

Characterization of OSSEOTITE® Surfaces on CP Titanium and Titanium Alloy Dental Implants

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The objective of this study was to characterize the dual acid-etched OSSEOTITE® surface (Implant Innovations, Inc.) on endosseous implants manufactured from either commercially pure titanium (CP Ti) or Ti-6Al-4V-ELI (Ti-alloy) with qualitative and quantitative microscopy. Scanning electron microscopy (SEM) and surface mapping microscopy (SMM) were used to generate images and surface microscopy data for both types of etched titanium.

For both CP Ti and Ti-alloy, three sample regions on thirteen (13) implants, each from a different manufacturing lot, were analyzed. The JSM 6460LV SEM (JEOL Ltd., Peabody, MA) produced images of the flute areas on each implant at 2000x magnification. Images were mapped with the MicroXAM 100 Surface Mapping Microscope (ADE Phase Shift, Tucson, AZ) which utilizes light interference from a white light source to obtain high resolution 3-dimensional scans of the surfaces. For each sample the SMM scanned an area of $81.41\mu\text{m} \times 61.65\mu\text{m}$ at 1000x magnification. Post-processing was performed on the original scans to level the data to the entire reference plane (using tilt removal), to remove noise in the data (using Gaussian smoothing), and to suppress unwanted data spikes (using median filter). In addition to the high resolution maps, SMM analysis generates the following quantitative parameters: Sq = Root Mean Square variation over the surface (μm); Sa = mean absolute height deviation over the surface (μm); and PV = distance from the highest peak to the lowest valley in the scan (μm).

Representative SEM images for CP Ti and Ti-alloy, shown in Figure 1, are visually similar although slight differences are observed due to the inherent etching characteristics of the materials. Representative 3-dimensional SMM images for both implants shown in Figure 2 are qualitatively similar. The surface mapping measurements data given in Table 1 show no statistically significant differences in Sa , Sq and PV values for the two types of titanium using the above referenced measuring equipment.

Although some visual differences are observed on the OSSEOTITE surfaces of CP Ti and Ti-alloy under the SEM, the statistical analysis of quantitative data from SMM showed no statistically significant difference for the surface mapping measurements ($P > 0.05$).

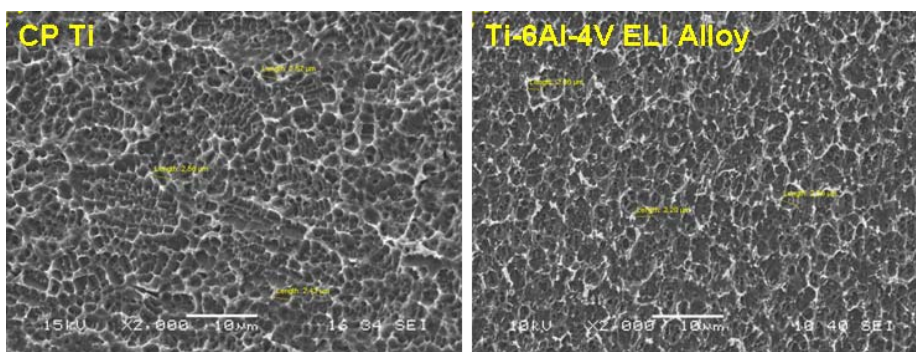


Figure 1. SEM images of OSSEOTITE® surfaces on implants manufactured from CP Ti and Ti-alloy.

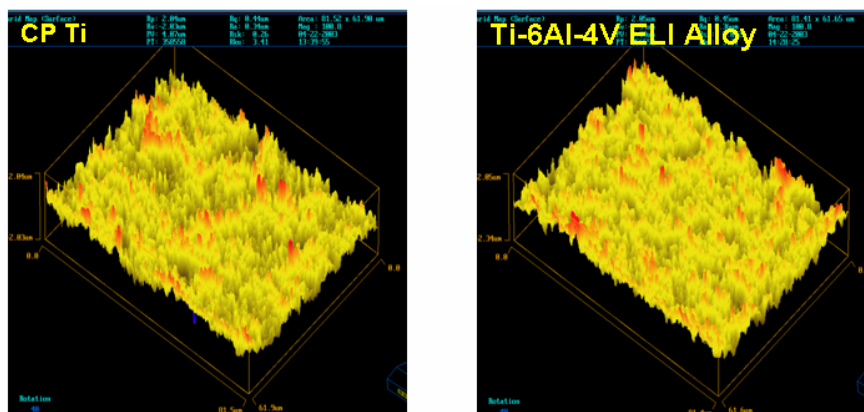


Figure 2. Surface Mapping Microscope images of OSSEOTITE® surfaces on implants manufactured from CP Ti and Ti-alloy.

Table 1. Data from surface mapping microscopy

| Number of Data Points = 39 From 13 samples | CP Ti | | | Ti-alloy | | |
|--|-------|------|------|----------|------|------|
| | Sq | Sa | PV | Sq | Sa | PV |
| | µm | µm | µm | µm | µm | µm |
| Mean | 0.46 | 0.36 | 3.68 | 0.46 | 0.36 | 3.75 |
| Std. Deviation | 0.10 | 0.08 | 0.82 | 0.06 | 0.05 | 0.54 |
| Median | 0.42 | 0.34 | 3.44 | 0.46 | 0.37 | 3.78 |
| Minimum | 0.32 | 0.25 | 2.38 | 0.34 | 0.27 | 2.78 |
| Maximum | 0.75 | 0.59 | 5.63 | 0.58 | 0.46 | 5.28 |

No statistically significant difference between the medians as $P > 0.05$ from Mann-Whitney (Wilcoxon) test for *Sq*, *Sa* and *PV*