We have studied the characteristics of bone ingrowth of a new porous tantalum biomaterial in a simple transcortical canine model using cylindrical implants 5×10 mm in size. The material was 75% to 80% porous by volume and had a repeating arrangement of slender interconnecting struts which formed a regular array of dodecahedron-shaped pores. We performed histological studies on two types of material, one with a smaller pore size averaging 430 µm at 4, 16 and 52 weeks and the other with a larger pore size averaging 650 µm at 2, 3, 4, 16 and 52 weeks. Mechanical push-out tests at 4 and 16 weeks were used to assess the shear strength of the bone-implant interface on implants of the smaller pore size.

The extent of filling of the pores of the tantalum material with new bone increased from 13% at two weeks to between 42% and 53% at four weeks. By 16 and 52 weeks the average extent of bone ingrowth ranged from 63% to 80%. The tissue response to the small and large pore sizes was similar, with regions of contact between bone and implant increasing with time and with evidence of Haversian remodelling within the pores at later periods. Mechanical tests at four weeks indicated a minimum shear fixation strength of 18.5 MPa, substantially higher than has been obtained with other porous materials with less volumetric porosity.

This porous tantalum biomaterial has desirable characteristics for bone ingrowth; further studies are warranted to ascertain its potential for clinical reconstructive orthopaedics.

In the last 20 years a variety of porous surfaces and materials has been used to obtain fixation of bone ingrowth in total hip and knee prostheses. The most common include titanium and cobalt-chrome-alloy sintered beads, diffusion-bonded titanium, fibre metal, and titanium plasma spray. Based on the clinical outcome and histological evidence from retrieved implants, it is clear that porous surfaces support tissue ingrowth or ongrowth and are generally effective for supplementing the stability of the implant by biological fixation.

Nevertheless, conventional porous materials each have certain deficiencies or weaknesses. For instance, sintered beaded and fibre metal coatings have a porosity which is limited to 30% to 50% by volume, a factor which directly limits the maximum interfacial strength that can develop by bone ingrowth. Conventional metallic porous materials are best suited for use as coatings on implants since they do not readily have the required mechanical and processing characteristics which would allow them to be used as bulk structural materials for implants, bone augmentation, or substitutes for bone graft.

A new porous biomaterial made of tantalum has recently been developed for potential application in reconstructive orthopaedics and other surgical disciplines. The material has an unusually high and interconnecting porosity with a very regular pore shape and size. It can be made into complex shapes and used either as a bulk implant or as a surface coating. Our aim in this study was to characterise this porous tantalum material in terms of the extent and rate of bone ingrowth as well as the strength of fixation at the interface.

Materials and Methods

Implants. The manufacture of the porous tantalum begins with the pyrolysis of a thermosetting polymer foam pre-
cursor to obtain a low-density vitreous carbon skeleton which has a repeating dodecahedron array of pores interconnected by smaller openings or portals. Commercially pure tantalum is deposited into and about the carbon skeleton using chemical vapour deposition/infiltration (CVD/CVI) to create a porous metal construct. Because of the crystallographic growth and orientation of the tantalum during deposition, the process results in a surface with a distinct microtexture as shown in Figure 1. Thin CVD/CVI films of 10 to 100 µm can impart very high mechanical properties because the deposit is typically 100% dense, with grain sizes of less than 1 to 5 µm and impurities of <0.05%. The typical thickness of the tantalum deposition is approximately 50 µm. An increase in thickness of the tantalum deposition can affect the pore size and mechanical properties.

Cylindrical implants 5 mm in diameter and 10 mm in length were made from porous tantalum (Implex Corporation, Allendale, New Jersey) for use in a canine model as a transcortical implant (Fig. 1). They had two different pore sizes. The mean pore size was determined using two techniques in each of which the data were expressed as a mean with 95% confidence intervals (CI). The first involved measuring the diameter of 100 dodecahedron-shaped pores, excluding the smaller connecting portals, based on secondary electron SEM images of the two pore sizes. This method gave a mean pore diameter of 547 µm (95% CI 537 to 557) for implants of smaller pore size and 710 µm (95% CI 696 to 724) for those of the larger. The second technique used the line intercept method based on the digital measurement of 1000 pore openings on SEM images of ten different implants. It included all pore lengths intercepting the grid lines, not just the full diameters of the pores, and therefore gave smaller mean pore sizes with larger CIs. By this method the mean pore size was found to be 430 µm (95% CI 413 to 447) in implants with the small
pore size and 650 µm (95% CI 629 to 679) in those with the larger size. The volume porosity of all implants ranged from 75% to 80%.

**Experimental study.** We used skeletally mature mongrel dogs weighing between 25 and 35 kg. Under standard aseptic surgical techniques a lateral approach was made to the femoral diaphysis. A specially designed C-shaped adjustable jig was clamped to the femur to ensure accurate and reproducible alignment and sizing of perpendicular drill holes. Bushings which fitted into the jig were used to guide pilot (2.5 mm) and final (4.95 mm) drills. All the implant sites were prepared using slow drill speeds and copious saline irrigation to minimise mechanical and thermal trauma to cortical bone. The final drill hole gave a slight press-fit of the transcortical implants which were inserted into the holes with 2 to 3 mm left proud of the periosteal surface. Four implants were inserted into each femur of each animal. After surgery the animals were allowed to recover without limitation of diet or activity.

Implants with a large pore size were the first to be manufactured and supplied for evaluation. This precluded a direct comparison of the two pore sizes in the same animals. Three animals with implants of large pore size (24 implants) were studied at each period of 2, 3, 4, 16 and 52 weeks and three (24 implants) with implants of small pore size at 4, 16 and 52 weeks. At the end of each study, the femora were removed and prepared for either undecalcified thin-section histology or mechanical testing.

**Histological examination.** Histological preparation included dehydrating, defatting, and embedding in acrylic. The implants were sectioned either longitudinally through the centre or transversely. All sections were polished and sputter-coated for analysis by backscattered SEM. The longitudinal sections were created as close to the centre of the implant as possible because only central sections gave a true impression of the extent of penetration of the ingrowth of new bone across the full diameter of the implant. We used computerised image analysis on the longitudinal sections to determine the extent of bone ingrowth, which was defined as the percentage of available porosity filled with new bone. Some sections were subsequently mounted on slides, ground, polished, and stained with paragon for qualitative examination by transmitted light microscopy.

**Mechanical testing.** We performed mechanical testing only on implants of small pore size. Twelve specimens from the four-week and six from the 16-week periods had a push-out test. Femora from each of the three animals in each group were randomly selected for mechanical testing. They were stripped of soft tissue and the proximal and distal femoral metaphyses excised, thus leaving the diaphyseal segment containing the implants. This was divided longitudinally into two halves with a band saw to give access to the implant inside the intramedullary canal. Each implant was pushed out of the femur with a cylindrical plunger of 4.8 mm diameter attached to the cross-head of a servo-hydraulic Instron test apparatus (Canton, Massachusetts).

The end of the plunger was brought into contact and aligned with the intramedullary end of the implant. The bone was supported in a metal cradle with the implant centred over a hole 5.5 mm in diameter to provide room for push-out (Fig. 2). Gaps in the curvature between the femora and the metal cradle were filled with cold-curing dental acrylic cement to give uniform support during mechanical testing. The cradle was mounted to a support on a universal joint which allowed alignment of the plunger with the implant. Load was applied to the implant at a cross-head speed of 0.05 cm/min, a rate which was selected based on previous studies. Load was applied until the bone-implant interface ruptured or there was compressive collapse of the implant as defined from the peak on the load-deformation curve.

Following the design of a previous study, after completion of each push-out test, the remaining femur was divided into halves through the implant site to allow measurement of the cortical thickness. This was done at four equidistant locations to obtain a mean thickness which was used for calculation of the bone interfacial area. The shear strength of fixation was calculated by dividing the peak load by this area. In instances when the implant underwent compressive failure before rupture of the bone-implant interface, a value for shear strength could not be calculated but it was assumed to be at least as great as those obtained from implants which were successfully tested.

**Statistical analysis.** Each implant in each femur was treated independently for statistical analysis. Sample independence was not verified in separate experiments since in previous studies this has always been presumed for the transcortical implant model. The data from all implants of a given pore size at a given time were tested for normality using the Kolmogorov-Smirnov and the Martinez-Iglewicz tests. For each data set the mean and 95% CI were calculated. When data were normally distributed, differences in the extent of bone ingrowth between the two types of implant at various times were compared using
unpaired Student’s t-tests at the 95% CI to assess significance. Data for shear strength from the successful mechanical tests at four weeks were expressed as a mean with 95% CI. An unpaired Student’s t-test was used to compare these with data from an earlier four-week mechanical study in which the dimensions of the implant, the animal model, surgical technique, mechanical test protocol, and sample size were virtually identical.¹

**Results**

**Histological analysis.** All the groups of data from the histological analyses were found to have a normal distribution and were evaluated by Student’s t-tests. Table I gives details of bone ingrowth and the results of statistical analysis on differences between means. In implants of large pore size, the mean extent of ingrowth at two and three weeks was 13.3% and 23.0%, respectively. At four weeks, the extent of bone ingrowth increased to a mean of 52.9% for the large pore size compared with 41.5% for the small pore size, a difference which was statistically significant. At 16 weeks, the difference in mean ingrowth between the large pore size (69.2%) and the small pore size (63.1%) was also significant. By 52 weeks, the mean extent of ingrowth of implants with a small pore size (79.7%) was significantly greater than that of those with the large size (70.6%).

Backscattered SEM showed a clear pattern of formation of new bone within the porous tantalum material. At two weeks, the primary source of the initial formation of bone was the intramedullary canal and the edges of the drill hole (Fig. 3). Ingrowth was generally scant and only small regions of close apposition of bone to the struts of the porous tantalum were observed. At three weeks it appeared that more new bone arose from, or was continuous with, the drilled edges of the cortex (Fig. 4). In some sections there was a slight periosteal reaction and new bone seemed to be

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**Table I. Extent of mean bone ingrowth (%) as a function of pore size and time**

<table>
<thead>
<tr>
<th>Time (weeks)</th>
<th>Bone ingrowth</th>
<th>95% CI for difference</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Small pore</td>
<td>Large pore</td>
<td></td>
</tr>
<tr>
<td>2*</td>
<td>-</td>
<td>13.3 (n = 24)</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(95% CI 10.8 to 15.8)</td>
<td></td>
</tr>
<tr>
<td>3*</td>
<td>-</td>
<td>23.0 (n = 24)</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(95% CI 20.0 to 26.0)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>41.5 (n = 12)</td>
<td>52.9 (n = 23)†</td>
<td>6.9 to 15.9</td>
</tr>
<tr>
<td></td>
<td>(95% CI 37.3 to 45.8)</td>
<td>(95% CI 50.4 to 55.4)</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>63.1 (n = 18)</td>
<td>69.2 (n = 24)</td>
<td>1.5 to 10.8</td>
</tr>
<tr>
<td></td>
<td>(95% CI 58.2 to 68.0)</td>
<td>(95% CI 67.0 to 71.5)</td>
<td></td>
</tr>
<tr>
<td>52</td>
<td>79.7 (n = 24)</td>
<td>70.6 (n = 23)†</td>
<td>-12.9 to -5.4</td>
</tr>
<tr>
<td></td>
<td>(95% CI 76.9 to 82.5)</td>
<td>(95% CI 68.3 to 73.0)</td>
<td></td>
</tr>
</tbody>
</table>

* implants of small pore size were not studied at two and three weeks
† 1 implant at four and 52 weeks was not included because of a sectioning error

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Fig. 3
Backscattered scanning electron micrograph of a two-week implant with a large pore size showing bone growth of 13%. New bone appears to arise from the intramedullary canal and the edges of the drill hole, with little bone on the periosteal surface. The bony trabeculae are immature and slender.

Fig. 4
Backscattered scanning electron micrograph of a three-week implant with a large pore size showing bone ingrowth of 21%. Compared with the implant at two weeks (Fig. 3) there is increased continuity of new bone with the drilled cortical edges, additional new bone arising from the periosteal surface and a general thickening of the bony trabeculae.
partly generated from the periosteal surface. Overall, there was more ingrowth than at two weeks and hence more regions of apparent contact of bone with tantalum struts. The four-week implants showed more complete ingrowth and many regions of apparent contact between new bone and the tantalum struts which remained incompletely surrounded by new bone. The ingrowth often extended abundantly above the periosteal aspect of the femur and showed cortical remodelling within the pores into Haversian systems. In some sections, particularly at four and 16 weeks, there was noticeable intracortical porosity adjacent to the implants, suggestive of a remodelling phenomenon associated with increased blood flow and bone turnover during the repair process (Figs 5 and 6).

**Mechanical testing.** Six of the four-week implants with small pore sizes were successfully tested mechanically in that the interface ruptured before mechanical collapse of the implant. The mechanical test data were found to have a normal distribution. The mean shear strength was calculated to be 18.5 MPa (95% CI 17.4 to 19.6). The remaining six implants at four weeks and all six implants tested at 16 weeks had compressive failure before rupture of the bone-implant interface. For both time periods, this suggested that the values of shear strength were higher than those calculated from the successful tests at four weeks.

**Discussion**

Our study has given an initial characterisation of the response of bone to a new porous tantalum biomaterial in a canine transcortical model. Substantial filling of the pores with new bone to 40% to 50% occurred by four weeks with

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**Figure 5** – Transmitted light photomicrograph of an interface region of a four-week implant with a small pore size. The reversal line from the original drill hole is evident and the microtexture of the tantalum struts is apparent (paragon ×15). **Figure 6** – Backscattered scanning electron micrograph of a 16-week implant of small pore size showing ingrowth of 76%. There are many regions of contact between new bone and the tantalum struts. A pronounced periosteal reaction has resulted in additional incorporation of the implant by new bone. Haversian remodelling is evident within the porous network.

**Figure 7**

Backscattered scanning electron micrograph of a transverse section through a 52-week implant with a small pore size with ingrowth of 84%. There is some residual porosity around the tantalum struts but relatively complete incorporation of the implant.
implants of both pore sizes. This resulted in a mean shear fixation strength of at least 18.5 MPa (≈2700 PSI). Compared with previous studies using porous-coated transcortical implants, high fixation strength occurred much earlier with porous tantalum. The data from this investigation are best compared with those of an earlier study in which sintered, beaded cobalt-chrome transcortical implants spanning similar pore sizes were used because both had equivalent protocols. The maximum mean shear strength obtained at four weeks with the beaded cobalt-chrome implants was 9.3 MPa (95% CI 8.3 to 10.3), a difference of 9.2 MPa (95% CI 7.8 to 10.6) which was significant (Student’s t-test; p=0.004). Studies using other porous metals and different implants and testing techniques have reported fixation strengths to cortical bone at four weeks ranging from 1.2 MPa to 13.1 MPa.

The increased rate of development of the interfacial shear strength with porous tantalum can best be attributed to the higher volume fraction available for ingrowth. While fibre metal coatings have a porosity of 40% to 50% and sintered-beaded coatings of the type studied by Bobyn et al of only 30% to 35%, the porous tantalum material examined in this study had a substantially higher porosity of 75% to 80%. This meant that for any given percentage filling, a greater volume of bone was present within the porous tantalum, thus giving a proportionate increase in interface strength. The end result was a faster rate of development of strength. The higher porosity of the porous tantalum also theoretically allowed a higher ultimate strength to develop. Clinically, however, the rate of fixation may be more important since the time required for secondary stabilisation of an implant by bone ingrowth can influence the load-bearing after operation.

The measured strength of the interface probably represents a lower bond since half of the implants at four weeks and all at 16 weeks failed in compression before rupture of the interface. The compressive failure indicated a certain reduction in mechanical properties associated with the high porosity of porous tantalum. The latter, however, has a high strength:weight ratio and overall mechanical properties which would be adequate for most clinical applications.

The pore sizes of both types of implant which we evaluated were at the upper limit of the characteristics of pore size of conventional porous materials. Nevertheless, the rates of bone ingrowth and the overall extent of filling of the porosities with new bone were very high. There were statistical differences in the mean extent of bone ingrowth between the two pore sizes at the different time periods. Implants with the large pore size initially had greater ingrowth, but by 52 weeks those with the small pore size were more completely ingrown. These differences may have resulted from the slight inherent variations in pore characteristics between the two types of implant or from interanimal variability in the healing response. In any case, the relative differences were not large and unlikely to result in any practical or meaningful clinical consequence.

It is possible that the surface microtexture of the struts forming the porous material contributed to the overall osteogenic response. Cell-culture studies and studies in animals with both unloaded and dynamically loaded implants have shown that microtextured surfaces such as those produced by grit blasting or acid etching are highly osteophilic. The histological studies clearly showed that the porous tantalum served as an effective scaffold for relatively complete incorporation with new bone by 16 weeks, with little change after 52 weeks of implantation.
Although not as realistic as a fully-functional load-bearing model, the transcortical model is very useful for the initial characterisation of new porous biomaterials. It allows control of several parameters which influence the bone-healing response. Using the appropriate instruments, holes can be drilled with accuracy and reproducibility, thus ensuring a uniform initial fit of the implant. The density of the peri-implant bone is consistent and thus allows equitable comparison of data within and between animals. Although implants for joint replacement are primarily surrounded by cancellous bone, retrieval analyses have shown that the most consistent and abundant source of bone ingrowth in hip prostheses is from cortical regions. The model has also been used in many previous studies of porous materials and therefore allows comparison with historical controls.1,3-6,8,20

From a manufacturing standpoint, tantalum is particularly well suited to the complex CVD/CVI process used for deposition on to the vitreous carbon substrate. It is a strong, ductile metal with excellent corrosion resistance. More than 50 years ago its potential in regard to human implants was studied in animal and human experiments.26-29 It has been used for a wide variety of implants30 including pacemaker electrodes,31 cranioplasty plates,32 ligation clips,33 femoral endoprostheses,34 as wire, foil and mesh for nerve repair,35 contrast media for airwave radiographic studies,36 and as a radiopaque marker for following bone growth and implant migration.37 Osseointegration has previously been demonstrated using non-porous tantalum implants in dental and orthopaedic applications for periods of up to 8 to 12 years.38-41 Its superb biocompatibility and suitable mechanical properties have led to its standardisation as a surgical implant material.38,42

The tantalum construct which we have evaluated represents a departure from conventional porous materials in many respects. Because of its high porosity, its structural stiffness is in the relatively low range of about 2.5 to 4.0 GPa,43 similar to subchondral bone, which could be advantageous in bone remodelling. The material could be used as a backing for direct compression moulding of polyethylene-bearing components or as a fixation surface on an implant substrate. Unlike sintered beads, fibre metal or porous materials used with plasma spray, its structural integrity allows it to be readily formed in bulk parts for the filling of bone defects or other reconstructive applications requiring standard or customised shapes and sizes of the implant. Its porous geometry may also be advantageous for combination with agents which favour osteoconduction or osteoinduction. Based on the results of our study we conclude that it offers interesting potential for orthopaedic reconstructive procedures and that further studies are warranted.

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