Acta orthop. scand. *52*, 145–153, 1981

OSTEOGENIC PHENOMENA ACROSS ENDOSTEAL BONE-IMPLANT SPACES WITH POROUS SURFACED INTRAMEDULLARY IMPLANTS

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Porous surfaced femoral components of hip prostheses stabilized by tissue ingrowth are often situated a certain distance away from the endosteal cortex in the diaphysis. The purpose of this study was to examine the significance of this space between an implant and the cortex on bone growth into the porous surface of the implant.

Intramedullary rods of different diameters with porous surface regions made of powder metal were inserted into the femurs of adult beagles. The rods had outside diameters of 2.5, 3.2, 4.5, and 5.5 millimeters; this variation produced endosteal bone-implant surface spaces ranging from 0 to 4 millimeters. The animals were sacrificed at 4, 8, 12, and 16 weeks.

Histological sections revealed that by 12 weeks the implants became generally surrounded by a thin shell of spongy bone which was joined to the endosteal cortex by bony trabeculae. This feature was most prominent for implants which were approximately 2 millimeters or less from the endosteum. Denser, more haversian-like bone developed up to and within those areas of implants which were in contact with the cortex.

The development of this intramedullary type of bone could significantly contribute to the fixation strength of clinical porous surfaced prostheses whose stems do not completely fill the medulla.

Key words: bone ingrowth; implant fixation; intramedullary; porous implants

Accepted 6.x.80

Porous surfaced stemmed femoral prostheses which are intended for attachment by tissue ingrowth have recently been introduced into clinical orthopaedic surgery (Pilliar et al. 1975, Cameron & Pilliar 1980). These implants are designed for fixation without bone cement so that problems associated with the use of cement both at the time of and after surgery can be eliminated (Willert & Semlitsch 1976).

Experimental studies on the concept of biological fixation of implants have clearly demonstrated bone growth into porous ceramics (Hulbert et al. 1970, Cameron et al. 1977), polymers (Howe et al. 1974, Spector et al. 1976), and metals (Galante et al. 1971, Hirschhorn et al. 1971, Bobyn 1977). Several investigators have established firm fixation of porous intramedullary rods or nails by osseous tissue ingrowth. In some of these studies the medulla was reamed out such that a uniform, tight fit of the implants up against endosteal cortical bone was achieved (Nilles et al. 1974, Dorre et al. 1976, Miller et al. 1976). In other studies the implants only came into partial contact with endosteal cortical bone (Collier et al. 1976, Ducheyne et al. 1977). Information on the growth of bone into a porous surfaced implant which is not at all in contact with the endosteal cortex has not been documented.

0001-6470/81/020145-09 $02.50/0

Since the distal portion of the stem of porous surfaced clinical prostheses often lies away from the cortex, this information is pertinent to the problem of establishing the fixation of clinical implants by bone ingrowth.

Experimental purpose and design

The purpose of this study was to investigate the osteogenic response to porous surfaced intramedullary implants placed within canine femurs near the mid-diaphysis region. A histological examination of the effect of the space between the implant and the cortex surface on bone formation around and within the porous surface structured implants was performed. The implant diameter was varied to provide a variation in the size of this space. It has been speculated that for the initial stabilization of a clinical porous surfaced implant to occur, it would be advantageous to keep the device non-load bearing in the early postoperative period so that bone ingrowth would not be adversely affected by too much movement of the implant relative to its attachment site (Cameron et al. 1973). Our experiment simulated this early non-loaded implant situation by using intramedullary rods that were non-functional and therefore non-load bearing. The effect of postoperative time on bone development in the region of the rods was also studied by varying the period of rod implantation prior to animal sacrifice.

MATERIALS AND METHODS

Implant fabrication and characterization

The implants were fabricated from cobalt-base surgical implant alloy (ASTM F-75). Using powder metallurgy techniques solid alloy rods 2.0 millimeters in diameter were coated with a multiple layer of powder particles in the size range of 45 to 150 micrometers. The particles, produced by inert gas atomization of the alloy, were generally spherical in shape. They were bonded to each other and to the solid substrate by sintering in a non-oxidizing atmosphere to produce a surface network of fully interconnecting voids within a surface region which was 30 to 35 volume per cent porous. The thickness of the porous coating was varied to produce implants with final diameters of 2.5, 3.2, 4.5, and 5.5 millimeters. The length of the porous coating for each implant was 25 millimeters. Only the central portion of each implant was porous coated; the ends were left uncoated and smooth surfaced (Figure 1A). The overall length of each implant was approximately 80 millimeters. Scanning electron microscopy of the porous surface indicated a pore size range of approximately 50 to 200 micrometers (Figure 1B). This range is within the range of approximately 50 to 400 micrometers previously determined by Bobyn et al. (1980) as being optimum for the development of the greatest fixation strength in the shortest time period for porous implants stabilized by cortical bone ingrowth. The porous coating was also identical with that used in one type of clinical prosthesis (Cameron & Pilliar 1980).

Surgery

Using standard sterile surgical techniques, the intramedullary rods were implanted bilaterally into adult canine (beagle) femurs. Each implant was introduced into the medulla via a hole drilled in the intracondylar notch such that the porous surfaced segment of the implant was approximately in the middle of the diaphysis (Figure 2). Postoperative X-rays showed that each implant was positioned essentially parallel to the longitudinal axis of the femur. No control was exercised over the position of each implant relative to the central axis of the medulla. The experimental protocol (implantation times and implant diameters) is given in Table 1. A total of six animals was used. There were no cases of infection and all animals remained healthy for the protocol length of time. The animals were sacrificed at 4, 8, 12, and 16 weeks. Post-mortem X-rays were taken to examine for the presence of formed intramedullary bone.

Histology

After animal sacrifice the femurs were removed and processed for histological examination of the bone-implant interfacial regions. The bone-implant samples were infiltrated with and embedded in polymethylmethacrylate and thin slices were cut through them with a low-speed, low-deformation diamond cut-off wheel. Each slice was glued onto a glass slide and further thinned to the desired thickness using petrographic grinding

Table 1. Experimental protocol

Dog number	Implant diameter (left leg)	Implant diameter (right leg)	Time (weeks)
287	3.2 mm	4.5 mm	4
288	3.2 mm	4.5 mm	8
289	2.5 mm	5.5 mm	8
311	3.2 mm	4.5 mm	12
312	2.5 mm	5.5 mm	12
313	2.5 mm	5.5 mm	16

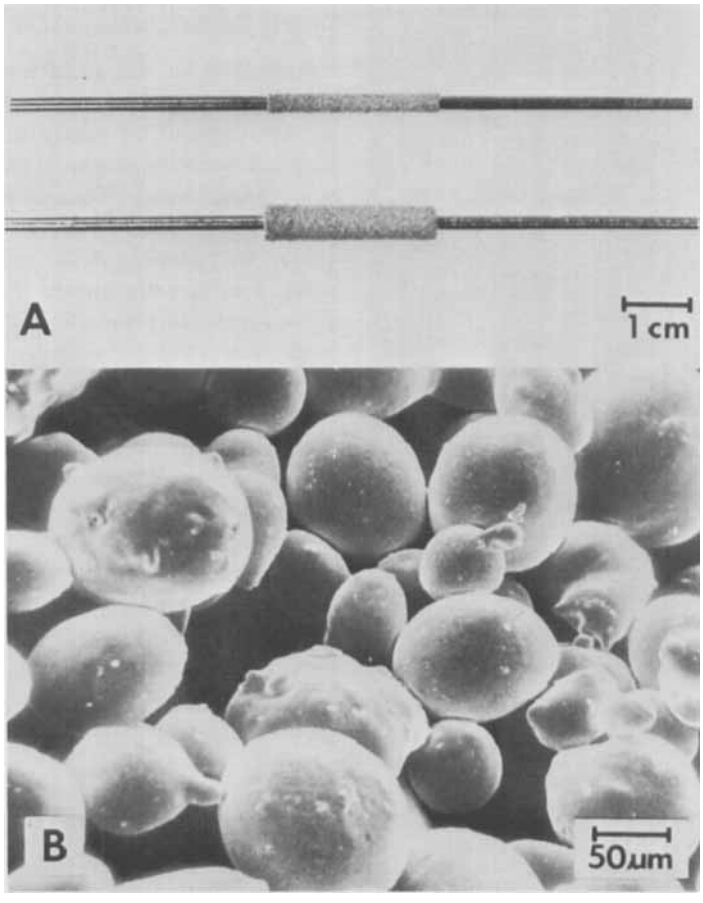

Figure 1. (A) Intramedullary rods with porous surface region diameters of 2.5 and 5.5 millimeters. (B) Scanning electron micrograph of the porous surface configuration.

techniques. Histological sections so produced were between 30 and 50 micrometers in thickness, sufficiently thin to permit cellular differentiation of tissue both in and around the implant using transmission light microscopy.

Longitudinal sections were cut through some of the bone-implant samples. Serial transverse sections were cut along the length of the other samples. Representative transverse sections cut approximately in the middle of the diaphysis of the femurs are shown in Figures 4 and 5.

Artifacts such as scratches or the inclusion of grinding debris within the thin sections are sometimes unavoidable with this type of histological preparation and may be noticed in some of the illustrated sections. In some of the illustrations bone trabeculae appear to be unattached to neighboring bone tissue; this appearance is due to the removal of tissue by the polishing procedure which is necessary to produce a sufficiently thin section

RESULTS

From the transverse histological sections it was determined that the average diameter of the medullae was approximately 6.5 millimeters. There was little variation from this figure because all the animals were approximately the same age and weight. Since the implants with diameters of 2.5 and 3.2 millimeters did not completely fill the intramedullary canals and were not centrally positioned within the canals, endosteal cortical bone-implant surface spaces ranging from 0 to 4 millimeters were observed in the histological sections. The implants with diameters of 4.5 and 5.5 millimeters more completely filled the canals such that smaller endosteal bone-implant surface spaces ranging from 0 to 2 millimeters were observed histologically.

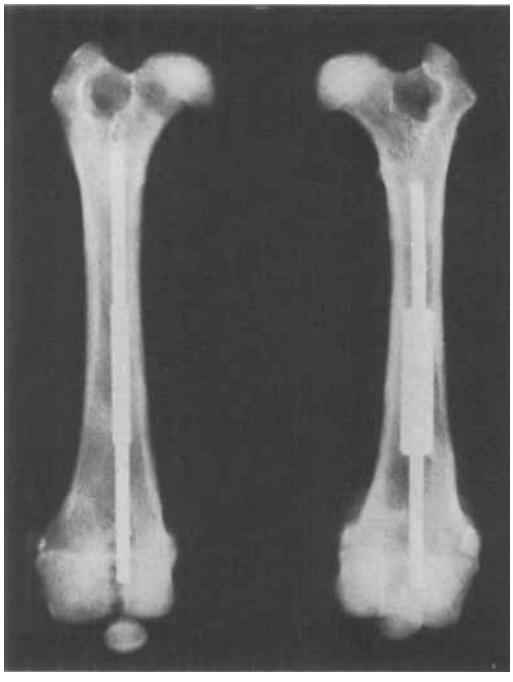

Figure 2. Post-mortem X-ray (16 weeks) showing the position of the implants within the femurs.

Smooth implant surface regions

Examination of the areas around the smooth surfaced segments of the implants at 4 weeks showed them to be mostly surrounded by soft tissue elements, regardless of the size of the space between the endosteal cortex and the implant.

At 8 weeks, bone trabeculae were seen in close contact with portions of the implants touching or nearly touching the cortex. Figures 3A and 3B show a particularly prominent example of this for a proximal portion of an implant that was initially in contact with the cortex and became partially encircled by dense bone tissue. Smooth implant surfaces further away from the cortex than about 0.5 millimeters were occasionally interfaced with a bone spicule but were mostly surrounded by soft tissue.

At 12 weeks the development of bone up to the implants was more pronounced than at 8 weeks. All the 12 week smooth implant surfaces were located between 1 and 3 millimeters from the endosteum. In a unique case dense bone bridged a space of approximately 1 millimeter between the

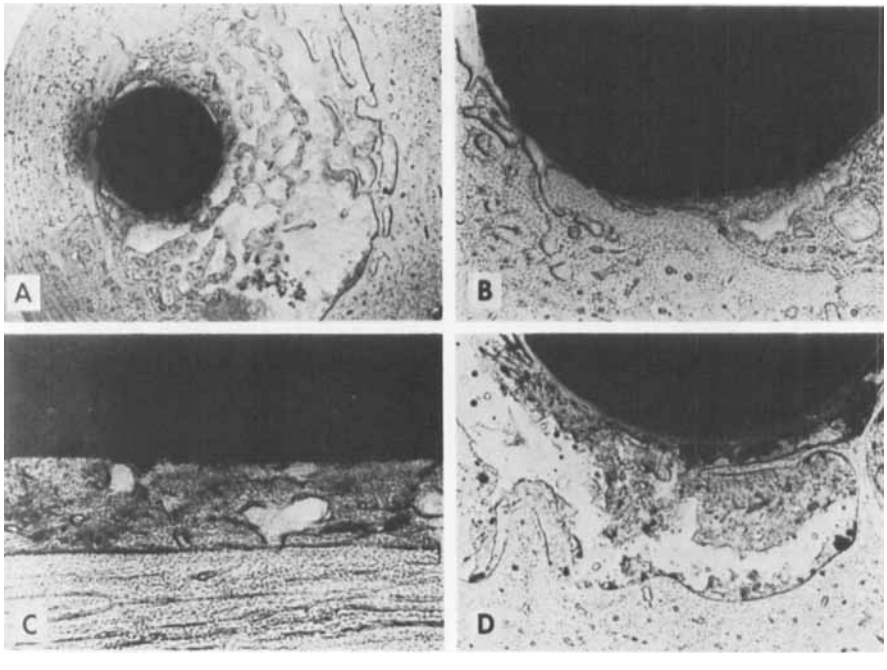

Figure 3. Smooth implant surface regions. (A) 8 weeks, X 12. (B) Higher magnification of an area shown in (A), X 60. (C) 12 weeks, X 15. (D) 16 weeks, X 60.

endosteal cortex and the implant and was in close contact with the smooth implant surface (Figure 3C). Usually a few thin bone trabeculae (about 200 micrometers in width) bridged the space between the endosteum and the implant. The degree to which these trabeculae touched or surrounded the smooth surfaces decreased as the endosteum-implant space increased.

At 16 weeks the results were similar to those at 12 weeks. Figure 3D shows an implant near the cortex with a soft tissue layer interposed between the smooth surface and neighboring bone trabeculae.

Porous implant surface regions

At 4 weeks the implants were generally surrounded by bone marrow and loose connective tissue regardless of the size of the endosteum-implant space. One exception to this finding was found where part of an implant was virtually in contact with the endosteal cortex; in this region calcified tissue had formed at the porous surface but not deeply within the interstices. In every other case, when an implant was situated away from the endosteal bone, very few if any bony trabeculae were seen in contact with the implant.

At 8 weeks a thin shell of osseous tissue partially surrounded each implant. In those cases where a region of an implant was within approximately 1 millimeter of the endosteal cortex, a greater amount of bone tissue surrounded or grew into the implant surface than when the implant was further away from the endosteal cortex (Figure 4A). In Figure 4B a cement (reversal) line indicating the transition zone from original cortical bone and newly formed intramedullary bone can clearly be distinguished. In some areas bone trabeculae bridged a space of approximately 2 millimeters between the endosteum and the implant. Generally, bone formation at the implant surfaces approximately 2 to 4 millimeters away from the endosteum was negligible.

At 12 weeks the implants were surrounded by a more complete shell of bone than at 8 weeks (approximately 200 micrometers in thickness).

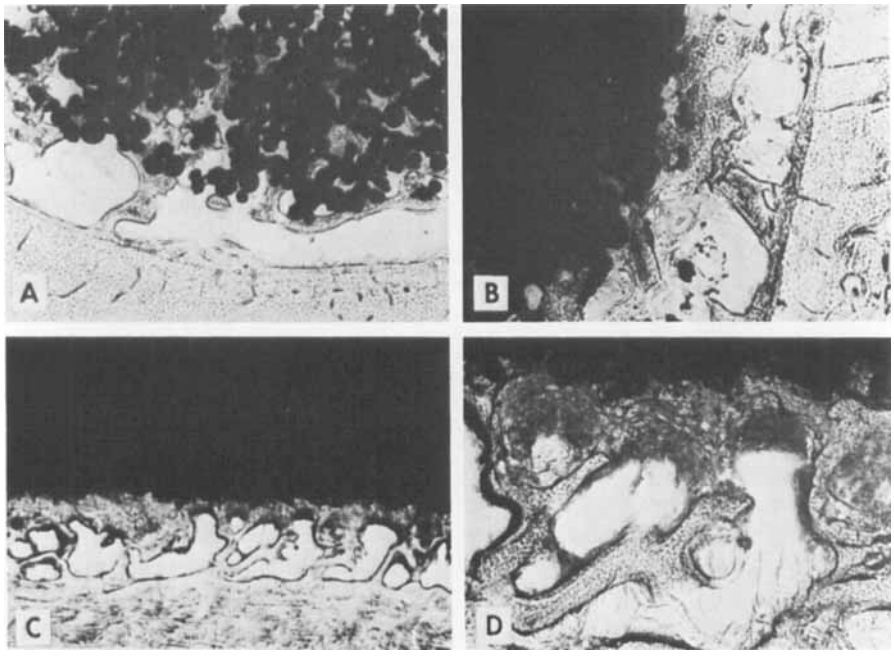

Figure 4. Porous implant surface regions. (A) 8 weeks, X 60, osseous tissue is visible deep within the porous surface structure. (B) 8 weeks, X 60, reversal line and new bone formation are visible. (C) 12 weeks, X 10, numerous bone trabeculae bridge a space of approximately 1.5 millimeters between the cortex and the implant surface. (D) Higher magnification of an area shown in (C), X 30.

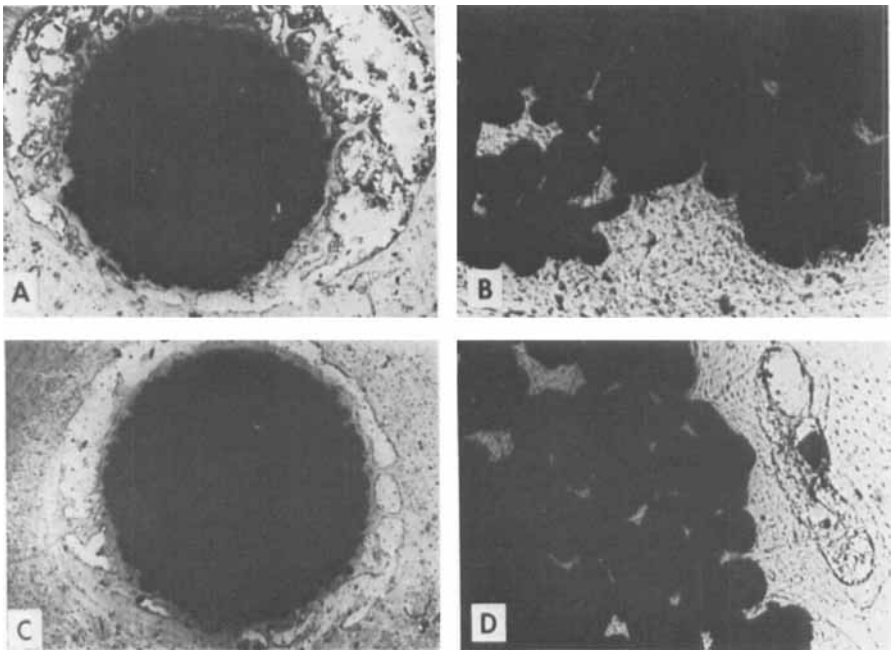

Figure 5. Porous implant surface regions. (A) 12 weeks, X 12, surrounding bony shell with bridging bone trabeculae are visible. (B) Higher magnification of an area from (A) indicating growth of bony shell into the implant porous surface structure, X 100. (C) 16 weeks, X 9, surrounding bony shell with bridging bone trabeculae are clearly distinguished. (D) Higher magnification of an area from (C) showing bone ingrowth, X 100.

No portions of any of these implants were found in contact with endosteal cortical bone. Numerous bone trabeculae bridged the endosteum-implant space for implant surfaces between approximately 0.5 and 2 millimeters from the endosteum (Figures 4C, 4D, 5A). In most of these sections the surrounding bony shell had formed deep within the porous surface structure of the implant (Figure 5B). Bone formation around implant surfaces between 2 and 4 millimeters from the endosteum was observed but trabecular bridges between this bone and endosteal bone were not as extensive and in some cases non-existent. In general it was noticed that the closer an implant was to the endosteal cortex, the greater was the degree of development of osseous tissue both up to and within the porous surface structure.

At 16 weeks the appearance of the bone-implant interfacial regions was much the same as at 12 weeks. The implant surfaces within 2 millimeters of the endosteum were surrounded by a thin bony shell which was joined to the endosteal cortex by spicules of bone (Figures 5C, 5D). The prominence of this feature decreased as the endosteum-implant space increased.

Radiographic evaluation of intramedullary bone formation

The bone which was observed histologically was not detectable in any of the post-mortem X-rays (e.g. Figure 2).

DISCUSSION

It is evident that with increased postoperative time there is a progressive organization of osseous tissue up to the implants and within the porous surface regions. The development of this intramedullary bone could be generally summarized as being minimal by 4 weeks, moderate by 8 weeks, and maximal by 12 weeks. It would seem that the presence of an implant within the medulla induces an osteogenic response which

results in bone development in regions where it would not normally occur. The mechanism responsible for this osteogenesis is not understood. Perhaps, initially, a simple foreign body reaction causes the phenomenon. Once some fixation by bone ingrowth has been established, loading forces could be transmitted to the implant. At this point other factors such as implant micromovement or a perturbation of the local stress field within the medulla may also play a role in the osteogenesis.

Response to smooth implant surfaces

The remarkable finding illustrated in Figure 3C indicates that bone development up to an implant surface can occasionally become very pronounced. Since the smooth portions of the implants were of a smaller diameter than the porous portions, they generally were situated a greater distance away from the endosteum. Hence, fewer cases of pronounced osteogenesis up to the smooth surfaces were observed compared with the porous surfaces. Overall, though, the osteogenic response to the smooth implant surfaces was similar to the response to the porous implant surfaces for a given size of endosteal cortex-implant space. Of course the effect of this response on the fixation of the two types of surfaces is different since the porous surface permits a greater degree of stabilization via tissue ingrowth and mechanical interlock.

Response to porous implant surfaces

The fact that the formed intramedullary bone was not detectable in the post-mortem radiographic analysis suggests that the inability to identify formed bone around the stems of clinical porous surfaced prostheses radiologically does not necessarily indicate that some type of bony supporting structure is not present.

Because the intramedullary bone was not dense enough to show up in the X-rays and did not form in a complete compact shell around the implants, it more closely resembled trabecular rather than haversian bone. The exception to this was when part of an implant was either very close to or in contact with the endosteal cortex. In these cases the ingrown bone was more compact and osteon formation was occasionally seen adjacent to the implant surface. This finding concurs with that of other investigators who showed that dense bone formation occurred within porous intramedullary implants which were initially placed in contact with endosteal cortical bone (Dorre et al. 1976, Miller et al. 1976).

As mentioned previously, the closer an implant was to the endosteal cortex, the greater was the degree of development of osseous tissue both up to and within the porous surface structure. This suggests that bone which formed around the implants originated from the endosteum (Figure 4B). It is also possible, however, that bone could develop from osteoprogenitor cells located within the medulla. The fact that bone development occurred extensively when implants were situated *away from the endosteum,* particularly for implants within approximately 2 millimeters of the endosteum, clearly indicates that implant contact with endosteal cortical bone *is not necessary* for this osteogenesis to occur.

Relevance to use of clinical prostheses

The results of this experiment give rise to some interesting implications concerning the clinical use of porous surfaced femoral stemmed prostheses. The findings suggest that the greatest amount of implant fixation by bone ingrowth in the shortest time could be established by arranging for the implant to be in contact with the endosteal cortex as much as possible around its circumference and along its length. This would necessitate using a prosthesis with a stem diameter equal to or nearly equal to the medulla diameter. However, in view of possible surgical misadventure (femoral shaft splitting) or long term detrimental bone remodeling (stress shielding with resulting disuse osteoporosis, Miller et al. 1976) occurring with a large diameter stem, such a design may not necessarily be recommended. It is conceivable, though, that a smaller diameter stem which *does not fill* the medullary canal could be significantly stabilized with time because of bone formation and remodeling within the medulla as observed in this study. The degree to which this formed bone is capable

of sustaining a load is not known. However, the formation of a bridge of trabecular bone between the implant and the cortex could provide a desirable energy absorbing structure. In addition, the use of a smaller diameter creates a lower stiffness component which would lessen the degree of stress shielding and the amount of disuse osteoporosis that might develop.

It was observed that a 12 week period was necessary for maximum tissue development in this animal model. It cannot be directly inferred that the same rate of tissue development would occur clinically. It must be remembered that the implants in this study were essentially non-load bearing. Some orthopaedic surgeons prefer to have their patients mobile and load bearing as soon as possible after surgery. It is not known whether the tissue which develops around a non-loaded implant (as in this study) would be similar to that which forms around an implant which is loaded soon after implantation because too much movement of an implant (a possible result of early load bearing) has been shown to inhibit the development of bone within a porous surface structured device (Ducheyne et al. 1977).

CONCLUSIONS

Non-loaded porous surfaced intramedullary implants become surrounded by and ingrown with osseous tissue in the absence of contact with endosteal cortical bone.

This osteogenic effect is most pronounced when the implant surface is within approximately 2 millimeters of the endosteum.

It is possible that the stems of clinical porous surfaced femoral prostheses which do not completely fill the medulla could become stabilized in part by the formation of this intramedullary type of bone.

ACKNOWLEDGMENTS

The authors are grateful for the financial assistance of the Medical Research Council, Canada, and the technical assistance of Mr. J. Cerar, Dr. G. M. Kent, and the staff of the Department of Surgical Research, Hospital for Sick Children, Toronto, Ontario, Canada.

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