Morsellized allografts for fixation of the hip prosthesis femoral component. A mechanical and histological study in the goat

Morsellized allografts for fixation of the hip prosthesis femoral component

A mechanical and histological study in the goat

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To simulate femoral intramedullary bone stock loss in revision surgery of failed total hip arthroplasties, a method was developed using impacted trabecular bone grafts. In 14 goats a cemented total hip arthroplasty was performed, fixating the stem within a circumferential construction of bone allografts. After 6 or 12 weeks, 4 goats were used for mechanical tests and 3 for histology.

The stability of the stems was determined in a loading experiment with roentgen-stereophotogrammetric analysis; loads of up to 1.44 times body weight were used. One aseptic loosening was seen with gross movements. In the other cases the most important movements were axial rotations (max. 0.24 degrees under 800 N) and axial translations (max. 0.16 mm under 800 N). After unloading some elastic recovery occurred. There were no differences between the 6 and 12-week groups. Histologically, revascularization and remodeling of the grafts were evident. Bone apposition and bone resorption of the grafts resulted in a mixture of graft and new bone. There was more new bone formation in the 12-week group, but the process was not yet completed. The use of impacted trabecular bone grafts in cases of severe intramedullary bone stock loss seems to be a promising revision technique.

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The main problem for revision surgery of failed femoral stems is bone stock loss, mainly seen in the intramedullary and calcar areas. Several methods to deal with this problem have been described (Amstutz et al. 1982, Callaghan et al. 1985, Turner et al. 1987, Rubash and Harris 1988). However, the results of femoral revisions by simply filling the defects with bone cement are not satisfactory. The uses of different types of structural bone grafts have been described (Borja and Mnaymneh 1985, McGann et al. 1986, Head et al. 1987, Oakeshott et al. 1987). However, we think that, following experience with revisions on the acetabular side, massive and structural grafts should not be used (Mulroy and Harris 1990).

The use of morsellized trabecular bone grafts in femoral revisions has been described earlier (Tyer et al. 1987, Wagner 1987, Allen et al. 1991). In our department, a bone-grafting technique employing impacted morsellized bone chips in combination with cemented cups was used successfully in severe cases of acetabular bone loss (Slooff et al. 1984). With the development of a special set of instruments, this method could also be employed on the femoral side. The stability of the stem in such a graft construction is important. In an in vitro study in femora of the goat, the initial stability immediately after insertion was determined (Schreurs et al. 1991, 1994). We now performed an in vivo study to obtain information about the mechanical stability of the stems post-operatively as well as histological data about consolidation and incorporation of the allograft.

Material and methods

All trabecular bone grafts used were harvested from donor goats under sterile conditions. Most grafts were obtained from the sternum. Other donor sites were the distal femur, proximal tibia and humeral head. Bacterial cultures of the grafts were taken. Grafts were freshly frozen and stored at –80 °C until implantation, and then thawed at room temperature. The maximal storage time was 6 months. To prevent bias due to different immunological reactions, familial relationships between donor and host goats were excluded. However, a standardized graft based on

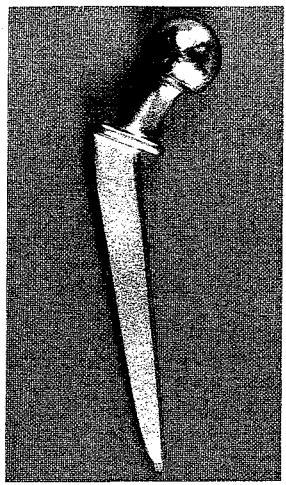

Figure 1. The femoral prosthesis with a collar.

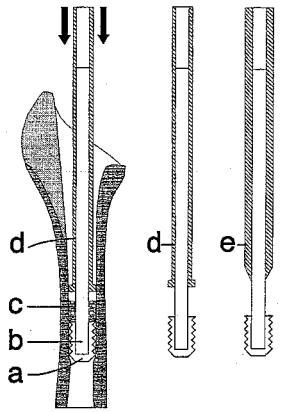

Figure 2. The graft impaction technique. Bone cement plug (a), metal rod (b), trabecular bone grafts (c), and metal tubes for axial (d) and radial (e) impaction of the grafts.

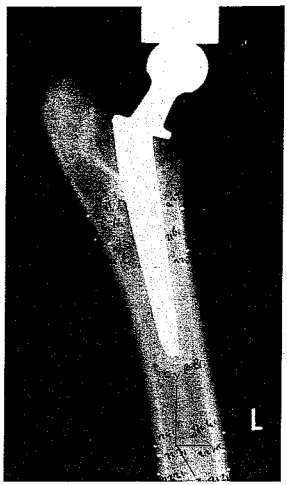

Figure 3. Femur with bone grafts and a prosthesis. The laboratory coordinate system is shown.

pooled bone grafts was not used. A commercially available total hip prosthesis for dogs (Mathys Bettlach, Switzerland, Type 2.30.702) was used (Figure 1). The bone cement applied was Sulfix.

14 adult goats (Capra Hircus Sana) were operated on the right hip under general anesthesia, using standard aseptic techniques. A dorsolateral incision was made and the hip was dislocated. After resection of the femoral head, the acetabulum was prepared and a cemented cup was inserted. The femur of the goat contains trabecular bone only proximally, which was removed with hand reamers (diameter 8–12 mm in 11 cases, diameter 8–14 mm in 3 cases). After cleaning the canal, an appropriately sized bone cement plug (AlloPro), screwed onto a metal rod (diameter 8 mm in 11 goats, 10 mm in 3 goats) was introduced in the medullary canal. The space between this rod and the cortical bone (2–3 mm) was filled with grafts in a retrograde fashion. By means of a special set of instruments, consisting of several types of tubes sliding over the central metal rod, the grafts were impacted (Figure 2). After completion of the filling process, the central rod was unscrewed and removed, leaving a central cavity surrounded by a stable intramedullary wall of bone chips. In this intramedullary bone graft construction, a stem was inserted. Cement was injected in a retrograde fashion in the graft construction, employing a cement syringe (Howmedica). Cement was injected 3.5–4 minutes after mixing; the stem was inserted after 4.5–5 minutes. For later mechanical testing, a tantalum pellet, contained in an acrylic strut, was glued to the tip of the stem prior to insertion. The goats were kept in a hammock for, at most, 2 days after the operation. AP and lateral radiographs were obtained immediately after the operation, after 6 and after 12 weeks. The position of the stem was mostly neutral in the AP and lateral views. In 2 goats, the prosthesis was placed in varus and retroversion, in another there was retroversion only.

Loading patterns of the goats were scored weekly, using visual grading of function, as described by Ypma (1981). The goats were kept in cages, allowing free walking, or in the meadow. The goats were killed by an overdose of pentobarbital sodium. In each group, 4 goats were used for the mechanical tests and 3 for histological examinations.

Mechanical testing (Figure 3)

The 3-D displacements of the prosthesis relative to bone (3 rotations and 3 translations) were measured using roentgen stereophotogrammetic analysis (RSA), as developed by Selvik (1989). The femora for the mechanical study were freshly harvested and stored at –80 °C until testing. After thawing, the femora were resected just above the condyles and the distal part was embedded in polymethyl methacrylate (PMMA). Tantalum pellets were inserted proximally and distally on the medial and lateral sides in the cortical bone. Two small PMMA rods containing tanta-

lum pellets were glued to the proximal medial and lateral parts of the prosthesis. Then the prosthesis/bone structures were loaded in an MTS-testing device. Relative to the vertical position, the femora were tilted 15 degrees in a lateral direction, and then internally rotated 45 degrees in order to obtain a physiological load on the femoral head (Ypma 1981, Bergmann et al. 1984). The load was applied stepwise from zero to 200, 500, 800 N and again unloaded. Each loading period lasted 10 minutes. 5 additional loading cycles were applied to the specimens which had been in situ for 12 weeks.

Stereoroentgenograms were taken before loading, 10 min after each loading step, and again 10 min after final unloading. These were evaluated on an Aristomat digitizer, and the 3-D pellet positions were determined with the RSA computer programs. Relative rotations around and translations along the coordinate axes were calculated (Figure 3). To increase the accuracy of the results, all roentgen stereo-films were measured 5 times, and the results were averaged.

Histological analysis

The goats received intravital fluorochromes: terramycin (Days 8–12, 25 mg/kg/day), alizaron complexon (6-week group, Days 23–27; 12-week group, Days 49–53, 30 mg/kg/day) and calcein-green (6-week group, Days 38–42; 12-week group, Days 80–84, 20 mg/kg/day). The goats were anesthetized and the descending aorta and the vena cava were cannulated. Then they were killed by an overdose of pentobarbital sodium. To visualize the vascularization of the graft, the descending aorta was perfused with at least one liter of a 25 percent suspension of Micropaque® in a physiological saline solution (Rhinelander and Baragry 1962). Thereafter the perfusion was continued with one liter of 12.5 percent Micropaque in a phosphate-buffered (0.1M, pH 7.4) solution of 4 percent paraformaldehyde. Both femora were harvested after perfusion by careful exarticulation in the hip and knee joint, leaving an ample musculature cover and intact periost. Further fixation was done by immersion for 1 day in a 3:7 mixture of 4 percent formalin and 96 percent ethanol. After removing excess soft tissues, fixation was continued for 10 days in a 4 percent buffered paraformaldehyde solution.

After fixation, the femora were contact-radiographed and sectioned with a water-cooled saw into slices of 2–3 mm. Radiographs of the slides were again made. For routine histological examinations, the sections were decalcified in 25 percent EDTA under radiographic control, embedded in PMMA, sectioned (7 µm), and stained with hematoxylin and eosin (HE). For fluorescence microscopy, the slices were dehydrated, embedded in Epon 812, and sectioned (30 µm) on a Leitz rotating diamond saw (Lubbe et al. 1988). The slices for microangiography were decalcified in 5 percent formic acid under radiographic control, after which the microradiograms were made with a Philips PW 1120 X-ray diffraction spectrophotometer.

All trabecular bone grafts had negative bacterial cultures. The average weight of the goats was 55 kilograms (44–66 kilograms). The mean operation time was 4 hours. There were no peri- or post-operative losses of goats. During the operation a small fracture of the proximal femur was seen in 3 cases, once in the calcar zone and twice in the posterior region. There were no post-operative dislocations or clinical signs of deep infections. In one goat (G12-G) a superficial wound infection was found at autopsy. All goats loaded the operated leg, although 3 of the 12 goats showed some limp at 6 weeks. After 12 weeks all but 1 goat showed normal walking patterns. 2 goats (G6-D, G6-E) had swollen and painful front legs due to overloading after the operation. These goats were treated successfully with paracetamol for few days.

Results

In 1 goat (G12-D), there was radiographic evidence of subsidence of the prosthesis relative to the cortical bone at 6 weeks and even more so at 12 weeks, with resorption of cortical bone, a radiolucent zone, an extensive reaction of the periosteum and endosteal lysis. In 4 goats (G6-A, G6-E, G6-G and G12-B), a mild proximal periosteal reaction was seen. There were no periarticular ossifications. In 2 goats (G6-A, G12-D), there was radiographic evidence of cup loosening. On the post-operative radiograms the area in which the graft was located was seen as a homogeneous radio-opaque structure. In some cases after 6 weeks, and in all cases after 12 weeks, this area had become more radiolucent.

Mechanical tests

During mechanical testing, one specimen (G6-D) was lost due to technical problems. The specimen (G12-D) was considered loose; during the loading experiment, excessive axial rotation of 6.1 degrees and axial translation of 3.4 mm were measured. Most rotation occurred around the axial Y-axis in all specimens; the movements around the medial-lateral X-axis and antero-posterior Z-axis were smaller.

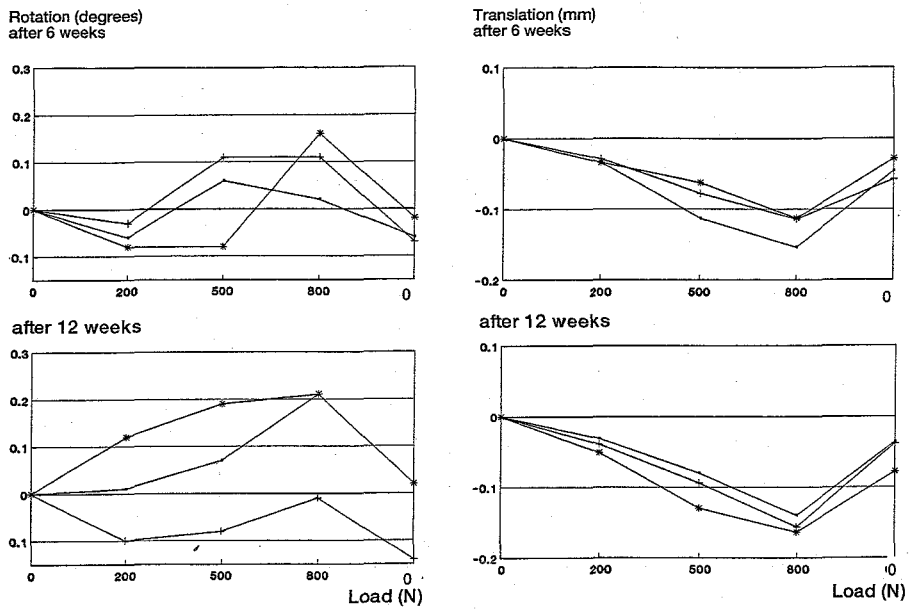

Figure 4. Axial rotations and translations from the unloaded case to stepwise increases in load, and again unloaded.

Although the initial rotation for the 200 N force was not in the same direction in all cases, with increasing load the directions of the rotations showed the same trends (Figure 4). The maximal rotation found was 0.24 degrees (G6-C). After subsequent unloading, there was some elastic recovery in all specimens. The maximal permanent rotation at 10 minutes after unloading was –0.07 degrees for the 6-week group (G6-C), and –0.14 degrees in the 12-week group (G12-B).

In both groups the maximal translations in X- and Z-directions were smaller than in the Y-direction, with 2 exceptions (G6-C—z 0.190 mm, G12-C—x 0.187 mm) (Figure 4). Axial translation increased with increasing load in all cases. After unloading, all specimens showed some elastic recovery. The maximal permanent axial translation after unloading was –0.058 and –0.078 mm in the 6- and 12-week groups, respectively. After 5 additional loading cycles, the 12-week specimens showed an average additional axial translation of 0.030 mm and an average additional axial rotation of 0.08 degrees. The standard deviations of the displacements measured in the mechanical study were 0.036 mm and 0.07 degrees for translation and rotation, respectively.

Histological study

Contact-radiograms confirmed in detail the change in trabecular appearance of the graft (Figure 5). In 2 cases (G6-G, G12-F), a fracture line in the cortical wall was seen on the microradiograms. The space between the prosthesis and cortical bone was well filled over the entire length, indicating sufficient impaction of the graft. Due to the damage to the endosteal circulation, the inner one-third of the cortical bone had become necrotic. In the cortical wall, a remodeling process of the necrotic bone was seen with vacuolization. The front of remodeling reached the graft after 6 weeks. At locations where no vascular invasion took place, the graft consisted of large pieces of trabecular bone showing microfractures due to the impaction process. Histologically, the grafted bone could be easily recognized by the empty osteocyte lacunae or, if seen, the pyknotic appearance of the osteocytes (Figure 6). Both at 6 and 12 weeks the original medullary fat was replaced by a loosely organized fibrin clot.

Infiltration of the graft by a front of loose connective tissue, vascular elements and macrophages was seen. The first activity of this revascularization and ossification front was noted after about 25 days in the endosteal cortex. In time, the front penetrated the

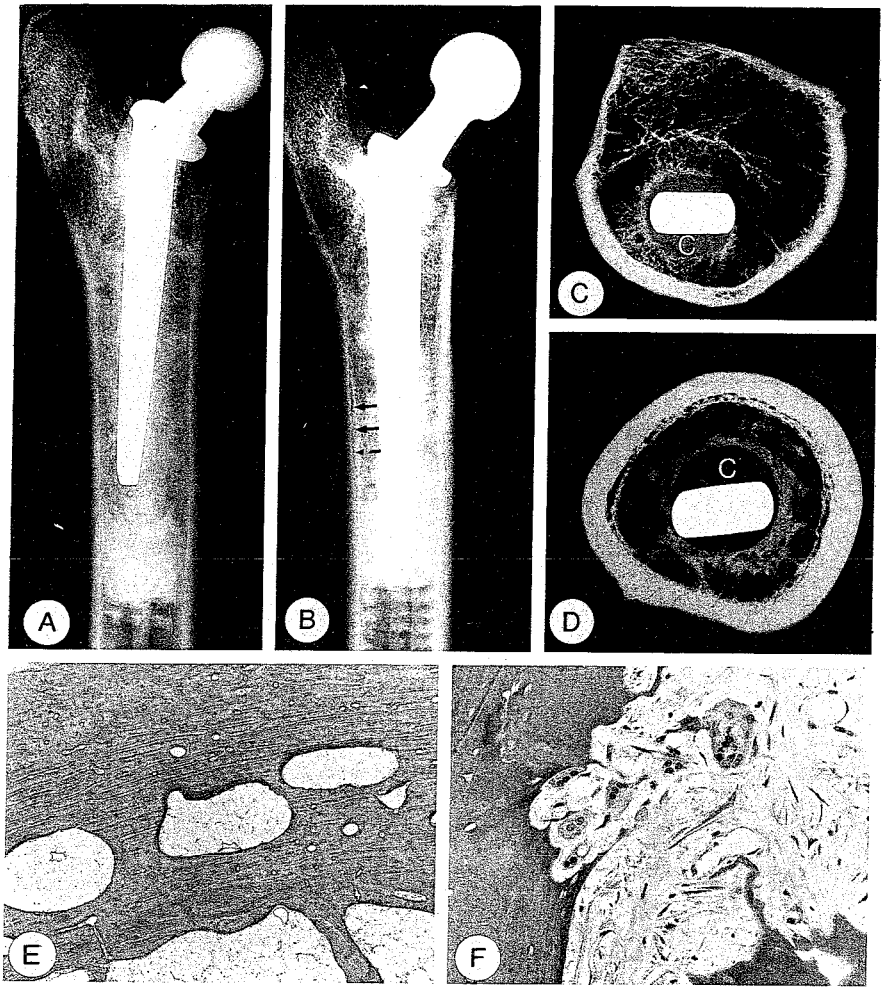

Figure 5. A and B The prostheses after 6 and 12 weeks, respectively. Note in A the change in trabecular appearance between the lateral proximal and more distal regions around the prosthesis. B. Locally, a radiolucent reactive line is present in the cortical bone (arrows). C and D Roentgenograms of thick sections of the proximal (C) and mid-shaft levels (D) of the femur after 12 weeks. Note the orientation of the trabeculae from the cement layer (C) to the preexisting cortical host bone. E Cortical porosis, ×30. F Local osteoclastic resorption of the graft. Note empty osteocyte lacunae, ×250.

more central parts of the graft. The process of bone apposition could be followed by the sequential polychrome labeling (Figure 7). Many osteoclasts and osteoblasts were involved in the processes of bone formation, incorporation and lysis of the graft. This process was not finished after 12 weeks. Graft tissue that was completely embedded in bone cement did not show any incorporation.

After revitalization and incorporation of the graft, the architecture of the graft changed, as assessed on the radiograms of the thick sections. The bony structure formed was a mixture of dead bone graft and woven trabecular bone, which was laid down on the graft. Most calcified intramedullary bone was located closely around the cement mantle, with bridges of trabecular bone to the cortical wall. This

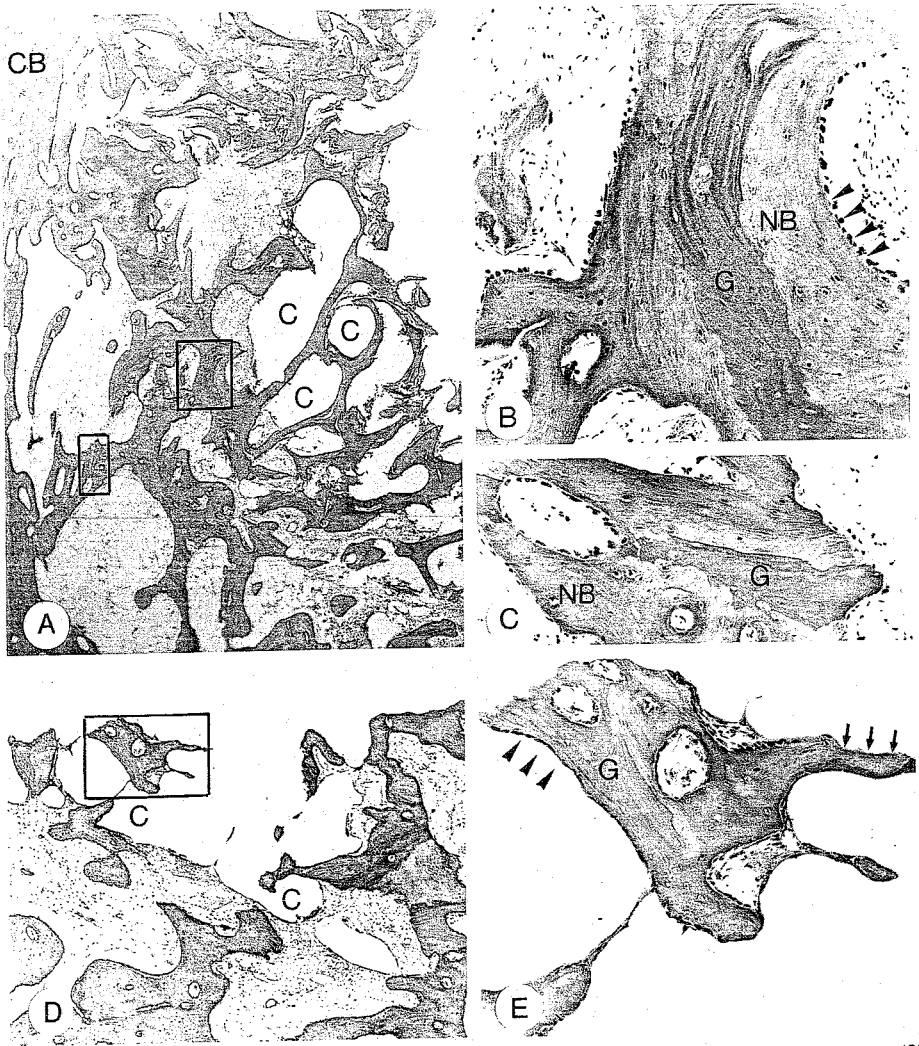

Figure 6. A Midshaft after 12 weeks. The graft is incorporated into a new bony structure that connects the cement layer (C) with the host cortical bone (CB). Note the penetration of the cement into the graft, ×18. B and C Enlargements of the encircled areas in A. Note that the trabeculae are a mixture of new bone (NB) and graft (G). Active osteoblasts are present indicating that active bone remodeling continues, ×150. D and E Interface between cement (C) and graft (G). E Enlargement of encircled area in D. The arrows point to a direct contact between cement and bone. Locally, a unicellular layer is present between the cement and bone (arrow heads), D ×30, E ×110.

trabecular arrangement was seen in its most complete form at the proximal part of the femur, indicating that the remodeling of the graft proceeded faster proximally than distally.

Cement penetration in the graft was at least 1 mm; sometimes there was penetration through the graft construction up to the cortical bone. At most places a small soft tissue interface (ca 20–100 µm) between cement and graft was seen, with a few multinuclear macrophages found in direct contact with bone cement. Occasionally there was direct contact between new bone and the cement layer.

In the G6-G specimen, clear signs of infection by large numbers of polymorphonuclear leucocytes and lysis of graft and cortical bone were seen. There was evidence that an infectious sinus, following the frac-

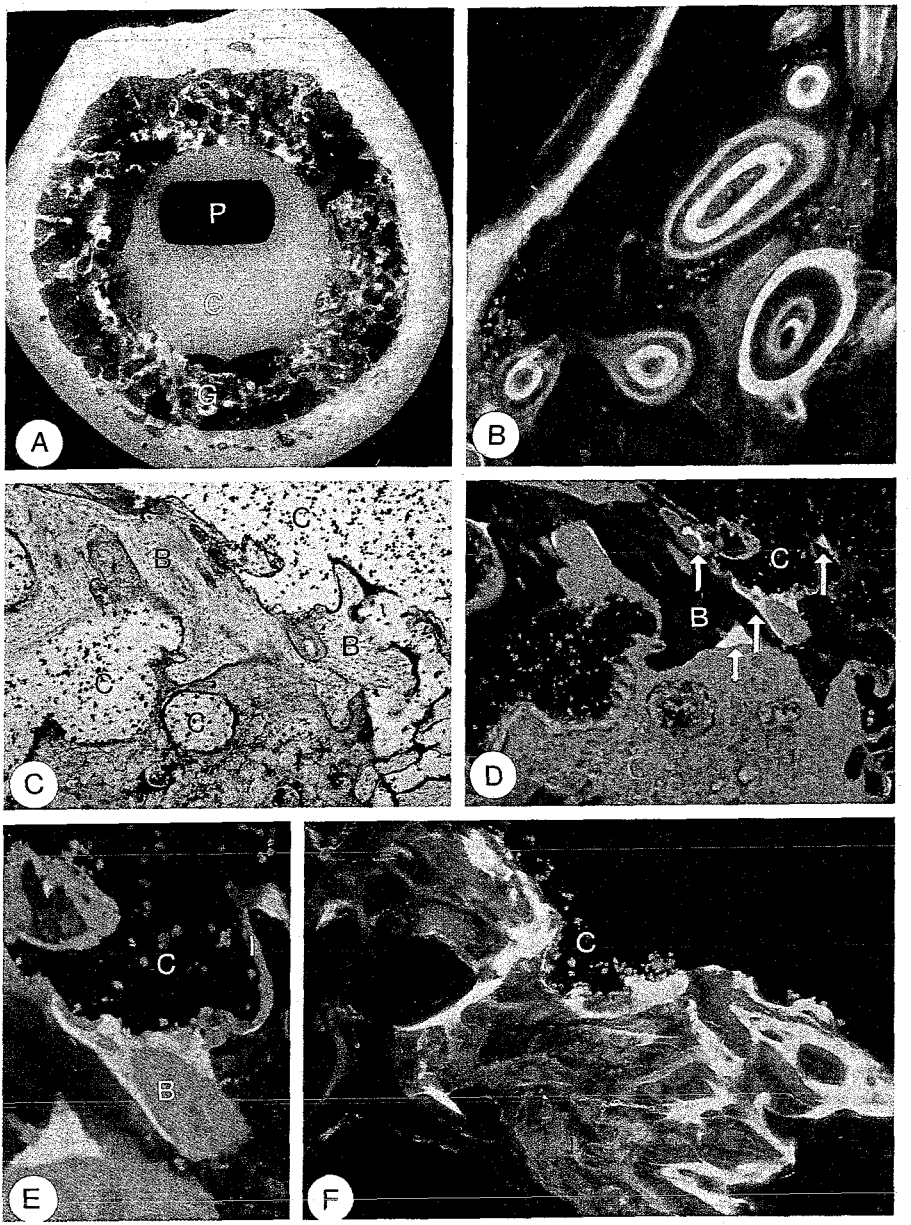

Figure 7. All micrographs are from the same specimen, 12 weeks after the operation. A Low-power fluorescence micrograph of thick section through the distal part of the femur. Note calcein green label throughout the graft (G). P cross-sectioned prosthesis, C cement layer, ×3.5. B Cortical remodeling after insertion of the prosthesis. Orange color is alizaron complexon, the yellow label is calcein green, ×120. C The cement (C)-bone (B) interface in basic fuchsin-stained undecalcified sawed section at mid-shaft level. D Fluorescence microscopy of the same section showing calcein green label (arrows) in the near vicinity of the cement (C). Note penetration of cement into the graft. The orange color is the fluorescence of the basic fuchsin, ×90. E Enlargement of D. Note calcein green labeled bone, and a thin basic fuchsin-stained soft tissue interface (I), ×220. F Fluorescence microscopy of unstained sawed section of cement (C) graft interface. The orange color is alizaron complexon, the yellow color is calcein green label of newly formed bone. Note different zones of alizaron complexon and calcein green label, a result of penetration of the front of new bone formation into the graft, ×140.

ture line, was developing. Another specimen (G6-E) also showed signs of infection, although more locally.

Discussion

The animal model selected for these experiments is thought to be very relevant to the human situation. The femoral canal of the goat is wide enough to perform the grafting technique, and the hard and smooth endosteal surface, with very little trabecular bone, is similar to the sclerotic endosteum usually encountered in revision surgery. The stem shape is similar to the human prosthesis. The goat recovers quickly, and shows normal loading patterns not long after hip surgery, in contrast to dogs. The loads applied in the mechanical testing procedure were realistic at 1.44 times body weight, and were even high relative to the loads of 1.10 times body weight measured in vivo by Bergmann et al. (1984) in sheep. The load direction, based on the same measurements by Bergmann et al. (1984), produced axial, torsional and bending components, all essential to assess stem stability (Mjöberg et al. 1984, Schneider et al. 1989, Burke et al. 1991). The RSA technique provides accurate 3-D motions of the stem relative to the bone, and has proved to be easy to use.

The results were certainly not optimal overall, with 1 definite loosening at 12 weeks, and 2 infected cases. Axial translation on maximal loading was very consistent in the 6- and 12-week specimens at 100–150 µm, of which 25–50 percent was permanent after the first loading cycle. Another average 30 µm of permanent axial translation was added after additional cycles of the 12-week group. Although these values were small relative to the precision of the RSA method, they were very consistent, and indicate that the prostheses still sink after 12 weeks when heavily loaded. The rotations were less consistent in values, but the trends pointed in the same direction. On the other hand, these relative displacements, both elastic and permanent, were small when compared to the direct post-operative situation, for which elastic axial translations up to 500 µm were measured on maximal loading, of which 320 µm did not recover in one case (Schreurs et al. 1991). Thus, the overall implication is that definite improvements in stability occur within 6 weeks, provided that failures do not occur, but that the integration process is not fully completed after 12 weeks, as can be calculated from the displacements for high loads.

This picture was fully confirmed by the histological findings. It was shown that the graft revascularizes and incorporates. However, this process had clearly not been completed after 12 weeks, and it seemed to progress faster proximally than distally, probably due to vascular disturbances in the distal cortex (Feith 1975, Rhinelander et al. 1979).

Acknowledgements

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