37

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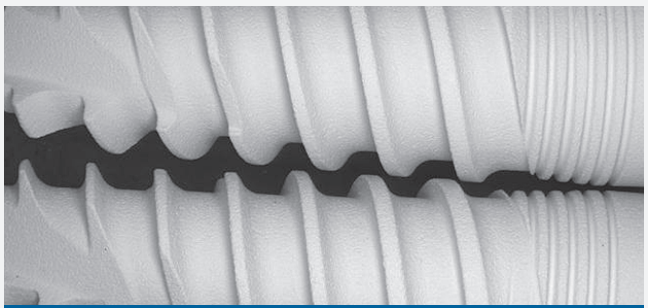

MIS®
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Characterizations of MIS Implant Surface.

Dr. Tal Reiner[1]

Introduction

Long-term clinical success of dental implants is dependent on a number of critical factors including implant design, bone quality and quantity, surgical techniques and clinician's skills. However above and beyond implant materials and geometry, the topography and chemistry of the implant; surface treatment and surface quality, is just as important in achieving high success rates.

Improving Osseointegration

Osseointegration is defined as the attachment of the bone to a dental implant, and is the critical factor related to the long-term success of dental implants. Implant surface treatments are employed to improve the capacity of anchorage into bone. This can be observed in an early healing phase in comparison with a simple turned implant surface.

Numerous studies suggest a predictable and more rapid osseointegration of implants using surface treatments in a combination of sand-blasting and acid-etching. Osteoblast proliferation and differentiation depends on the micro and nanostructures on the surface of the implant that closely mimic the natural bone matrix. MIS implant surfaces most closely mimics the natural cancellous (spongy) bone configuration and has enhanced surface purity when tested against other major implant brands using SEM technology.

Managing Contaminants

The chemical composition of the implant surfaces can vary due to manufacturing finishing's such as titanium machining, thermal treatment, cleaning and sterilization procedures. Surface contaminants, such as trace metals, ions, lubricants and detergents left over from machining and cleaning processes require the careful control of implant surfaces as a procedure in itself, to ensure the quality of the implant.

MIS implants undergo routine stringent surface characterization and validation procedures using SEM (Scanning Electron Microscopy) and XPS (X-ray Photoelectron Spectroscopy) that verify low carbon percentage on the surface of the implant and low level of other contaminants.

Raw Materials

Titanium and its alloys are amongst the most commonly used implant materials in dental implant production, as it features highly desirable biocompatibility. MIS implants are comprised of Titanium alloy Ti-6Al-4V-ELI (Grade 23) ELI=Extra Low Interstitials (contaminations), and is a higher purity version of Ti-6Al-4V (Grade 5), conforming to the ASTM F136-08E1 Standard Alloy for Surgical Implant Applications. It is particularly corrosion resistant with very high tensile strength and facture resistance properties.

Characterization of the MIS Implant Surface

The surface of a dental implant determines the initial phase of biological response to the inserted implant. The scanning electron microscope (SEM) is very powerful tool for surface characterization. It uses a high-intensity voltage electron beam which scans the implant surface. The electrons interact with atoms in the sample, producing various detectable signals containing information about the sample surface topography and composition.

Images and spectra are generated utilizing 3 types of detectors:

1. SE detector; generating high resolution images of the surface at high magnifications, up to X 10,000.

2. BSE detector; generating images including contamination detection. Contamination appears as a black dot on the white Titanium background.

3. EDS detector; enables obtaining the chemical composition spectrum of any chosen area or point, to the depth of 1-2 micro-meters.

X-ray Photoelectron Spectroscopy (XPS) is a surface chemical analysis technique that can be used to analyze the surface chemistry of a material. It measures the elemental composition at the parts per-thousand range, from the upper 10 nm of the surface. Upper oxide thickness can also be calculated.

MIS implants taken from the production line, are characterized on a daily basis by SEM microscope and every quarter annually, by XPS analysis as a routine quality inspection procedure.

Protocol

A conclusive summary of quality inspections by MIS Implants as performed via SEM microscope analysis and XPS analysis, and an illustration of recent inspection results.

Methods: Implants are inspected following surface treatment and packaging in a sleeve within an inner tube. Never touching the surface, implants are removed from the package by forceps inserted into the inner screw thread. Implants are fixed onto a sample holder above a layer of a carbon conductive two-sided adhesive tape.

An in-house SEM: Tescan electron microscope with a Bruker EDS detector is used for the characterization of the surface. Internal software analyzes the percentage of impurities per-surface area using contrast analysis on BSE images.

XPS analysis is done at a near-by university by Dr. Kamira Weinfeld, employing VG Scientific Sigma Probe instrument.

Results: SE and BSE images of various MIS implant surfaces from recent production lots.

[1]MIS Materials Discipline Manager

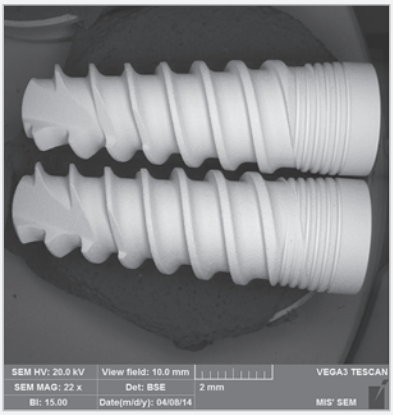
Possible contaminants on implants are blasting media residues or organic dot impurities. Contamination incidence in daily inspections does not exceed 0.2% of the surface area.

Recent XPS analysis of an MIS SEVEN® implant production lot is shown in table 1, where a low carbon percentage on the surface is shown.

The lower the carbon percentage is, indicates the increased hydrophilic properties of the surface. A hydrophilic surface attracts blood to initiate the process of osseointegration. Current literature demonstrates a link between improved bone healing and early osseointegration with hydrophilic properties.

Using an XPS instrument, the upper Titanium oxide layer thickness was also calculated. Aluminum and Vanadium in the table originate from the raw material substrate under the Titanium-oxide.

Conclusions: Using surface characterization technology, MIS can guarantee that our implant surfaces uphold the highest standards of surface quality with a 99.8-100% pure Titanium-oxide surface, as well as the validation of full coverage by sand-blasting and acid-etching. These surface treatments help eliminate various surface contaminants while increasing the implant surface area; generating a hydrophilic surface with micro and nanostructures for optimum osseointegration.



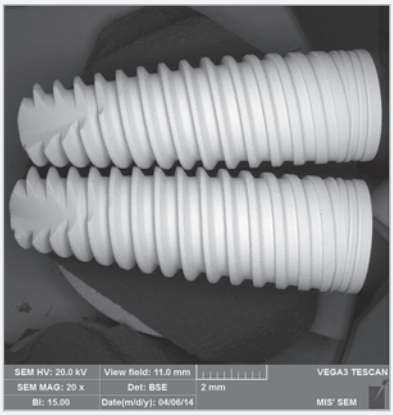


Fig. 1-2 BSE images of MIS implants: SEVEN (left) and C1 (right)

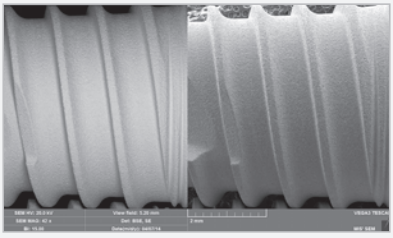


Fig. 3 Images of mid-section of MIS SEVEN implant: BSE (left), SE (right)

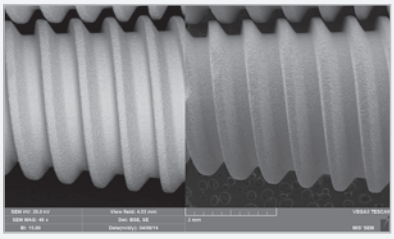


Fig. 4 Images of mid-section of MIS C1 implant: BSE (left), SE (right)

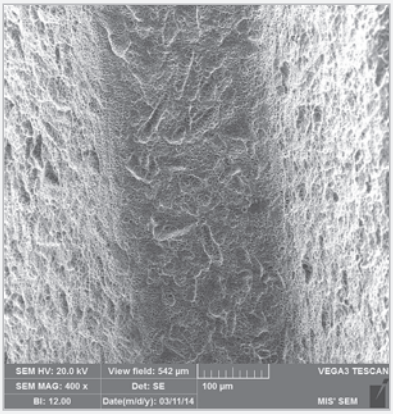


Fig. 5 SE image X400 between threads of MIS M4 implant

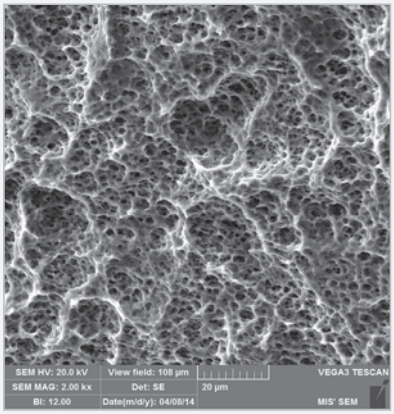


Fig. 6 SE image X2000 of MIS SEVEN implant

Sample/ measurement	Carbon	Titanium	Oxygen	Aluminum	Vanadium	Titanium-oxide layer thickness (nm)
#1, average	15.80	20.61	57.42	3.91	0.28	3.30
#2, average	12.26	22.09	59.77	3.55	0.48	3.21

Table 1. XPS atomic concentrations (%) and Titanium-oxide layer thickness from routine validation of MF7-10420, lot W14001674

The MIS Quality System complies with International Quality Standards: ISO 13485:2003 - Quality Management System for Medical Devices, ISO 9001: 2008 - Quality Management System and CE Directive for Medical Devices 93/42/EEC. MIS products are cleared for marketing in the USA and CE approved.

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