

# Impaction bone grafting with freeze-dried irradiated bone. Part I. Femoral implant stability

## Cadaver experiments in a hip simulator

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**ABSTRACT** Processed freeze-dried irradiated allografts seem to be used less than instead of fresh-frozen allografts for impaction bone grafting in revision hip arthroplasties. Although biologically acceptable, their use is discouraged because of their questionable mechanical properties following freeze-drying and irradiation procedures.

To address this question, we impacted freeze-dried grafts in 6 cadaveric femurs and loaded with a cemented Charnley prosthesis. The routinely used fresh-frozen allografts were used as controls in the contralateral side. These constructs were compared simultaneously in a walking hip simulator for their stability during 900,000 loading cycles. The mechanical parameters were axial inducible displacement and subsidence of the implant.

The former parameter was lower in the implant mounted on freeze-dried impacted grafts than that mounted on the fresh-frozen bone. The latter parameter was also lower in the freeze-dried group. At the end of the test, we found no implant loosening in either group and their ‘pull out’ resulted in cement-prosthesis debonding, which showed the mechanical integrity of the impacted grafts.

Freeze-dried grafts provide more stable fixation of the stem than fresh-frozen morselized grafts, when tested in a hip simulator.

femur and achieve a stable reconstruction in revision hip arthroplasty. With this technique, implant stability depends on the quality of the impacted grafting material, which becomes a load-bearing component of the reconstruction (Malkani et al. 1996, Kärrholm et al. 1999).

The use of processed freeze-dried bone for impaction bone grafting has been questioned as regards its mechanical properties (Duncan et al. 1998), although it would be useful as a substitute for lack of fresh-frozen femoral heads and protection of the recipients from disease transmission (Delloye 1994). However, recent clinical studies have reported good results using freeze-dried bone, which suggests that it would be an acceptable alternative to classical fresh-frozen bone (de Roeck and Drabu 2001, Mazhar et al. 2001, Thien et al. 2001).

In the present paper, we studied whether a stable femoral reconstruction can be achieved (in vitro) using irradiated freeze-dried bone instead of fresh-frozen bone. We therefore performed an impaction bone grafting procedure on cadaver femurs, and compared both of these grafting materials. The implant stability was then measured during 900,000 loading cycles in a hip simulator.

## Material and methods

### *Femur preparation*

6 pairs of femurs were harvested within 24 hours

Gie et al. (1993b) and Ling et al. (1993) have popularized impacted morselized allografts to restore the bone stock of a deficient proximal

of death and the soft tissues were removed. The donors were male subjects, aged 77 (33–92) years, with a height of 181 (175–186) cm and a weight of 85 (70–95) kg. The femurs were relatively large. The radiographs of the specimens showed no evidence of focal disease. Left-right symmetry was also assessed by densitometry. The femurs were frozen at  $-30^{\circ}\text{C}$ , pending use. Both left and right femurs were thawed and the femoral neck resection was done symmetrically with a template to obtain  $10^{\circ}$  anteversion and a  $45^{\circ}$  slope. They were placed in a vertical position, leaning on their condyles, and using three perpendicular plates to ensure an identical position. The distal metaphysis was embedded in polymeric cement. The femurs were placed under the simulator, wrapped in gauze and continuously irrigated with 2% formalin in 0.9% saline until the end of the test (about 10 days). To simulate the extensive bone loss that occurs in aseptic loosening of a hip arthroplasty, we created a bone defect, which measured 18 mm in diameter, by drilling the medullary cavity it extended to a point where the distal femur flared out. The proximal femoral cortex was further thinned out with broaches to permit the implantation of a commercially available (large) 403 Charnley-Kerboul hip prosthesis (Bone and Joint Research, Luxemburg).

### *Morselized grafts*

Human femoral heads were supplied by the local university bone bank. All grafts were procured at the time of primary hip arthroplasty for osteoarthritis, and stored at  $-80^{\circ}\text{C}$ . The heads were shaved off of all their soft tissues (articular cartilage remnants and synovium) (Bavadekar et al. 2001). To obtain fresh-frozen morselized grafts, the femoral head was simply thawed in normal saline at room temperature and morselized with the fine rasps of the Noviomagus bone mill (Spierings, Nijmegen, NL). The size of the chips was mean 3.3 (SD 1) mm. Fresh-frozen grafts were not defatted or fat-reduced in any way. To obtain freeze-dried morselized grafts, segments of femoral heads were washed with a water jet, defatted, freeze-dried and then irradiated. After rehydration (30 min in saline), the femoral head segments were morselized, using the same bone mill.

### *Impaction procedure*

One femur (the left or the right) was reconstructed using fresh-frozen bone while in the contralateral one, we used freeze-dried bone. In the absence of a specific impaction instrument for the Charnley-Kerboul prosthesis, reconstruction was done with the X-change revision instrument (Stryker-Howmedica, Brussels, Belgium), using the technique described by Gie et al. (1993a) and the manufacturer's instructions. We found acceptable the differences between the Charnley-Kerboul prosthesis stem shape and the Exeter stem designed shape of the X-change instrumentation impactors. We selected an intramedullary plug based on the size of the resected femoral head. Impaction was done retrogradely, layer by layer, by introducing and impacting a few grams of morsels. The procedure was stopped when the final impactor could not be driven any further by the operator's gliding hammer. The final proximal packing was done, using the tamps. The proximal impactor and the guide rod were then withdrawn from the femur. Palacos E flow with gentamicin cement (Schering Plough SA, Brussels, Belgium) was inserted retrogradely into the 'neo-medullary' canal 3 minutes after mixing and kept under pressure until the fifth minute. A (small) 301 Charnley-Kerboul hip prosthesis was cemented under fluoroscopy to assess axial alignment (varus-valgus), and ensure a  $10^{\circ}$  anteversion of the implant.

### *Mechanical testing*

The stability of the implants was monitored on a dynamic simulator, as described by Munting and Verhelpen (1993). Femurs were submitted to a load equivalent to  $1.5 \times$  body weight at a frequency of 1 Hz. The load was applied by a pneumatically-powered actuator on the 28 mm prosthetic head. This actuator was tilted to a  $20^{\circ}$  angle in a mediolateral direction and  $6^{\circ}$  in the anteroposterior direction. The loading curve had an M shape and was similar to that observed in vivo when walking with crutches. Two extensometers were used to monitor the implant movements in the femur. The first extensometer measured the axial movement (Figure 1) of the implant, while the second one evaluated the rotation of the implant along the axis of its stem (changes in the anteversion angle of the implant). The measurements were obtained

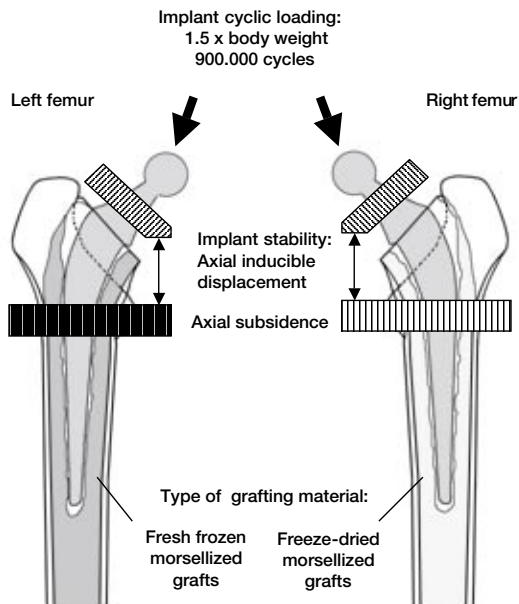


Figure 1. Schematic illustration of the set-up. Two aluminum blocs were used to monitor axial movements. The first (horizontal rectangle) is fixed to the femur while the second (oblique) is fixed to the neck of the prosthesis. Displacement between these two blocks is measured with extensometers.

when the implant was unloaded (swing phase of the gait) and loaded (stance phase of the gait), at the beginning of the test and every  $1 \times 10^5$  cycles until  $9 \times 10^5$  cycles. Axial displacements ( $\mu\text{m}$ ) were directly derived from the axial extensometer. Rotational angles (degrees,  $^\circ$ ) were calculated as: arc tangent (horizontal displacement/offset of a horizontal extensometer). The permanent implant displacement (axial subsidence) and rotational migration ( $^\circ$ ) were measured in the unloaded state. The temporary displacement was called 'inducible displacement'. The axial inducible displacement ( $\mu\text{m}$ ) was calculated as the difference between the loaded displacement ( $\mu\text{m}$ ) and the unloaded displacement ( $\mu\text{m}$ ). The rotational inducible displacement ( $^\circ$ ) was calculated as the difference between the loaded angle ( $^\circ$ ) and the unloaded angle ( $^\circ$ ).

Conventional radiographs of the implant and femur were taken before and after each test.

### Statistics

To compare the results with fresh-frozen allografts or freeze-dried allografts, we used analysis of variance (ANOVA) with repeated measures (SPSS

10.0, SPSS Inc., Chicago, IL). The dependent variables were the axial and rotational inducible displacements or subsidence. The within-subject variable was the type of graft (freeze-dried or fresh-frozen). The number of loading cycles was introduced as a second within-subject factor. Such a model estimates whether the overall behavior (the whole curve) is different when using one type of graft or another.

### Results

During the preparation of the defect in the left femur of one pair, the cortex became so thin that a 10-cm longitudinal crack was immediately seen. Nevertheless, the impaction bone grafting procedure was done, as intended, with freeze-dried bone. This pair of femurs was further tested but, because of this crack, this pair was excluded from the comparison of the two study groups.

On the whole, we found good implant stability during the test and only small axial and rotational displacements. In no case did the cyclic loading cause an implant macro-movement.

The axial inducible displacement of the prosthesis with freeze-dried morselized grafts was lower ( $p < 0.05$ ) than with the fresh-frozen bone (Figure 2 A). In the freeze-dried group, the inducible displacement was about 110 (SD 38)  $\mu\text{m}$  while in the fresh frozen group, it was about 175 (SD 26)  $\mu\text{m}$ . The ANOVA also showed that the inducible displacement values were not significantly affected by the number of cycles in the control and freeze-dried groups, which would no significant rise, or fell, in inducible displacement occurred during the test.

The implant axial subsidence increased rapidly during dynamic cyclic loading until  $1 \times 10^5$  cycles in both groups, after which the prosthetic implant became a relatively more stable and the subsidence rate declined (Figure 2 B). However, the subsidence was less in the freeze-dried group than in the control group at any stage of the test ( $p < 0.01$ ). At the end of the test, the subsidence of the implant was 265 (SD 76)  $\mu\text{m}$  with fresh-frozen grafts and 81 (SD 35)  $\mu\text{m}$  with freeze-dried grafts. The subsidence increased during the simulation ( $p < 0.001$ ) in both groups.

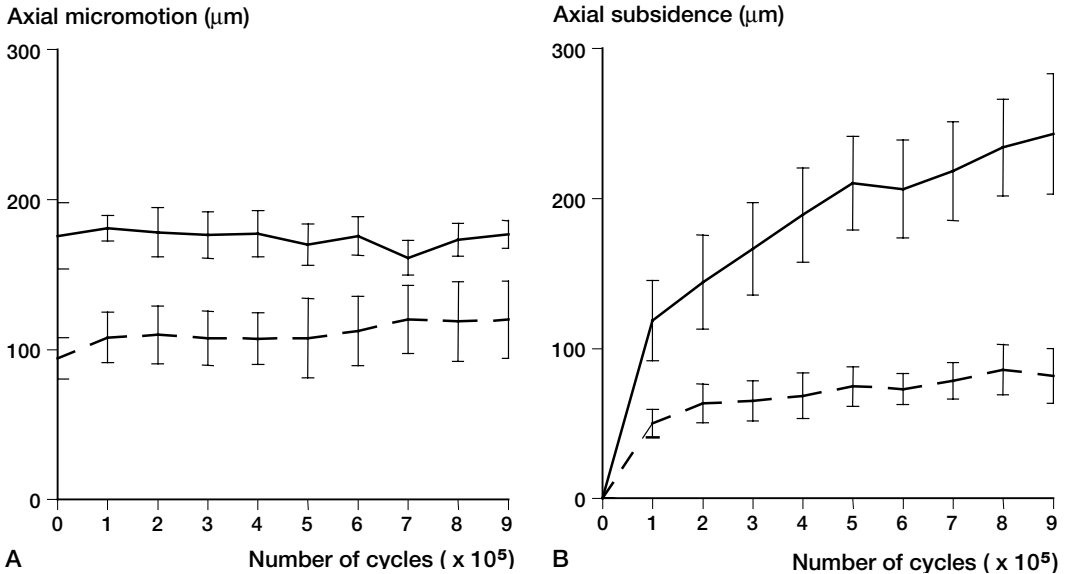


Figure 2. Graphs showing the mean axial inducible displacement (A) and subsidence (B). Error bars represent  $\pm 1$  standard error of the mean,  $n = 5$ . Interrupted line = freeze-dried bone and solid line = fresh-frozen bone.

The rotational inducible displacement of the implant was extremely small in both groups (less than  $0.1^\circ$ ). ANOVA showed that this movement was not affected by the number of cycles, and that it was about the same in both groups. The actuator pushed the head steadily more in one direction and slightly turned the prosthesis. Therefore, very small angles of rotational migration ( $< 0.5^\circ$ ) were seen, but these angles were, on the whole, smaller in the freeze-dried group ( $p < 0.02$ ), and tended to increase during the test in both groups ( $p < 0.05$ ).

No implant migration or radiolucent line was detected on the radiographs at any time. Cracking of the cement did not occur. Implant recovery and pull-out were usually difficult and a hammer had to be used. It was extremely difficult in the freeze-dried group, but easier in the fresh-frozen group. Pull-out did not result in a shear separation in the graft layer. On the contrary, the cement-implant interface failed, leaving an intact cement mantle with impacted graft layer inside the femoral diaphysis.

As regards the pair of femurs that was rejected, the results using the left femur (with a 10-cm diaphyseal crack, but filled with freeze-dried bone) were interesting. During the test, we saw the crack open and close during every loading cycle. How-

ever, the implant was macroscopically stable. It had a final inducible displacement of about  $270 \mu\text{m}$  and subsidence of  $180 \mu\text{m}$ . These values exceeded those of the freeze-dried group, but resembled those of the fresh-frozen group.

## Discussion

Our findings indicate that a stable femoral reconstruction can be achieved with irradiated freeze-dried bone as filling material for impaction bone grafting. Contrary to expectations, the femoral implant stability was even greater with freeze-dried bone than with fresh-frozen bone.

When the reconstruction was performed with freeze-dried grafts, the implants showed less inducible displacement and less subsidence than with the fresh-frozen control. This suggests that the gradual and permanent collapse of the graft layer occurred more slowly in the freeze-dried group. Rotational inducible displacement and 'migration' merely confirmed these results, but mainly showed no loosening in both groups.

No reports are available on long-term walking simulation with impaction bone grafting. Up to  $9 \times 10^5$  cycles corresponds to 1 year of normal

walking and such large numbers of cycles compare favorably with previous in vitro studies (Malkani et al. 1996). We found changes in the behavior of the implant before and after 100,000 cycles (Figure 2). The load applied in the simulator was limited to 1.5 body weight for technical reasons (mainly for a femur to withstand one million loading cycles), but this corresponds to a walk with crutches (Davy et al. 1988). No signs of dramatic failure of the graft layer were seen.

The displacement values measured during our simulation were relatively small. This must have several technical explanations. First, the loading was not as high as the full weight bearing gait or as other experiments (Berzins et al. 1996). Secondly, we used an unpolished stem that limited the gliding of the implant into the cement mantle (Kärholm et al. 1999). Thirdly, we directly measured the displacement of the implant relatively to the proximal femur (Figure 1), instead of measuring the displacement of the actuator (Malkani et al. 1996) so as to reduce the error of measurement. Fourthly, we used a good impaction procedure. When performed ex vivo, the operating conditions are excellent, the femur is in vertical position and fixed to the table. At every step, and for both types of grafts, hammering was stopped when the proximal impactors could not be driven further into the femoral diaphysis. In this situation, while the force of impaction was manually performed and not standardized, differences in the impaction quality can be explained only by differences in the grafting material. Finally, as regards the creation of an artificial bone defect, the cortical thickness was frequently less than 1 mm, but never as thin as encountered in some revisions. However, the rather low axial subsidence of the implant reported here (less than 300  $\mu$ ) was about the same as that reported by Kärholm et al. (1999) in a clinical study.

Some authors have reported that simply reducing fat by rinsing fresh frozen morselized bone graft in warm saline improves the biomechanical properties (Ullmark 2000, Höstner et al. 2001). This might be an important cause of for the differences between implant stability with fresh-frozen grafts and defatted freeze-dried irradiated bone.

Further experiments comparing the behavior of both types of grafts (during and after impaction)

are needed to understand the paradoxical results found during this simulation; namely, that a material known to have lower mechanical properties (irradiated freeze-dried bone) can yield to a more stable reconstruction.

No competing interests declared.

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