UNIKLINIK KÖLN
Zentrum für Zahn-, Mund- und Kieferheilkunde
Klinik und Poliklinik für Mund-, Kiefer-, und Plastische Gesichtschirurgie und Interdisziplinäre Poliklinik für Orale Chirurgie und Implantologie

(BDIZ EDI) Implant-Study 2016

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

PRELIMINARY STUDY REPORT

Name of Manufacturer:
Alpha Dent Implants GmbH

Analyzed Product(s):
Implant Active LOT 0351068434

Head:
Prof. Dr. Dr. **Joachim E. Zöller**

Interdisciplinary Policlinic for Oral Surgery and Implantology Dep. for Craniomaxillofacial and Plastic Surgery;

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In cooperation with the
European Association of Dental Implantologists
BDIZ-EDI. Quality & Research Committee

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1. 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 the University of Cologne, Germany and the BDIZ EDI (European Association of Dental Implantology) with its Quality and Research (Q&R) Committee (www.bdizedi.org) performed a scanning electron microscopic study and analyzed the surfaces of 23 enossal titanium implants of several manufacturers at the Interdisciplinary Policlinic for Oral Surgery and Implantology, Department for Craniomaxillofacial and Plastic Surgery, University Cologne[1]. The tested implants showed isolated and/or extensive deposits. Depending on manufacturing process, accumulations of organic material (carbon) or inorganic material like aluminum, silicon, phosphor, sulfur, chlorine, potassium and calcium were found.

In 2011-2012 we performed the same protocol on 57 dental implants from different manufacturers. However, the manufacturing of implants requires an adequate system of quality controls. Although some manufacturers have made substantial improvements since our first survey in 2008, the study in 2011-2012 again singled out a few implants with larger areas of surface blasting residue and selective organic
impurities.[2]

The BDIZ EDI[3], representing more than 5,500 active implantologists in Europe, was asked in its general meeting to continue these analyses periodically and to publish the results in the European EDI Journal.

While using the same material an methods regarding the technical setup this study allows comparisons to the results of previous studies.

As a continuance of the two studies cited above the aim of this study is to verify improvements of manufacturing and quality management as well as to demonstrate the high quality level of the participating manufacturers and implant companies.

1) Duddeck DU; Comparative investigation of various implant surfaces by SEM-Analysis. (Posterpresentation) 18th Annual Scientific Meeting of the European Association of osseointegration, 30 September - 3 October 2009, Monaco, France

2) Duddeck, DU. et. al; Surface characteristics and quality of implants in sterile packaging, EDI Journal 2013-1

3) The BDIZ EDI has set the preliminary standards for a qualifying procedure of all implant systems and maintains structured continuing education. The primary tasks of BDIZ EDI are to provide members with support and advice and to improve the quality of implant materials.

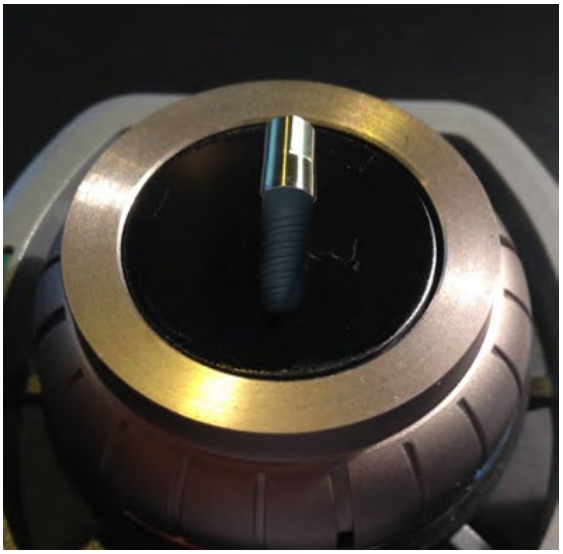
2. Material and Method / Study Protocol

2.1 Scientific Workstation and Test Procedure

The scientific workstation is a Phenom proX Scanning Electron Microscope, equipped with a high-sensitivity backscattered electron detector that allows compo- sitional and topographical imaging modes. EDX analyses are performed with a thermoelectrically cooled Silicon Drift Detector (SDD)

Workstation with Phenom proX Scanning Electron Microscope

ithout touching the surface, each implant will be taken out of the package with sterile forceps and will be fixed on the sample holders. After the vacuum is generated in the electron micro- scope imaging and EDX-analyses will be completed.



2.2 3D Roughness Reconstruction

With a specific 3D roughness reconstruction application, based on a „shape from shading" technology, the SEM system used in this study is able to generate three- dimensional images and submicrometer roughness measurements.

3D imaging helps to interpret sample characteristics and makes images under- standable. In addition the system is able to measure the average roughness (Ra) and the roughness height (Rz). Due to shape-from-shading technology Ra and Rz data in this study are to be generally understood merely as approximate values.

2.3 SEM-Examination of Implant Surface

Scanning electron microscopy (SEM) enables the topical evaluation of the implant surface. In particular at low voltages and small working distances, images with high contrast can be obtained. The high-sensitivity backscattered electron detector is generating images in compositional and topographical modes to a magnification of 20.000x.

Besides information about morphology and surface topography, the BSE detector allows to draw conclusions about the chemical nature and allocation of different remnants or contaminations on the sample material.

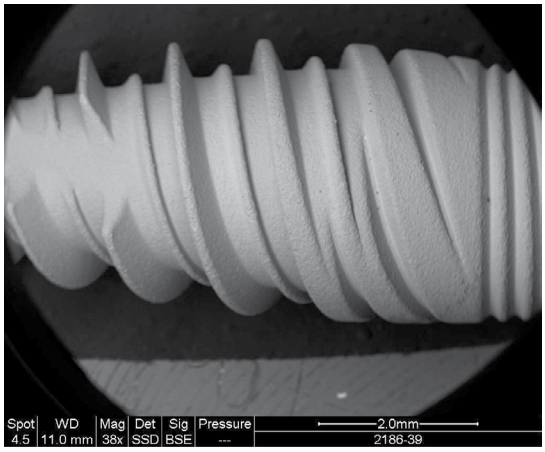
2.4 Qualitative and Quantitative Analysis of Implant Surfaces (EDX)

Energy Dispersive X-ray Spectroscopy (EDX) analyzes X-rays generated by the electrons of the electron beam (CeB6 electron source) while they are interacting with the sample. Each element emits specific X-ray peaks. The element identification software allows to identify even hidden elements within the sample via the spot mode analysis. All results are verified using iterative peak stripping deconvolution.

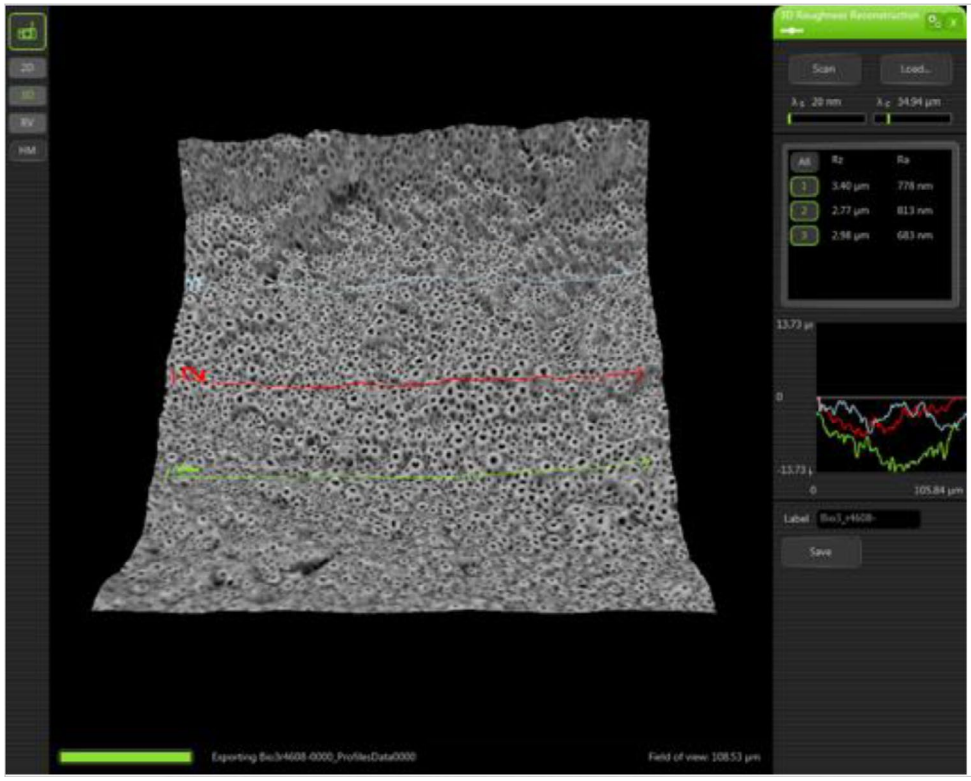
An area-analysis and one or more spot analyses are performed for each tested implant (analysis of spots and areas by EDX). An area-analysis covers the entire implant area in the focus of the microscope. For a spot analysis, the electron beam is focused on a specific area to get information about selective accumulations on the implant surface.

If necessary, elemental mapping reveals the distribution of elements within the sample. Selected elements can be mapped. Compiling these elements with the backscattered image gives a clear insight into the distribution of elements within the sample. Line scan allows analysis to be performed over a selected line. A line profile of every selected element is displayed on the screen.

3. Alpha Dent Implants LOT 0351068434

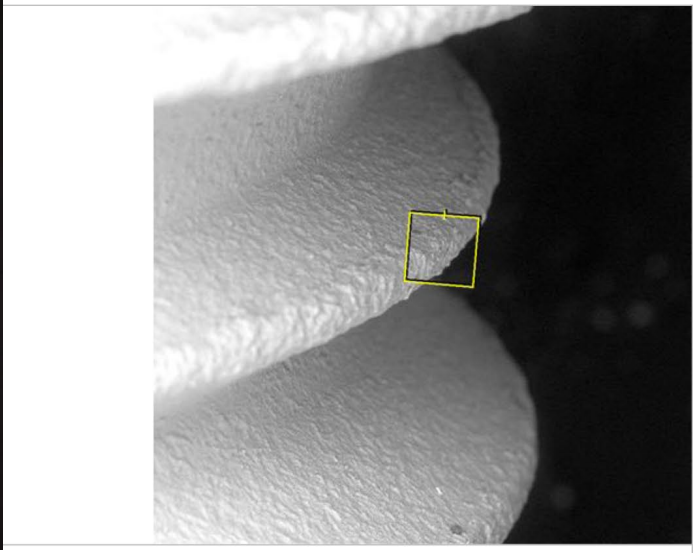


3.1 3D Roughness Reconstruction

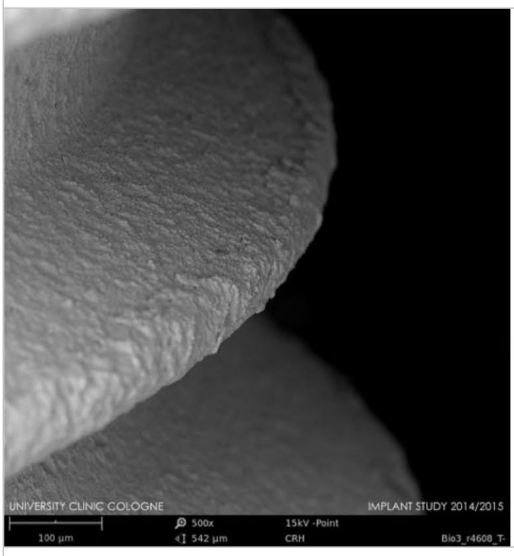


3.2 Surface-Topography Material Contrast Images (Thread)

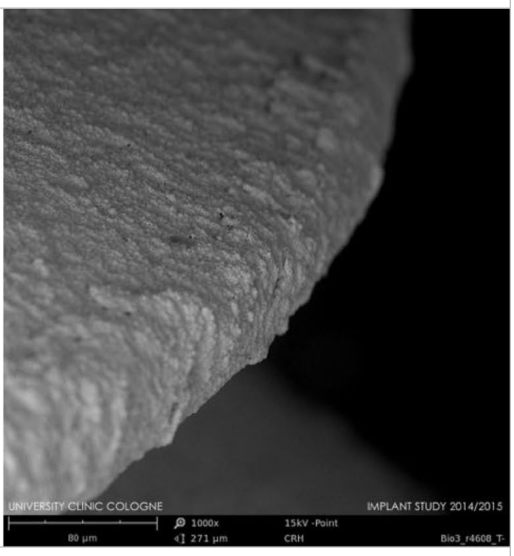
Phenom camera



Field of view



500x



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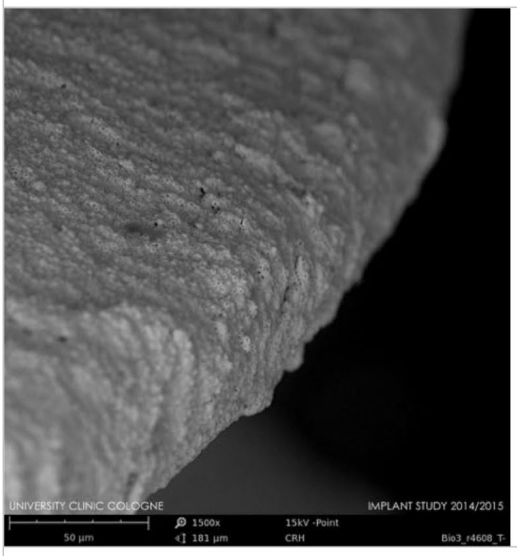

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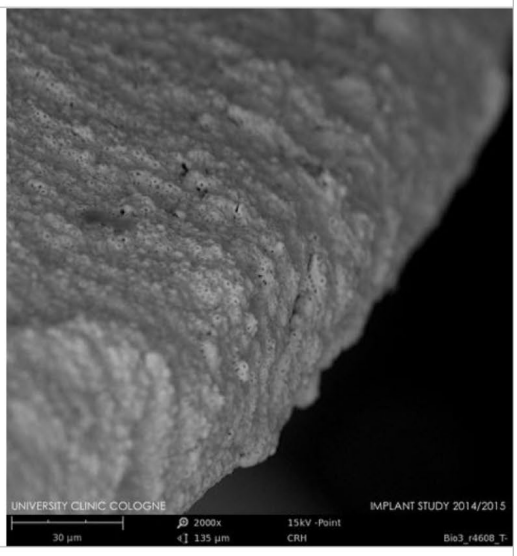

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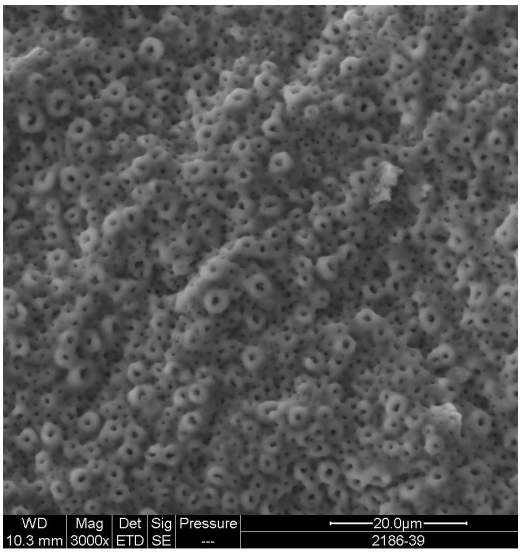
Surface-Topography – Material Contrast Images (Thread)



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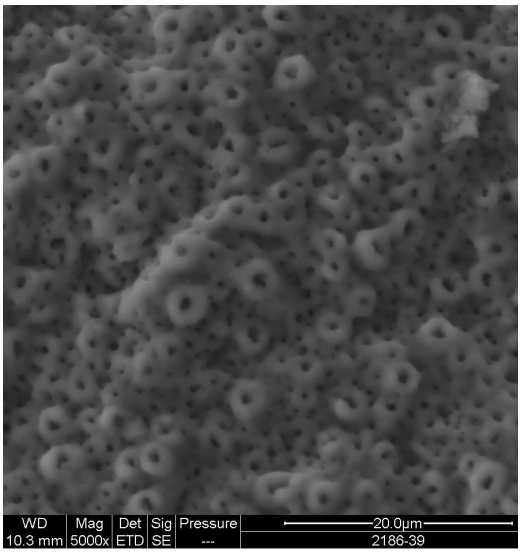

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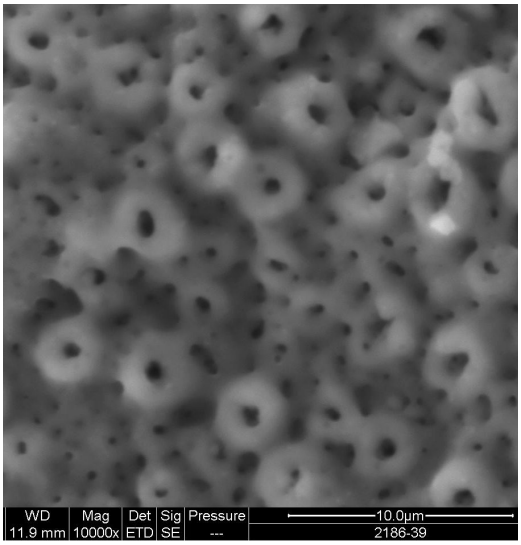

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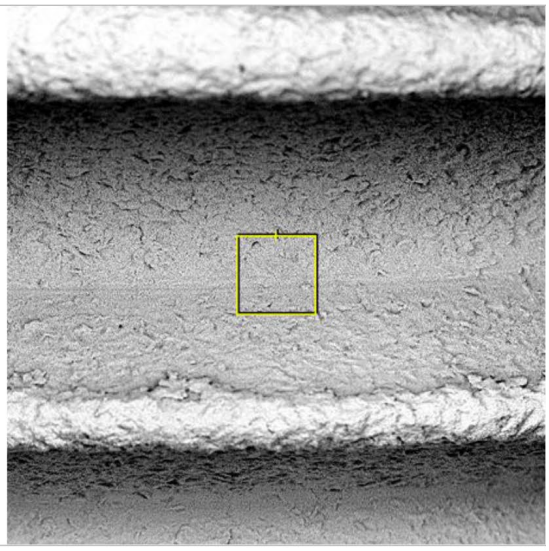
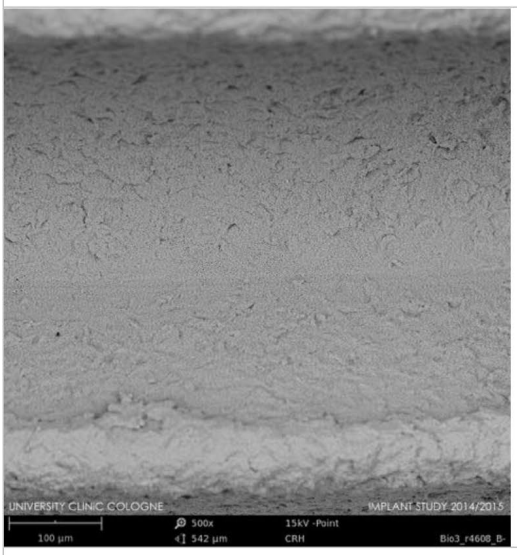
3.3 Surface-Topography – Material Contrast Images (Body)

Phenom camera



Field of view



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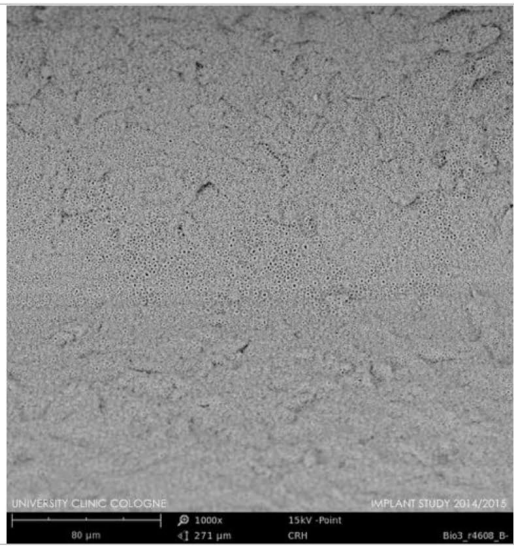

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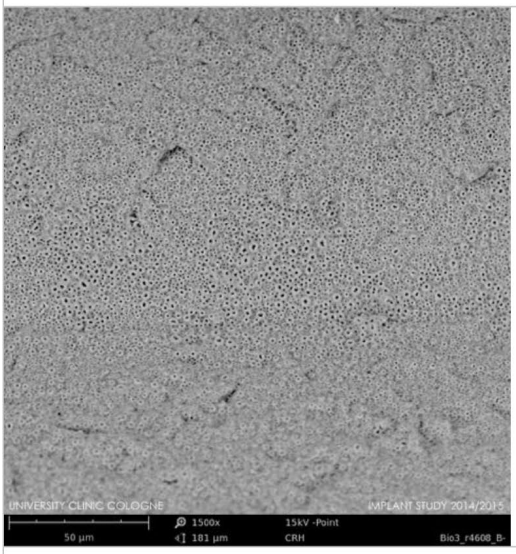

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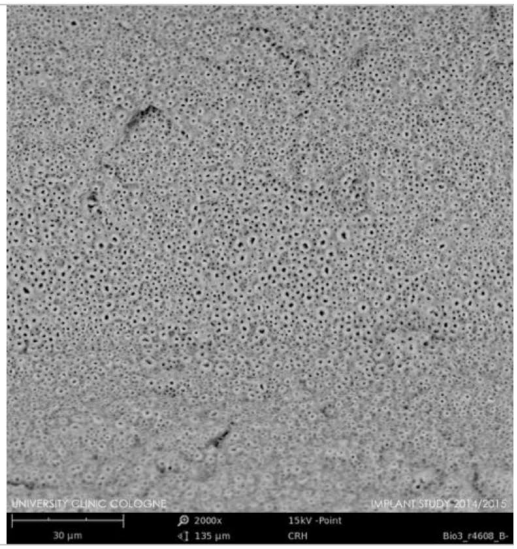

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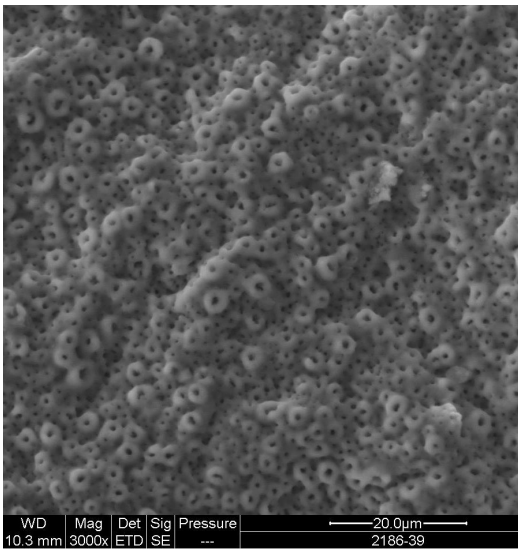
Surface-Topography – Material Contrast Images (Body)



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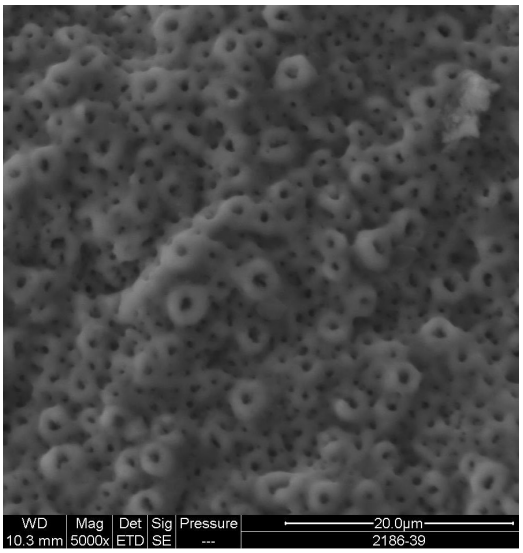

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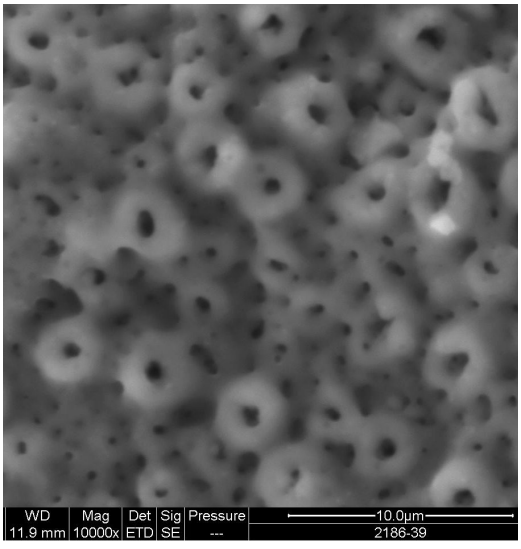

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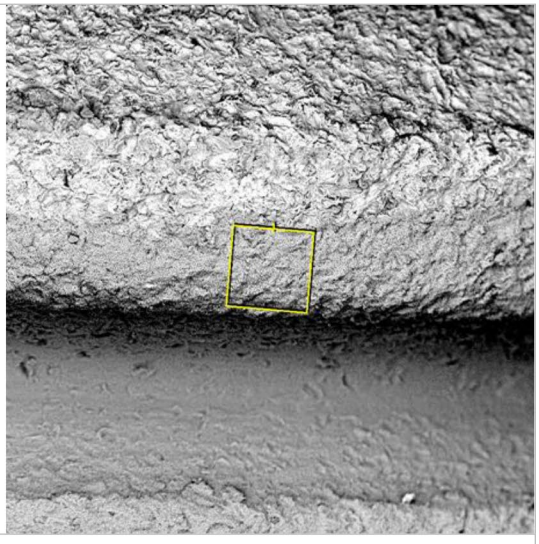
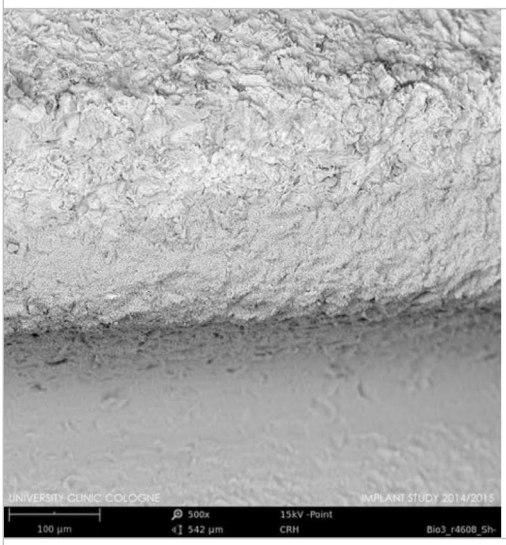
3.4 Surface-Topography – Material Contrast Images (Shoulder)

Phenom camera



Field of view



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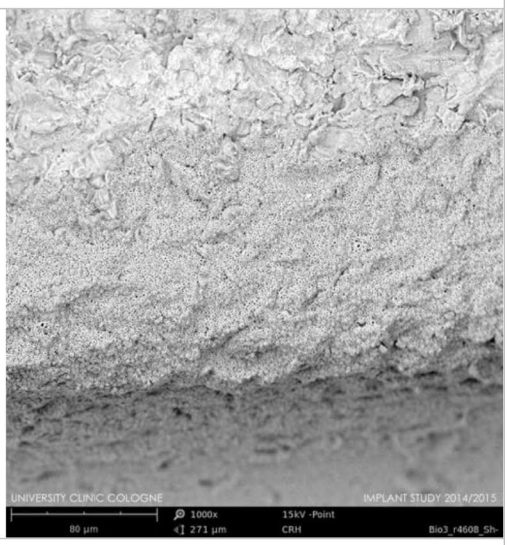

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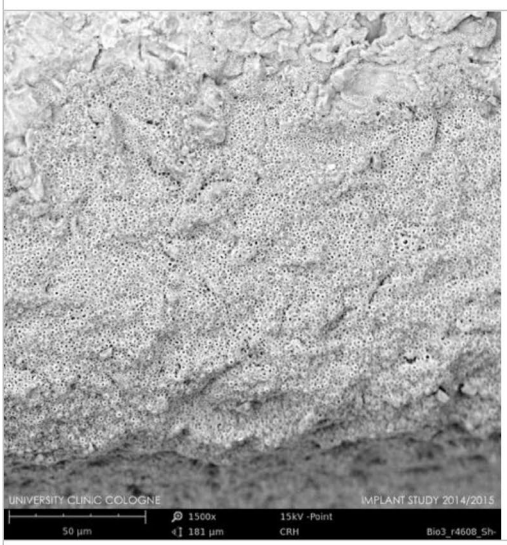

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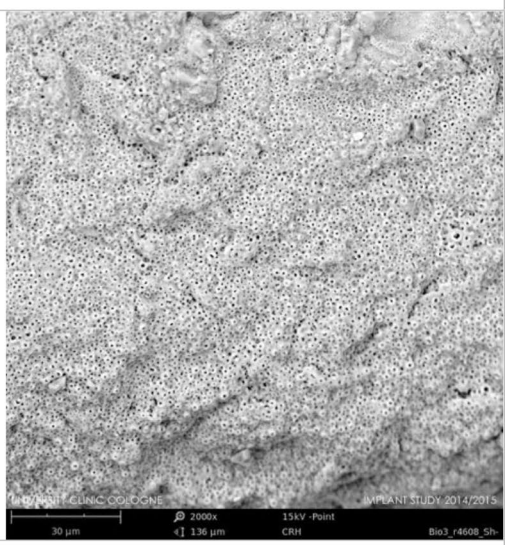

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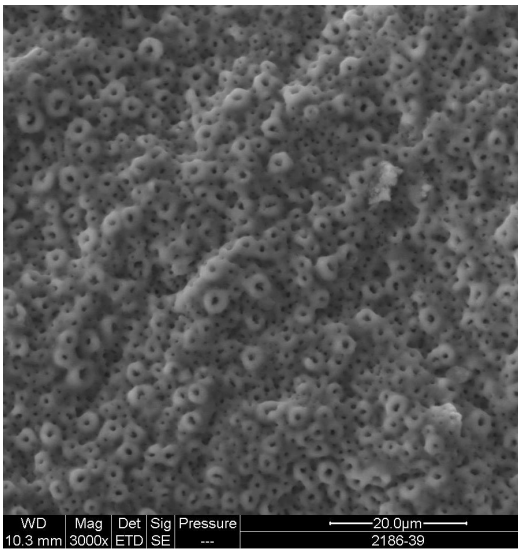
Surface-Topography – Material Contrast Images (Shoulder)



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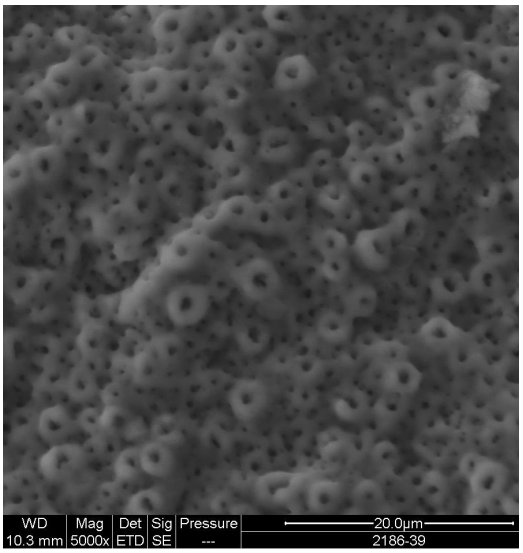

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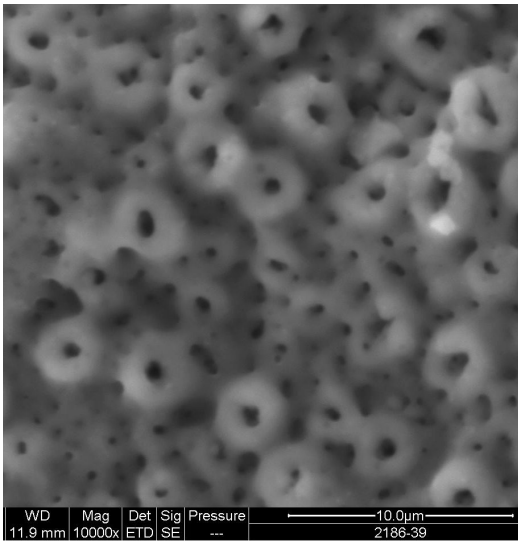

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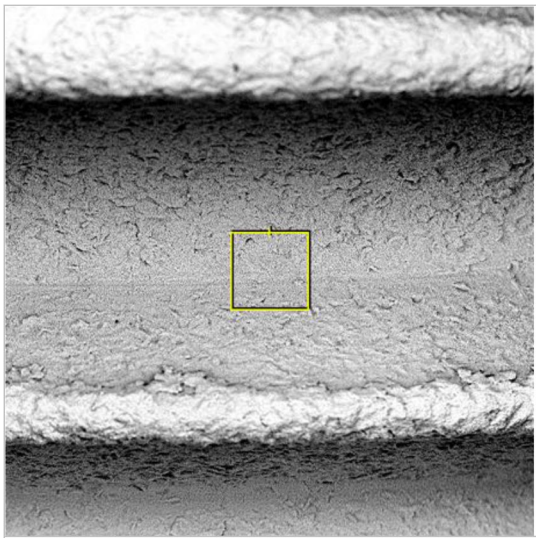
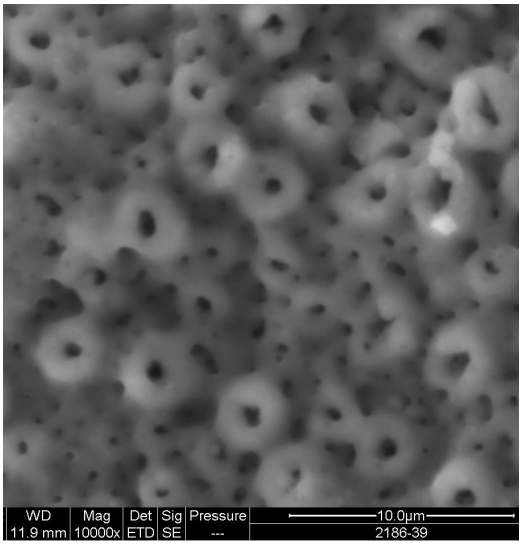
3.5 EDX Area Analysis

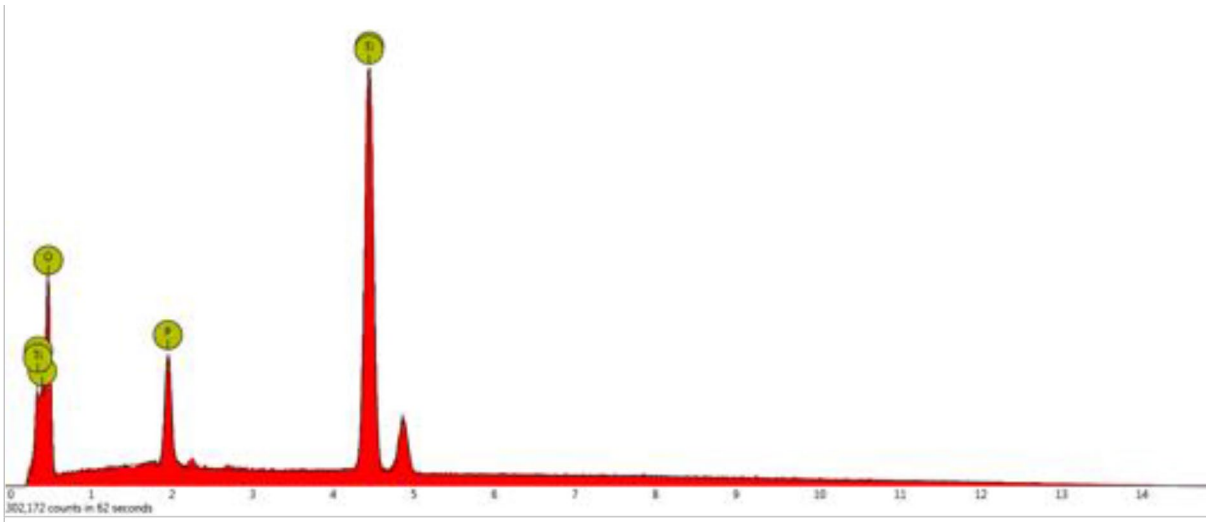


Field of view



Area

Anatomic percentage		Certainty
O	77.2 %	0.99
Ti	19.7 %	1.00
P	3.1 %	0.99



Quantitative elemental analysis

4. Synopsis

Name of Manufacturer:	Alpha Dent Implants GmbH
Analyzed Product(s):	Implant Active LOT 0351068434 Exp. Date: 2020-09
Title of Study:	Implant-Study 2016 Quantitative and qualitative element-analysis of implant-surfaces by SEM and EDX
Investigators:	Dr. Dirk U. Duddeck
Study centre	Interdisciplinary Outpatient Dep. For Oral Surgery and Implantology, Dep. for Craniomaxillofacial and Plastic Surgery, University of Cologne
Study carried out by:	dedeMED – Materials Research & Consulting, Berlin
Studied period:	July – November 2016
Methodology:	Phenom proX Scanning Electron Microscope, equipped with high-sensitivity backscattered electron detector (compositional & topographical modes) EDX Analysis: Detector type: Silicon Drift Detector (SDD) Thermoelectrically cooled (LN2 free) Detector active Area: 25 mm^2 X-ray window: Ultra-thin Silicon Nitride (Si3N4) window allowing detection of elements C to Am Energy resolution Mn Kα ≤ 140 eV Max. Input count rate: 300,000 cps
Summary/Conclusions:	Implant Active LOT 0351068434, provided by Alpha Dent Implants GmbH for this analysis showed no significant traces of inorganic or organic elements on its surface. Stages of manufacturing process, mechanical processing and surface cleaning comply with normative standards and have no deviations.

5. Coordinating investigator(s) Signature(s)

Study title: Implant-Study 2016/06/11 Quantitative and qualitative element-analysis of implant-surfaces by SEM/EDX

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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: Dr. Dirk U. Duddeck

Date: 29.11.2016