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BONE INGROWTH INTO POROUS COATED CANINE TOTAL HIP REPLACEMENTS. QUANTIFICATION BY BACKSCATTERED SCANNING ELECTRON MICROSCOPY AND IMAGE ANALYSIS

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Abstract

Bone ingrowth into titanium fiber mesh porous-surfaced canine total hip replacement prostheses was evaluated and quantified using a computer assisted image analysis system attached to a scanning electron microscope equipped with a back scattered electron detector. Excellent contrast between the bone, the porous metal and the soft tissues resulted in the backscatter mode, allowing easy differentiation of these components in real time by the image analysis based on gray scales. By three weeks the mean (± standard deviation) amount of bone ingrowth expressed as a percentage of porous layer measured 7.2% (± 1.5%) for the acetabular components, and 3.9% (± 1.7%) for the femoral components. At six weeks the amount of bone ingrowth increased to 10.5% (± 1.3%) for the acetabular components and 8.5% (± 1.4%) for the femoral components. Cementless prosthetic fixation using porous surfaced prostheses holds great promise in joint replacement surgery, and the ability to quantitate the amount of bone ingrowth will permit the evaluation of the efficacy of various techniques to improve bone ingrowth.

Key Words: Bone ingrowth, Joint replacement, histomorphometry, backscattered electrons, scanning electron microscopy, image analysis.

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Introduction

Total joint replacement surgery using man made prostheses to replace diseased joints has provided dramatic relief of pain and improvement in function for many patients with end stage arthritis. Approximately 100,000 total hip replacements and 100,000 total knee replacements are done annually in the United States and an equal number in the rest of the world. In the past, the vast majority of these prostheses were attached to the skeleton using surgical bone cement made of polymethylmethacrylate. Although this form of prosthetic fixation was remarkably successful over a short time, mechanical loosening was a problem over the long term, with approximately 10% of the components becoming loose by 10 years necessitating further surgery (Stauffer, 1982; Sutherland, et al. 1982).

Porous-surfaced, uncemented prosthetic components have recently been introduced to avoid the problem of cement failures and long term mechanical loosening (Galante, et al. 1971). Bone ingrowth into the porous surfaces of these prosthetic components is believed to provide remarkable long term fixation of the prosthetic components to the skeleton. These uncemented, porous-surfaced prostheses are being used with increasing frequency as attractive alternatives to conventional cemented prostheses particularly in the young and active patient (Engh, et al. 1987; Galante, et al. 1971).

Obtaining consistently reliable fixation of these components by bone growth into the porous surface, however, remains a problem (Cook, et al. 1988; Collier, et al. 1988; Engh, et al. 1987; Harris and Jasty, 1987; Pilliar, et al. 1981). Appropriate porous surface, rigid initial prosthetic stability, intimate apposition of the porous surface to the prepared bone, and weight bearing stresses are believed to influence the degree of bone ingrowth into the porous surfaces (Harris and Jasty, 1987). Although bony ingrowth has been shown to occur in the porous-surfaced total joint replacement components in animal studies as early as three weeks, the amount of bone ingrowth has been small and variable (Cameron, et al. 1976; Park and Kenner, 1976; Pilliar, et al. 1981; Rivero, et al. 1988; Russotti, et al. 1987). Preliminary studies of porous surfaced prostheses retrieved from patients who had undergone cementless total joint replacement surgery have also failed to show extensive bony ingrowth. Cook, et al. (1988) and Collier, et al. (1988) have examined porous-surfaced prostheses retrieved from human patients and found minimal or no bone ingrowth in the majority of the components.

It is clear from the experience gained to date that many design features of the prosthetic components and surgical techniques used to implant them can influence the ability to obtain bone ingrowth into the porous surfaces. In order to optimize the parameters required to maximize the bone ingrowth into the porous surfaces, careful, controlled experimental studies using animal models are necessary. It would also be important to quantify the amount of bone ingrowth so that the efficacy of the various techniques can be compared in a quantitative manner.

In this study, we have used a canine model to study the fixation of porous-surfaced total hip replacement prostheses by bone ingrowth. We used scanning electron microscopy (SEM) to quantify the bone ingrowth at various time periods, so that we can optimize the design and surgical parameters to maximize the ingrowth of bone into the porous surfaces of the prosthetic components and hopefully their long term stability.

Materials and Methods

Total hip arthroplasty using porous coated prosthetic components was performed on 14 fully mature mongrel dogs of either sex weighing between 25 and 35 kg. All animals were screened by a veterinarian to insure good health. Skeletal maturity was assured by establishing the closure of proximal epiphyseal growth plate on radiographs.

Surgeries were carried out on the right hip of all animals, using titanium fiber mesh surfaced total joint replacement components. An attempt was made to optimize the design of the component to allow intimate fit with the bone as described below. The hemispherical acetabular components shown in Figure 1, were made out of commercially pure titanium and contained four holes in the central portion for the insertion of anchoring screws. A titanium fiber mesh of 200 μm pore size and 40% porosity was sintered on the outside surface of the acetabular shell to provide the porous surface for bone ingrowth. The outer diameter of the acetabular component including the porous layer was 29 mm. Four titanium anchoring screws inserted through the acetabular component to the ischium, ilium and pubis were used to provide rigid fixation of the acetabular component immediately at the operation. A two mm thick polyethylene liner provided the articulation with the prosthetic femoral head.

The femoral components, also shown in Figure 1, were made out of Ti-6Al-4V alloy. They had a trapezoidal cross sectional shaped proximal body and a cylindrical cross sectional shaped distal stem, each of which were 3.0 cm in length. The configuration of the proximal body of the prosthesis was made so that the medial-lateral dimensions increased proximally. This conical shape of the proximal half of the component was chosen to conform to the proximal femoral metaphysis in the canine to achieve intimate contact and rigid implant stability. The center of the femoral head was offset 18 mm from the horizontal and 16 mm from the vertical to the base of the neck. The 16 mm diameter femoral head was made to match the polyethylene liner in the acetabular component while allowing full range of motion of the hip without impingement. The prosthesis had a collar to seat on the proximal medial femoral cortex.

Prior to surgery, antero-posterior and lateral radiographs of the femur were obtained and transparent acrylic templates of the prosthetic components (taken at 5% magnification), were overlapped on the dog femoral and acetabular outlines to assess the ideal size of the prosthetic components. Since only one size of the acetabular and femoral components were available, only the dogs that fit the radiographic templates were included in the study.

Precise and reproducible surgical techniques were used to insert the acetabular and the femoral components. All surgeries were performed with general anesthesia using a posterolateral approach. The gluteus maximus tendon was detached slightly proximal to its insertion and reflected proximally. The short external rotators were detached at their insertion on the trochanter, and posterior and anterior capsulectomies were carried out. The hip was dislocated posteriorly and the femoral neck was osteotomized with a power saw. The acetabulum was prepared by carefully reaming with precision reamers that increased in diameter by 0.5 mm to remove all of the articular cartilage and subchondral bone. The acetabular component was then placed into the reamed cavity of 29 mm at 30 degrees of abduction and 30 degrees of forward flexion and stabilized with 4.5 mm diameter titanium screws through the acetabular component. Prior to the insertion of the screws, the contact between the porous coating and the native bone was inspected through the holes contained in the acetabular component. After tightening of all screws, the Polyethylene liner was impacted into the shell.

For the insertion of the femoral component, the femur was drilled with a series of drills that increased by 1.0 mm increments in diameter to a final size of 10.7 mm. A femoral rasp that corresponded to the shape of the femoral component proximally but had a stem portion that was 0.3 mm smaller than the femoral component was then used to rasp the femoral canal. The femoral component was then press fitted into the femoral canal until the collar of the prosthesis contacted the cut surface of the medial femoral neck. These precise surgical tools and techniques were used in the hopes of obtaining intimate apposition between the porous surface and the prepared bone, and immediate rigid stability of the prosthesis.

The dogs were allowed to ambulate unrestricted as soon as they recovered from anesthesia. They were also exercised twice daily out of their pens during the post-operative period. All dogs were radiographed two days post-operatively to assess the position of the femoral component and at three weeks and then at six weeks. Fluorochrome labels were administered during the postoperative period. These consisted of Vibromycin 10 mg per kg daily for the first half of the observation period, and Declomycin 10 mg per kg for the second half of the observation period.

Seven dogs were sacrificed at three weeks after surgery and the other seven were sacrificed at six weeks after surgery using barbiturate overdose. We chose these time periods based on previous studies of bone ingrowth which showed that identifiable early ingrowth of mineralized bone takes place by three weeks and formation of lamellar bone occurs by six weeks (Harris and Jasty, 1987).

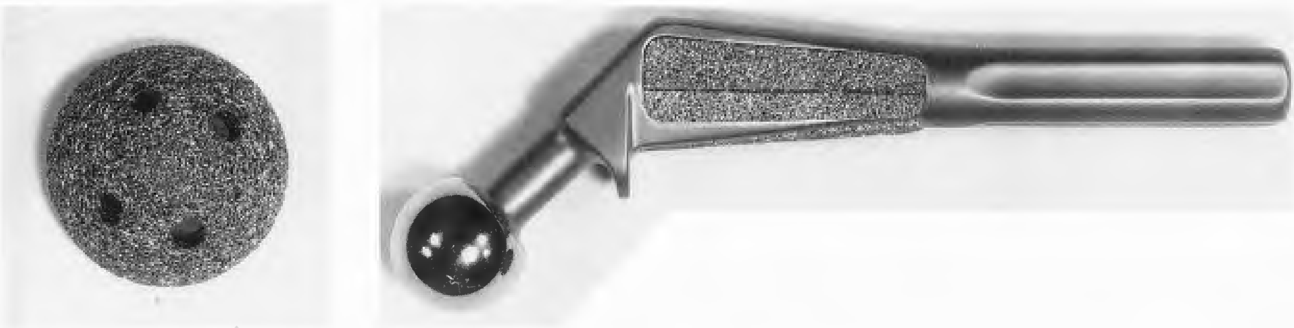


Figure 1. The porous surfaced acetabular (left) and femoral (right components).

At sacrifice, the whole pelvis and both femora were harvested and contact radiographs obtained. The periacetabular areas were then transected at the ischium, ilium, and pubis. The femoral condyles were removed from the femur. The specimens containing implants were immediately fixed in buffered formalin and then gradually dehydrated in graded alcohols of increasing concentrations starting with 40% and ending with 100% over a period of 30 days. They were then imbedded in polymethylmethacrylate in a well oriented coordinated system.

The embedded specimens were sectioned serially in a sagittal orientation for the acetabular components, and a transverse orientation for the femoral components using high speed circular water cooled alumina saw (DO-All, Watertown, MA). Twelve to fifteen sections were obtained from each of the components. The surface of these sections was ground using a 600 grit silicon carbide abrasive paper on a lap wheel, and the specimens were mounted on a series of metal plates. The surface of the specimens was coated with gold in a sputter coater, and examined in a Stereoscan S90 SEM (Cambridge Instruments, England) equipped with a backscatter electron (BSE) detector (K.E. Developments Ltd., Cambridge, England) to quantify bony ingrowth. Representative sections were mounted on glass plates with cyanoacrylic and further ground to 30 to 50 microns. The thin sections were stained with hematoxylin, eosin and toluidine stains to permit histological assessment. Representative sections were also examined unstained under ultraviolet light to assess the fluorochrome labels.

Quantitative measurements of the bone ingrowth into the porous layer were obtained by using a high speed, computer assisted, image analysis system attached to the SEM. The BSE mode was used during most of this analysis to permit differentiation between the bone and metal (Boyde and Jones, 1983; Becker and Sogard, 1979). For this analysis, the porous layer on each section was divided into several contiguous polygonal fields spanning the porous surface. The area fraction of bone and metal within each of these fields was measured based on the gray levels of the bone and the porous metal. Since the metal is brighter in the image than the mineralized bone, it was possible to distinguish the bone and the metal from each other by thresholding for the brightness of the different components in the image. The BSE images were digitized into 768 by 512 pixels in real time, thresholded, and the pixels above and below the thresholded levels were counted individually by the computer (Microvax II, Digital Equipment Corporation, Maynard, MA). Four different measurements were used to express both the quantity and extent of bone ingrowth:

1. The total amount of bone in the porous layer was obtained by dividing the area occupied by bone within each field by the area of the field (top of the mesh to the solid substrate) and averaging all of the analysis area for the acetabular component and for the femoral component.
2. The area density of the ingrown bone was expressed as a percentage of the pore area available for bone ingrowth by dividing the area occupied by the bone by the total pore area (excluding the metal).
3. The percentage of the prosthesis surface area which obtained any degree of bone ingrowth or bone apposition was calculated separately by counting the number of fields that contained any degree of bone ingrowth or apposition divided by the total number of fields examined.
4. The depth of bone penetration was also calculated as a separate measurement by assessing the depth of the bone penetration into the porous layer as a percentage of the porous layer thickness in each of the fields.

Results

None of the hips dislocated during the post-operative period. At sacrifice, all of the implants were observed to be well anchored to the skeleton. On gross examination, neither adverse response to the implant materials nor any infections were noted.

Radiographic analysis showed no evidence of radiolucencies at the bone-porous coating interfaces, either on the immediate post-operative roentgenograms or the follow up roentgenograms. Normal trabecular pattern within the acetabulum and the femur was maintained during the six weeks of observation.

Morphologic examination of sections showed extensive ingrowth of bone into the porous coating both at three and six weeks (Figs. 2 and 3). At three weeks most of the ingrowth bone was woven bone, but by six weeks much of it had organized into mature lamellar bone. In some areas the ingrown bone was seen to be intimately associated with the metal wires without separation of the wires and the ingrown bone by layer of fibrous tissue. In other areas a thin layer of fibrous tissue, usually one to two cell layers thick, separated the metal wires and the ingrown bone. Most of the bone ingrowth

Table 1. Quantification of Bone Ingrowth

	Area Fraction	Density	Depth	Surface
3 Week Acetabulum	7.2 ± 1.5	16.0 ± 3.4	53.2 ± 9.6	82.4 ± 3.9
3 Week Femoral	3.9 ± 1.7	9.5 ± 4.9	32.6 ± 18.4	61.7 ± 26.0
6 Week Acetabulum	10.5 ± 1.3	21.5 ± 4.4	66.2 ± 8.3	76.0 ± 14.9
6 Week Femoral	8.5 ± 1.4	22.4 ± 2.8	60.1 ± 12.8	85.7 ± 9.1

appeared to be the result of ingrowth from the surrounding bone into the mesh. However, many areas of de novo bone formation inside the mesh were observed at three weeks. Fibrocartilage or endochondral ossification was very rare. Fluorochrome label showed continuing bone on the surface of the coating both at three and six weeks.

In spite of the precise surgical techniques used to obtain intimate bone-porous surface apposition, small gaps (less than 0.5 millimeters in thickness) occurred at the bone porous surface interface in one three week dog around the acetabular component, and in almost all of the femoral components (Fig. 4). Bone ingrowth was absent in the gap regions, and these regions were occupied by dense fibrous tissue. Bone ingrowth however, occurred in regions adjacent to these gaps in which there was intimate apposition between the bone and the porous surface.

BSE SEM imaging permitted easy differentiation of the bone, the metal wires and the soft tissues with minimal edge artifacts. The uniform brightness of the field and the large differences in the brightness levels between the bone and the metal allowed easy quantification of the bone ingrowth based on the brightness levels. The thresholding of the bone and the metal could be done in real time, thereby enhancing the speed of the analysis. Pseudocoloring of the image based on the brightness threshold levels allowed accurate visual verification of the thresholding process since it was possible to visualize the full image and the pseudocolored image on the same monitor. Therefore, there was no need to precisely standardize the beam current or the threshold levels. Quantitative measurements of bone ingrowth in each of the analysis areas took approximately 30 seconds per field and both the acetabular and femoral components from a single dog could be analyzed in less than eight hours.

Area fraction measurements showed that at three weeks the total amount of bone ingrowth obtained into the porous layer (defined as the areas from the top of the porous layer to the solid substrate) in dogs receiving the uncoated prostheses measured 7.2% ± 1.5% for the acetabular components and 3.9 ± 1.7 for the femoral component (Table 1). The metal wires themselves occupied an additional 54% of the porous layer. The area density of bone within the pore space available for bone ingrowth therefore measured 16% ± 4% for the acetabular components and 10% ± 5% for the femoral components. The differences between bone ingrowth into the acetabular and femoral components were statistically significant at P less than 0.01 using students T test.

At three weeks the depth of bone penetration into the acetabular components measured 53% ± 10% whereas the femoral components obtained a depth of penetration 33% ± 18%. The percentage of the acetabular surface that obtained bone ingrowth at three weeks measured 82% ± 4% for the acetabular components and 62% ± 26% for the femoral components. Thus, the femoral components obtained bone ingrowth over less of their periphery and the bone grew into less of the depth of their porous coating compared to the acetabular components.

At six weeks the bony ingrowth into the acetabular components increased to 10.5% ± 1.3% and for the femoral components the bony ingrowth increased to 8.5% ± 1.4%. There was significantly greater bone ingrowth into the acetabular and femoral components at six weeks than at three weeks. Similarly, there was an increase in the area density of bone in the pore area, the surface area of the implant periphery into which bone grew and the depth of bone penetration at six weeks (Table 1). The differences in the average amount of bone ingrowth into the acetabular and femoral components became less dramatic at six weeks. However, one of the seven dogs obtained minimal bone ingrowth into the femoral component even at six weeks (area fraction of 2.5% of the porous layer) while all of the acetabular components obtained good bone ingrowth at both three and six weeks.

DISCUSSION

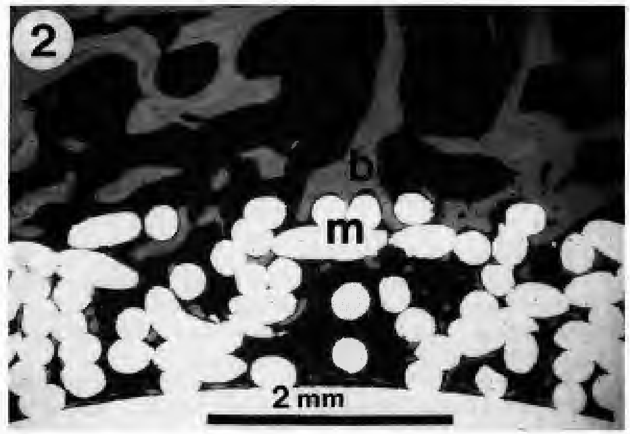
In this study, using well designed prosthetic components and precise surgical techniques it was possible to obtain excellent bone ingrowth into porous surfaced uncemented canine total hip replacement prostheses. However, histological and quantitative BSE SEM studies have shown that the amount of bone ingrowth is variable and depends of multiple factors such as the adequacy of the apposition between the porous coating and the prepared bone bed, rigid initial prosthetic stability, and site of implantation.

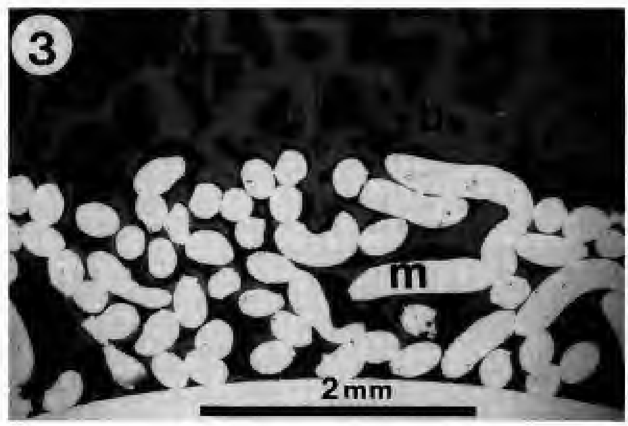
Bone ingrowth has been obtained as early as three weeks in these canine studies employing weight bearing and functionally loaded joint replacements. However, the bone ingrowth was more substantial into the acetabular components than the femoral components at three weeks. Several factors may account for this difference. It is technically easier to prepare the acetabulum than the femur since the acetabulum has a simpler hemispherical geometry unlike the femoral canal which has a complex internal geometry. Using current surgical instrumentation the acetabulum can be reamed to match the hemispherical outer contour of the acetabular component without creating gaps at this interface. The bone surface in the acetabulum is predominantly cancellous and therefore, more vascular than the endosteal surface of the femur. Of greater importance, perhaps, may have been the ability to reliably obtain initial stability of the acetabular component under physiological loads by using screws. It is known that in certain phases of the walking cycle, when the femur is flexed, large torsional moments are created about the hip. During such activities screws may provide the required stability to the acetabular components while press fitting the cylindrical shaped femoral component may not provide adequate rotational stability under such torsional loads. Even though the bone ingrowth into the porous surfaces was present in all of the femoral components at six weeks, one of the components demonstrated substantially lower amount of bone ingrowth, possibly related to the lack of initial rotational stability and the other factors mentioned above.

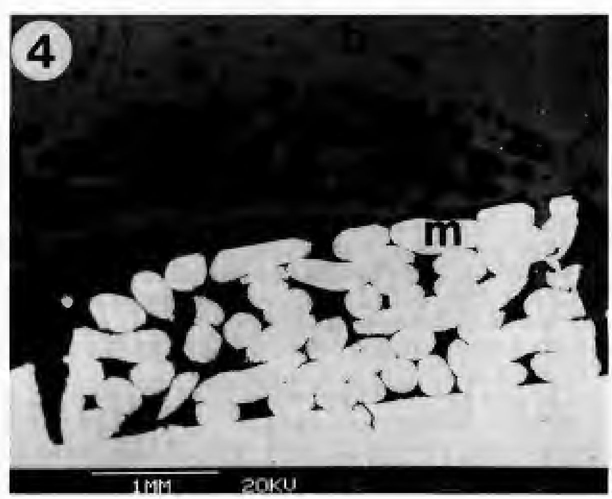
While the amount of bone ingrowth is a relatively good indicator of the prosthetic fixation, this measurement alone may not determine the prosthetic stability. The stability of the prosthesis depends critically on the strength of the interface between the bone and porous coating (Ducheyne et al., 1978). Not only the total amount bone ingrowth is important in determining the interface strength, but also the distribution and location of the bone ingrowth contribute to the prosthetic stability. The extent of the implant periphery into which bone ingrowth occurs may be an important indicator of the shear strength at the bone-prosthesis interface, while the depth of bone penetration may be an important indicator of the tensile strength at the interface. In this study we individually quantified these various parameters. While all of these parameters in combination may be good indicators for the implant stability, mechanical studies measuring the relative displacement of the prosthetic components under increasing loads are required to establish the prosthetic stability.

The amount of bone ingrowth that is necessary to provide fixation of porous surfaced prostheses to the skeleton is largely unknown. Quantitative measurements of bone ingrowth in this study suggests that the density of ingrown bone at six weeks approaches that of the normal cancellous bone density in the canine. Thus, it would seem that establishing normal bone density in the porous coating is desirable in transferring the loads to the adjacent skeleton in a physiological manner.

Uncemented fixation of the joint replacement prosthesis to the skeleton by bone ingrowth into the porous surfaces of the prosthetic components is an exciting development in orthopaedic surgery. However, the experience with these devices has been short and many questions remain in using such devices. The long term success rates of porous surfaced uncemented prostheses are largely unknown. Experimental studies using canine models (Harris and Jasty, 1987) and studies on prosthetic components retrieved from human patients (Cook et al., 1988, Collier et al., 1988) have begun to elucidate the parameters required for obtaining optimum bone ingrowth into these prostheses. Several exciting methods to stimulate or enhance bony ingrowth into these devices such as coating the prostheses with osteoconductive hydroxyapatite coatings (Geesink et al., 1987), osteoinductive proteins as well as using external electric stimulation (Park and Kenner, 1976) may hold even greater future for these prostheses. Well controlled canine studies with quantitative measurements of bone ingrowth are necessary to determine efficacy of the various parameters such as surgical techniques, prosthetic designs and bone stimulating







Figures 2 and 3. Bone ingrowth into an acetabular component at three (**Fig.** 2) and six (**Fig.** 3) weeks. **Figure 4.** Bone ingrowth into an femoral component at six weeks. Note the absence of bone ingrowth in the vicinity of the gap at the bone-porous coating interface. B = bone; M = metal fibers.

agents to improve the bone ingrowth into these devices. BSE SEM imaging provides an excellent method to analyze the bony ingrowth into these devices, and in combination with computer assisted image analysis allows quantification of bone ingrowth into these devices, so that the above parameters can be optimized and hopefully improve the long term success rates of total joint replacements.

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Discussion with Reviewers

P.G.T. Howell: How did a variation in thresholding of the BSE signal affect the results? What methods did the operators use to standardize their beam current etc. for the recording of their measurements on both a single sample and between the samples?
Authors: The bone, metal and the void spaces are not distinguished based on their absolute threshold levels, but on their relative threshold levels. Since the unthresholded and thresholded images are displayed on the same monitor in different pseudocolors, it is possible to choose the threshold levels at which the thresholded images match the unthresholded images. A relative threshold level of each feature is established based on the geometrical superimposition of the unthresholded and thresholded images, thereby eliminating the need for precisely standardizing the beam current and the threshold levels on a single sample and between the samples.

H.U. Cameron: In the acetabulum was there total area contact or was there dome or rim contact? If so, where was the bone ingrowth most dense, around the rim or in the dome?
Authors: There was total contact between the prepared bone and the porous coating in most instances, using the techniques described for implantation of the acetabular components. There was some variability in the regional distribution of bone ingrowth among the dogs, but in general the most dense bone ingrowth occurred around the dome of the acetabular components.

H.U. Cameron: Was the bone ingrowth found most heavily around the screws?
Authors: Yes. In general, bone ingrowth was found to occur most consistently and most heavily into the porous coating immediately adjacent to the screws used to fix the acetabular component. It is difficult to speculate why this occurs however. It is possible that the screws provided the best compression of the porous surface to the acetabular bone in these regions thereby providing more bone ingrowth. It is also possible that local alterations in the stress patterns produced by the screws might have resulted in more bone ingrowth.

H.U. Cameron: On the femoral side, did the bone ingrowth occur better when the porous layer was adjacent to the cortical bone or cancellous bone? Where in the femur was the bulk of the bone ingrowth found?
Authors: The small sample size and the variable fit of the femoral components make the analysis of the distribution of the bone ingrowth on the femoral side difficult. In general, the heaviest bone ingrowth seemed to occur at the distal end of the porous

coating.

R. Bloebaum: How many representative sections, and number of fields were analyzed?
Authors: Twelve to fifteen sections were cut from each component. All of the serial sections were analyzed for the acetabular components. Only every other section was analyzed for the femoral components. All of the fields were analyzed for each of the sections examined for the quantification of bone ingrowth.

R. Bloebaum: How do the authors justify making inferences from the canine data to the clinical events under load bearing conditions in patients?
Authors: It is true that canine data should not be used to describe what would happen in the clinical situations with human patients. For example, canine bear significantly lower weight on their hips (1.6 times body weight or about 50 kg in the present series) than humans (2.5 times body weight or 175 kg for a 70 kg person), and the findings on the canine might not hold in the human. In spite of these large differences however, canine studies are enormously valuable in the investigation of the new prosthetic designs for humans, since histologic data from humans are difficult to obtain, and long term follow-up data from humans will take a long time to collect. If a particular prosthetic design is not successful in the canine, it is doubtful that it would be successful in the human who bear much heavier loads on their hips. If a particular design is successful in the canine, it may not mean that it would be successful in the human however, and caution should be exercised in using the canine data to predict the outcome of those prosthetic components in human patients. Till long-term clinical follow-up data on these newer prosthetic components is available, canine studies provide good models for optimizing the various design features of the prosthetic components. In this study, we have shown that hemispherical porous surfaced acetabular components, stabilized with screws, obtained excellent bone ingrowth in the canine while the cylindrical porous surfaced femoral components do not. Therefore, further work is needed to improve the design of the femoral components to be used in the human patients.