

KÖLN

UNIKLINIK Zentrum für Zahn-, Mund- und Kieferheilkunde

Klinik und Poliklinik für Mund-, Kiefer-, und Plastische Gesichtschirurgie und Interdisziplinäre Poliklinik für Orale Chirurgie und Implantologie

Implant Study 2011/2012

Quantitative and qualitative element-analysis of implant-surfaces by SEM

SEM Images and EDX-Analysis **Medical Instinct** BoneTrust plus LOT 605898

In cooperation with the European Association of Dental Implantologists BDIZ-EDI **Quality & Research Commitee**



Project manager: Dirk U. Duddeck, D.D.S. Head of Surface Analyses

Interdisciplinary Outpatient Dep. for Oral Surgery and Implantology Dep. for Craniomaxillofacial and Plastic Surgery University Cologne Kerpener Str.62 D 50937 Köln

fon: +49 (0)221 478 5771 fax: +49 (0)221 478 6721 mobile: +49 (0) 171 5477991 mail: duddeck@dedemed.de

Background and Aim

Implant surfaces are modified by microstructures and surface extension to improve osseointegration. Numerous studies showed an increased adhesion and osteoblastic matrix-production on retentive titanium surfaces.

In 2008 we performed a scanning electron microscopic study and analyzed the surfaces of 23 enossal Titanium implants of several manufacturers at the Interdisciplinary Outpatient Department for Oral Surgery and Implantology, Department for Craniomaxillofacial and Plastic Surgery, University Cologne¹.

The tested implants showed selected and / or laminary deposits. Depending on manufacturing process, accumulations of organic material (carbon) or inorganic material like aluminum, silicon, phosphor, sulfur, chlorine, potassium and calcium were found. 2011-2012 we performed the same protocol on 57 dental implants from different manufacturers.

The aim of this study was to present topographic effects of the different manufacturing processes and to analyze potential impurities.

Material and method / study protocol

SEM-examination of implant surface (SEM-method)

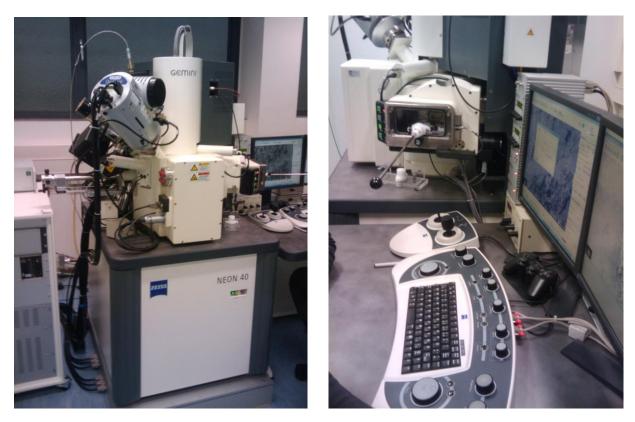
Scanning electron microscopy (SEM) enables the topical evaluation of the implant surfaces. The Inlense-Detector is located inside the electron column of the microscope and is arranged rotationally symmetric around the optical axis. In particular at low voltages and small working distances, images with high contrast can be obtained. Besides information about morphology and surface topography, the Inlense-Detector images differences in the work function (e.g., electronic variations) on the sample with high lateral resolution and allows drawing conclusions about the chemical nature and allocation of different remnants or contaminations in the sample material.

Qualitative and quantitative analysis of implant surfaces (EDX)

Energy Dispersive X-ray (EDX) was used for the appropriate elemental analysis. Each element emits specific X-ray peaks. An area-analysis and one or more spot analyses are performed for each tested implant (analysis of spots and areas by EDX). An area analysis covers the entire implant area lying in the focus of the microscope. For a spot analysis, the electron beam is focused on a specific area to get information about selective accumulations on the implant surface.

Scientific workstation and test procedure

Without touching the surface, implants were taken with sterile forceps out of the package and fixed onto the sample holder. Before closing the chamber, implants were blown off with nitrogen in order to remove material artifacts as dust. The so induced nitrogen peak in the following EDX-analysis was excluded by analysis-software. Afterwards the vacuum was generated and imaging as well as measuring was done.



Zeiss Surface Scanning Electron Microscope with GEMINI[®] Column

Results

Compared to the preceding study of 2008 a variety of implants in the current study showed significant improvements regarding residues of blasting material (i.e. Bego, Camlog).

The implant provided by Medical Instinct showed no significant traces of inorganic or organic residues

SYNOPSIS

Name of Company:	Medical Instinct	
Name of analyzed Product:	BoneTrust plus Screw implant LOT 605898 Ø 4.0 / L 14,5 mm	
Title of Study:	Quantitative and qualitative element-analysis of implant-surfaces by SEM	
Investigators:	Dirk U. Duddeck DDS.	
Study centre:	Interdisciplinary Outpatient Dep. for Oral Surgery and Implantology, Dep. for Craniomaxillofacial and Plastic Surgery, University of Cologne	
Studied period:	January 1, 2011 - May 30, 2012	
Methodology:	Zeiss Surface Scanning Electron Microscope with GEMINI [®] Column equipped with two detectors for secondary electrons: in-lens detector and conventional secondary electron detector.	
	EDX Analysis	
Summary / Conclusions:	The implant provided by medical instinct showed no significant traces of inorganic or organic residues	

COORDINATING INVESTIGATOR(S) SIGNATURE(S)

STUDY TITLE:	Quantitative and qualitative element-analysis of implant- surfaces by SEM
STUDY AUTHOR(S):	<u>Dirk U. Duddeck</u> , Shaghajegh Iranpour Joachim E. Zöller
	Interdisciplinary Outpatient Dep. for Oral Surgery and Implantology, Dep. for Craniomaxillofacial and Plastic Surgery, University of Cologne
	Head: Prof. Dr. Dr. Joachim E. Zöller, Address: Kerpener Str. 62, D 50937 Köln, Germany, eMail: dirk.duddeck@uk-koeln.de

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

INVESTIGATOR:

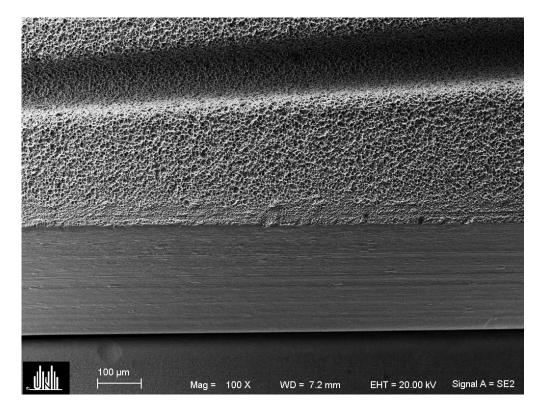
DATE:

Dirk U. Duddeck March 10th 2013

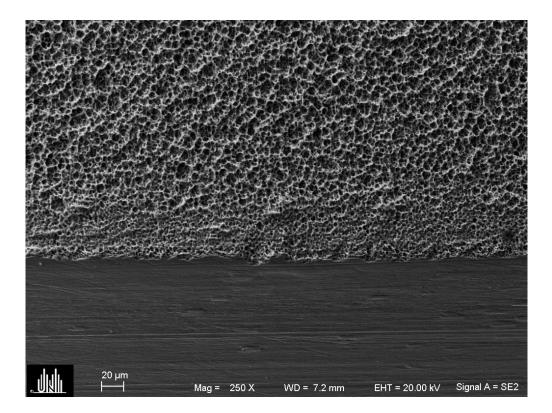
D. Dudder

APPENDIX

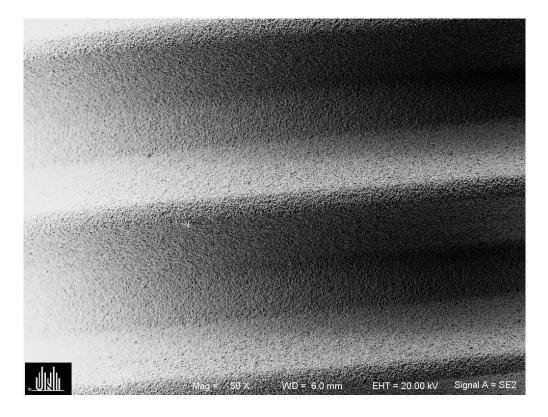
SEM IMAGES / EDX ANALYSIS



Implant shoulder SE 100x



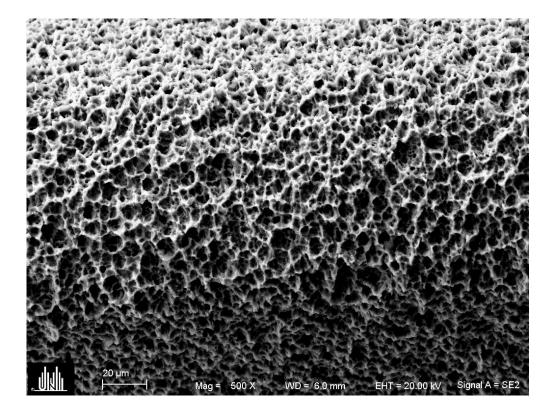
Implant shoulder SE 250x



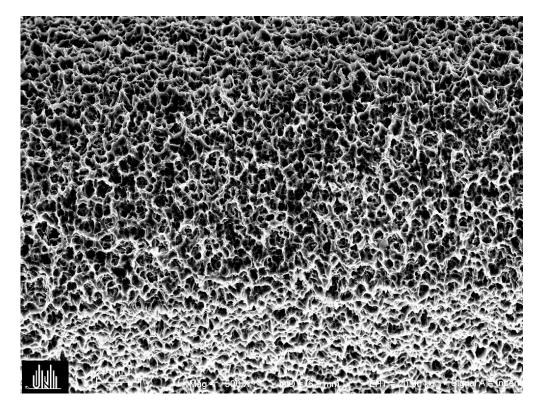
Implant surface SE 50x



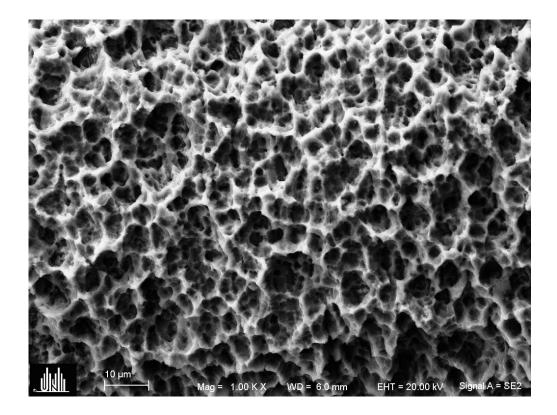
Implant surface SE 250x



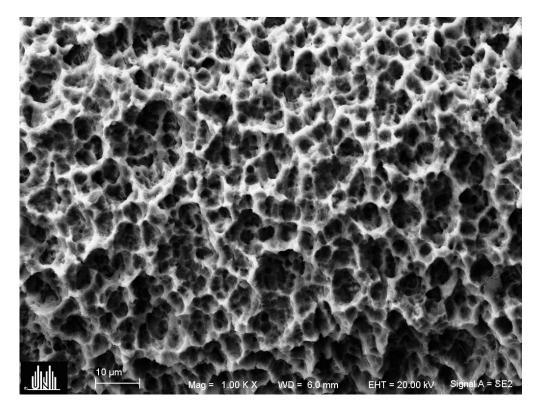
Implant surface SE 500x



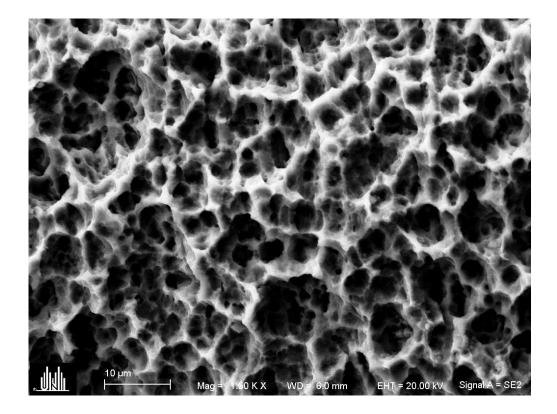
Implant surface Inlense Detector 500x



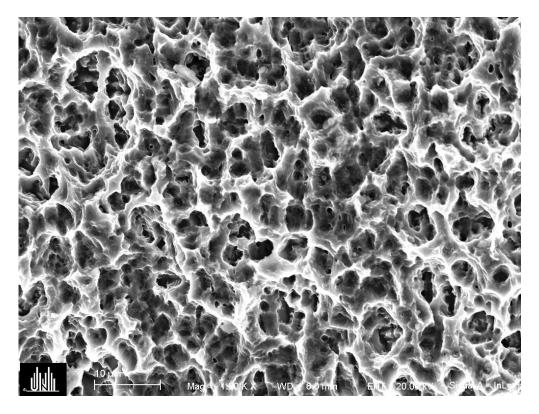
Implant surface SE 1000x



Implant surface Inlense Detector 1000x

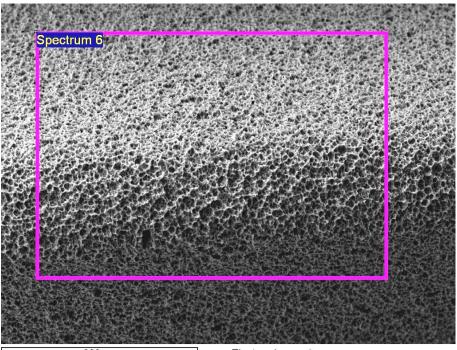


Implant surface SE 1500x



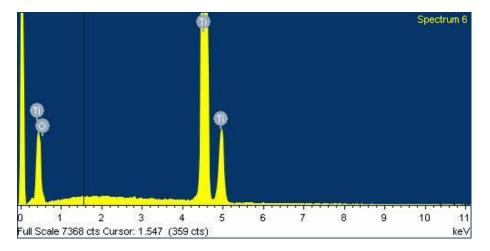
Implant surface Inlense Detector 1500x

EDX surface analysis



200µm

Electron Image 1



Element	Weight%	Atomic%
ок	4.74	12.96
Ti K	95.26	87.04
Totals	100.00	