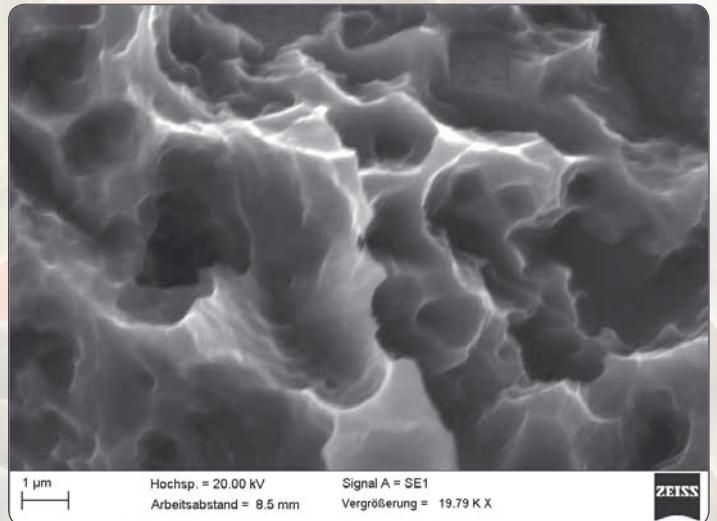
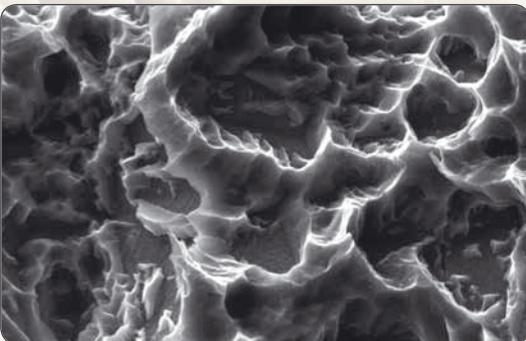
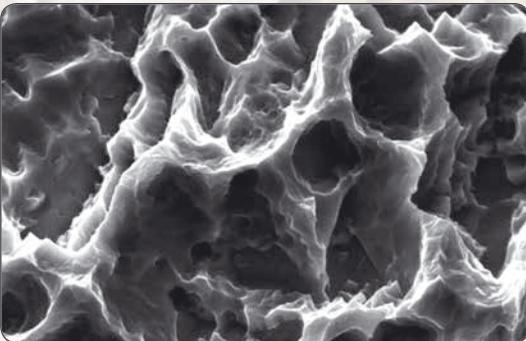


ICX

The FAIR Implant-System

SURFACE OF THE ICX-Premium



SURFACE OF THE ICX-Premium

Analysis of surface topography of the ICX-Premium

The surface characteristics of dental implants play a key role regarding the osseointegration process. The implants need a specific surface roughness to be incorporated fast, permanently and without complications into the jaw tissue. Therefore, different procedures are applied to roughen the dental implant's surface. Significantly greater success rates, enhanced bone-to-implant contact (BIC) and greater biomechanical and functional stability have all been demonstrated by rough surface implants compared to those with smoother surfaces [1-2].

The extent of the bone-to-implant interface appears to increase with increasing surface roughness [3]. The ICX-Premium surface is sandblasted with korundum, which results in clusters, followed by zones upon acid etching (Fig1). Micro-rough surfaces increase the rate of cell spreading and the number of cells attached to the surface, and increases the rate whereby cells produce factors regulating the differentiation of bone-forming cells (osteoblasts) and reduce the activity of bone-destroying cells (osteoclasts) [4-5]. It has been reported that the surface roughness of sandblasted and acid etched surfaces as e.g. the ICX-Premium is favorable for biochemical anchorage of dental implants and show stronger bone response [6-8]. Preclinical and clinical data from literature indicate that these surfaces had excellent osseointegration properties [9,10,11]. Extern (performed e.g. from Nanoanalytics) and Intern (Fig.1) Energy Dispersive X-ray Analysis (EDX) reveal the topography of the surfaces and provide qualitative results of the chemical composition of the different

implants. Periodical X-ray Photoelectron Spectroscopy (XPS, performed RMS Foundation, Bettlach, Switzerland) is used to perform chemical analysis on the surface of the implants.

Scanning electron microscopy (SEM) enables the topical evaluation of the implant surfaces. 2D images of SEM measurements (in x-y scale and height details z- scale) are performed and show clusters and zones (Fig.2).

The qualitative analysis surface topography of the implants is evaluated by scanning electron microscope (SEM, roughness has been estimated using dedicated software to convert conventional SEM images into 3D data (Alicona Imaging)). (Fig.3).

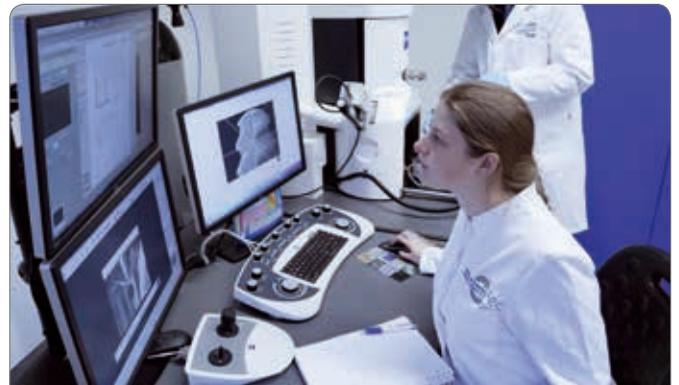


Fig. 1: Employees (L.Goege Dipl. Biologist and J. Ockenfels, Certified Technician for Machine Technology, Dernaue) of the „medentis medical evidence centers“ (m²ec) work in crossfunctional research groups to develop and implement new innovations with „state of the Art“ technology (e.g. Zeiss Raster electron microscope (Zeiss, Jena Germany)). (Image source medentis, Dernaue, Germany, 2014)

Quantitative topography measurements of the ICX-Premium surface are conducted with a confocal microscope μ surf (performed by Nanofocus, Oberhausen, Germany) according to ISO Standard 25178, micro-geometry and layer thickness.

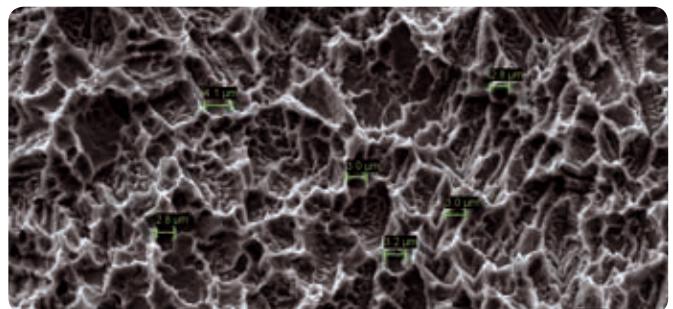
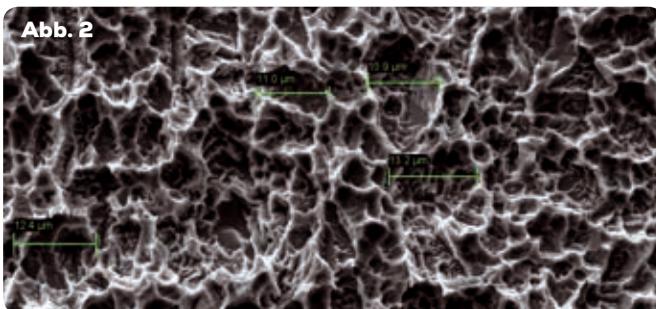


Figure 2: SEM picture (Zeiss, Jena, Deutschland) showing the sandblasted and acid etched surface of the ICX-Premium implant. (Zeiss), Magnification 3000x, Zeiss Mikroskop. The implant surface is sandblasted which results in clusters (left), followed by zones upon acid etching (right) (image taken by Lina Goege Dipl. Biol., medentis medical evidence center, Dernaue, Germany, 2014)

SURFACE OF THE ICX-Premium

Extremely rough surfaces or threads can be measured and evaluated without any problems as well. The determined standardized and reproducible area roughness parameters offer a solid base for the reliable control of the quality-critical process. The averaging amplitude parameters Sa (mean roughness), Sq (arithmetic roughness), and extreme amplitude parameters Sp (peak height), Sv (valley depth), and Sz (maximum height) give information of the height of the surface profile. The mean roughness (Ra) of the ICX-Premium surface ranged between 1 and 3 μm . Studies [4] indicated that sandblasted and acid etched surfaces show a good bone response, anchoring of the fibrin scaffold and osseointegration.

The FAIR Premium **ICX** Implant-System

Fig. 3

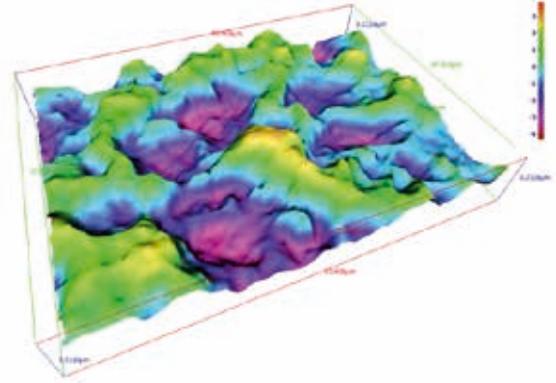
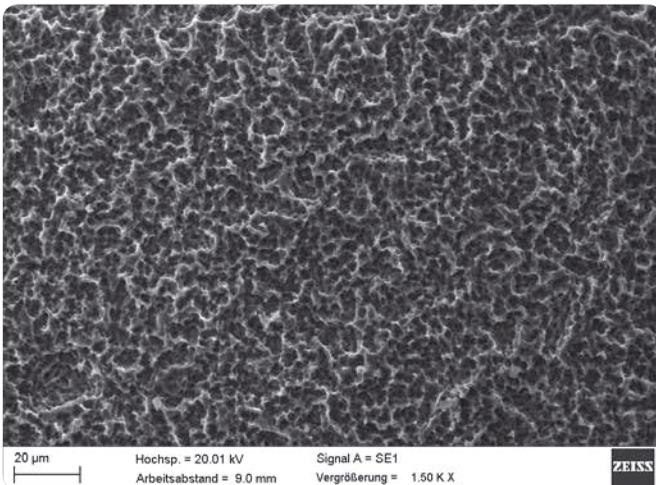
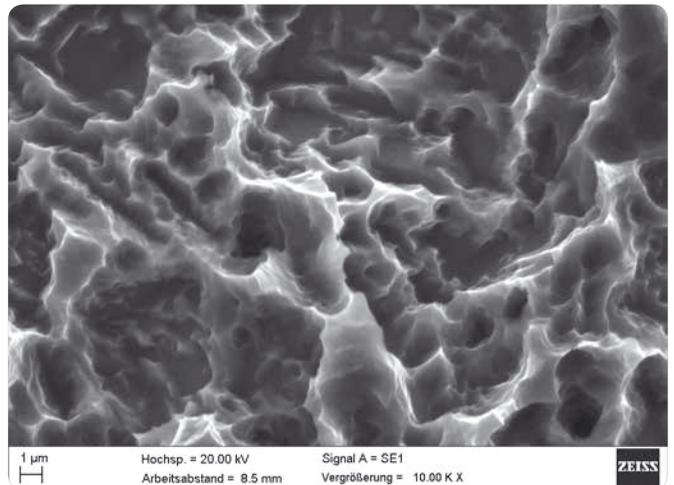


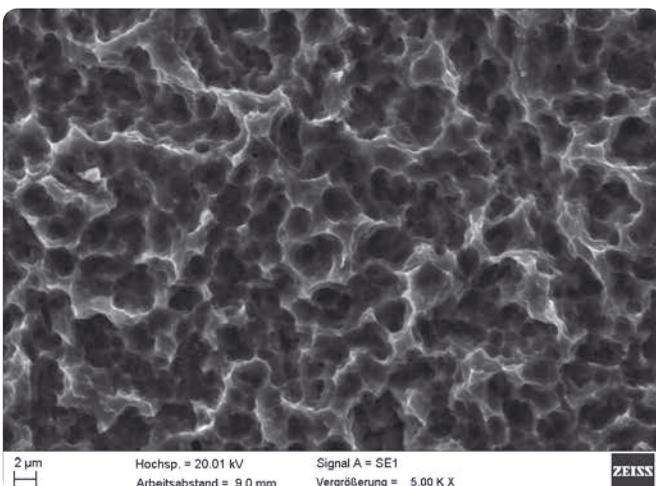
Fig. 3: ICX-Premium surface in 3D evaluated with Alicona Software, which is a software package that turns any SEM with digital imaging into a true surface metrology device. Using stereoscopic images the software automatically retrieves 3D information and presents a highly accurate, robust and dense 3D dataset. The results are obtained irrespective of the SEM magnification providing metrology at macro and micro levels (image taken by J. Ockenfels Certified Technician for Machine Technology, medentis medical evidence center, Dernau, Germany, 2014)



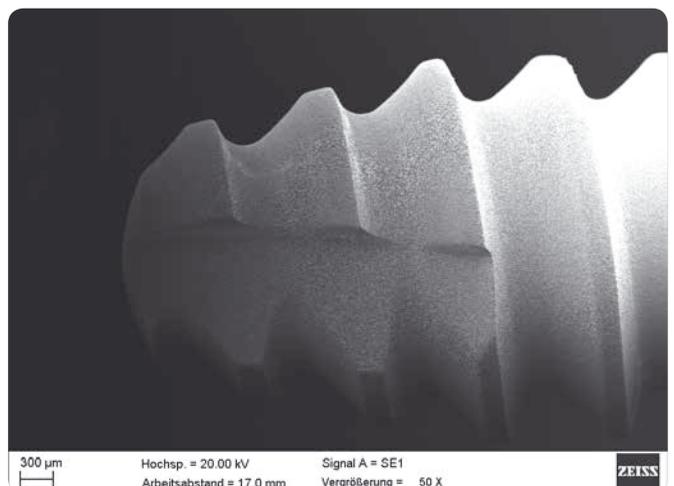
Surface of the ICX-Premium Magnification 1500 X



Surface of the ICX-Premium Magnification 10000 X



Surface of the ICX-Premium Magnification 5000 X



ICX-templant Implant Magnification 50 X

SURFACE OF THE ICX-Premium

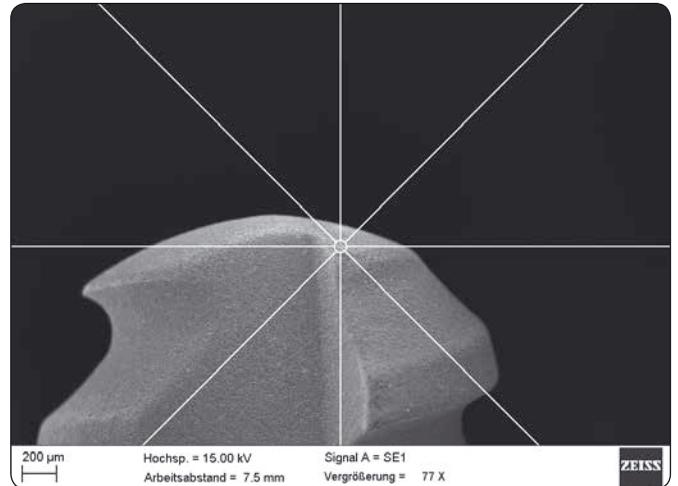
Effects of the surface properties of the ICX-Premium on cell cultures

The surface characteristics of a dental implant are crucial as these are the decisive factors for the successful and permanent adhesion with the jaw bone. In order to grow together quickly and sustainably, the surface of the implant has to have the correct characteristics to allow protein to bind to the implant. Several in vitro studies have demonstrated increased osteoblast proliferation on moderately roughened surfaces [12, 13]. Furthermore, cell differentiation has proven to be influenced by surface roughness [12, 13] and cell alignment by the surface orientation [12, 13]. An Adhesion cell culture study with ICX-Premium surfaces is performed at the University Hospital Mainz (directed by Dr. med dent. Julia Karbach, Mainz)

Conclusion:

The surface structure (morphology) of the ICX-Premium implants, as exposed by SEM microphotograph (Fig.1), is featured by a good surface porosity. The surface roughness is well-documented and reproducible. The main roughness parameter

Ra has according to literature good acceptable values which promote osseointegration [3]. The surface purity of the ICX-Premium implants, as exposed by SEM microphotographs and checked by EDX-SEM instruments, is normal. The surface chemical composition of the implants, as analyzed by XPS instruments, represents acceptable values of the main elements usually found on the dental implants surfaces that underwent blasting and media cleaning [14-16].



Apical end of the ICX-Premium Implant Magnification 77 X

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