EFFECT OF STEM MODULUS IN A TOTAL HIP ARTHROPLASTY MODEL

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The purpose of this study was to determine the biological effects of the elastic modulus of the femoral stem in canine hip arthroplasty.

Cementless total hip arthroplasty was performed in 12 dogs, six had a low elastic modulus polyacetal resin stem and six had a high modulus stainless steel stem. The components were otherwise similar.

At six and 12 months after operation, radiographic and histomorphometric analysis showed that those with steel implants had more cortical porosity than did the other group (p < 0.01).

We suggest that the elastic modulus of the implant is an important factor in controlling cortical bone resorption. A low modulus femoral prosthesis can significantly decrease bone resorption which might otherwise eventually lead to implant failure.

It is well known that the presence of a stiff prosthesis in the proximal femur alters the normal physiological state of the surrounding bone (Jacob and Huggler 1980; Crowninshield et al 1981; Cook et al 1982; Huiskes 1984; Küßwetter et al 1984; Engh, Bobyn and Glassman 1987). Several in vitro studies using strain gauge analysis have confirmed that following implantation of a stem the strain levels in the cortical bone are shifted distally, bypassing the proximal femur so that only 40% of the natural stresses may be present in the cortical bone (Oh and Harris 1978; Lewis et al 1984; McBeath, Schopler and Seireg 1979; Djerf and Gillquist 1987). This so-called 'stress shielding' may eventually lead to bone resorption and ultimately to implant failure (Brown and Ring 1985).

Disuse osteoporosis of the proximal femur appears to be more pronounced when large metal femoral stems are used, in particular those designed for biological ingrowth (Küsswetter et al 1984; Brown and Ring 1985; Luba, Maistrelli and Barrington 1985; Turner et al 1986; Engh and Bobyn 1988; Sumner et al 1988). Other in vitro studies have suggested that a more physiological state of the cortical bone can be achieved by reducing the material stiffness of the implant (Tarr et al 1979; Lewis et al 1981; Manley et al 1982; Manley et al 1983; Lewis et al 1984; Djerf and Gillquist 1987). However, no comparative morphometric studies have been done in animals to confirm the theoretical advantages of a low modulus or iso-elastic implant. The purpose of our paper is to assess and quantitate the biological effects of the modulus of elasticity of a prosthesis implanted into the canine femur.

MATERIALS AND METHODS

Cementless total hip arthroplasties were performed on the right hips of 12 adult male mongrel dogs. The animals were skeletally mature, aged two to five years and weighed 25 to 31 kg. Radiographically all had normal pre-operative appearances of the hips and pelvis. They were selected with reference to a pre-operative sizing template to ensure a proper interference fit.

The operations were performed under general anaesthesia using standard sterile technique and intravenous antibiotics (Kefzol and Mandol 20 mg/kg). The hip was approached anterolaterally. A 23 mm, high-density polyethylene pegged acetabular cup was used in them all (Rob. Mathys Co). In half the animals a press-fit collared polyacetal resin stem (elastic modulus = 5000 MPa) reinforced by a 2 mm steel core (Rob. Mathys Co) was implanted in the femur. The other half had a collared
stainless steel stem (elastic modulus = 200 000 MPa) of identical size and geometry (Fig. 1). In both groups, a stainless steel femoral head was placed on the end of the Morse-type tapered neck.

Postoperatively the dogs were allowed unrestricted activity and were exercised daily. Anteroposterior and lateral radiographs of the hips were taken postoperatively and at three month intervals. Force plate analysis, using a strain gauged instrument platform (Advanced Mechanical Technology, Inc, Newton, USA), was performed on all the dogs at the end of follow-up. Six animals, three from each group, were killed by intravenous barbiturate injection at six months and the remainder at 12 months. The pelvis and both femurs were removed and dissected from the soft tissues. Contact radiographs of the entire specimens were obtained. The specimens were then fixed and embedded in Spurr’s low viscosity medium (Spurr 1969). Both the test and the control femurs were then cut transversely 1 cm distal to the implant tip and 1, 3 and 5 cm proximal to the tip, using a Buehler Isomet lowspeed saw and a carbide blade. A low-energy fine-detail radiograph of these sections was obtained before the tissues were fixed with cyano-acrylate to a plastic backing. The exposed surface of the section was ground, polished and surface stained with toluidine blue to a depth of approximately 5 μm. The tissue was examined microscopically by transmitted incident light. Initial quantitation was undertaken on the Zeiss Video Plan system.

Each section was divided into quadrants; anterior, posterior, medial and lateral. Comparable areas from each quadrant were compared both in the test and in the control femora. Bone porosity was expressed as a percentage of the area of compact bone occupied by non-osseous spaces, such as haversian canals and resorptive cavities and each test femur was compared with its contralateral control. Measurements were made of the mean cortical thickness and the mean thickness of the fibrous membrane at the bone implant interface.

The data obtained was analysed on a Macintosh SE computer using a Student’s t-test for the statistical evaluation of the numerical data.

RESULTS

There were no infections, fractures or dislocations. At post-mortem, all the components were found to be clinically well fixed with no evidence of loosening. The force plate analysis confirmed that all dogs bore weight adequately on both the operated and the control limbs and that there were no significant differences between the two study groups in peak vertical force and vertical impulse measurements.

**Radiographic analysis.** From the post-mortem contact radiographs the surgical fit of the implant was assessed according to the method of Engh and Bobyn (1988). A consistently accurate fit was found. Contact of the stem approached a 90% fill in the intertrochanteric region and 80% in the distal shaft. The femur and stem dimensions were found to be similar in the two groups.

Both groups showed radiographic changes of bone remodelling in the calcar region; cortical bone resorption was present in five of the six metal specimens but in only two in the polyacetal group. All the specimens exhibited endosteal new bone around the implant tip, but only in the metal group were these changes extensive.

By three months a uniform radiodense line was seen...
at the surface of all the polyacetal stems; there was little change in width or density at further follow-up periods. None of the implants showed signs of subsidence, loosening or malposition.

**Histomorphometry.** Fine detail radiographs were taken of the intact specimens in two planes and of the sections cut through various levels of the implant. The restoration of trabecular structure proximally and the formation of a linear shell of bone around the implant distally was quantified from these radiographs.

Direct juxtaposition of bone to the surface of the implant (osseo-integration) was not seen. A membrane of fibrous connective tissue was interposed between the bone and the implant in all cases. The thickness of this membrane varied from site to site but had an average thickness of approximately 43 μm around the polyacetal implants and 49 μm around the metal implants. This difference is not statistically significant. The important feature of this membrane was that it was composed of dense collagenous fibrous tissue with almost no histiocytes, lymphocytes, foreign-body giant cells or any other reactive or inflammatory cells. The fibrocytes were elongated and few in number, confirming the mature and organised nature of this collagenous layer. The lack of active remodelling in the adjacent bone was taken to indicate good stable fixation. Polarised light microscopy showed that the collagen fibrils were organised into intertwining bundles mostly parallel to the surface of the implant. The fibrils seemed to be anchored to the surrounding shell of bone in the pattern seen at ligamentous insertions (Sharpey's fibres). The bony trabeculae of the ring-like shell about the implant were composed of mature, well organised bone. The endosteal surfaces were smooth with no evidence of active resorption. Osteoblastic activity was indicated by the presence of a thin layer of unmineralised bone (osteoid) and rows of plump osteoblasts. Near the proximal end of the implants there was good restoration of the overall trabecular structure, suggesting stability and a good pattern of stress transfer. In cross-section the cortical bone demonstrated more resorption cavities and haversian canals in the implanted femora than in the controls (Fig. 2). The bone around the metal stems had an average porosity 6.5% greater than the controls, compared to 1.8% for the polyacetal stems (p < 0.01). Comparison between the six- and 12-month specimens showed no evidence of progression of these changes with time, indeed the average density at 12 months was greater than at six (Fig. 3). Figure 4 shows that the difference in porosity between the two experimental groups was significant in all except the lateral quadrant of the femur. The difference between the two study groups was greater at the proximal levels (p < 0.01) than at the most distal level where significance was borderline (p < 0.05, Fig. 5).

Other parameters measured included the mean cortical thickness, and the mean membrane thickness
but no significant differences were found between the two study groups.

There was no evidence of particulate matter in the fibrous membrane at any of the levels examined either with transmitted or polarised light. The enlarged haversian systems within the cortices were smooth and rounded suggesting a slowly developing imbalance between bone formation and resorption rather than active osteoclastic activity. The lack of fibrous tissue within the lucent zones is typical of disuse atrophy from stress shielding.

**DISCUSSION**

This comparative study has shown that cortical bone response can be affected by the stiffness of the femoral stem after cementless total hip arthroplasty. The increase in cortical porosity, although observed in both study groups, was significantly higher in the animals that received metal implants. Since the implants were the same in size and geometry, and since the force plate analysis showed similar weight-bearing status in the two groups, it can be concluded that the disparity in cortical porosity was secondary to the difference in elastic modulus of the materials of the two kinds of stem. The proximal to distal gradient of increased porosity was observed mainly around the metal stems, suggesting distal transfer of the load along the stiffer prosthesis even in the absence of porous coating or direct bone bonding to the implant.

Both the metallic and the polyacetal implants developed non-reactive fibrous membranes of similar thickness at their bone–implant interfaces. Although cortical porosity was greater around the metallic implants there was no evidence of progression of these osteoporotic changes, which suggests that a state of equilibrium in the bone remodelling process had resulted and that the morphological differences were a consequence of the different material properties of the two stems. Other factors which might affect bone remodelling in the longer term include such variables as stem size and geometry, cortical revascularisation, type and extent of surface coating material and the degree and location of osseo-integration.

We believe that our findings may have clinical significance and that the biomechanical differences between bone and implant will prove important in the long-term survival of the large, non-cemented femoral components in use today. The negative bone remodelling response which these prostheses produce may well prove to be more important than the quality of the actual interface bond itself. The use of a lower modulus or composite femoral stem would allow better load sharing and might ultimately achieve a more stable biomechanical harmony.

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