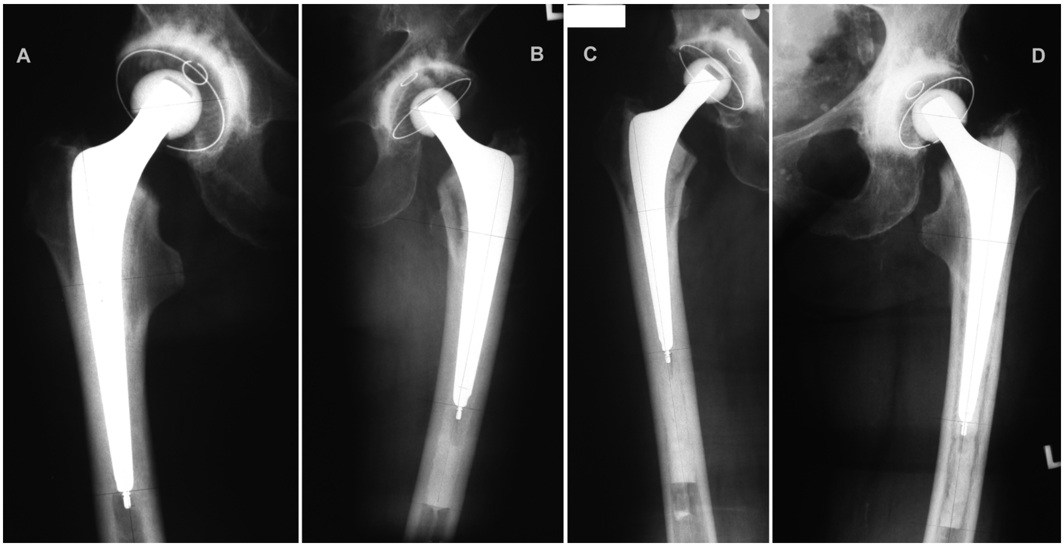

Figure 3. A. Centralizer plug contact; no cement distal to tip of the stem; grade D cement mantle. B. Leaking of plug and migration of 53 mm as a consequence of high pressurization cementing technique; complete filling of the intramedullary cavity; grade A cement mantle. C: Migration of 74 mm as a consequence of high pressurization cementing technique; slight radiolucent line at the tip of the prosthesis; grade B cement mantle. D. Poor cement mantle quality and migration of 53 mm; thin mantle of cement; radiolucent zones measuring < 1 cm; and defect in the mantle with direct prosthesis-bone contact grade C2.

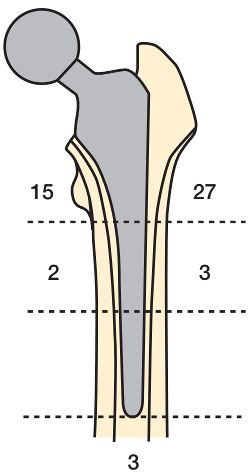

Figure 4. Cement mantle defects for Gruen zones 1–7.

"excessive migration" of plugs. The lowest risk, 0.38, was found in the "moderate migration" group. The cement mantle defects resulted in poorer cement mantle grading ($p < 0.001$).

Discussion

Only a firmly blocked intramedullary canal ensures an adequate cement "pressurizing technique", which increases the cement-bone interface pressure (Harris and McGann 1986), cement penetration (Oh et al. 1978, Bean et al. 1988) and shear strength (Markolf and Amstutz 1976, Benjamin et al. 1987, Bannister and Miles 1988).

Regardless of design and materials, in the ideal situation there should be no intramedullary cement leakage and plug migration during cement and stem insertion (Song et al. 1994, McCaskie et al. 1997). Various experimental studies have been published on the efficacy of intramedullary plugs (Oh et al. 1978, Lee and Ling 1981, Beim et al. 1989, Maltry et al. 1995, Prendergast et al. 1999, Yee et al. 1999, Heisel et al. 2003). Pressure measurements, testing of shear stresses, and examination of the effects of back bleeding have been done; a few comparative studies have analyzed the clinical outcome and performance of cement restrictors (Thomsen et al. 1992, Bulstra et al. 1996, Visser et al. 2002).

In this study, we concentrated on different clinical and anatomical factors that may have an influence on plug migration or failure. We found the extent and percentage of migrating cement restrictors to be high, but similar to the results for gelatine plugs in other clinical studies (Visser et al. 2002, Ilizaliturri, Jr. et al. 2004). The rate of distal plug positioning had a significant and adverse affect on the occurrence of cement mantle defects. The experience of the surgeon had a direct effect on cement mantle quality in our series, irrespective of plug stability. We found the lowest risk of poor cement grading in the "moderate migration" group, defined as having a distal plug position of 2–5 cm, and not in the "stability" group. This finding may be misleading at first sight. It should be noted that most of the tilted plugs and all centralizer plug contacts were found in the "stability" group, and this may have worsened cement grading. However, moderate plug migration of this cement restrictor design can be regarded as a logical and "normal" consequence of good high-pressurization cementing technique in these cases. Excessive plug migration (> 5 cm) was clearly associated with poorer cement grading irrespective of the surgeon's experience. This finding suggests that even experienced surgeons may be unable to create and maintain adequate intramedullary cement pressure in cases where the plug is found to migrate excessively.

Some parameters are beyond the surgeon's control. There was a correlation between instability of the plug and increasing intramedullary diameter at the isthmus. Consequently, large plugs showed a higher frequency of leakage than smaller ones. These results make sense, if we take in account that the force on the plug surface increases with the square of the intramedullary radius. Furthermore, even in a large canal the friction between plug and femoral cortex depends on the chosen plug oversize. Also, the number of 30 stovepipe femora with larger canals and no distinctive isthmus certainly had an influence on plug stability.

Apart from large canal diameter, we also found a correlation between cement leakage and a proximally located isthmus. A plug position that has to be chosen below the isthmus can be regarded as a reason for the frequency of incomplete occlusions with cement leakage in these cases.

There was also a correlation between tilting of the plug and short distance between plug and tip of the prosthesis. These are obvious results because there is a high risk of distal stem centralizer-to-plug contact and pinning damage in these cases. Initial proximal malplacements and/or pulling back of the plug when the insertion device is removed are the most obvious explanations.

It is important to point out some weaknesses of our study. We had no intraoperative recording of the plug position before introduction of the cement and stem. Thus, we had to define migration based on the intraoperative attempt to place the restrictor 1 cm below the stem tip. Measurements of migration distance might therefore be influenced by possible initial malplacements; true migration is unknown. Since there is no consistent definition of plug failure in the literature, the wide definition of "stability", and "moderate migration" and also the narrow definition of "excessive migration" (= failure) with a migration distance of over 5 cm was chosen in order to ensure that no possible initial malplacement would be classified as failure. We believe that it would also be possible to find more significant coherences between the shapes of the medullary canal and plug stability or cement mantle quality in a larger group of patients. All measurements were done on standardized anteroposterior radiographs. The results, especially the intramedullary diameter at the isthmus and cement grading, would have been different on lateral views. However, most of the measurements and anatomical landmarks would have been identical.

We found a correlation between plug failure and poorer cement mantle quality even with surgical experience. For this particular design of plug, some moderate plug migration seems inevitable and can be regarded as evidence of good cement pressurization. We recommend use of the spherical testing probe to measure the minimum intramedullar diameter of the oval femoral canal, and the choice of plug should be at least one size (2 mm) larger to ensure sufficient stability. A more reliable plug design should be considered for patients with wide intramedullary canals and/or high isthmus, which should give the surgeon a lower risk of poor performance and failure.

Contributions of authors

RGB: study concept/study design, literature search, data acquisition, data analysis and interpretation, manuscript drafting and revision for important intellectual content, approval of final version of submitted manuscript. SJB:

guarantor of integrity of the entire study, literature search, manuscript drafting and revision for important intellectual content; approval of final version of submitted manuscript. MT: guarantor of integrity of the entire study; literature search, manuscript drafting and revision for important intellectual content, approval of final version of submitted manuscript. SS: statistical analysis, approval of final version of submitted manuscript. CH: guarantor of integrity of the entire study; study concept/study design, literature search, data acquisition, data analysis and interpretation, manuscript drafting and revision for important intellectual content, approval of final version of submitted manuscript, manuscript editing.

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