Cement penetration and primary stability of the femoral component after impaction allografting

A BIOMECHANICAL STUDY IN THE CADAVERIC FEMUR

C. Albert, S. Patil, H. Frei, B. Masri, C. Duncan, T. Oxland, G. Fernlund

From The University of British Columbia, Vancouver, Canada

This study explored the relationship between the initial stability of the femoral component and penetration of cement into the graft bed following impaction allografting.

Impaction allografting was carried out in human cadaveric femurs. In one group the cement was pressurised conventionally but in the other it was not pressurised. Migration and micromotion of the implant were measured under simulated walking loads. The specimens were then cross-sectioned and penetration of the cement measured.

Around the distal half of the implant we found approximately 70% and 40% of contact of the cement with the endosteum in the pressure and no-pressure groups, respectively. The distal migration/micromotion, and valgus/varus migration were significantly higher in the no-pressure group than in that subjected to pressure. These motion components correlated negatively with the mean area of cement and its contact with the endosteum.

The presence of cement at the endosteum appears to play an important role in the initial stability of the implant following impaction allografting.

Failure of the femoral component in total hip replacement (THR) is often associated with a loss of bone stock in the proximal femur which can make revision procedures challenging. Impaction allografting is a technique that uses morsellised bone graft to reconstruct the femoral canal or acetabulum before a new implant is cemented in place. This procedure gained popularity over the last decade because of its potential for reconstitution of bone stock, which is particularly important when dealing with young patients with moderate to severe bone loss.

Impaction allografting is associated with several clinical problems, including a high prevalence of intra- and post-operative fractures and high levels of implant migration (> 10 mm). Although the mechanisms by which migration develops are not fully understood, inadequate compaction of the graft bed, defects in the cement mantle and absorption of the endosteal surface are believed to be contributing factors.

Many studies have shown radiological evidence of remodelling of the graft following impaction allografting. However, histological reports from autopsies and biopsies have revealed that the graft bed had not fully remodelled into viable bone, even up to eight years after the impaction allografting procedure. It has been shown in a cadaveric experiment that during femoral impaction allografting the penetration of cement into the graft bed is greater than expected, filling virtually the entire intramedullary canal at the level of mid-stem. Penetration of cement to the endosteal cortex is a limiting factor that prevents bone remodelling, as cement is not biodegradable. Therefore, a construct having reduced cement penetration, particularly in the proximity of the endosteal surface, may enhance local vascularisation and allow the formation of new bone in these cement-free areas. Results from a finite element analysis have suggested that lower levels of cement penetration could be achieved by reducing cement pressure or increasing its viscosity. A potential drawback of reducing cement penetration in impaction allografting is that the shear strength at the endosteal interface is lower in the absence of cement contact, which may lead to excessive migration of the stem. However, the importance of contact of the cement with the endosteal surface on the primary stability of the stem is not known.

This study aimed to examine the effect of the depth of cement penetration into the graft bed on the primary stability of the femoral stem after impaction allografting. We hypothesised that by not pressurising the cement a reduction in penetration would be achieved versus the conventional pressurised cementing technique.
We also hypothesised that there is a relationship between cement contact with the endosteum and the primary stability of the stem. We tested our hypotheses in the human cadaveric femur.

**Materials and Methods**

Impaction allografting was performed on eight pairs of human cadaveric femurs. The femoral heads were removed from the specimens and loss of bone was simulated with a high-speed burr. All the trabecular bone was removed from the proximal femur, and lytic defects were created in the cortical shell. The loss of bone achieved represented a class 2 defect according to the EndoKlinik classification system.24 Trabecular bone graft from 15 femoral heads and 15 femoral condyles was morsellised with a Lere bone mill (DePuy, Warsaw, Indiana), giving a particle size distribution of between 0.6 mm and 13 mm, with 50% by weight of the particles being smaller than 4 mm.21

The femurs were potted in dental stone (Tru-Stone, Heraeus Kulzer, Armonk, New York) at 13˚ of adduction and subjected to cyclical loading on a biaxial servohydraulic testing machine (Instron Model 8874, Instron, Canton, Massachusetts). The loads applied simulated 50% of expected walking loads (2500 cycles) followed by 100% of walking loads (5000 cycles). Two force components were applied sinusoidally at 1 Hz: a cranio-caudal component ($F_{cc}$) with peak values of 0.4 to 2.3 times body-weight, and an anteroposterior component ($F_{ap}$) with peak values of -0.1 to 0.3 times body-weight for the walking load cycles.25 The loads were scaled for a 70 kg individual, and the two components were phased such that their maximum peak values coincided. The $F_{cc}$ was applied at 13˚ from the longitudinal axis of the femur, resulting in a mediolateral component ($F_{ml}$) and a proximodistal component ($F_{pd}$) as shown in Figure 1. The anteroposterior load ($F_{ap}$) was applied with the rotary actuator by controlling the moment, with an offset of 32 mm between the femoral head and the line of action of the actuator.

The three-dimensional motion of the implant relative to the bone was measured at the reference point shown in Figure 1, using a custom-built system similar to designs used previously.26,27 The system, shown in Figure 2, consisted of six linear variable differential transformers (GCD-121-250, Shaevitz Sensors, Hampton, Virginia) mounted on an aluminium frame which was fixed rigidly to the femur with seven pyramid-tip set screws. In order to achieve adequate fixation of the screws to the femur, all local soft tissue was removed and the periosteal surface was sanded, cleaned with acetone, and sealed with cyanoacrylate. The set-screw-femoral interface was strengthened using polymethylmethacrylate (Lecoset, LECO Corp, St Joseph, Michigan). The sensors measured the motion of a triangle that was rigidly fixed to the lateral side of the implant, 5 cm below its shoulder, with a 5 mm square steel pin through a hole in the femur.

The relative motion between the implant and the bone was calculated from the measured motion of the triangle relative to the frame, using a custom program implemented in Matlab (MathWorks, Natick, Massachusetts). The measured motion was separated into migration (permanent) and micromotion (reversible), each of which had three translational components (posterio, lateral and distal), and three rotational components, (valgus/varus, flexion/extension, and retroversion/anteversion). Migration was defined as the dif-

<table>
<thead>
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<th>Specimen pair</th>
<th>Gender</th>
<th>Age (yrs)</th>
<th>Implant size used</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Male</td>
<td>85</td>
<td>1 EXT*</td>
</tr>
<tr>
<td>2</td>
<td>Female</td>
<td>84</td>
<td>1 EXT</td>
</tr>
<tr>
<td>3</td>
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<td>Unknown</td>
<td>2 EXT</td>
</tr>
<tr>
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<td>Male</td>
<td>56</td>
<td>1 EXT</td>
</tr>
<tr>
<td>5</td>
<td>Female</td>
<td>69</td>
<td>1 EXT</td>
</tr>
<tr>
<td>6</td>
<td>Male</td>
<td>52</td>
<td>2 EXT</td>
</tr>
</tbody>
</table>

* EXT, extended offset
The accuracy of the system in measuring translation was evaluated against a micrometer precision dial gauge by attaching the sensors to an overreamed composite femur (Model 3303, Pacific Research Laboratories, Vashon, Washington), and applying translations to the implant relative to the bone along each of the three axes. The mean error observed was 1.6 \( \mu \text{m} \) (0.0 to 5.8) in 12 translation measurements over a range of 200 \( \mu \text{m} \). The accuracy of each sensor was also measured. A maximum error of 2.2 \( \mu \text{m} \) was observed over a range of 450 \( \mu \text{m} \) (mean 0.8 \( \mu \text{m} \) (0.0 to 2.2) for 60 measurements). The accuracy of rotation was evaluated analytically from the maximum individual sensor errors, yielding a maximum rotation error of 0.004˚.

Non-parametric statistical analysis was used to compare the results between the two groups because the variances differed substantially between the groups for some of the motion components. Motion was compared between the pressure group and the no-pressure group using Wilcoxon’s matched-pairs tests, and a significance level of 0.05 was used. For the components that showed a significant difference between the pressure and no-pressure groups, linear regression models were used to examine the relationship between migration and micromotion.

After structural testing, the implant was removed and the cavity filled with coloured polymethylmethacrylate (LECO Corp). The femurs were cut into transverse cross-sections, 7 mm thick, with a diamond saw (model 310 CP, Exakt Apparatebau, Norderstedt, Germany). The levels of cross-
Cement contact = length of contact between area of the canal occupied by cement (cement area): cement with the endosteal surface (cement contact) and the penetration was characterised as the percentage of contact of the cement was measured using the Image-Pro 4.5 software. Penetrated bed. Each slide was photographed and the penetration of clearly the area of penetration of the cement within the graft was placed on a dark blue background, to distinguish more voids, and photographed with a digital camera (resolution 3.2 megapixels). The slides were placed on a light box to distinguish the graft from the ground to 200 µm, and stained with alizarin red S. The slides 

Table II. Cement contact with endosteum, cement area (i.e. area of canal occupied by cement), and graft porosity for the pressure and no-pressure group at 11 matched-level cross-sections (see Fig. 3).

| Level | Pressure group Cement contact (%) | No-pressure group Cement contact (%) | Pressure group Cement area (%) | No-pressure group Cement area (%) | Graft porosity (%)
|-------|----------------------------------|-------------------------------------|--------------------------------|-----------------------------------|----------------
| 1     | 28 (0 to 59)                     | 9 (0 to 32)                         | 52 (32 to 83)                  | 33 (23 to 46)                     | 68 (64 to 75)     
| 2     | 30 (26 to 44)                    | 7 (0 to 20)                         | 53 (35 to 74)                  | 26 (20 to 29)                     | 60 (60 to 72)     
| 3     | 42 (28 to 73)                    | 20 (4 to 29)                        | 57 (37 to 82)                  | 40 (24 to 69)                     | 60 (60 to 72)     
| 4     | 59 (32 to 86)                    | 41 (10 to 82)                       | 73 (43 to 96)                  | 57 (35 to 97)                     | 60 (60 to 75)     
| 5     | 71 (49 to 98)                    | 46 (28 to 91)                       | 83 (50 to 100)                 | 59 (38 to 97)                     | 65 (52 to 74)     
| 6     | 70 (49 to 97)                    | 36 (0 to 52)                        | 80 (52 to 99)                  | 55 (38 to 76)                     | 64 (52 to 78)     
| 7     | 72 (48 to 100)                   | 40 (0 to 60)                        | 80 (59 to 99)                  | 60 (43 to 76)                     | 66 (54 to 82)     
| 8     | 82 (67 to 100)                   | 40 (0 to 100)                       | 87 (73 to 100)                 | 57 (32 to 100)                    | 69 (61 to 79)     
| 9     | 80 (45 to 100)                   | 36 (0 to 100)                       | 89 (75 to 99)                  | 57 (30 to 100)                    | 66 (52 to 81)     
| 10    | 81 (27 to 97)                    | 25 (0 to 65)                        | 91 (70 to 98)                  | 45 (16 to 73)                     | 65 (54 to 78)     
| 11    | 26 (0 to 91)                     | 11 (0 to 38)                        | 50 (4 to 94)                   | 34 (0 to 57)                      | 57 (40 to 71)     

Graph showing cement contact with endosteum for the pressure and no-pressure groups, at 11 matched-level cross-sections. Shown are means and standard deviations (SD).

The measurements of cement contact and cement area were performed by a single person (CA) and were each analysed with a two-factor analysis of variance (ANOVA), in which the factors were group (pressure vs no-pressure), and level (defined as a repeated measure). The graft porosity was analysed with a one-factor ANOVA (level) which was defined as a repeated measure. Student-Newman-Keul analysis was used for post hoc comparisons, and the significance level was 0.05.

Linear regression models were used to examine the relationship between the mean cement contact and cement area from all 11 matched levels, and the components of the motion that were significantly different between the two groups.

Results
The cement contact and cement area results are shown in Table II and Figure 3 for each group at all cross-sectional levels. The main effect of pressure was significant for both cement contact and cement area (p = 0.0014 and p = 0.0013, respectively). There was an average of 30% more cement contact.
and 25% more cement area in the pressure group than in the no-pressure group. The effect of level was also significant (p < 0.001 for both variables). Levels 4 to 10 had significantly higher cement contact and cement area than levels 1, 2, 3 and 11 (p < 0.05), but they did not differ significantly between levels 4 and 10, or between levels 1, 2, 3 and 11. There was no interaction effect between the two factors.

The results for graft porosity are shown in Table II. The effect of level on graft porosity was significant (p < 0.001). Porosity was relatively constant along the length of the implant, averaging 66%, and did not differ significantly between levels 1 and 10 (post hoc comparisons with Student-Newman-Keuls p > 0.4). Below the tip of the implant, at level 11, the porosity was slightly lower than at all other levels (post hoc comparisons with Student-Newman-Keuls p < 0.01).

The components of migration and micromotion for each group at the end of the cyclical loading are shown in Tables III and IV, respectively. Two of the migration components, distal translation and valgus rotation, differed significantly (p = 0.028) between the two groups (Fig. 4). The median distal migration and valgus rotation migration were 12.1 and 3.2 times greater in the no-pressure group (Table III). The resultant of the translational migration components ranged between 19 μm and 27 μm in the pressure group, and between 45 μm and 792 μm in the no-pressure group. Of all the micromotion components, only distal translation was significantly different between the groups (p = 0.028, Fig. 4c). The median distal micromotion was 4.6 times greater in the no-pressure group (Table IV). The resultant of the translational micromotion components ranged between 10 μm and 31 μm in the pressure group, and between 22 μm and 70 μm in the no-pressure group. Distal migration also significantly correlated with the micromotion in the same direction (slope of the linear fit to the data (m) = 12.8, y-offset (b) = -101 μm, R² = 0.78, linear regression, p < 0.001).

Distal migration and micromotion throughout the 5000 cycles of walking loads are shown in Figure 5. In the pressure group, distal micromotion was mainly constant (Fig. 5a). The trend of micromotion in the no-pressure group was more variable, being roughly constant in three specimens, increasing slightly in one, and decreasing in two. The implant settled more quickly in the pressure group, where most of the migration occurred within the first 2000 cycles (Fig. 5b). In the no-pressure group, the implants were still migrating distally at 5000 cycles, with a median migration of 10.9 μm (0.3 to 27.1) during the last 1000 cycles, compared with 0.5 μm (-1.1 to 3.4) in the pressure group.

The three motion components that differed between the pressure and the no-pressure groups (distal migration, valgus rotation migration and distal micromotion) correlated significantly with both cement contact and cement area (Table V and Fig. 6). Two specimens, both of which were in the no-pressure group, showed substantially higher distal migration than the others, and corresponded to the two largest specimens in that group (Pairs 3 and 6, Table I).

### Discussion

When using the impaction allografting technique penetration of cement through the graft bed has been observed to reach the endosteal surface of the femur, creating an extensive cement-host bone interface at mid-stem level. The presence of cement at the endosteal surface compromises the potential for incorporation of the graft at that site, but its importance for primary stability of the implant is not known. In this study, we carried out impaction allografting on cadaveric femurs with and without pressurising the cement to examine the effect of cement penetration on the motion of the implant under simulated walking loads.

In vitro mechanical tests are commonly performed to assess new hip implant designs or surgical techniques preclinically. The relevance of in vitro tests is supported by studies demonstrating that excessive micromotion at the bone-implant interface inhibits successful bone ingrowth in cementless implants, which may lead to early loosening of the implant, and that cemented implants with inferior clinical results also display greater in vitro micromotion. As an in vitro model our study did not model biological processes. There was no bleeding in the canal during the procedure, which may have affected cement penetration. However, it has been shown experimentally that the intramedullary blood pressure did not significantly affect the depth of penetration in primary cemented THR. It has been suggested that early migration of the implant could be a
result of a combination of post-operative consolidation of the graft, shear failure, and/or slippage at the host-bone interface. Other mechanisms that have been proposed to affect longer-term implant migration in impaction allografting, including graft incorporation/fibrous invasion, cement fatigue, and cancellisation of the femoral canal, could not be modelled in this experiment. The effect of these mechanisms on long-term subsidence of the implant in impaction allografting has not yet been determined. The importance of primary stability is emphasised by reports of significant subsidence in the early post-operative days. In clinical studies using RSA some implants were seen to have subsided more than 1 mm within the first three months after operation. It was also noted that more than half of the subsidence observed at six weeks was usually seen within the first two weeks.

Our specimens represented class 2 bone defects. Most of the trabecular bone had been removed from the proximal femur, and the intramedullary canal was expanded. This type of bone loss is within the range commonly targeted by impaction allografting, but does not represent the most severe cases. As the migration of the implant has been observed to be proportional to the severity of the bone loss, we would expect to see greater migration with a model of more severe bone loss.

Migration of implants previously seen in cadaveric studies of impaction allografting has varied greatly, with average distal migrations ranging between 12 µm and 1 mm. There were many variables in these studies including the type of specimen, the magnitude and orientation of the loading, the number of loading cycles, and the techniques used to...
Comparison of these results with those of another study shows that two other studies used a six degree of freedom movement measurement system similar to ours and found similar results in all movement components. Berzins et al used loads approximately twice as high as ours but only 50 load cycles, whereas Chassin et al used only ten cycles, with approximately half our loads. Two other studies reported distal migration of an order of magnitude higher than ours but only 50 load cycles, whereas Chassin et al used RSA measurement with other studies reported distal migration of an order of magnitude higher than ours, but one used an extensometer measurement with loads approximately twice as high as ours and 13 times more.

Previous research has demonstrated that the cement penetration in impaction allografting is affected by graft porosity. In our results, the lower porosity of the graft below the tip of the implant may explain the lower contact between the cement and the endosteum in that region. However, the porosity of the graft was roughly uniform along the length of the implant, and the lower cement-endosteum contact in the proximal region is probably a result of the wider canal at that site. Our measurements of graft porosity at all levels were within the range previously reported in another in vitro study.

It is not clear how much cement is necessary for the structural support of the implant in impaction allografting. Without cement, the morsellised bone does not provide sufficient structural support for the stem. Clinical studies have found a link between excessive subsidence and the presence of zones where the cement mantle was less than 2 mm thick. This indicates the importance of sufficient thickness of the cement mantle between the implant and the graft bed, without which the cement could be more susceptible to early fatigue failure. A recent in vitro study found that penetration of cement into the graft bed reaches the endosteal surface, and that the strength of the endosteal interface with graft/cement is proportional to the amount of cement contact. In the present study, constructs with more than 50% of cement contact with the endosteum generally resulted in substantially lower distal migration and micromotion than did those with less contact. This indicates that allografting study indicate that migration during the first two weeks may be a good predictor of long-term migration. Therefore, the differences in the patterns of early migration observed between our pressure and no-pressure groups indicate that longer term stability of the implant is likely to be compromised if the cement is not pressurised.

The regression parameters are given in Table V.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Factor</th>
<th>Slope</th>
<th>R</th>
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</thead>
<tbody>
<tr>
<td>Distal migration (µm)</td>
<td>Cement contact</td>
<td>-9.557</td>
<td>0.68</td>
</tr>
<tr>
<td></td>
<td>Cement area</td>
<td>-14.090</td>
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</tr>
<tr>
<td>Valgus rotation migration (°)</td>
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<td>0.65</td>
</tr>
<tr>
<td></td>
<td>Cement area</td>
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<tr>
<td>Distal micromotion (µm)</td>
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<td>0.59</td>
</tr>
<tr>
<td></td>
<td>Cement area</td>
<td>-0.896</td>
<td>0.77</td>
</tr>
</tbody>
</table>
the regions of cement-endosteum contact are potentially critical to the primary stability of the implant. There may be a conflict between the biological and structural goals of impaction allografting. A biologically favourable construct is one with limited cement penetration, but the morsellised graft bed may not provide sufficient support for the implant without contact of the cement with the endosteum.

Attempts have been made to improve the mechanical properties of the morsellised graft bed by increasing the number of impactions,48 rinsing the graft,47,49 freeze-drying44 and/or irradiating the graft,49,50 and by optimising the size distribution of the graft particles.37 However, improvement of graft compaction will only be of clinical consequence if the implant is being supported largely by the graft bed. Future biomechanical studies should aim to determine the minimum graft packing necessary to support the implant without contact of the cement with the endosteum, how to achieve this level of packing consistently, and how to prevent the cement from reaching the endosteum. But if the graft cannot provide sufficient support for the implant, efforts should be focused on how to control the cement penetration profile such that cement-endosteum contact occurs in regions not targeted for reconstruction of bone stock. The presence of cement at the endosteal surface in patients with impaction allografting has been shown to result in excessive migration in bone impaction hip revision surgery: a radiostereometric analysis of four cases.64

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References


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