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**Zentrum für
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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 Scanning electron microscopy (SEM)

SEM Images and EDX-Analysis

Champions Kugelkopf

LOT 602480

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



Project manager:

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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 more than 40 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-/BSE-method)

Scanning electron microscopy (SEM) enables the topical evaluation of the implant surfaces. Backscattered electron imaging (BSE) allows drawing conclusions about the chemical nature (density) and allocation of the different contaminations in the sample material..

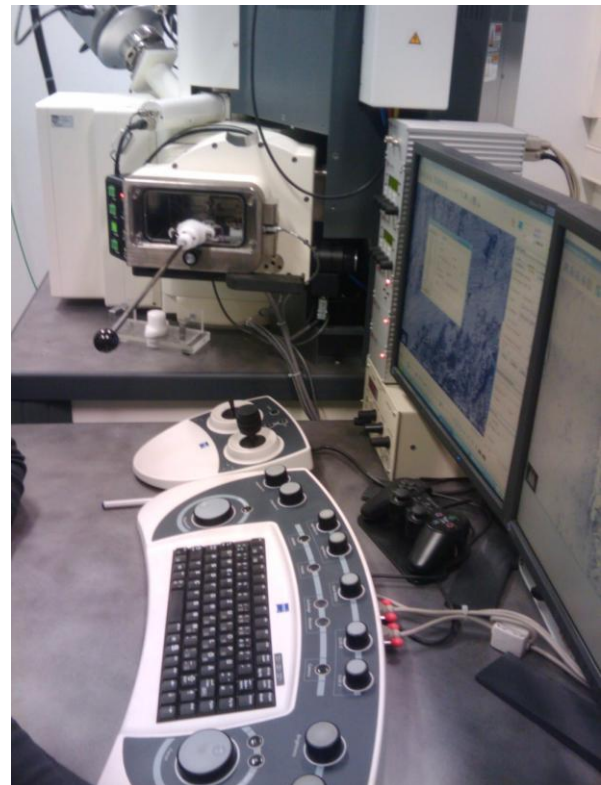
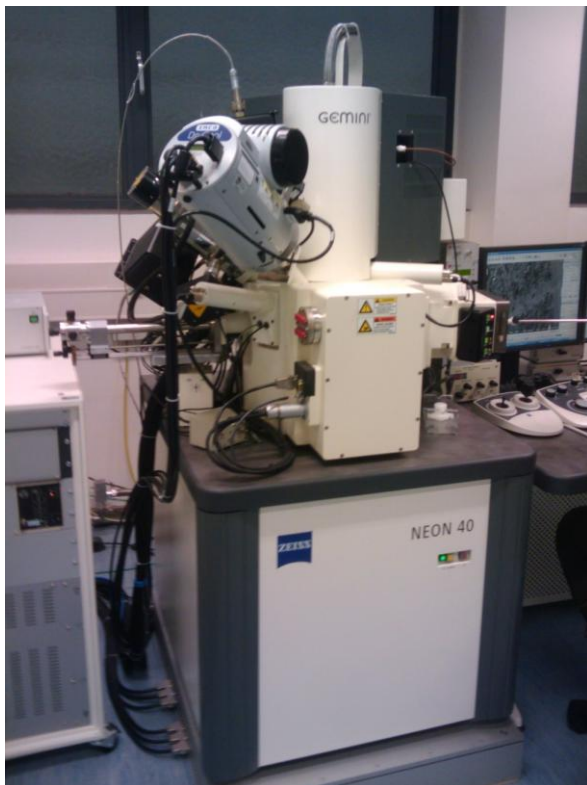
Qualitative and quantitative analysis of implant surfaces (EDX)

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.

1) Duddeck, D., Oberflächenuntersuchung von Implantaten mit dem Rasterelektronenmikroskop, Dissertationsschrift, 2009

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). An implant with circumferential traces of organic material in 2008 (Bicon) was not re-examined, since the manufacturer has announced a new sterile packaging in 2012 designed to prevent the contact of the implant with the plastic container. **The implant provided by Champions-Implants showed no significant traces of inorganic or organic residues**

SYNOPSIS

Name of Company:	Champions-Implants GmbH – Flonheim, Germany
Name of analyzed Product:	Champions Kugelkopf - LOT 602480
Title of Study:	Quantitative and qualitative element-analysis of implant-surfaces by SEM
Investigators:	Dirk U. Duddeck DDS; Scharaje Kaviani
Study centre:	Interdisciplinary Outpatient Dep. for Oral Surgery and Implantology, Dep. for Craniomaxillofacial and Plastic Surgery, University of Cologne
Studied period:	January 1, 2010 - May 30, 2012
Methodology:	Zeiss Surface Scanning Electron Microscope with GEMINI® Column equipped with two detectors for secondary electrons: BSE detector and conventional secondary electron detector. EDX Analysis
Summary / Conclusions:	The implant provided by Champions-Implants 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): Dirk U. Duddeck, Scharaje Kaviani
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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*

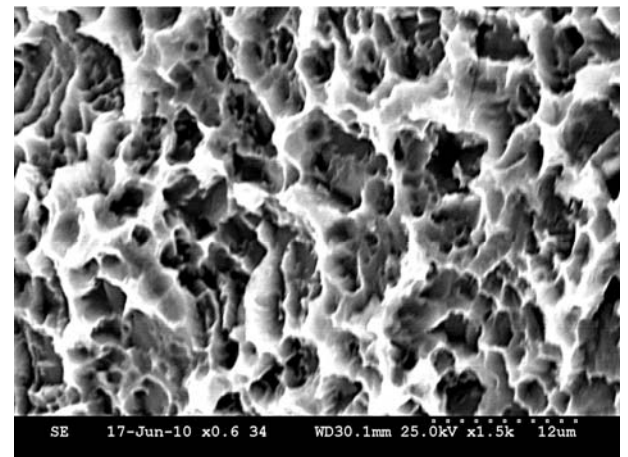
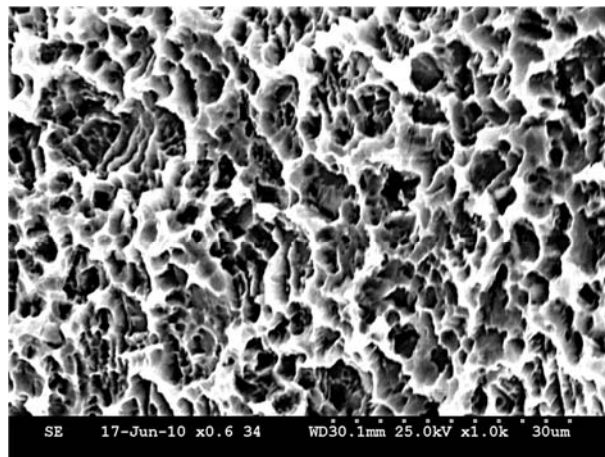
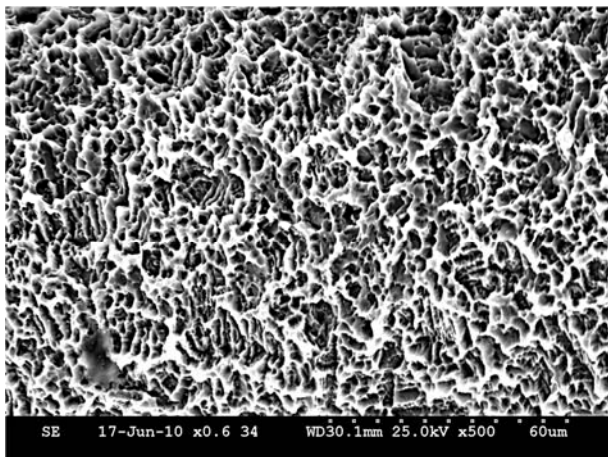
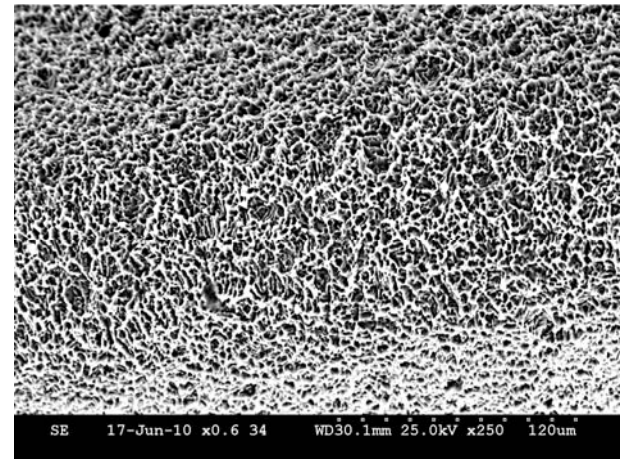
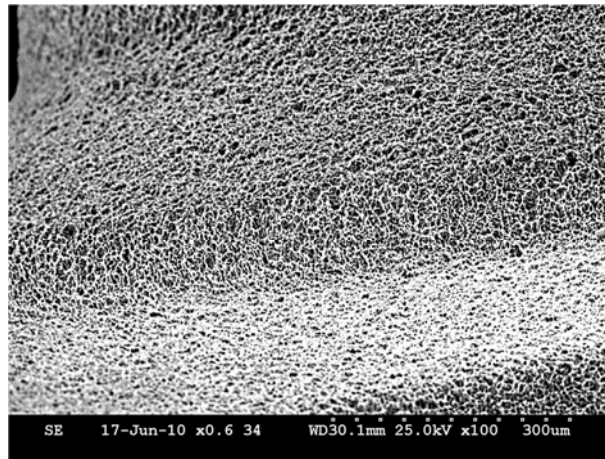
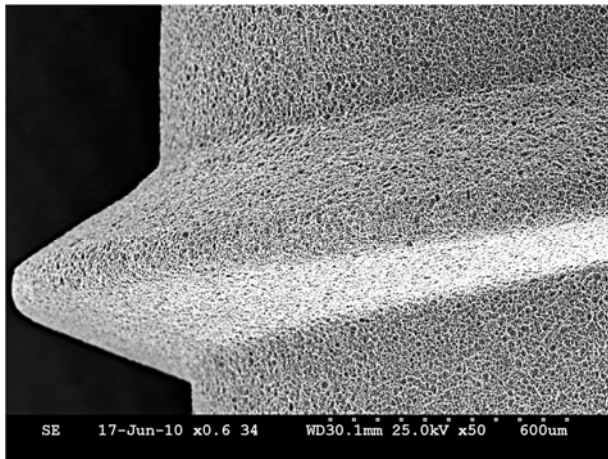
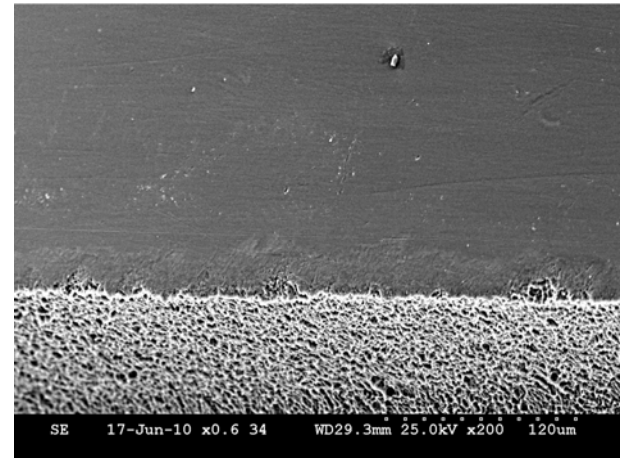
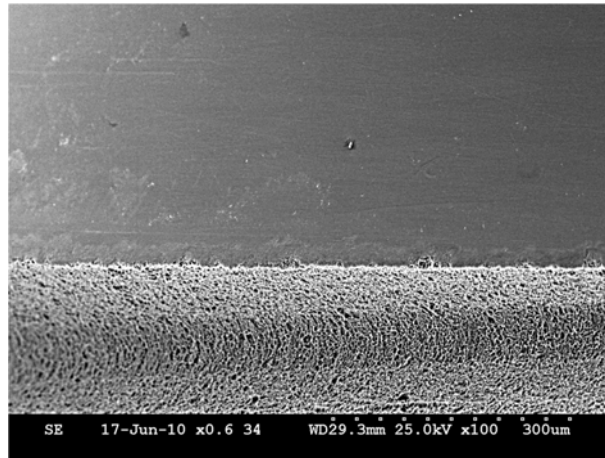
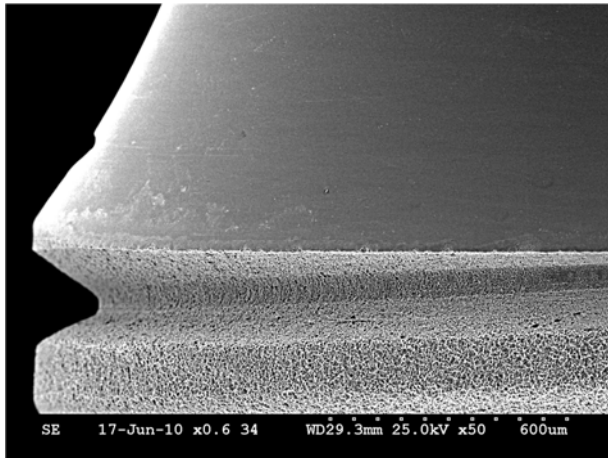
INVESTIGATOR: Dirk U. Duddeck DDS

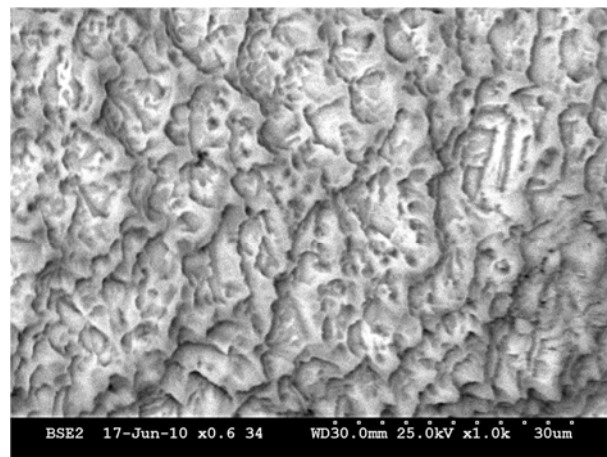
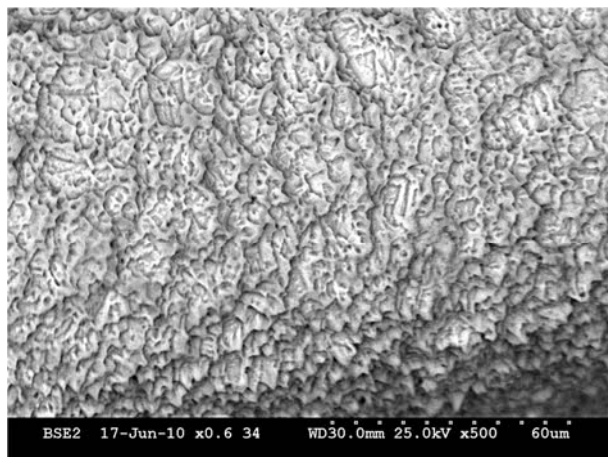
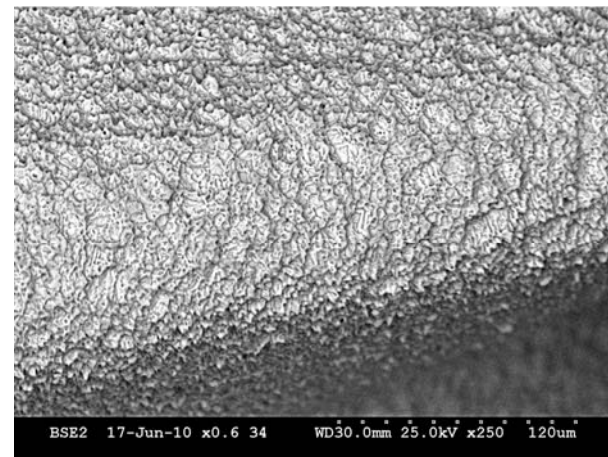
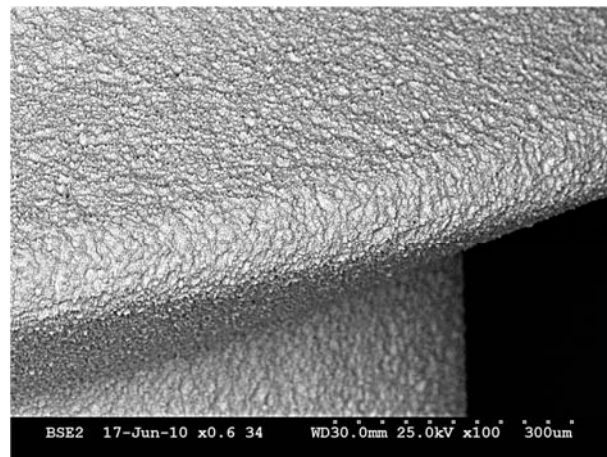
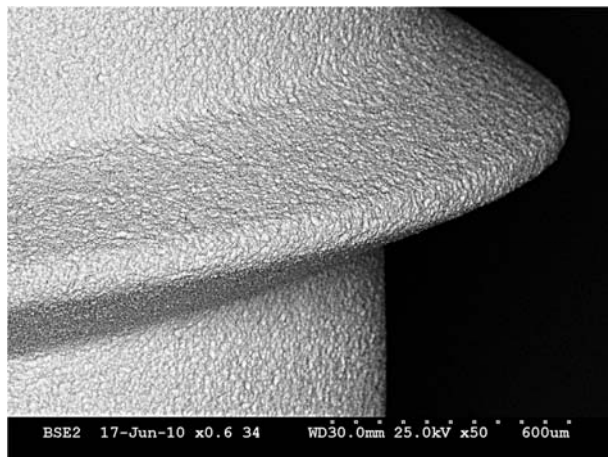


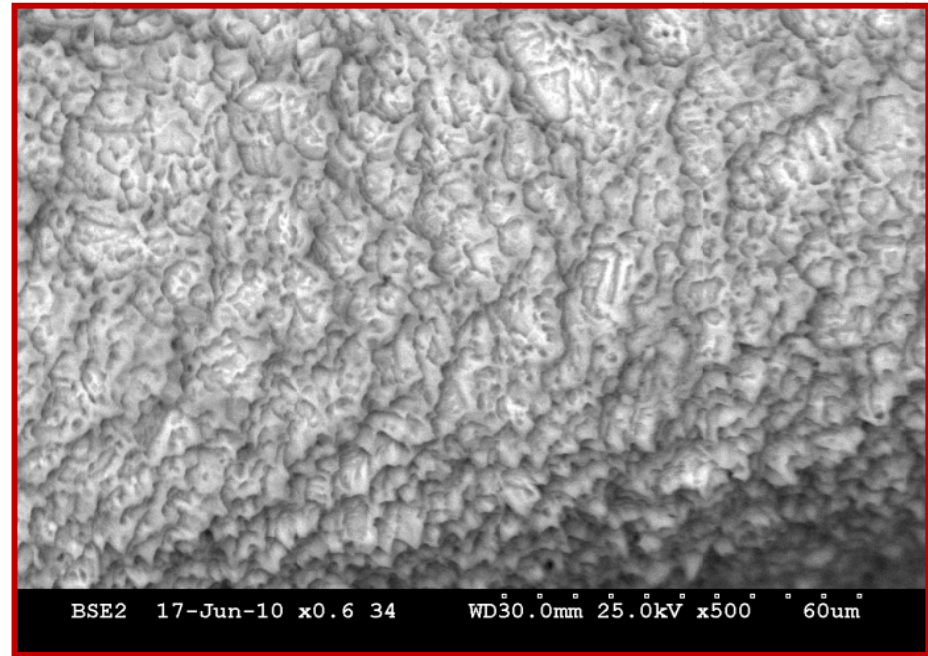
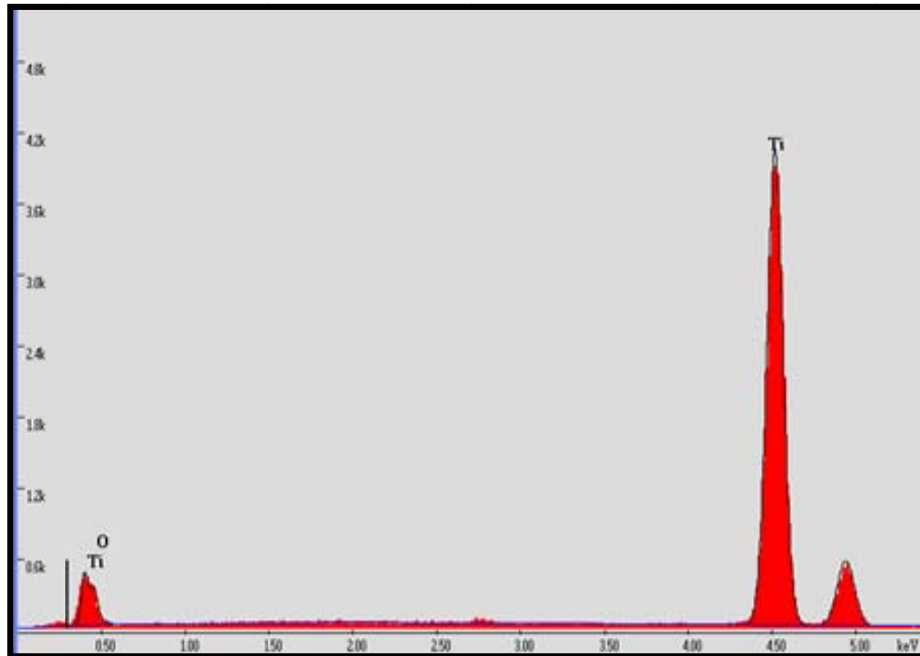
DATE: May 30th 2012

APPENDIX

SEM IMAGES / EDX ANALYSIS







Element	Wt %	At %
O K	2,50	7,13
Ti K	97,50	92,87
Total	100,00	100,00