**Qualitative and Quantitative Analyses of NanoTite-Surfaced Implants**

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**Introduction:** The objective of this study was to characterize the surface of experimental implants treated with a new proprietary surface treatment called discrete crystalline deposition (DCD) to deposit nanometer-scale calcium phosphate hydroxide (nano-CaP) crystals to obtain the resulting surface called NanoTite™. Field Emission Scanning Electron Microscope (FE SEM) was used to obtain high resolution images of the surface to visualize the size, shape and distribution of the nano-CaP crystals, and standardized software was used for quantitative analysis of crystal coverage.

**Materials and Methods:** Custom-designed rectangular implants, 6.0 mm x 4.0 mm x 1.5 mm, intended for antero-posterior placement into the distal metaphyses of Wistor rat femora, were manufactured from Ti-6Al-4V-ELI alloy. The implants were dual-acid etched (DAE, known as Osseotite which is proprietary to 3i) and were then deposited with nano-CaP crystals by the DCD process, which is a sol-gel based deposition technique. The particle size of the nano-CaP crystals used as a raw material in the DCD process ranged from 20nm to 70 nm. By controlling the various process variables, it was possible to achieve different categories of coverage, classified as light, medium, and heavy.

An FE SEM, model JEOL JSM-6700F (JEOL USA Inc, Peabody, MA), was used to obtain high resolution imaging of the implant surface in order to visualize the size, shape and distribution of the nano-CaP crystals. The quantitative analysis of the FE SEM images was carried out to estimate the surface area coverage of the nano-CaP crystals using Scandium software (Soft Imaging System Corp., Lakewood, CO).

**Results & Discussion:** From the analysis of high resolution images obtained by FE SEM, it was determined that the particle size (of 20nm to 70nm) did not change significantly from the raw material and the particles retained their crystalline nature after processing. Figure 1 shows the three categories of particle coverage as seen in FE SEM. The quantitative area coverage was calculated using Scandium software where the nano-CaP particles were color-coded as phases and calculates the area covered by the phases. Light, medium, and heavy categories exhibited 25-30%, 55-60%, and 80-85% area coverage, respectively. Figure 2 shows the nano-CaP particles color-coded in Scandium software for area coverage calculation.

1 µm x 1 µm sample area at 30,000x

Light, 25-30% Medium, 55-60% Heavy 80-85%

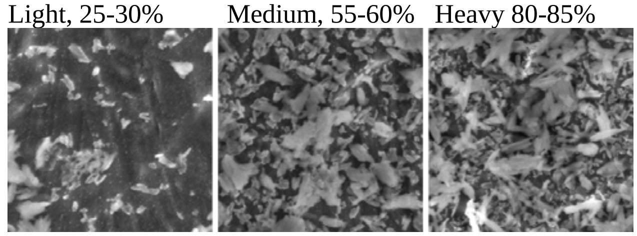

Figure 1. Field Emission SEM Images Showing Size, Shape and Distribution of Nano-CaP Crystals with Various Particle Coverages on DAE Surface

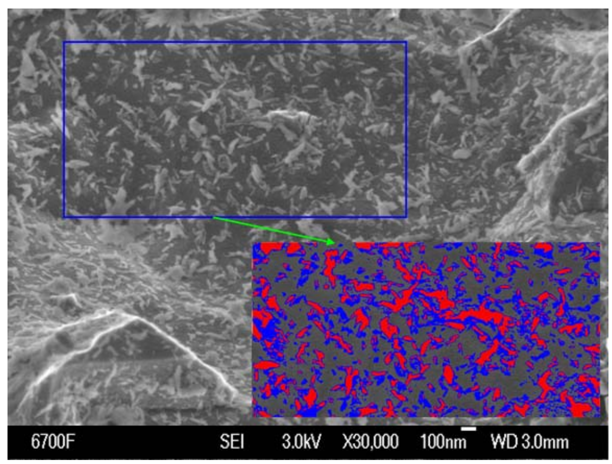


Figure 2. Phase Color-coding in Scandium Software

**Conclusions:** The analysis of size, shape, and distribution of the particles, based on high resolution images obtained from Field emission SEM, was useful to characterize the DAE implant surface deposited with nano-CaP particles. The Scandium software was used for quantifying the light, medium and heavy surface area coverage of the nano-CaP particles.