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MECHANICAL PROPERTIES OF TOTALLY PERMEABLE TITANIUM COMPOSITE PYLON FOR DIRECT SKELETAL ATTACHMENT

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Abstract

Composite pylons containing a solid titanium core with drilled holes surrounded by a porous sintered titanium shell have been fabricated and tested in bending along with the raw cores and pylons composed of the porous titanium alone. The new pylons were designed with the concept of enhanced ingrowth of bone and skin cells and are intended for direct skeletal attachment of limb prostheses considering requirements for long-lasting anchorage to the residuum bone and a need for a safe skin-implant seal. Load-displacement thresholds were determined after which the integrity of the porous component may be compromised. The composite pylons have a flexural strength and stiffness substantially greater than that of pylons composed of the porous titanium alone. The drilled holes in the solid insert have been shown to have virtually no effect on the flexural strength of the pylon, while meeting a requirement for total permeability of the device for unrestricted cell ingrowth. The predicted strength of the pylons and associated failure modes are in close agreement with those measured.

Keywords

Mechanical Properties; Titanium; Stress Cracking; Implant Design; Brittle Fracture; Sintering; Implants; Direct skeletal attachment

Introduction

Porous titanium and non-titanium structures were investigated in several studies as scaffolds for skin and bone cells and demonstrated good cell adhesion, proliferation and differentiation [1–5]. Analysis of design variables affecting bone apposition to implants demonstrated that implant surface texture is the most significant characteristic with rough surfaces providing a stronger bond compared to a smooth surface [6]. Porous implants can provide a safer barrier against infection if invaded by the host tissues at early stages after implantation [7]. The better epithelial cell adhesion and spreading decreases a risk of detachment (avulsion) of the surrounding tissues from the implant [8, 9]. These facts make porous structures promising for implantation to the residuum bone with the purpose of direct skeletal attachment (DSA) of limb prostheses [10, 11]. However, the reduction of flexural strength due to porosity is a fundamental limitation of using porous implants in DSA where a need to withstand the high compression and bending stresses is necessary [12, 13]. It is a challenge to combine the permeability of the porous implants with the flexural strength determined by the tasks of safe locomotion.

In our previous work [14] we reported flexural strengths of the order of 480 MPa for the composite porous titanium pylon for skin and bone integration (SBIP-3), manufactured by Poly-Orth International, Sharon, MA. That was more than two times higher than in human long bones [15, 16] and than the value estimated in the study by Frossard and colleagues on the gait of patients with directly attached transfemoral prostheses [17]. The increase of the strength was achieved by sintering Ti powders together with the Ti cross-bar insert. However, the fact that the insert was solid compromises the concept of complete permeability of the implanted pylon. An additional problem is the risk of brittle fracture of the porous cladding, which may occur at the lower bending stresses than those causing the insert failure.

This paper describes the mechanical properties of the porous pylons made with and without the cross-bar inserts. The new development compared to previous reports [14, 18] is that the insert is manufactured with a spiral pattern of drilled holes running along the webs in order to make the pylons more permeable for better in-growth of bone and skin cells such that the pylon becomes an integral part of the skeleton.

The current study demonstrated that the permeability due to perforating the solid insert did not affect significantly the pylon's strength. The fracture characteristics in bending have also been determined. Overall results suggest that a found combination of design parameters can be promising for the implants for direct skeletal attachment.

Materials and Methods

Manufacturing of the pylons for testing

Ten inserts with a cross-shape cross section and the web thickness of 1 mm and 3 mm wide (Fig. 1) were machined using 3 mm round rods Ti6AL-4V ELI (SmallParts, Seattle, WA). In five of the samples, 0.5 diameter holes were drilled in a spiral pattern, with a 1 mm vertical distance between each hole (Fig. 2-a). The other five samples were kept solid. The inserts were sintered (ADMA Products Group, Hudson, OH) with Ti powders provided by the ADMA using 5 mm diameter cylindrical boron nitride molds (Payne Engineering & Fab. Co., Canton, MA) (Fig. 2-b). Additionally, five samples were sintered at the same molds without inserts. The high temperature sintering was conducted in vacuum using titanium powders sieved to (-80+200) mesh. Samples were sintered at 1090°C for 4 hours which was above the beta transus temperature of 996°C.

The sintered titanium powder structure is shown in Figure 3-a. The pylon diameter after sintering had shrunk from 5 mm to 4.2 mm. The average range of 45 to 50% porosity has been estimated for the sintered parts considering the measured weights and geometry of the pylon samples. Figure 3-c shows a cross bar insert at the end portion of the pylon. The pore size was in a range of 30 μm – 200 μm , established earlier as optimal for skin and bone cells' adhesion, proliferation and differentiation [5, 19–22].

Three-point bend tests

Three-point bend samples were tested with a span of 19 mm. An angled probe at the Instron 1123 tensile machine (Norwood, Massachusetts) is shown in Figure 4-1. The vertical bend force (N) was measured and plotted against the displacement (mm) of the center of the pylon sample while the probe 1 was traveling downwards bending the sample 2. The pylon samples with the inserts were oriented in the X position (45° orientation) for testing.

The first set of tests was carried out on the raw materials: (i) a 3 mm solid rods (ii) a 3mm wide cross-shaped bar without holes tested in the 45° orientation and (iii) the same cross-shaped bar with the holes. Similar three-point bend tests were performed on 4.2 mm

diameter pylon samples with (iv) the cross-shape inserts with spiral holes coated in porous titanium and (v) on the samples of porous sintered titanium powders with no solid cross-shape insert.

Mathematical modeling of mechanical properties of the porous pylon

The mechanical properties of the porous pylon, such as flexural modulus and flexural strength can be estimated as follows. A shape function Φ , is defined such that at any position within the cross section of the pylon, the function returns a value equal to the fractional material property at that point. For example, if the co-ordinate, (x,z) were to lie within the solid titanium insert then the function would return the value 1, while if that point were to lie within the porous cladding then the function would return a number between 0 and 1, representing the fractional value of the property of interest relative to the fully dense solid. The two fractional properties relevant to the porous cladding are elastic modulus $P(\phi)$ and tensile strength $S(\phi)$, where ϕ is the volume fraction of porosity.

$$P(\phi) = (1-\phi)^{5.5} \quad S(\phi) = (1-\phi)^3 \quad (\text{Eqn. 1})$$

If the co-ordinate (x,z) lies outside the pylon or within a hole in the web of the solid insert then the shape function Φ returns 0. The flexural modulus of the pylon is given by

$$E_F = E_{Ti} \cdot \frac{\int_{-r}^r \int_{-\sqrt{r^2-z^2}}^{\sqrt{r^2-z^2}} \Phi_{x,z,P(\phi)} \cdot z^2 dx dz}{\frac{\pi}{4} r^4} \quad (\text{Eqn. 2})$$

where z is the perpendicular distance from the plane of zero bending strain, x is the distance from the axis of the pylon parallel to the plane of zero bending strain and r, the radius of the pylon. The flexural modulus clearly depends on the orientation of the cross-shaped insert with respect to the plane of bending. Since the variation in flexural modulus with orientation is small, the flexural modulus of the pylon may be determined from the average of the flexural modulus at all orientations i.e.,

$$\bar{E}_F = E_{Ti} \cdot \frac{\int_0^{\pi/4} \int_{-r}^r \int_{-\sqrt{r^2-z^2}}^{\sqrt{r^2-z^2}} \Phi_{x,z,P(\phi)} \cdot z^2 dx dz d\theta}{\frac{\pi^2}{16} r^4} \quad (\text{Eqn. 3})$$

For a typical pylon in which the volume fraction of porosity in the cladding is in the range 45 to 50%, the variation of flexural modulus with orientation is approximately $\pm 6\%$ of the mean flexural modulus which itself is 16.6% of the modulus of solid titanium. The measured flexural modulus of 11.8GPa compares favourably with the predicted flexural modulus between 11.4 GPa at 50% porosity to 12.9GPa at 45% porosity, given the inherent over estimation of small displacements based on the measurement of crosshead deflections in a screw driven testing machine.

The solid insert may be made permeable to allow the in-growth of bone and skin by drilling a series of holes in the arms of the cross-shaped insert. One geometry considered in the current study is the placement of holes on a spiral pattern with adjacent holes along the length of the insert being on each consecutive arm with a pitch of 8x the hole diameter. Thus the longitudinal separation of holes between adjacent webs would be such that the centre to

centre spacing of the holes would be twice the hole diameter. The effect on flexural modulus would be minimal. For a series of 0.5mm diameter holes located in the centre of each web, the maximum reduction in the flexural modulus at the location of the hole would be 3.5%, but averaged along the length of the insert would be less than 0.6%. In subsequent calculations, the effects of the drilled holes will be ignored. The stress in the bending pylon at any distance z from the centre is given by

$$\sigma = \frac{Mz}{I} \quad (\text{Eqn. 4})$$

where M is the imposed bending moment and I the moment of inertia. The corresponding strain in the pylon at that point is simply

$$\varepsilon = \frac{\sigma}{E_F} = \frac{Mz}{E_F I} \quad (\text{Eqn. 5})$$

Since the pylon is composed of different materials which, in contact at a given point, must experience the same bending strains, then the stress at any point in the composite pylon is

$$\sigma_{x,z} = \frac{Mz}{I} \frac{E_{Ti} \cdot \Phi_{x,z,P}(\varphi)}{E_F} \quad (\text{Eqn. 6})$$

Results

The force vs. displacement curves are depicted in Figure 5. Each curve shown is the average of the load vs. deflection data from 5 tests per condition. The solid 3 mm rods exhibited the maximum bend force of about 1600 N (Fig. 5-1). Both solid and perforated cross-shaped bars showed practically the same maximum bend forces of about 800 N (Fig. 5-2 & 5-3), indicating that the 0.5 mm holes drilled into the webs did not affect the flexural strength. All three samples showed extensive plastic deformation during bending. The corresponding breaks are shown in Figures 3-b and 3-d. Not the failure crack that was formed during the bend test in the insert in Figure 3-d.

The maximum bend force for the sintered pylon with the insert (Fig. 5-4) exhibited smaller values as compared with the cross-shaped bar itself (Fig. 5-2 & 5-3). This is most likely due to the grain growth during the sintering cycle. The sintered insert, however, still showed significant plasticity up to 5.5 mm displacement prior to failure (Fig. 3-d).

Tests demonstrated that the insert carried the entire bend load, and that the flexural strength of the insert defined the overall strength of the whole pylon.

The Fig. 6 depicts the enlarged graphs 4 and 5 from the Figure 5. These graphs show that flexural strength of the pylon without the insert (Fig. 6-5) is significantly smaller than that of the pylon with the insert (Fig. 6-4).

The maximum bend force of the pylon without insert is approximately 60 N at a displacement of about 0.5 mm. For the pylon with the insert, the same displacement of 0.5 mm (and therefore the same deformation of the porous portion) (see Fig. 6-4 & 6-5) required a force of approximately 290 N, as illustrated by the dotted lines in Figure 6.

The data obtained in the testing allows for calculating the flexural strength S for the pylons with and without inserts using the formula (Eqn. 7), developed for approximation of a composite structure by a homogeneous rod [18]:

$$S = \frac{LF}{\pi r^3} \quad (\text{Eqn. 7})$$

where L is the span, F is the bending force, and r is the radius of the pylon. The calculations give the flexural strength 400 ± 35 MPa for composite pylons with an insert; and 34 ± 3 MPa for pylons without an insert.

At the onset of yield the maximum stress in the outer edge of the pylon is given by:

$$S_{onset} = \frac{My}{I} = \frac{FL}{4} \cdot \frac{D}{2} \cdot \frac{64}{\pi D^4} = \frac{8FL}{\pi D^3} \quad (\text{Eqn. 8})$$

where M is the bending moment, y is the distance from the center of the bar, I is the second moment of inertia, L is the span, F is the bending force, and D is the diameter of the pylon. After the test piece yields, the maximum stress in a bending bar undergoing full plastic deformation is given by:

$$S_{plastic} = \frac{M}{H} = \frac{FL}{4H} \quad (\text{Eqn. 9})$$

where H is the plastic section modulus. For a cylinder $H = \frac{D^3}{6}$, for a cross shape

$H = \frac{T}{4} (W^2 + WT - T^2)$, where W is the width of the cross and T the thickness of the web.

The Table 1 shows the measured and calculated flexural modulus and flexural strength for each of the 5 conditions tested, the measured values being the mean of 5 tests per condition.

Discussion

In bending, it can be assumed that the beam is deemed to have “failed” when either the outer edge of the porous cladding fails or the outermost edge of the solid insert yields. In 3pt. bending tests however, the solid insert may yield and can continue to deform plastically before the surrounding porous cladding has cracked. However, it is also possible that the porous cladding will crack while the solid insert continues to support the imposed bending strains and can continue to carry additional load until it too fails after extensive plastic deformation. The consistency between the calculated fully plastic bending stress in each of conditions 1 through 4, i.e. all the tests in which the sample is either a solid or contains a solid insert indicates that the ultimate load carrying capacity of the pylon is determined by the insert.

Figure 7 show the predicted stress in the porous cladding at the outer edge of the pylon and at the outer most extent of the solid insert, assuming that both materials are perfectly elastic. For the example shown, a 4.2 mm diameter pylon with a 3 mm wide x 1 mm thick insert and a porosity level of 50%, it is evident that the stress at the outer edge of solid insert reaches the yield strength of the insert before the outer edge of the porous cladding attains its

Figure 8 shows how porosity will affect the load at which the insert begins to yield in a 3pt bend test with a 19 mm span for a 5mm diameter pylon with a 3 mm wide x 1 mm thick insert. The applied load at which we should see the onset of plasticity in the insert would be

~ 420N @ 45% porosity and 520N @ 50%. The load required for cracking of the porous cladding at 45% porosity is calculated at ~500N while at 50% porosity would be ~420 N. This seems to tie in well with the observation of cracking at about 500N.

The critical fraction of porosity, ϕ , at which the “failure” mechanism changes from one of yielding of the insert to fracture of the porous cladding, is found when

$$\frac{w}{D} \cdot \frac{\Phi_{\frac{w}{2} \cos \theta, \frac{w}{2} \sin \theta, P(\phi)}}{\Phi_{0, \frac{D}{2}, P(\phi)}} \cdot S(\phi) \cdot \frac{\sigma_{Ti}}{\sigma_{Ti 6Al 4V}} = 1 \quad (\text{Eqn. 10})$$

where w is the width of the insert and D is the diameter of the pylon and the pylon is oriented at an angle θ with respect to the plane of bending. Porosity levels above the critical value result in yielding of the insert before the cladding cracks, while porosity levels lower than the critical value will result in cracking of the porous cladding prior to yielding of the insert.

For the pylon of current design, the critical volume fraction of porosity is 40% when the insert is at 45° and 32% when at 0°, values, which are just either side of the measured cladding porosity of 35% (Figure 8). While the calculated load for cracking of the porous coating increases above about 40% porosity, it is unlikely that this would be realized in practice with the actual load probably remaining at the minimum value of ~500N. As such, it would be expected that the porous cladding would exhibit cracking at a lower applied moment than the solid insert begins to yield. After the cladding has cracked, the load continues to be carried by the insert which will continue to deform elastically then plastically.

It is not possible to calculate analytically the maximum load that the insert will support, as this depends on how effective the porous cladding on the compression side of the bending pylon is at resisting further bending, i.e. its ability to sustain compressive loads, contribute to the overall moment of inertia and retention of the bond between the porous cladding and the insert to transfer the shear loads across the cross-section.

In the current test, which shows extensive bending deformation at loads greater than that predicted for cracking, i.e. 680N as opposed to 500N, it appears that the porous cladding does retain some structural integrity on the compression side allowing the load to further increase as the insert continues to deform as a plastic hinge. Most importantly, the load carrying capacity of the pylon containing the drilled insert is approximately 8x that without the insert.

Fatigue tests on the porous implants were previously conducted without holes in the cross-shape inserts (14). The samples tested at 10 Hz at 70 percent of the loads/stresses relevant to those associated with gait on prosthesis resulted in no failure after 5,000,000 cycles, when the test was terminated. No damage was detected on the sample after 5,000,000 cycles. The authors realize that the holes in the insert may result in greater fatigue and plan to conduct similar tests in the future.

The dimensions of the holes in the inserts were taken to provide sufficient space for large cells of skin and bone, but not decrement significantly the strength of implants. Continuous holes of 500 microns made in the current inserts were found sufficient for bone remodeling in the composite scaffolds [26]. It will be a purpose of the further studies to get a proof that the selected dimensions are optimal for migration and growth of the cells throughout the entire implant.

A study was conducted on cell cultivation on the implants manufactured with the current process except drilling the holes in the insert (5). The study demonstrated that after 7 days of cultivation human fibroblasts and rabbit bone marrow cells tightly interacted with the implants. Cells adhere, migrate, proliferate and produce confluent layers growing both on the surface of the implant surface and in its depth. Animal studies with the implants presented in this paper which had the holes in the solid insert are planned in the future. If the further clinical tests would not demonstrate cell ingrowth within the holes drilled in the solid insert, their dimensions will be modified, and the mathematical analysis and mechanical tests will be conducted with the approach presented in this paper.

Conclusions

A porous titanium pylon with more permeable insert has been designed and manufactured with the aim at enabling the complete in-growth of bone cells which exhibits mechanical properties similar to that of a solid titanium insert, but far superior to those of a porous pylon without an insert.

The mechanical response of the composite structure can be predicted using a combination of conventional elastic beam bending theory coupled with a numerical solution enabling upscaling of the design from animal to human dimensions.

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Figure 1.

Cross-section of the pylon with the solid cross-shape insert and the surrounding porous cladding. The sample was metallographically polished down to 6 microns. Dashed lines indicate projections of the holes in the web (see Fig. 2-a)

Figure 2.

a.- 3mm wide Ti-6Al-4V cross-shaped insert showing examples of drilled holes in web (shown by the arrows) and 5mm diameter sintered pylons; **b.** – composite 5 mm pylons sintered with the inserts **a.**

Figure 3.

a. - porous cladding; **b.** - cracking of cladding; **c.** - end of sintered section; **d.** - failure of insert.

Figure 4.
Bend test set-up. **1** – probe; **2** – sample.

Figure 5.

Force vs. Displacement in 3-pt bend. Curve 1 – solid 3mm round rod; Curve 2 – cross bar without holes; Curve 3 – cross bar with holes. Curve 4 – sintered pylon with the cross bar insert having holes; Curve 5 – sintered Ti powder pylon with no insert (see Fig. 6). The graphs show average values.

Figure 6.

Force vs. Displacement in 3-pt bend. Curve 4 – sintered pylon with the cross bar insert having holes; Curve 5 – sintered Ti powder pylon with no insert (see Fig. 5). The graphs show average values.

Figure 7. Maximum stress in insert and porous cladding with increasing bending moment (assuming linear elastic behavior), together with the expected strengths of the insert and the porous cladding.

Figure 8.
Effect of porosity on the load at which yielding of the insert and cracking of the porous cladding of the pylon occurs (span = 19 mm) for insert orientations of 0 and 45°.

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Table 1

Measured and calculated flexural modulus and flexural strength.

Sample Type	Measured Flexural Modulus (GPa)	Calculated Flexural Modulus (GPa)	Load/Stress at onset of yielding (Eq.8)	Maximum Load/Ultimate Strength (Eq.9)	Calculated Loads ³ (N)
3mm round bar (Ti-6Al-4V) ¹	41.6±1.5	106	880±42 N 1577±42 MPa	1583±49 N 1671±52 MPa	n/a ⁷
3mm x-bar in 45° orientation ¹	49.2±1.2	106	500±20 N 1474±60 MPa	856±19 N 1479±33 MPa	n/a ⁷
3mm x- bar in 45° orientation with web holes	47.4±1.7	106	485±20 N1429±60 MPa	822±17 N 1420±29 MPa	n/a ⁷
4mm Pylon ² with web	32.4±1.2	27.2	554±26 N 314±15 MPa	697±17 N 310±7 MPa 1204±29 MPa ⁵	440, 597 ^{4 a} , 597 ^{4b}
4mm Pylon ² without web	8.3±1.1	6.9	n/a ⁶	63±8 N 36±4 MPa	84 ^{4a}

¹The calculated second moment of inertia, I , of the 3mm wide cross-shape of $2.42 \times 10^{-12} \text{ m}^4$ is independent of orientation. The second moment of inertia of the 3mm diameter solid rod was $3.98 \times 10^{-12} \text{ m}^4$ [23]. The plastic section modulus, H , of the 3mm wide cross-shape is $2.75 \times 10^{-9} \text{ m}^3$ and the 3mm diameter solid rod is $4.5 \times 10^{-9} \text{ m}^3$ [24].

²The sintered titanium powder was assumed to have a porosity of 45%.

³Calculated loads are based on a tensile modulus of 106GPa for Ti, a tensile yield strength of 880MPa for Ti-6Al-4V, and 380MPa for Ti.

⁴The two calculated loads represent the onset of cracking in the titanium coating and the onset of yielding in the Ti-6Al-4V web.

⁵The two stresses refer firstly, to the ultimate strength of the cylindrical pylon as a whole and secondly, the stress being carried by the cross-shaped insert alone, assuming that the porous Ti coating had failed.

⁶The sample exhibited brittle cracking and did not yield or undergo any noticeable plastic deformation.

⁷The “calculated loads” for yield and ultimate strength would be determined by substituting a value for both the yield and ultimate strength in flexure of Ti-6Al-4V into equations 8 and 9 and backing out the imposed forces required to generate those stresses. The ultimate bending strength of Ti-6Al-4V would be expected to lie about midway between the ultimate strength in tension (~1180MPa) and the ultimate strength in compression (~2140MPa) [25], as half the sample is loaded in tension while the other half is loaded in compression. The measured ultimate strength in bending thus falls within the accepted range for this material. The measured yield strengths in bending correspond to a value that is approximately midway between the yield strengths in tension (~880MPa) and in compression (~1790MPa). The actual values are sensitive to interstitial impurity content, particularly oxygen and hydrogen.