

Structural Comparison of Advanced and Conventional Bone Ingrowth Technologies

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INTRODUCTION:

In recent years, several new “advanced” bone ingrowth technologies have been introduced with widely ranging structural characteristics. As such, there has been a renewed interest in identifying which characteristics contribute most to optimizing bone ingrowth and thereby differentiate these technologies from conventional ones.

Previous research has focused predominantly on porosity and average pore size [1]; however, more recently, others have suggested that specific surface area could be of importance as well [2]. Greater roughness and friction have been promoted as a means to enhance initial implant stability; however, historically it has been difficult to accurately characterize surface roughness of highly textured and porous structures and variability in friction testing materials, conditions, and methods make it difficult to compare results between studies.

The purpose of this study is to show how specific surface area and surface roughness of porous coatings can be characterized using the same two-dimensional metallographic cross-sections as are currently used to measure porosity and pore size. The structural characteristics of several ingrowth technologies are also evaluated and compared using all of these techniques to help identify the most important structural parameters for implant stability and osseointegration.

METHOD:

Five clinically successful porous ingrowth structures were evaluated: a CoCr bead coating (Porocoat™, DePuy), a Ti bead coating (Roughcoat™, Smith & Nephew), an asymmetric Ti particle coating (Stiktite™, Smith & Nephew), a porogen-produced Ti coating (CSTi™, Zimmer), and a reticulated Ta foam structure (Trabecular Metal™, Zimmer). Cross-sectional samples were obtained from implant components. These were then mounted, ground, and polished using standard metallographic techniques.

A digital image of each cross-section (Fig. 1, left) was captured at a resolution 3.14 μm/pixel. Analysis was done by first converting each of the metallographic images into a black & white binary image, wherein black pixels represented the solid structural features, and white pixels represented void space (Fig. 1, right). The black & white images could then be easily used to characterize the porosity, pore size, specific perimeter length, and surface roughness of each section using Image-Pro Plus 6.0 (Media Cybernetics, Bethesda, MD).

Porosity and pore size were measured using standard techniques [3]. Specific perimeter length, a depiction of the relative specific surface area of each structure, was calculated as the average perimeter length of all of the solid structural features per square millimeter of evaluation area. Two surface roughness characteristics (roughness average and skewness) were also calculated from coating thickness measurements obtained at 44-μm intervals across the entire evaluation area. The roughness average (R_a), the root mean squared roughness (R_q , used in the calculation for skewness), and the skewness (R_{sk}) were calculated using the following standard formulas:

$$R_a = \frac{1}{n} \sum_{i=1}^n |y_i| \quad R_q = \sqrt{\frac{1}{n} \sum_{i=1}^n y_i^2} \quad R_{sk} = \frac{1}{nR_q^3} \sum_{i=1}^n y_i^3$$

where n is the number of coating thickness measurements obtained and y is the difference between an individual coating thickness measurement and the mean coating thickness. At least 3 sections of each ingrowth technology were analyzed with an overall cross-sectional evaluation area of at least 34 mm² to ensure that representative values were obtained.

RESULTS:

The porosity, pore size, specific perimeter length, roughness average, and skewness for each technology are shown in Table 1. The CoCr bead, Ti bead, and CSTi structures all had a porosity of about 50%. Only the Asym Ti and Ta foam structures had a porosity greater than 60%. The average pore size ranged from about 180 to 400 μm, all falling within the 100- to 400-μm range previously reported as being optimal for bone ingrowth [1]. Specific perimeter length ranged from 5.22 mm/mm² for the Ta foam structure to 9.05 mm/mm² for the Asym Ti structure. Average roughness ranged from around 110 μm for the CoCr and Ti bead structures to over 200 μm for the Ta foam. While the

Ta foam had the greatest roughness average, its strongly negative skewness indicates that the roughness consists of a much higher ratio of valleys-to-peaks. Conversely, the Asym Ti coating had a roughness average of 150 μm, but with a lower magnitude of negative skewness (i.e. a greater ratio of peaks-to-valleys).

Table 1. Results of Structural Characterization

Structure	Total Cross-Sectional Evaluation Area [mm ²]	Porosity [%]	Pore Size (MVIL) [μm]	Specific Perimeter Length [mm/mm ²]	Roughness Average (Ra) [μm]	Skewness (Rsk)
CoCr bead	58	50 ± 2	182 ± 14	8.96 ± 0.31	110 ± 8	-1.2 ± 0.3
Ti bead	34	48 ± 3	237 ± 26	7.25 ± 0.21	109 ± 10	-1.2 ± 0.2
Asym Ti	150	62 ± 3	194 ± 18	9.05 ± 0.74	150 ± 20	-0.6 ± 0.3
CSTi	74	53 ± 2	194 ± 6	8.35 ± 0.04	131 ± 3	-1.7 ± 0.2
Ta foam	142	68 ± 1	396 ± 9	5.22 ± 0.11	216 ± 28	-1.7 ± 0.2

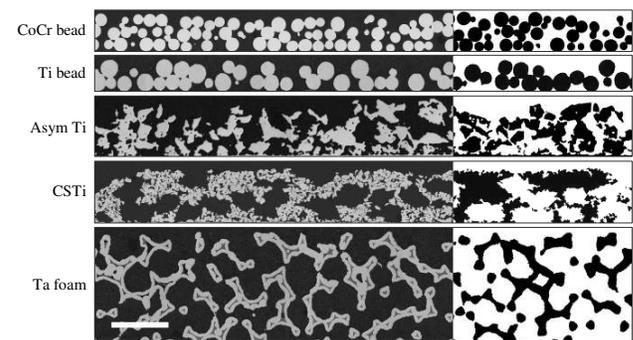


Figure 1. Representative cross-sectional images (left) and examples of images processed for analysis (right) for the five structures (all images are at the same magnification; white scale bar = 1 mm).

DISCUSSION:

The new evaluation methods were found to adequately characterize the relative specific surface area and roughness of each of the structures evaluated. Importantly, the methods were easy to apply in the same way to different structures to produce directly comparable results.

Increased porosity and increased roughness are two characteristics that distinguished the two newer advanced bone ingrowth technologies (the Asym Ti and Ta foam structures) from the more conventional technologies. The Asym Ti and Ta foam structures differed, however, in skewness, pore size, and specific surface area.

Previous testing has indicated that the Asym Ti coating has greater friction against cancellous bone than the Ta foam structure [4]. Since the Ta foam was shown to have a greater roughness average, this characteristic alone does not appear to explain the difference in frictional properties obtained. However, the skewness values indicate that the Asym Ti coating has a greater ratio of peaks-to-valleys than the Ta foam. Penetration of these peaks into the bone could enable the Asym Ti coating to better resist lateral micromotion, a possible reason for the greater friction found in the previous testing.

Previous research has also shown a trend toward greater bone ingrowth and greater shear strength for stable implants with a smaller average pore size down to about 175 μm [5]. Structures with smaller pores also tend to have greater specific surface area, in other words a greater density of surface available for cellular attachment.

Despite these differences, all of these structures have been shown to be clinically successful [6-10]. Further study would be needed to more definitively attribute specific structural characteristics to improvements in the rate, extent, and reliability of osseointegration.

- [1] Kienapfel, et al., *J Arthro*, **14**(3):355-68, 1999. [2] Li, et al., *Porous Metals and Metallic Foams*, 267-70. [3] ASTM F1854-09. [4] Heiner and Brown, *ORS*, 1623, 2007. [5] Clemow, et al., *JBMR*, **15**(1):73-82, 1981. [6] Engh, et al., *J Bone Joint Surg*, **77A**(6):903-10, 1995. [7] Danesh-Clough, et al., *J Arthrop*, **22**(2):195-203, 2007. [8] Bourne, et al., *Orthopedics*, **31**(12):92-6, 2008. [9] Bloebaum, et al., *J Arthrop*, **12**(8):920-9, 1997. [10] Helm, et al., *J Arthrop*, **24**(6):941-4, 2009.