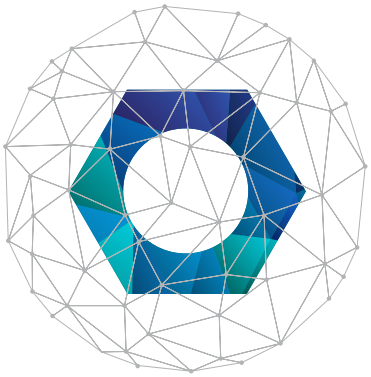
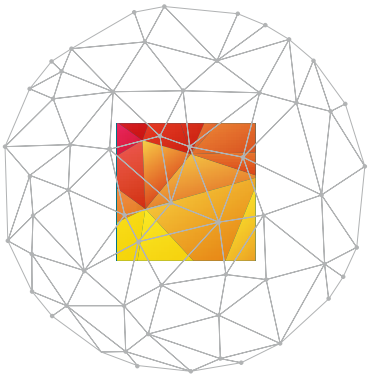
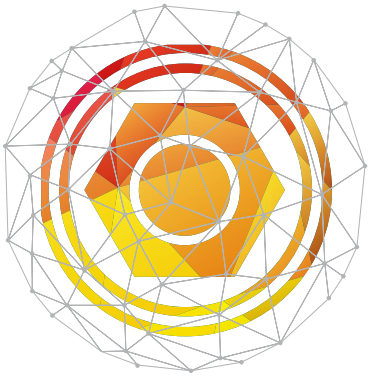




Alpha-Bio Tec Implant Purity

November 2014

Alpha-Bio Tec. Quality Assurance (QA) department performs a routine Quality Assurance (QA) and Quality Control (QC) procedures.

This report was managed by Polina Pavlovsky, Engineering Manager and Osnat Harari, Quality Engineer.

Scientific advisor: Prof. Ofer Moses, Tel-Aviv university

AlphaBio TEC Simplantology

Executive Summary

Background

The following document describes routine Quality Assurance (QA) and Quality Control (QC) procedures performed by the Alpha-Bio Tec. QA department on implants. The examples and details are provided here for the SPI implant. Alpha-Bio Tec. provides this document to academic and professional communities, in order to share information about production and QA as well as demonstrating the Company's high production standards.

Alpha-Bio Tec

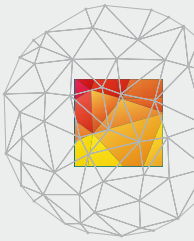
Alpha-Bio Tec. specializes in the development and production of advanced dental solutions, focusing on implants and prosthetics. Alpha-Bio Tec. developed the SPI, the original spiral implant.

Since it was established in 1988, Alpha-Bio Tec. has spearheaded dental implantology innovation, supporting its products through rigorous manufacturing and quality assurance standards. Alpha-Bio Tec. has a research and development team comprised of top-tier dentistry experts.

Alpha-Bio Tec Implant Surface

The Alpha-Bio Tec. Implant Surface is created through a sand-blasting process to form a macro surface of 20-40 microns and a double thermal acid etching process to create micro pitting between 1 to 5 microns. The advantages of this implant surface - confirmed by retrospective clinical data showing an overall clinical success rate of 98.3% and a 99.6% when using the immediate loading procedure - are to increase early bone-to-implant contact (BIC); increase stability; shorten healing period; and produce higher performance predictability.





Quality Assurance and Quality Control

Alpha-Bio Tec. products are compliant with the world's leading quality systems and standards: ISO 13485:2003 including the Canadian Medical Devices Conformity Assessment System and Council Directive 93/42/EEC.

In addition, Alpha-Bio Tec. has gained FDA approval for immediate loading of single tooth for SPI and ARRP implants. Its medical devices are CE-approved and cleared for marketing in the USA.

All this allows clinicians using Alpha-Bio Tec. products to achieve proven, long term success, supported by a Lifetime Warranty for its wide range of implants.

SEM and XPS analyses

Alpha-Bio Tec. implants are routinely examined by third party, certified laboratories as part of Alpha-Bio Tec. Standard Operating Procedures (SOPs). The following report, which is an example of such examination, describes Alpha-Bio Tec. implants from batch 14058302 that were analyzed in the Tel Aviv University, WOLFSON APPLIED MATERIALS RESEARCH CENTRE, by two different experts: one for the scanning electron microscopy (SEM) and the other for x-ray photoelectron spectroscopy (XPS) analysis. For explanation of technical terms please refer to the dictionary in Annex 1.

Conclusions

This report demonstrates the excellent degree Alpha-Bio Tec. implants surface cleanliness and microstructure of Alpha-Bio Tec. implants subject as shown by SEM and XPS examinations.

Alpha-Bio Tec. implants and thus their surface were proven to provide predictable clinical outcomes as shown in retrospective and prospective clinical studies as further detailed below.

Materials and Methods

§ SEM

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 different contaminations in the sample material. Secondary electron imaging (SE) facilitates drawing conclusions about the surface topography.

Implant surface was observed by §SEM with §§BSE and §§§SE field. SEM images were taken from various parts of the implant, area 1 from the coronal part, area 2 from the apical part of the implant, Figure 1 and 2 correspondingly.

§§§§ XPS

X-ray photoelectron spectroscopy (XPS) (see Appendix A) measurements were performed in UHV (2.5×10^{-10} Torr base pressure) using 5600 Multi-Technique System (PHI, USA). The samples were irradiated with an Al Kα monochromated source (1486.6 eV) and the outcome electrons were analyzed by a spherical capacitor analyzer using the slit aperture of 0.8 mm. All the measurements were done at a take-off angle (the angle between the sample surface and the analyzer) of 45°. The samples were slightly charged during measurements and this charging was compensated with the charge neutralizer and mathematically (C1s at 285 eV was taken as an energy reference for all the peaks, mathematical shifts are given on the presented spectra*).

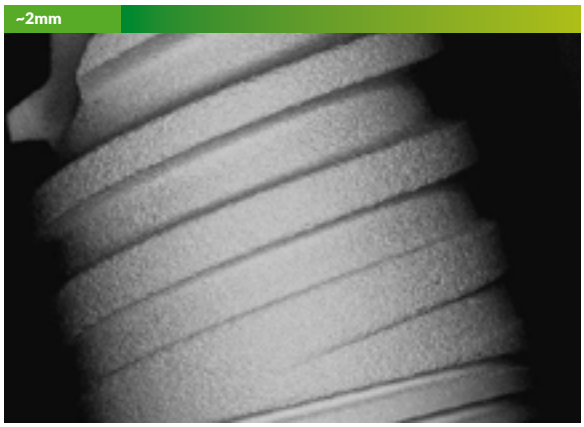
Goal

Demonstration of compositional and chemical bonding analysis of Alpha-Bio Tec. dental implant in predefined different points.

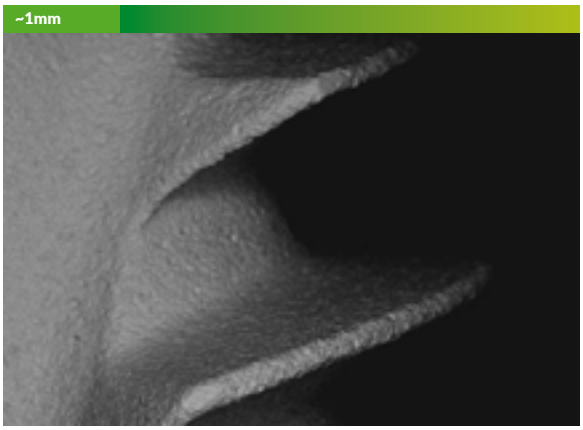
Results

a. § SEM Examinations

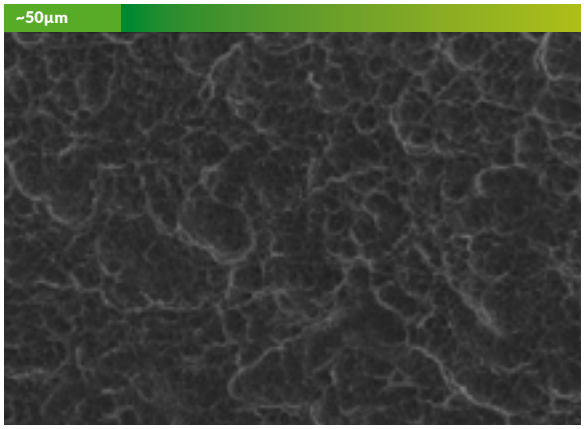
Implant surface was observed by §SEM with §§BSE field. SEM images were taken from various parts of the implant, area 1 from the coronal part, area 2 from the apical part of the implant, Figures 1 and 2 respectively.



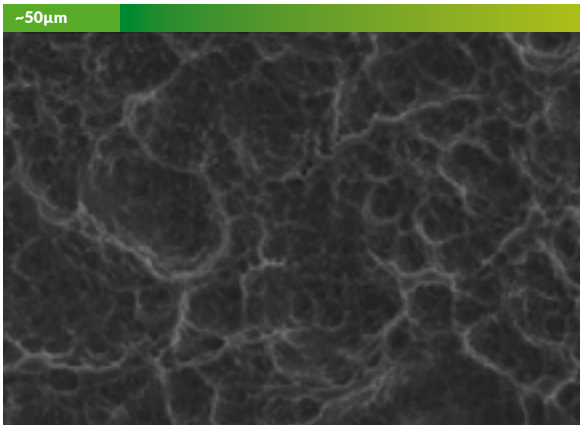
1 Coronal part overview as observed by SEM



2 Apical part overview as observed by SEM



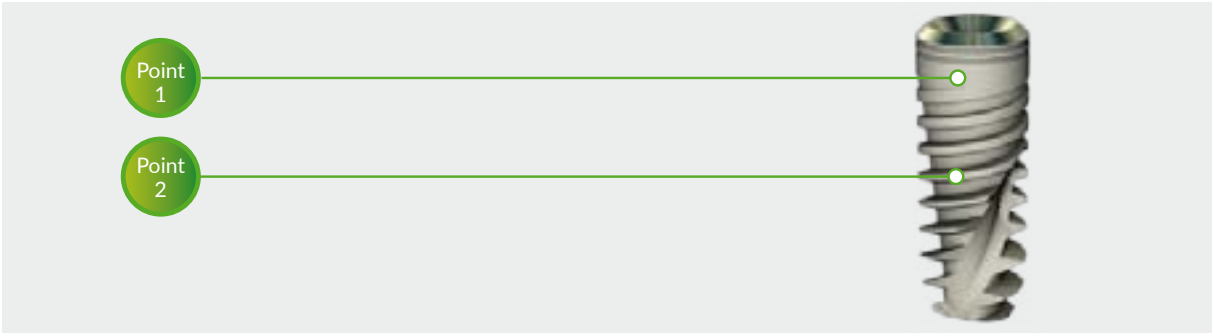
3 Surface morphology of the coronal part



4 Surface morphology of the apical part

b. §§§§ XPS Examination

The sample was analyzed in two different points as shown on the presented image in Figure 5; point 1 from flat area in the coronal part and point 2 from the thread area (mid of threaded part).

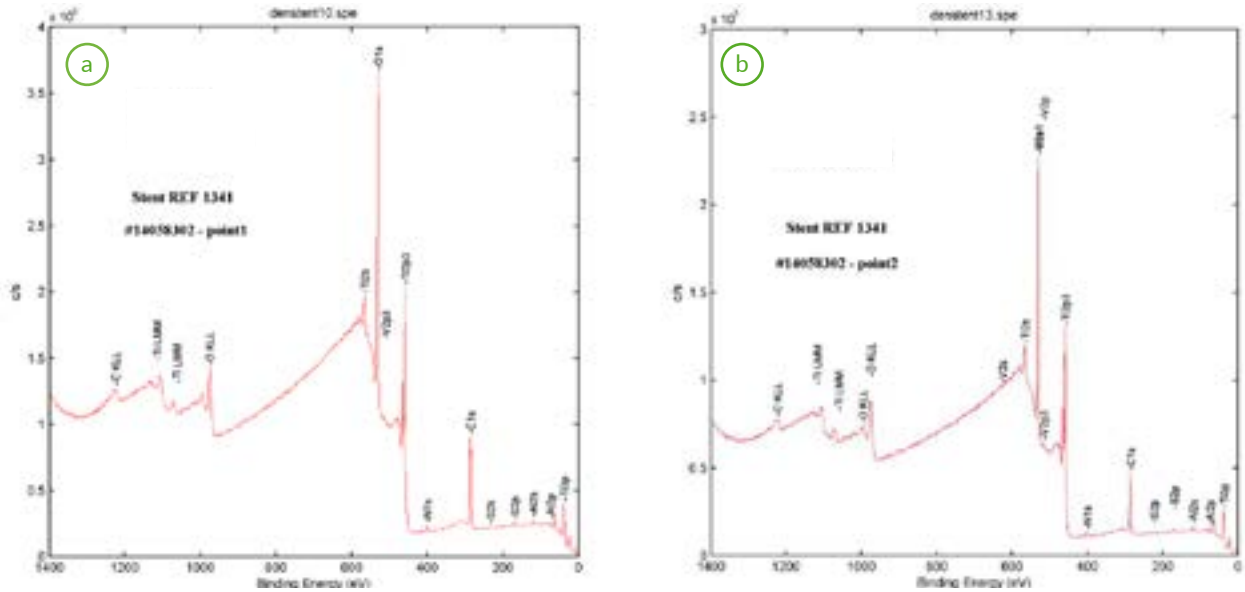


5 Image of analyzed implant

The XPS spectra obtained from the analyzed areas are shown in Figure 6 and the quantitative atomic concentration results are summarized in Table 1.

Table 1- XPS Atomic Concentration

At%	O	Ti	C	Al	V	S	N	Cl
Point 1	47.13	16.87	30.98	2.60	0.40	0.59	1.38	0.04
Point 2	49.80	17.99	27.17	2.82	0.42	0.60	1.19	0.03



6 (a), (b) XPS spectra in the flat (point 1) and thread area (point 2) respectively

Summary and Conclusions

This report demonstrates the excellent surface cleanliness and structure of Alpha-Bio Tec. implants through SEM and XPS examinations.

The atomiccomposition that is demonstrated in this report, proves the excellent purity of the ABT implant. This Atomic composition combined with implant surface morphology is reported in many independent, objective scientific reports as facilitating successful osseointegration[1-6].

Despite the lack of broad scientific consensus regarding what is the optimal composition of outer implant surface to ensure osseointegration, Alpha-Bio Tec. implants surface have proven they provide predictable clinical outcomes in retrospective and prospective clinical studies. The results also support the low failure rate of ABT implants that are returned from users (the company provides life time warranty and "no questions asked" return policy that assure good visibility of actual implants failure rates).

As part of Alpha-Bio Tec's standard operating procedures (SOPs), its implants are subject to the strict analytical evaluations concerning the implants surface cleanliness and structure. These evaluations, which are performed internally as well as by third party academic institutions, enable Alpha-Bio Tec. to verify the high quality of its production process.

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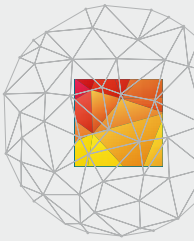


Appendix 1 - Dictionary

§ SEM - scanning electron microscope

A scanning electron microscope (SEM) is a type of electron microscope that produces images of a sample by scanning it with a focused beam of electrons. The electrons interact with atoms in the sample, producing various detectable signals that contain information about the sample's surface topography and composition.

§§BSE

Backscattered electrons (BSE) consist of high-energy electrons originating in the electron beam that are reflected, or back-scattered, out of an examined specimen in SEM device.

§§§SE

Secondary electrons (SE) are the emitted lower-energy electrons that result from inelastic scattering. The energy of secondary electrons is typically 50 eV or less.

§§§§ XPS- X-ray Photoelectron Spectroscopy

X-ray photoelectron spectroscopy (XPS) is a surface-sensitive quantitative spectroscopic technique **that measures the elemental composition** at the parts per thousand range, empirical formula, chemical state and electronic state of the elements that exist within a material. XPS spectra are obtained by irradiating a material with a beam of x-rays while simultaneously measuring the kinetic energy and number of electrons that escape from the top 0-10 nm of the material being analyzed. XPS requires high vacuum (P ~ 10−8 millibar) or ultra-high vacuum (UHV; P < 10−9 millibar) conditions, although a current area of development is ambient-pressure XPS, in which samples are analyzed at pressures of a few tens of millibar

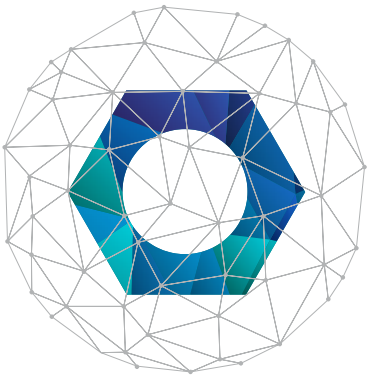
Appendix 2: Performed Measurements

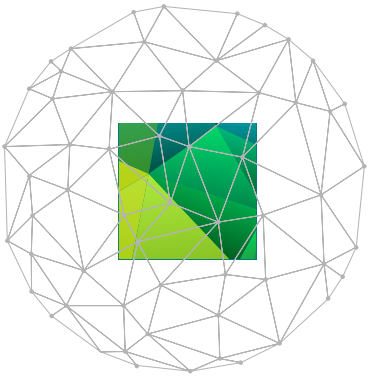
* Survey: spectrum in a wide energy range (0 - 1400 eV). It gives an estimate of the elements present on the sample surface and is taken at a low resolution.

** Utility Multiplex: spectra taken for different peaks in a low energy range window at an Intermediate (Utility) Resolution. It is taken for all the elements present for the atomic concentration (AC%) calculation. An AC table is given as an output of these measurements. AC calculation accuracy:

± 2%	for AC around	50%
± 5%	-	20%
± 10%	-	5%
± 20%	-	1%

*** High Resolution Multiplex: spectra taken for different peaks in a low energy range window at a High Resolution (PE = 11.75 eV, **0.05 eV/step**). These measurements allow precise energy position and peak shape determination, necessary for bond bonding analysis.





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