CLEAN IMPLANT FOUNDATION

TRUSTED QUALITY MARK 2017-2018
REPORT OF ANALYSIS

Name of Manufacturer:	MIS Implants Technologies
Analyzed Product(s):	V3 D4.3 L13 LOT W17005210 (ex factory)
	V3 D4.3 L13 LOT W17005210 (ex factory)
	V3 D4.3 L13 LOT W17005210 (ex factory)
	V3 D3.9 L10 LOT W16012292
	V3 D3.9 L10 LOT W17004237
Period of Analysis:	August - November 2017
Type of Analysis:	Full-Size High-Resolution SEM Imaging (FSHR)
	Area + Spot-Imaging by Backscattered Electrons (BSE)
	Quantitative and Qualitative Elemental-Analysis (EDS)

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mmri.berlin
medical materials research institute

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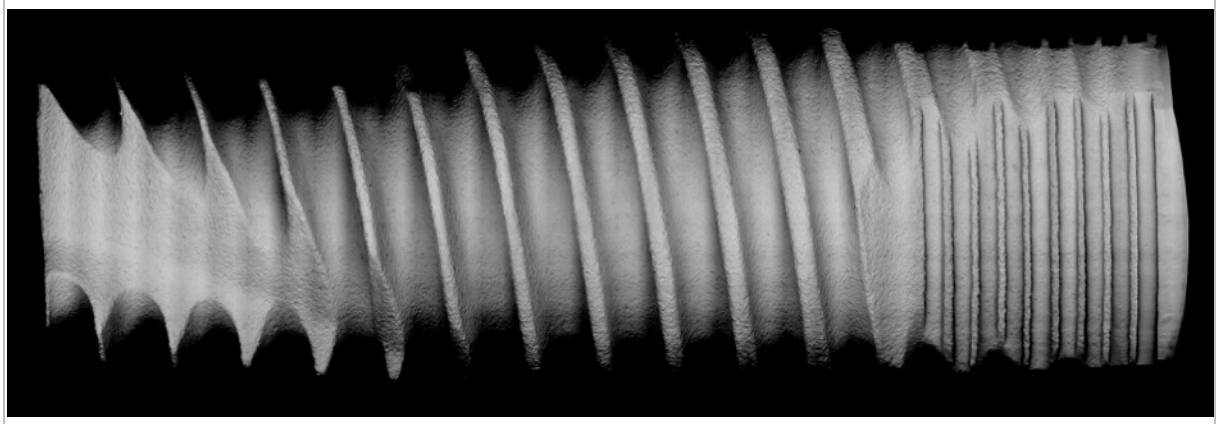
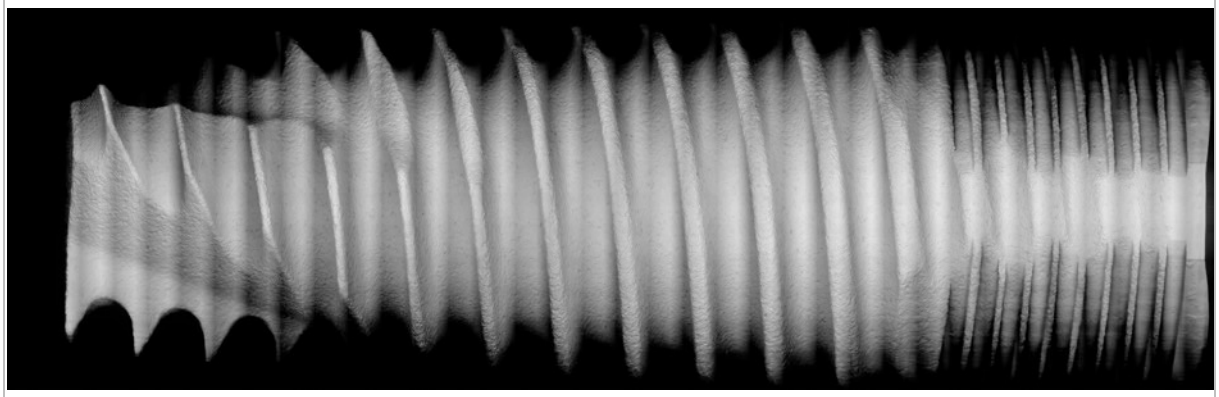
1 ABSTRACT / SUMMARY

1.1 FSHR SEM Images of Samples ex factory

Images are not to scale



Sample #1: V3 D4.3 L13 LOT W17005210; valid 2022.04



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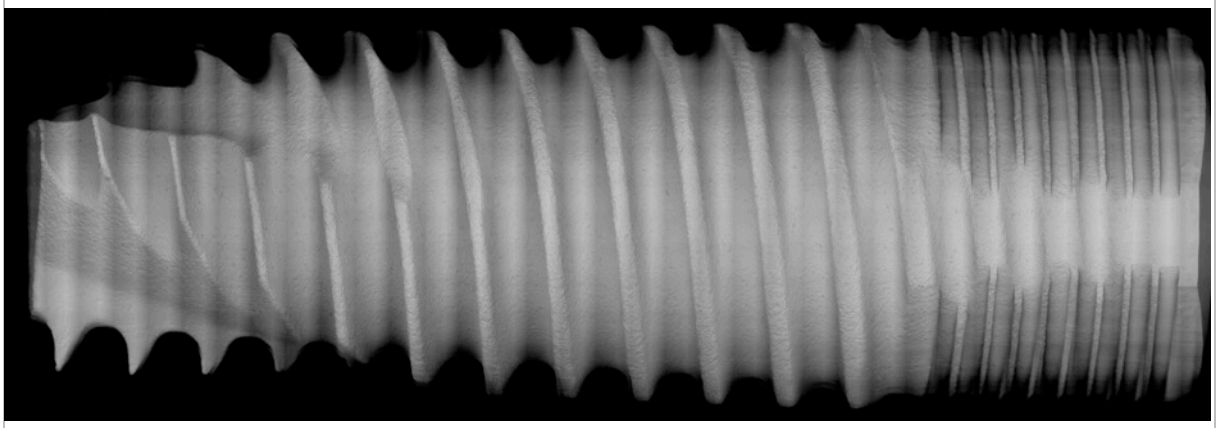
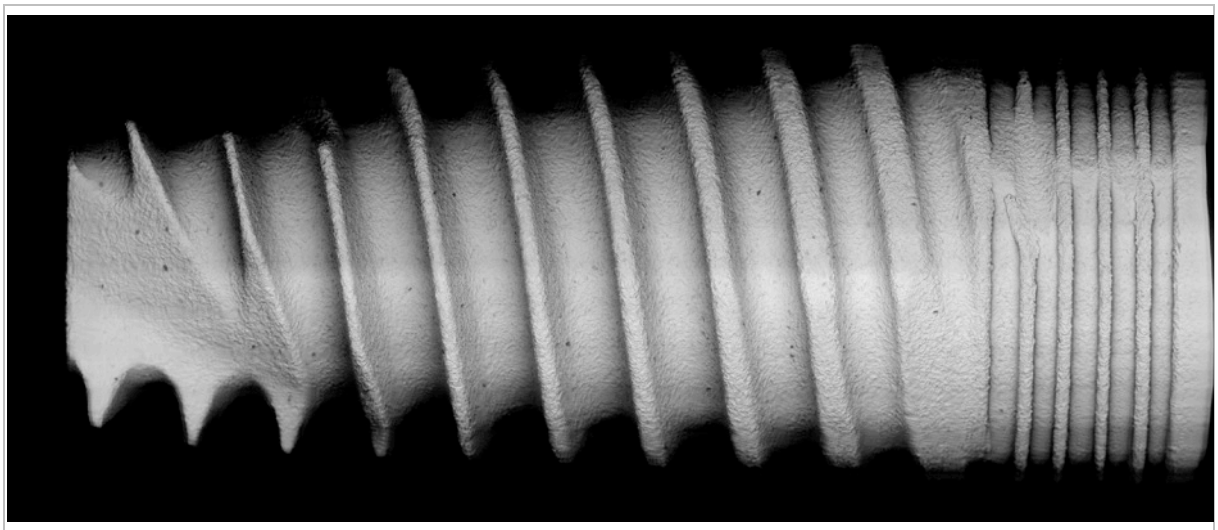


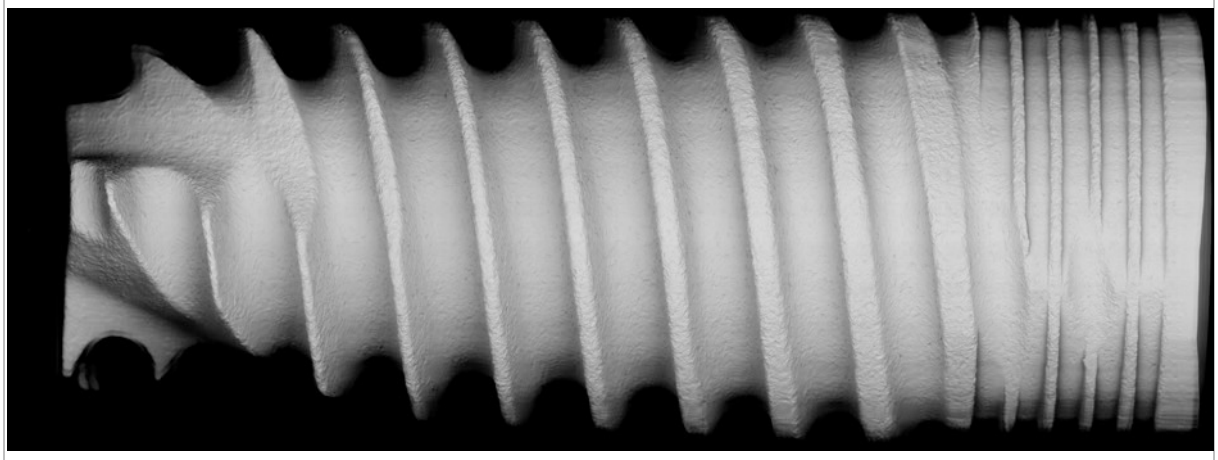
Sample #3: V3 D4.3 L13 LOT W17005210; valid 2022.04

1.2 FSHR SEM Images of Samples Provided from Practices

Images are not to scale



Sample #4: V3 D3.9 L10 LOT W16012292; valid 2021.10



Sample #5: V3 D3.9 L10 LOT W17004237; valid 2022.03

1.3 Summary

Organic particles were not found. Only one implant (sample #4) showed aluminum-oxide particles (20-30µm, random distribution) as remnants of the blasting process.

Requested clinical documentation of implants from the device family was provided. Two peer-reviewed publications with 14 months follow-up of 112 implants (JOMI, 2014) and 24 months follow-up of 33 implants (JOURNAL OF OSSEO-INTEGRATION, 2016) showed survival rates of 100 percent (see summary of articles in the appendix).

2 Protocol of Analysis

2.1 Sample Acquisition

For the intended quality assessment five samples from each implant device / device family of every participating company will be selected through a mixture of mystery shopping (two samples) and direct factory order (three samples) to assure that the samples are selected randomly.

2.2 ISO Class 5 Cleanroom Environment - DIN ISO 14644-1

In order to avoid artifacts on the unpacked implant samples during the transfer into the SEM all implants have to be unpacked and analyzed in the scanning electron microscope under cleanroom conditions according Class 100 US Fed. 209 and ISO class 5 (DIN ISO 14644-1).

Without touching the surface, each implant will be taken out of the package with sterile forceps and will be fixed on the sample holders. During this procedure the implant surface that is to be analyzed will not get in contact to any other material. After the vacuum is generated in the electron microscope imaging and EDS-analyses will be completed.

2.3 SEM Imaging / Analysis Accreditation - DIN EN ISO/IEC 17025

All collected samples are subjected to the same quality analysis protocol performed by independent laboratories that are in the process for - or completed - a Quality Management System according to DIN EN ISO/IEC 17025 (general requirements for the competence of testing and calibration laboratories)*. These Laboratories have to implement a quality system aimed at improving their ability to consistently produce valid results. This includes the quality standard according to DIN EN ISO 9001:2015 as well as implementation of international standards for microbeam analysis – scanning electron microscopy such as ISO 16700:2016 (Guidelines for calibrating image magnification), ISO 14595:2014 (Guidelines for the specification of certified reference materials CRMs) and DIN ISO 22309:2015-11 (Quantitative analysis using energy-dispersive spectrometry (EDS) for elements with an atomic number of 11 (Na) or above). The laboratories undergo regular audits and multiannual re-assessments by external, independent accreditation bodies (e.g. DAkkS).

*) DAkkS accreditation procedure number for this analysis is 112668.

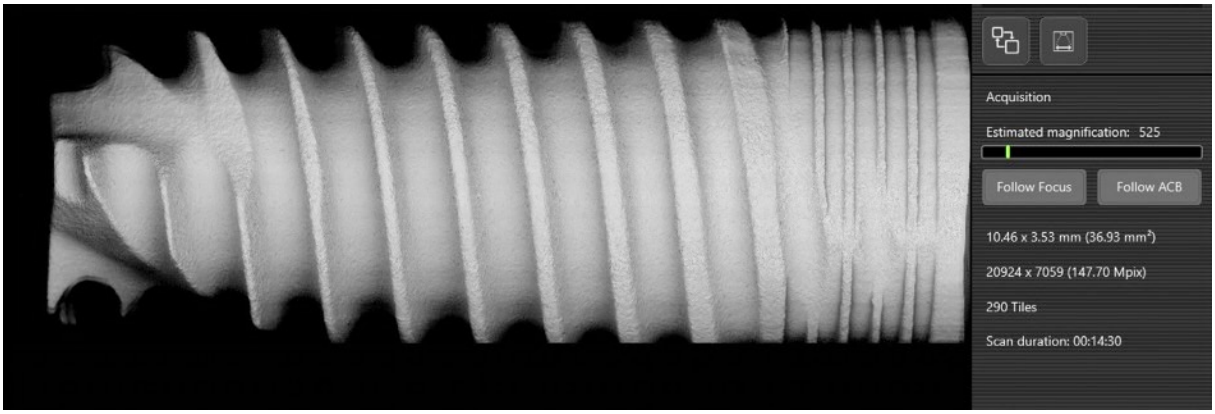
Workstation with Phenom proX Scanning Electron Microscope

Fixed implant (example) on the sample holder

The scientific workstation is a Phenom proX Scanning Electron Microscope, equipped with a high-sensitivity backscattered electron detector. Energy Dispersive X-ray Spectroscopy (EDS) analysis is performed with a thermoelectrically cooled Silicon Drift Detector (SDD). Backscattered electron imaging (BSE) allows drawing conclusions about the chemical nature (density) and allocation of the different contaminations and/or remnants on the sample material. Systematic scanning of the surface reaches approx. one third of the implants surface in a viewing angle of 120 degrees.

2.4 FSHR SEM Image

In order to achieve a complete overview of the sample and comprehensive surface quality information in high resolution, implants are scanned at a magnification of 500x in “Automated Image-Mapping” mode. This technique produces more than 360 single high-resolution SEM images that are digitally composed to one large image with an extreme high resolution, the FSHR image (Full-Size High-Resolution). The composed image allows to count the particles precisely in the visible field and to identify areas of interest for the subsequent spot-analyses.

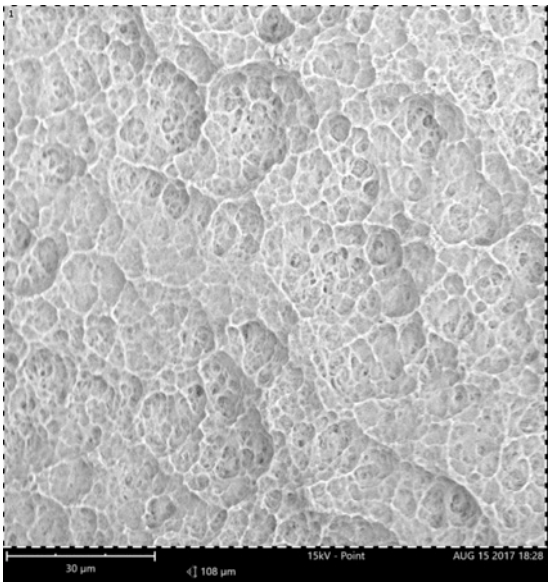


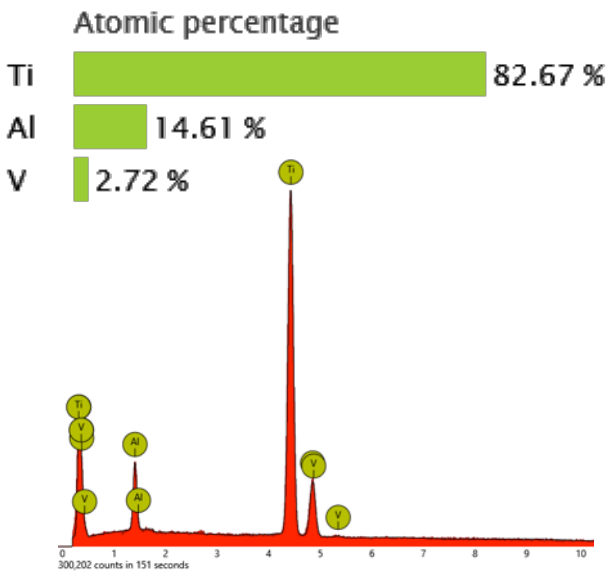
FSHR image (example illustration)

2.5 Qualitative and quantitative analysis of implant surfaces (EDS)

Energy Dispersive X-ray Spectroscopy (EDS) analyzes X-rays generated by the electrons of the electron beam (CeB_6 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.

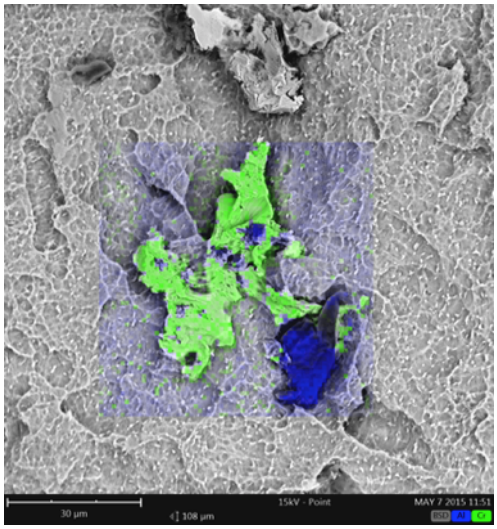
An area-analysis and one or more spot analyses are performed for each tested implant (analysis of spots and areas by EDS). An area-analysis covers the entire implant area in the focus of the microscope. For a spot analysis, the electron beam is focused on a specific area to get information about selective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





Area EDS analysis of a titanium grade 5 implant

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.



Example of EDS mapping (2,500x):
green = chrome; blue = aluminum

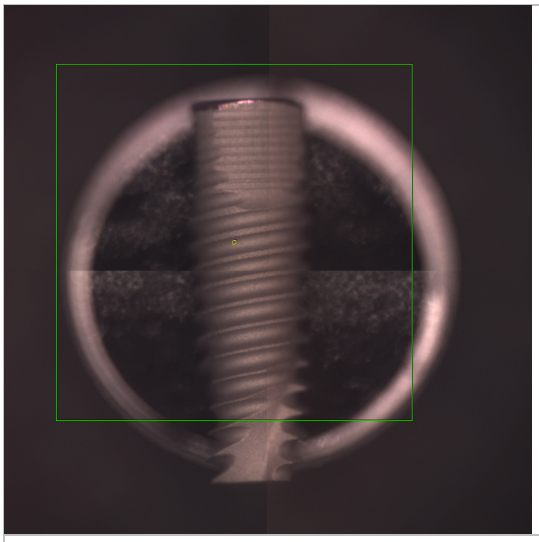
3 Sample #1: V3 D4.3 L13 LOT W17005210

3.1 Full-Size High-Resolution SEM Image

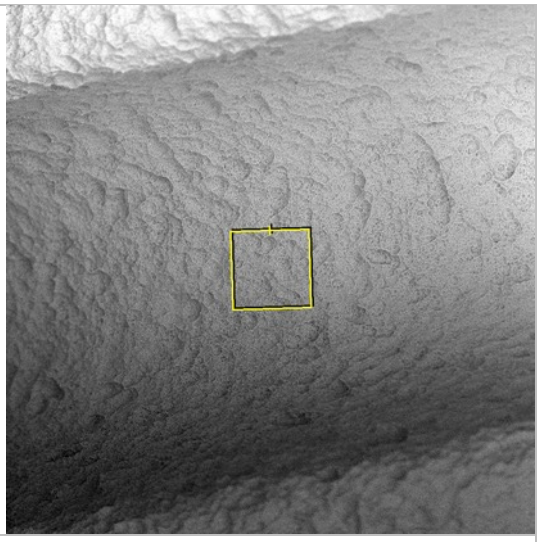
FSHR-SEM image (digitally composed, approx. 500x)

3.2 SEM Imaging Sample #1

3.2.1 SEM Images Implant Body

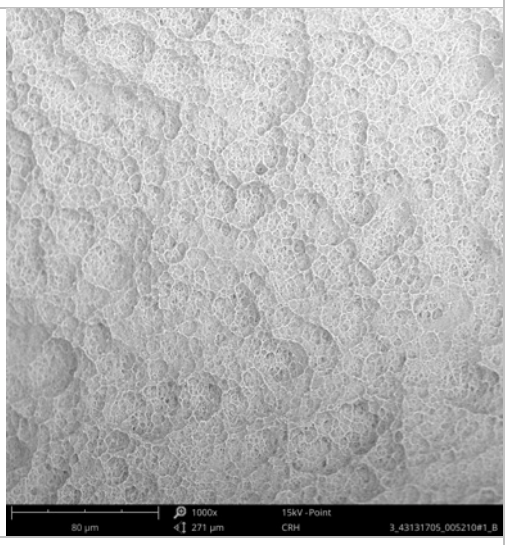


Phenom camera



Field of view

500x



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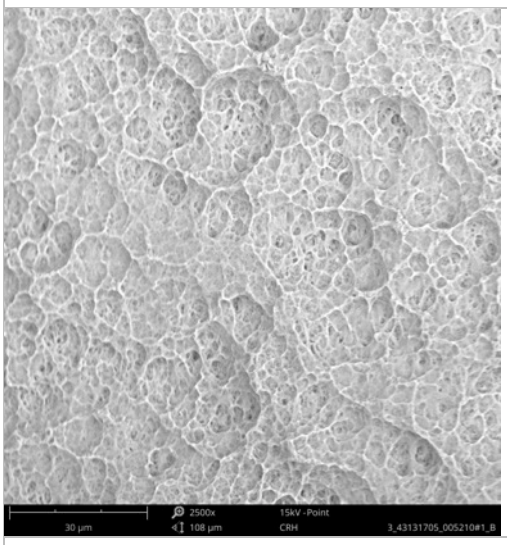

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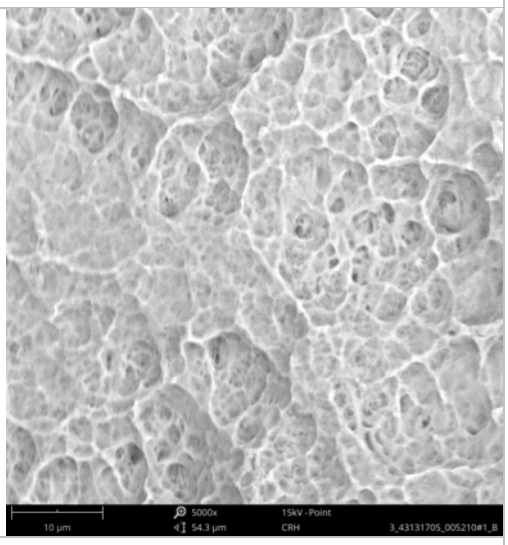

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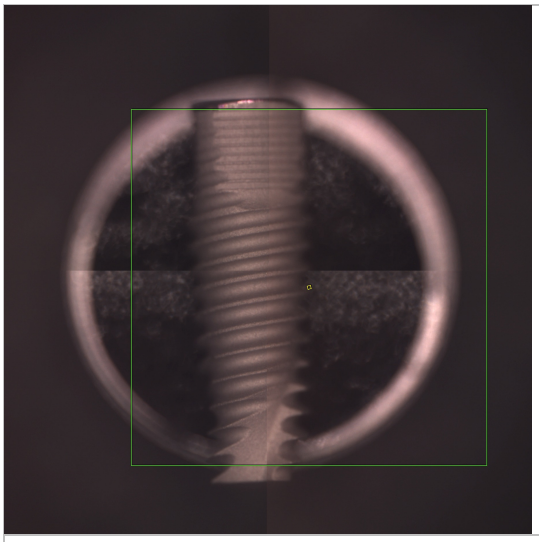
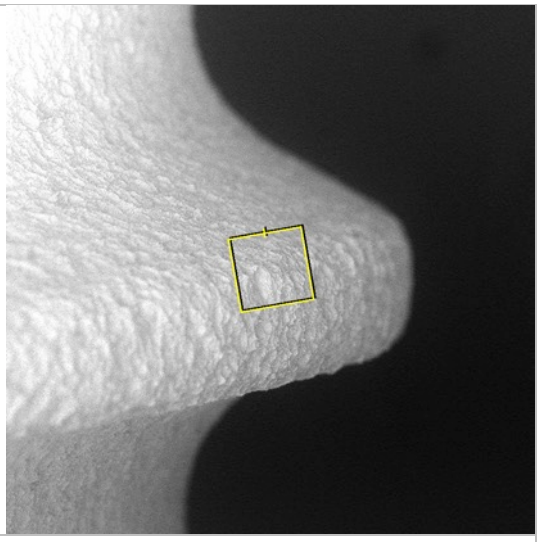
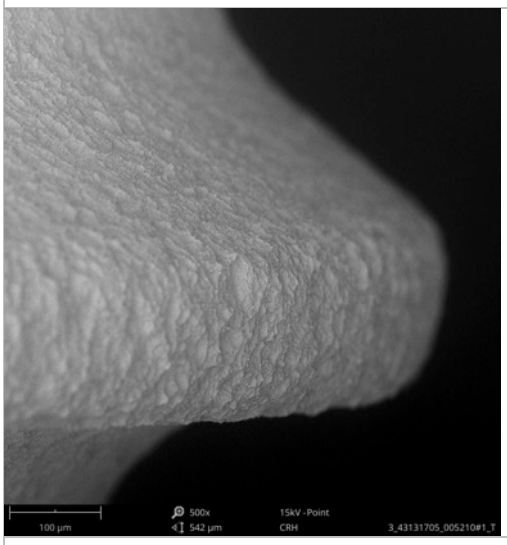
3.2.2 SEM Images Implant Thread



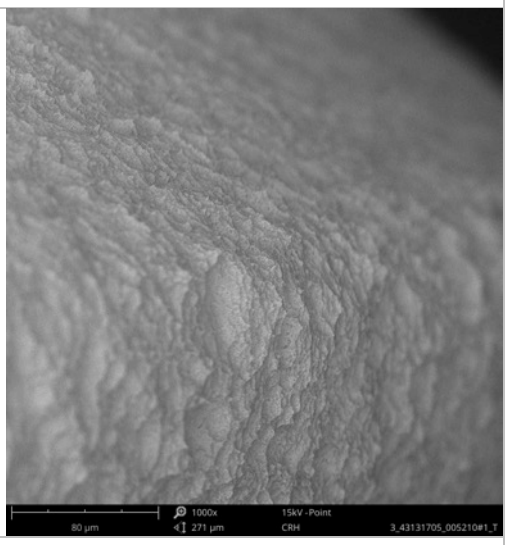
Phenom camera



Field of view



500x



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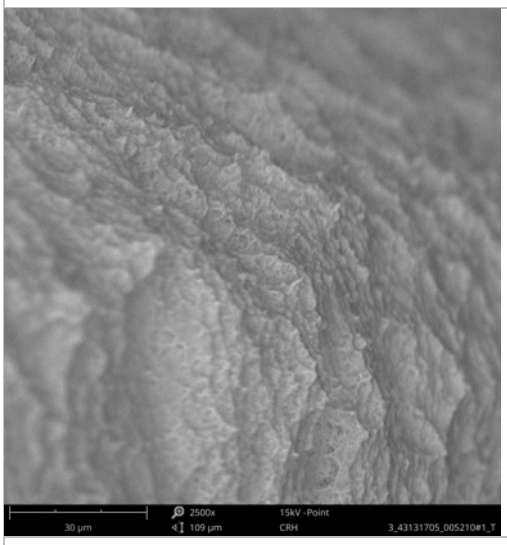

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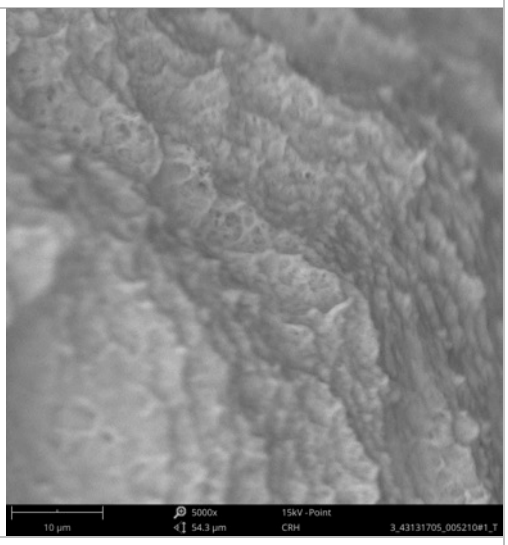

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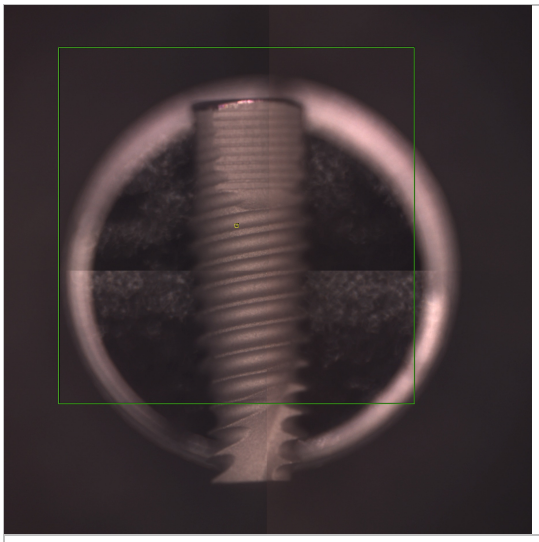
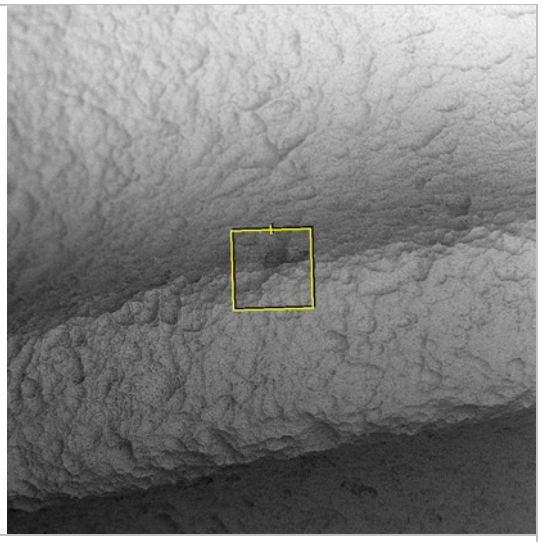
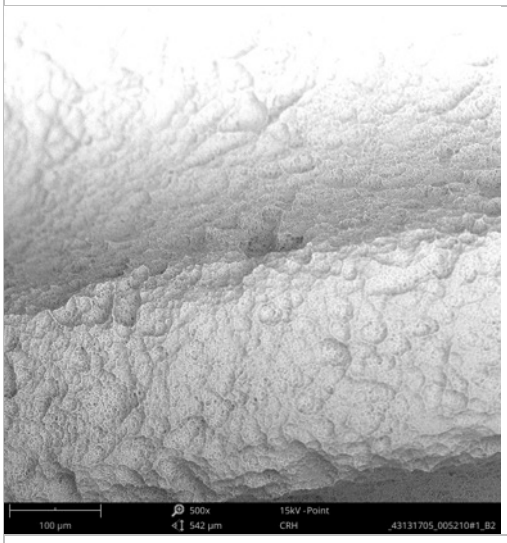
3.2.3 SEM Images Spot_1



Phenom camera



Field of view



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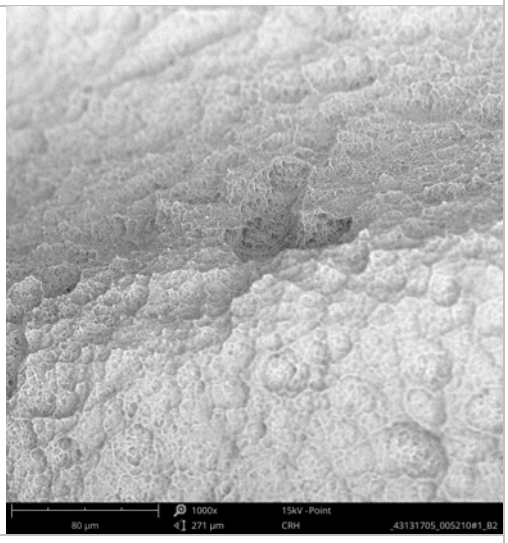

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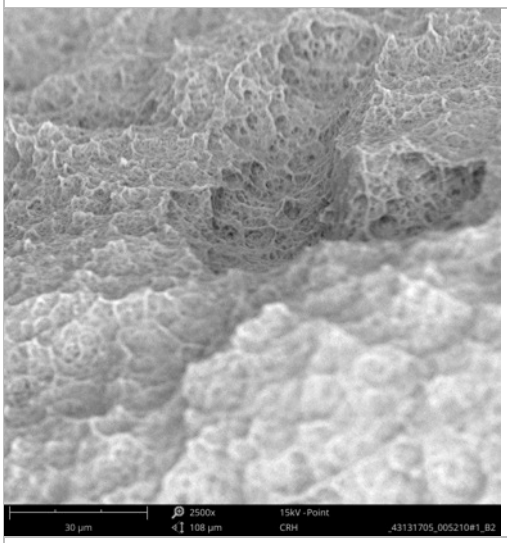

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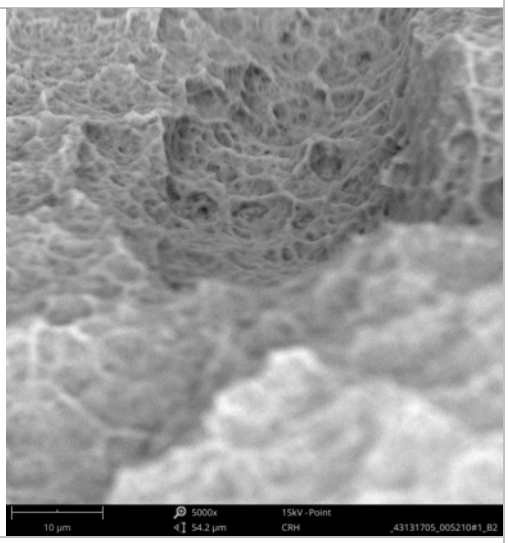

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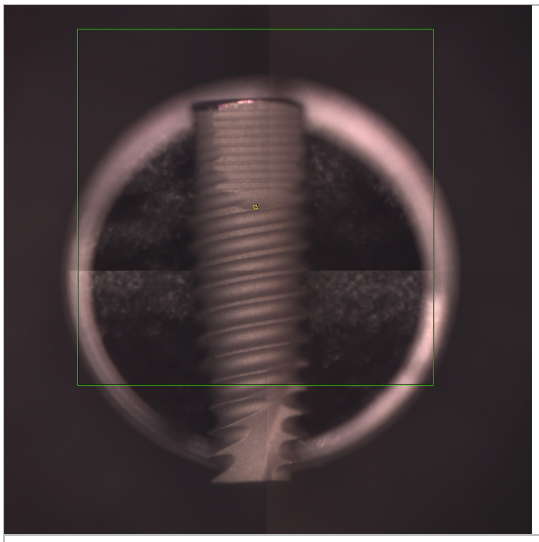
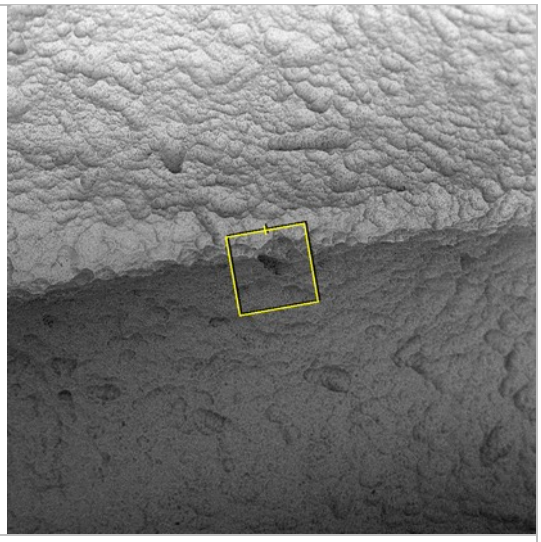
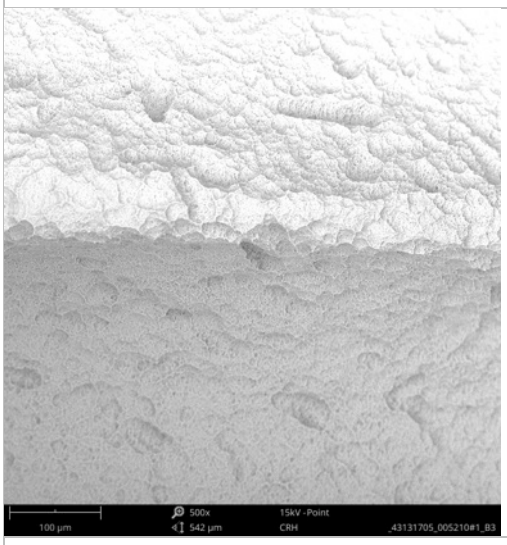
3.2.4 SEM Images Spot_2



Phenom camera



Field of view



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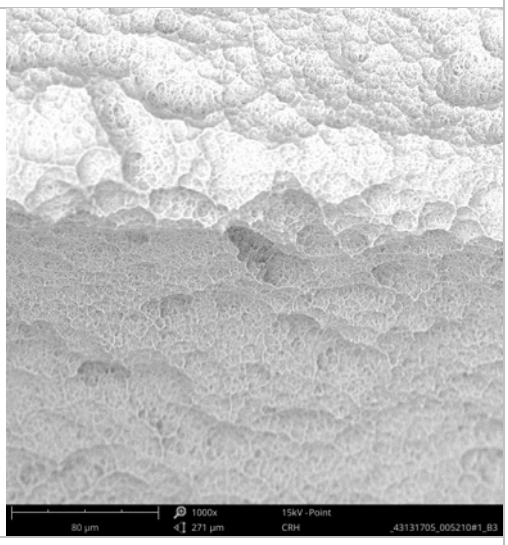

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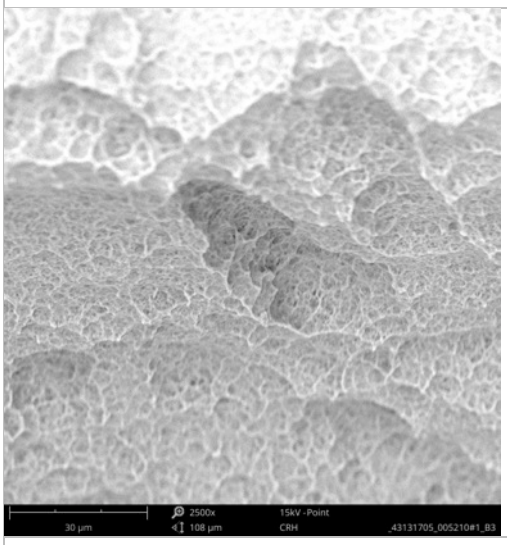

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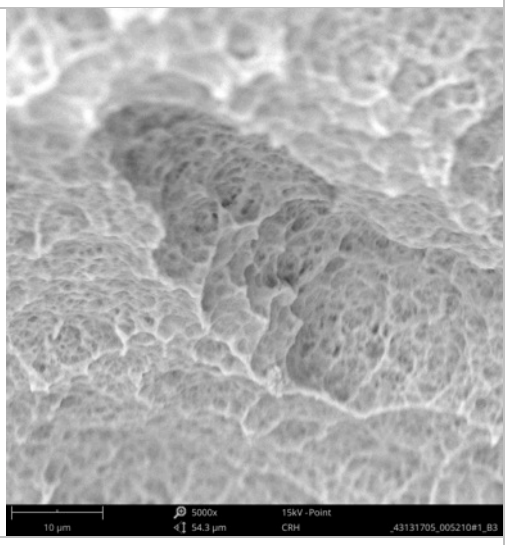

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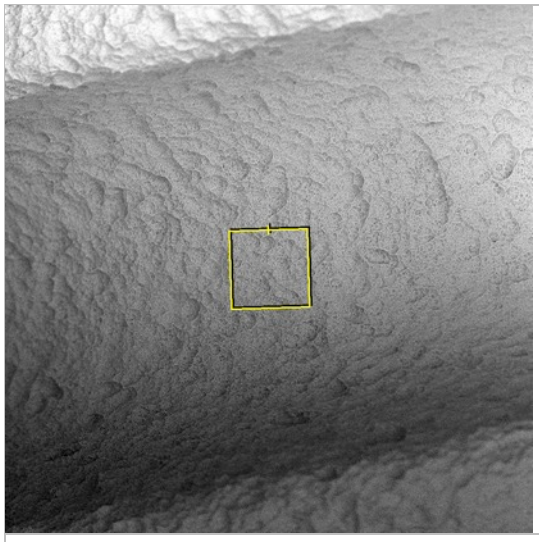
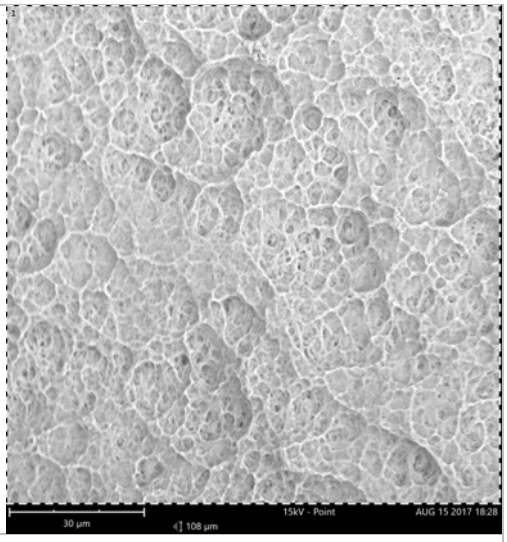
3.3 Elemental Analysis (EDS) Sample #1

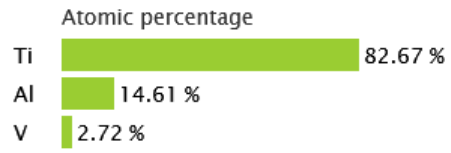
3.3.1 EDS Area Analysis



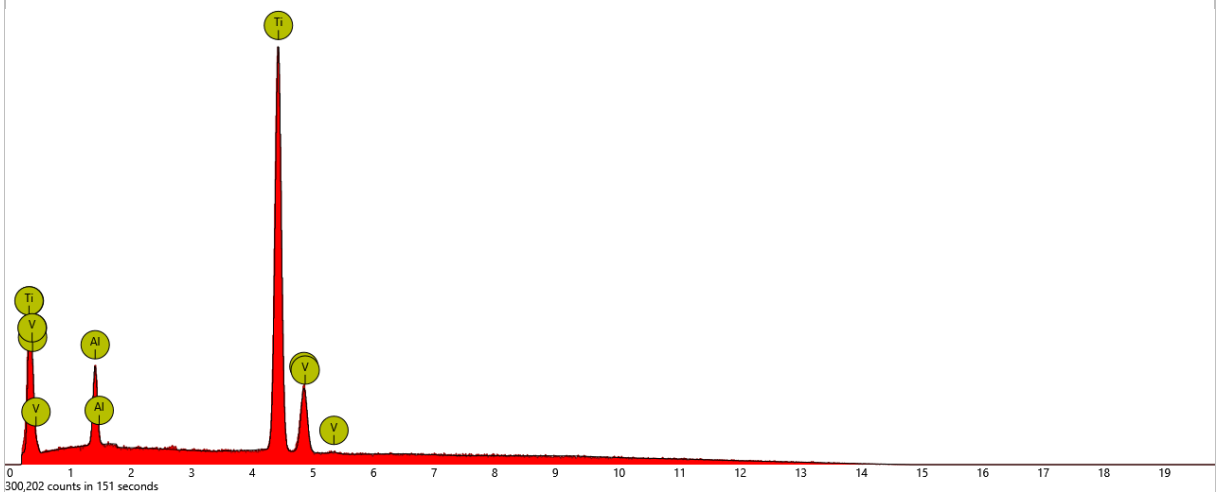
Field of view



Area analysis



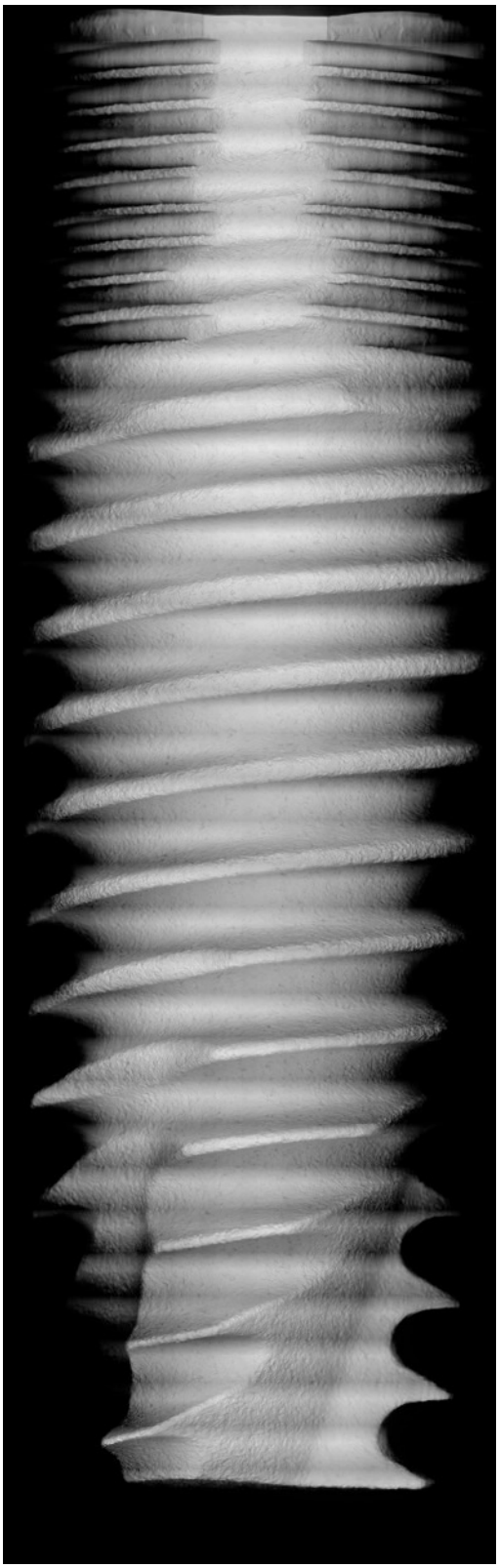
Quantitative elemental analysis



Qualitative elemental analysis

4 Sample #2: V3 D4.3 L13 LOT W17005210

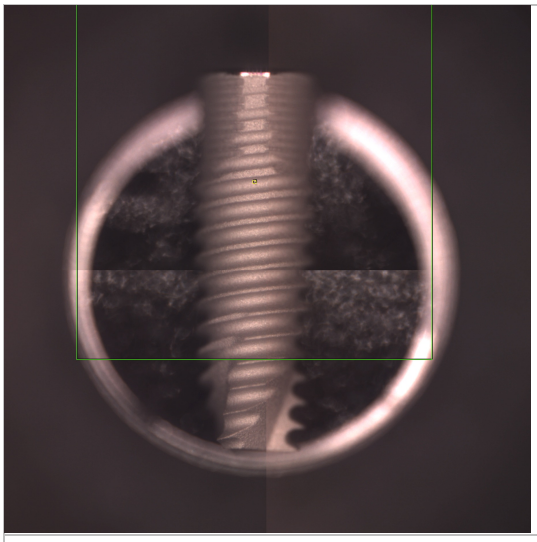
4.1 Full-Size High-Resolution SEM Image



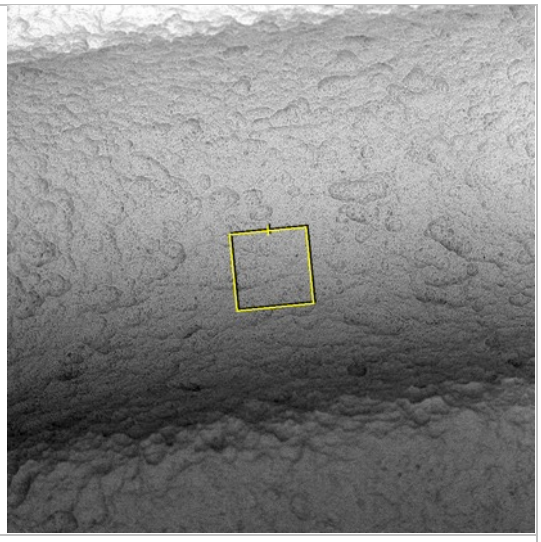
FSHR-SEM image (digitally composed, approx. 500x)

4.2 SEM Imaging Sample #2

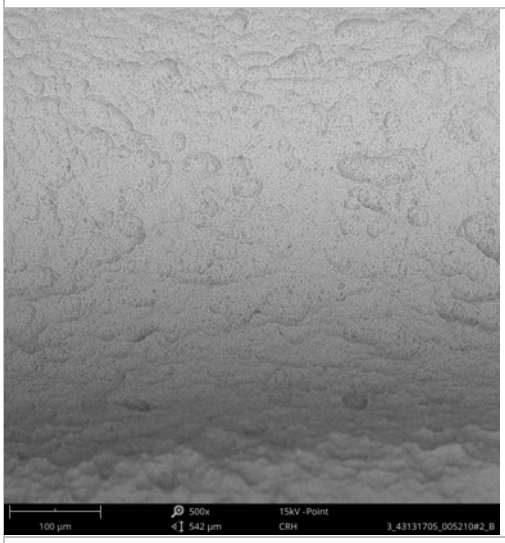
4.2.1 SEM Images Implant Body



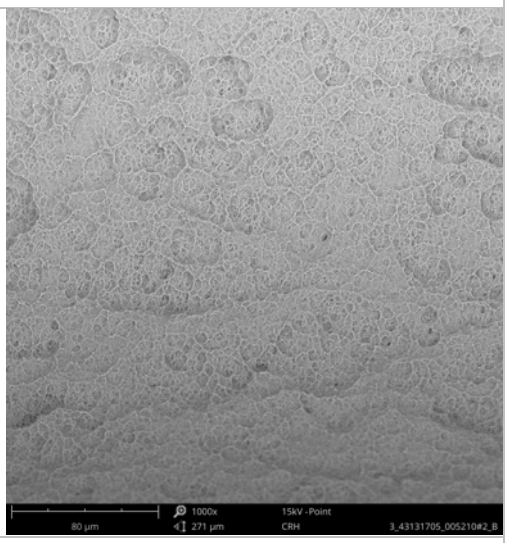
Phenom camera



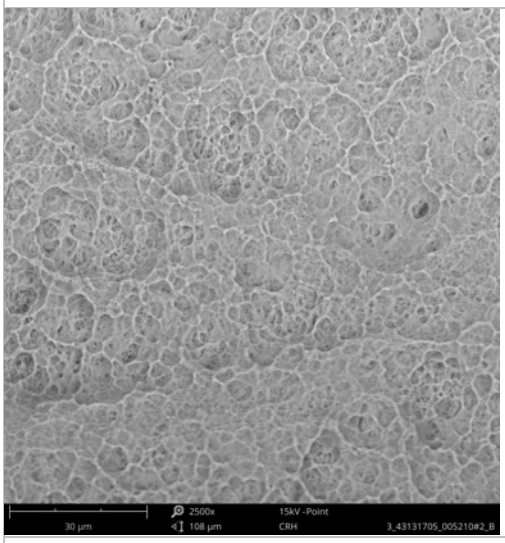
Field of view



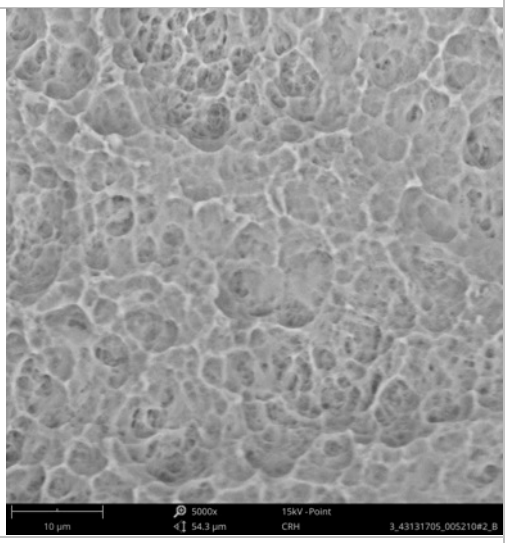
500x



1.000x

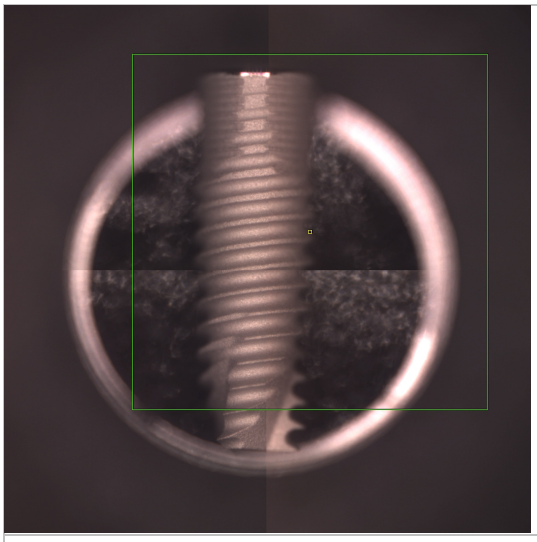


2.500x

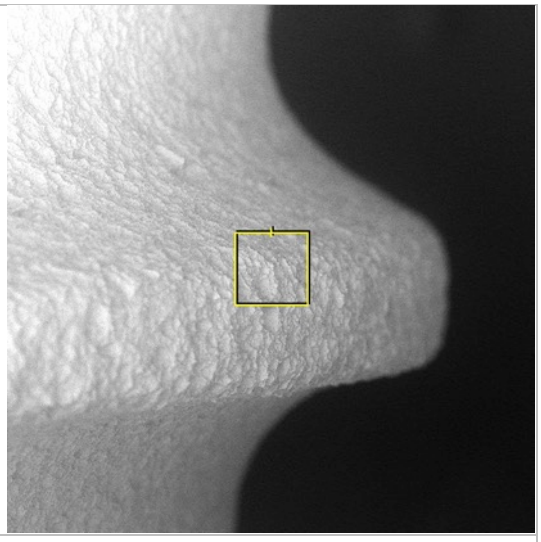


5.000x

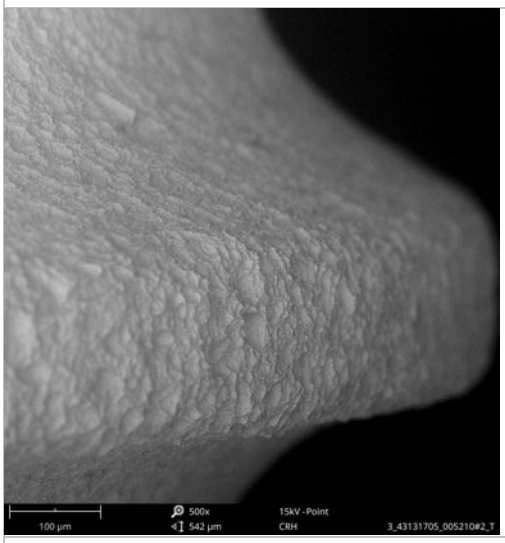
4.2.2 SEM Images Implant Thread



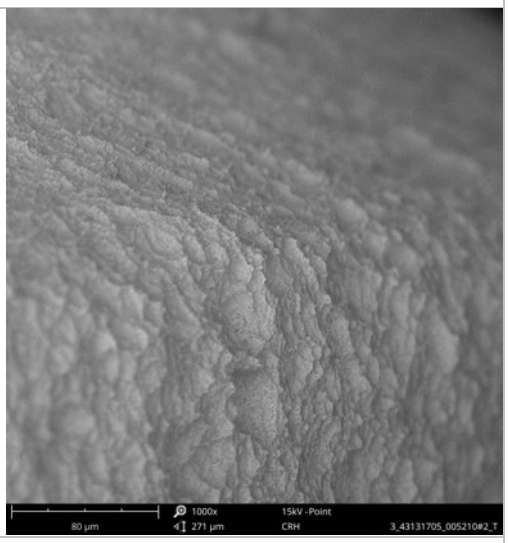
Phenom camera



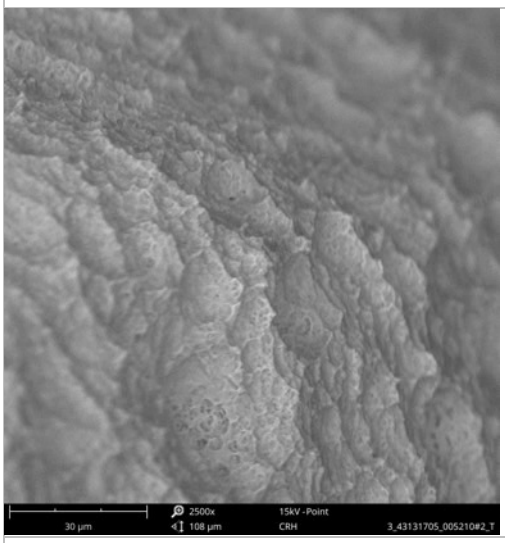
Field of view



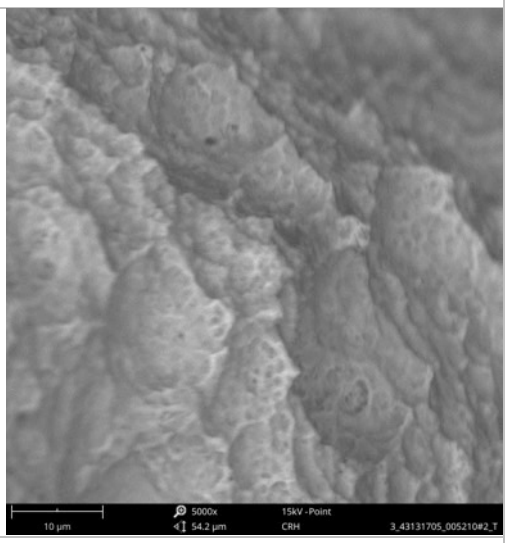
500x



1.000x

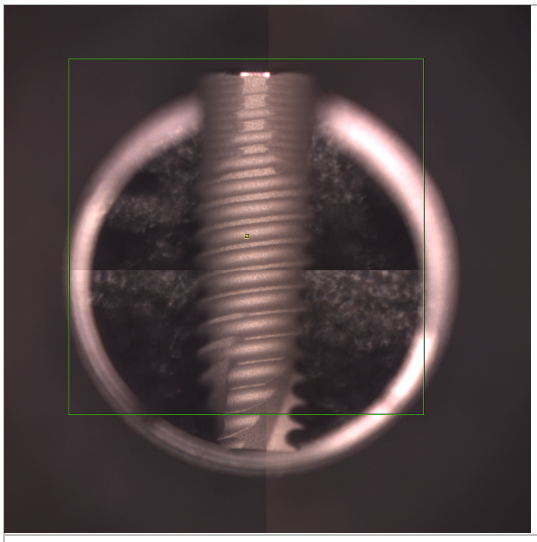


2.500x

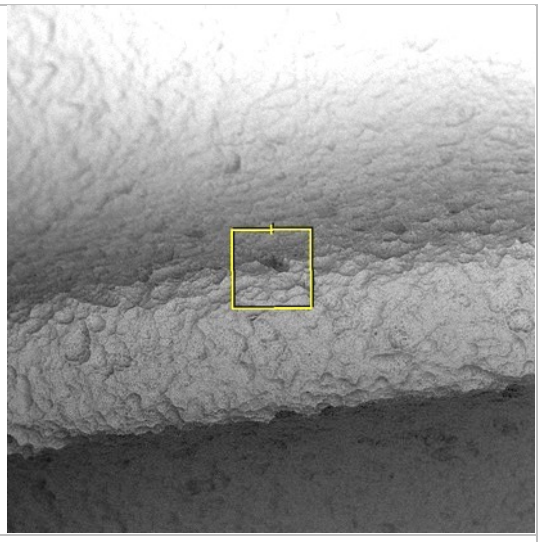


5.000x

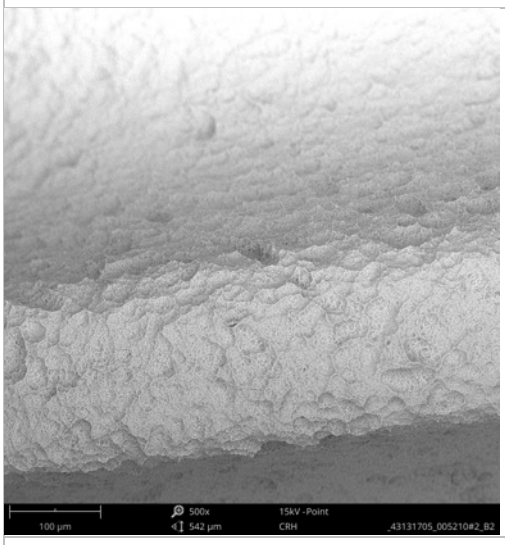
4.2.3 SEM Images Spot_1



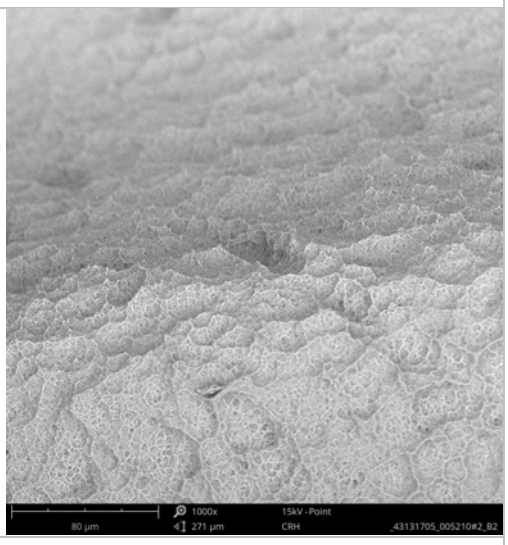
Phenom camera



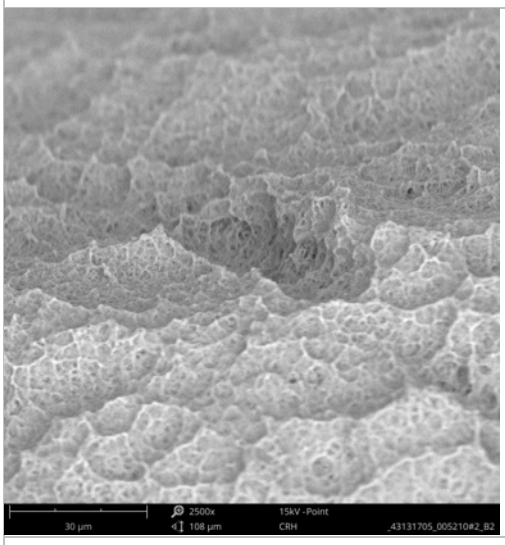
Field of view



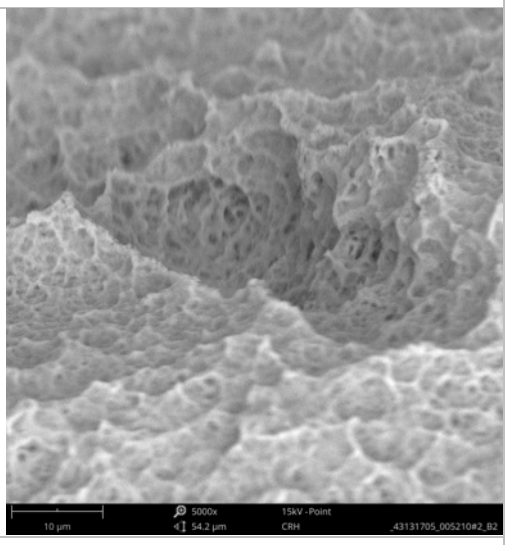
500x



1.000x



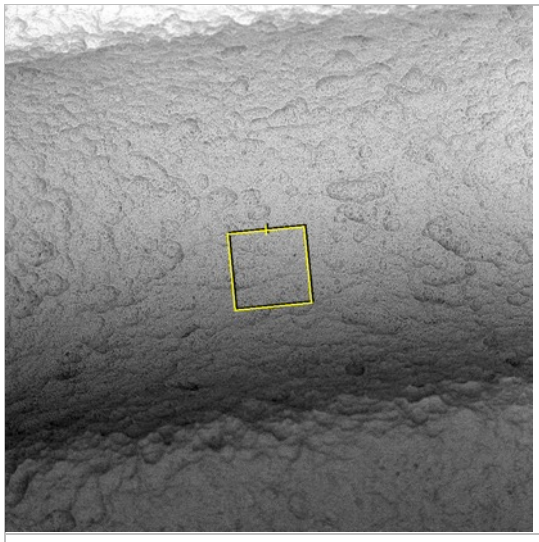
2.500x



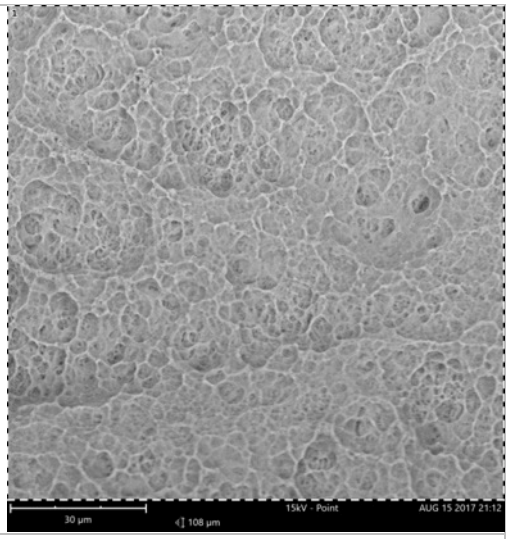
5.000x

4.3 Elemental Analysis (EDS) Sample #2

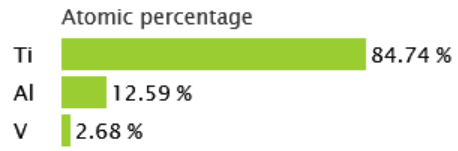
4.3.1 EDS Area Analysis



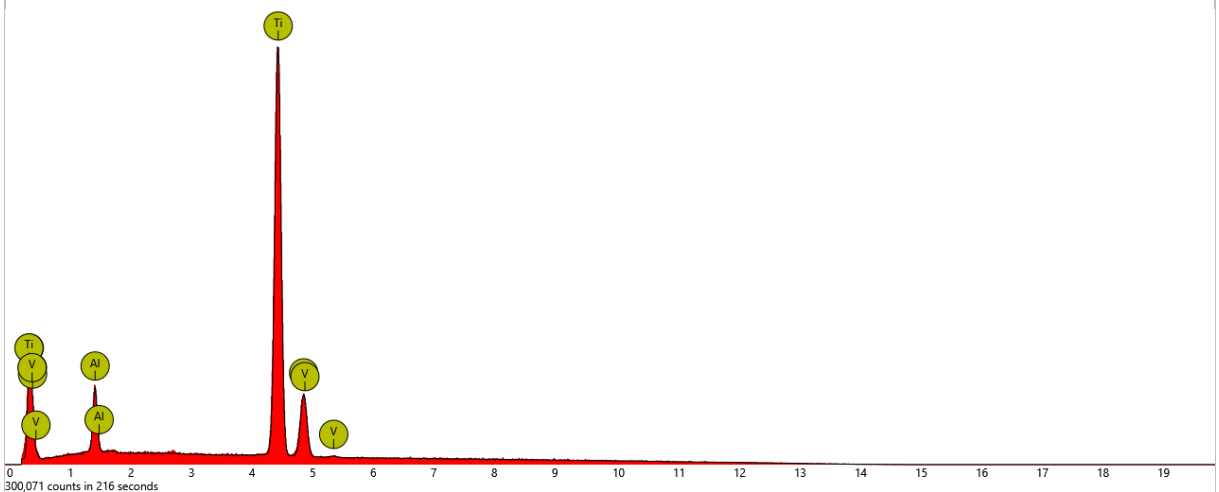
Field of view



Area analysis



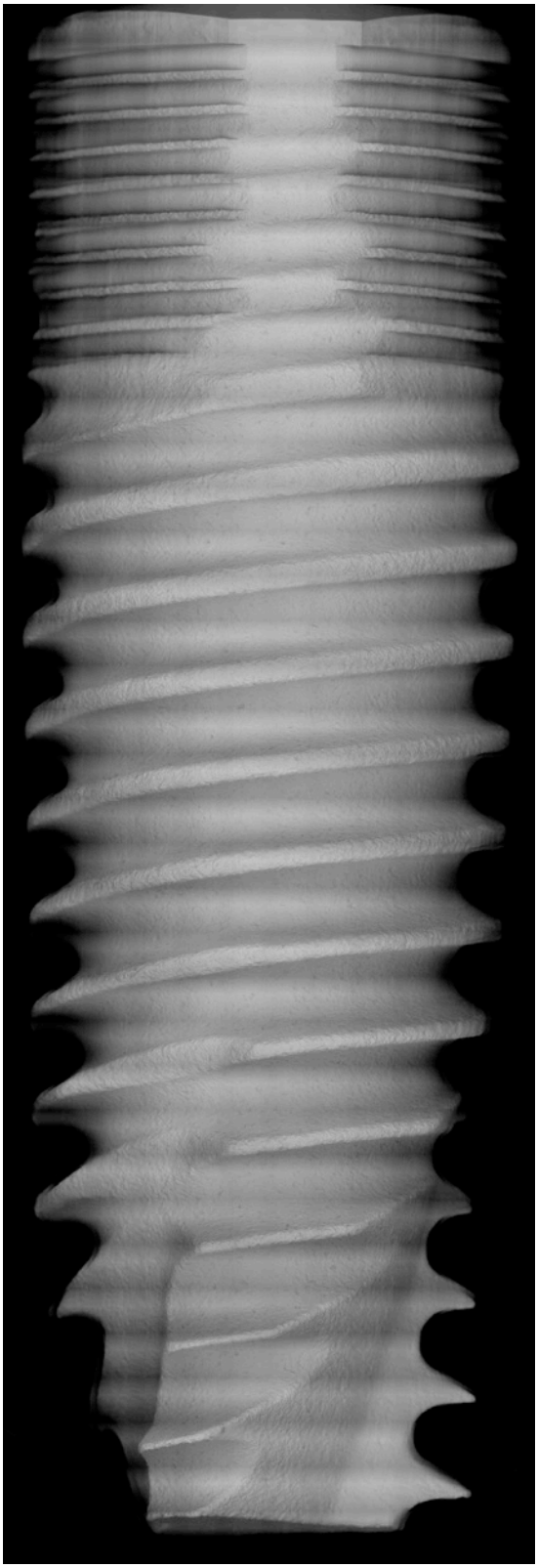
Quantitative elemental analysis



Qualitative elemental analysis

5 Sample #3: V3 D4.3 L13 LOT W17005210

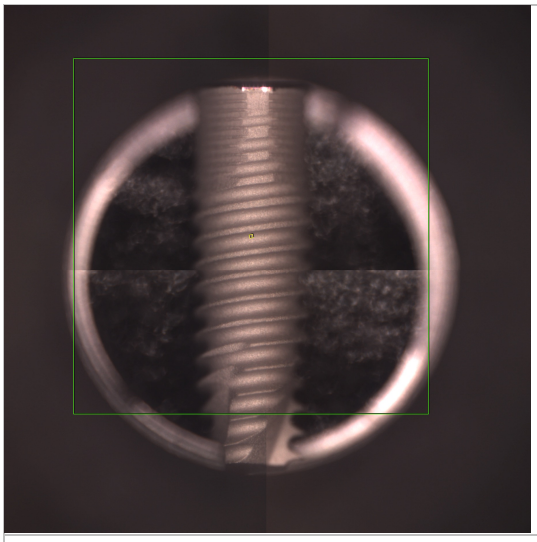
5.1 Full-Size High-Resolution SEM Image



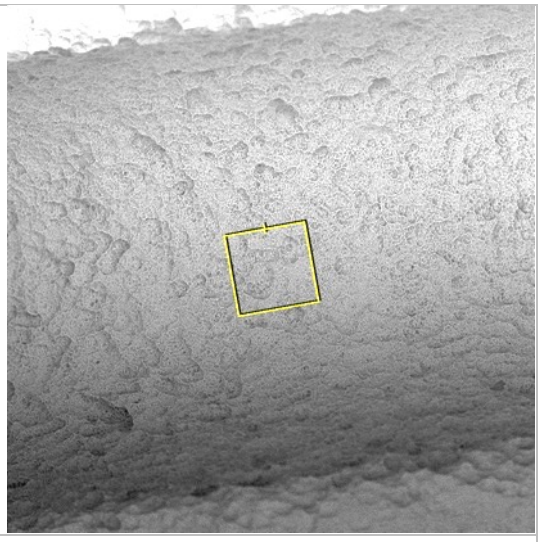
FSHR-SEM image (digitally composed, approx. 500x)

5.2 SEM Imaging Sample #3

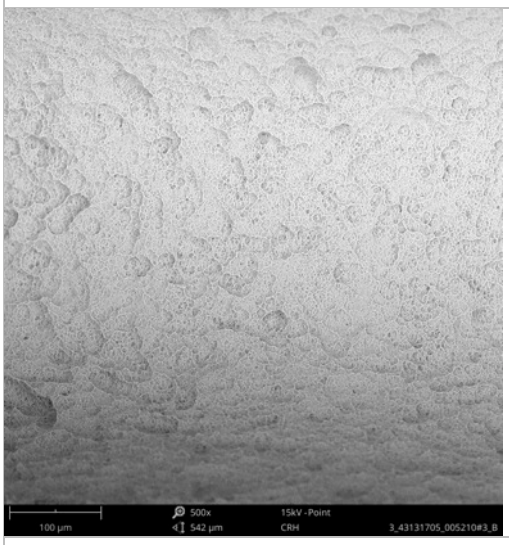
5.2.1 SEM Images Implant Body



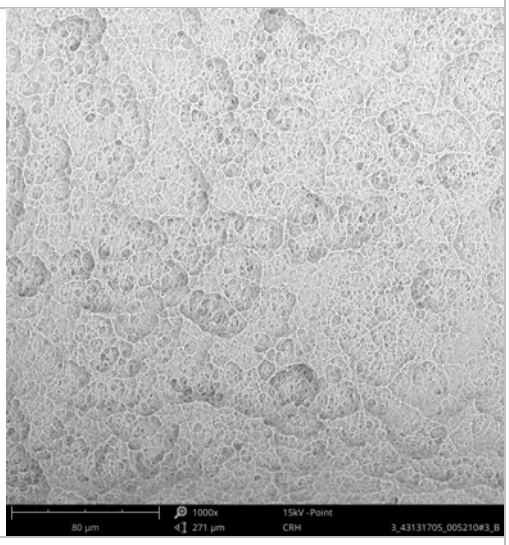
Phenom camera



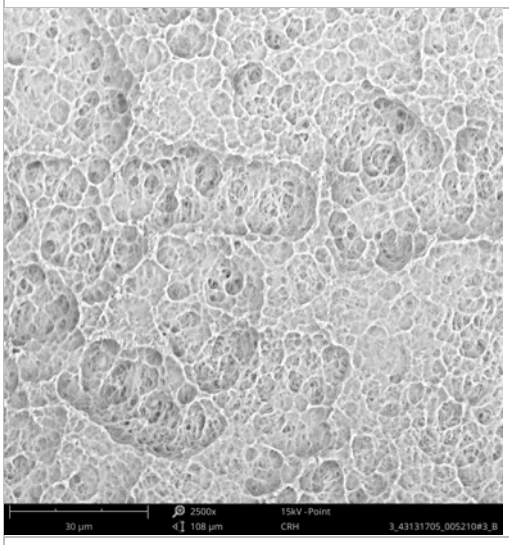
Field of view



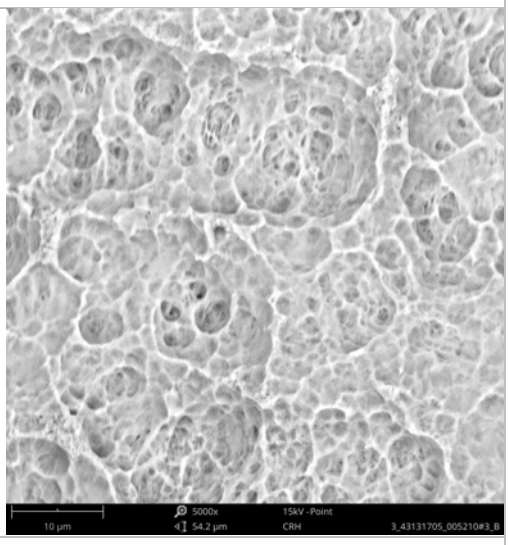
500x



1.000x

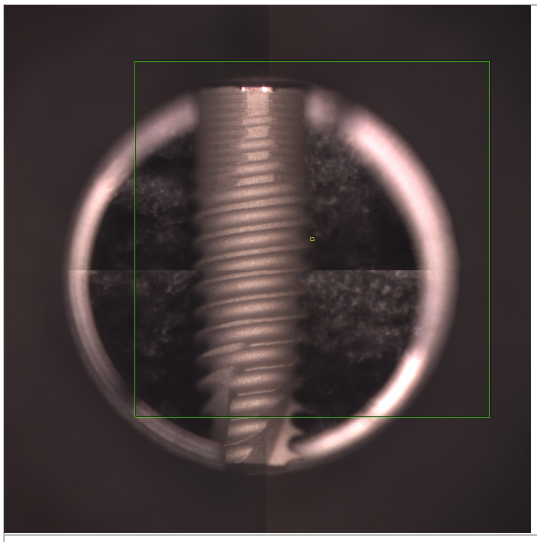


2.500x

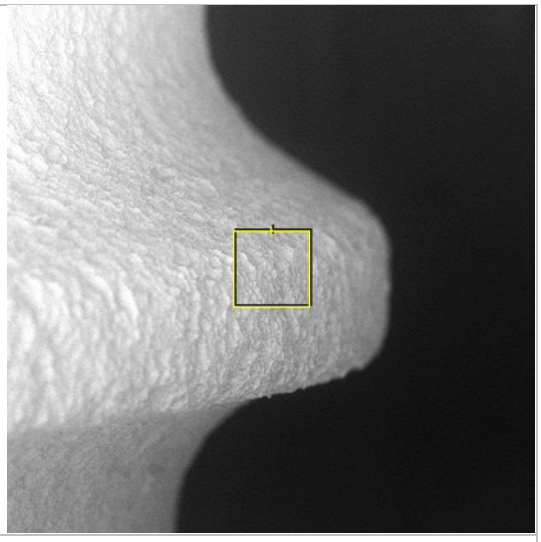


5.000x

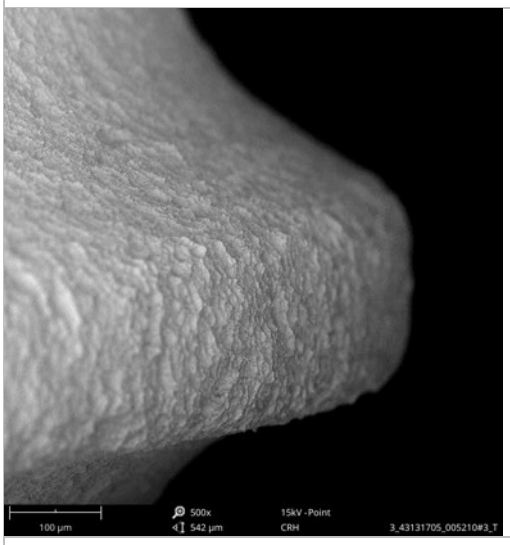
5.2.2 SEM Images Implant Thread



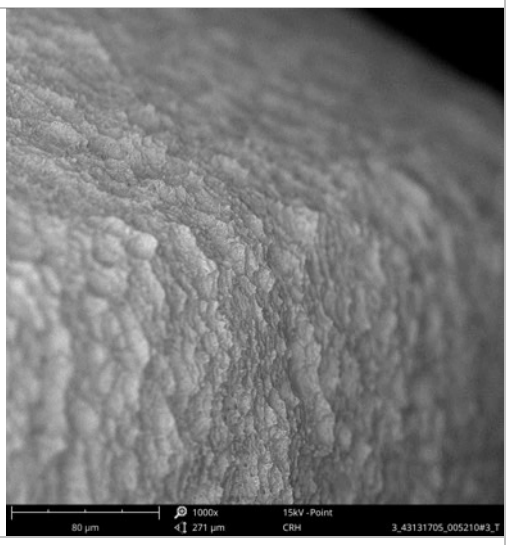
Phenom camera



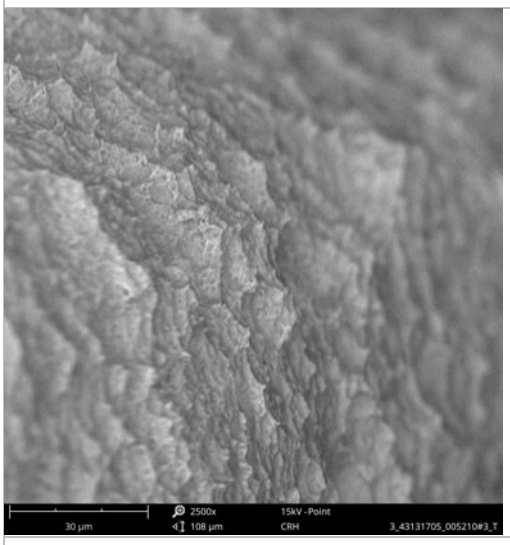
Field of view



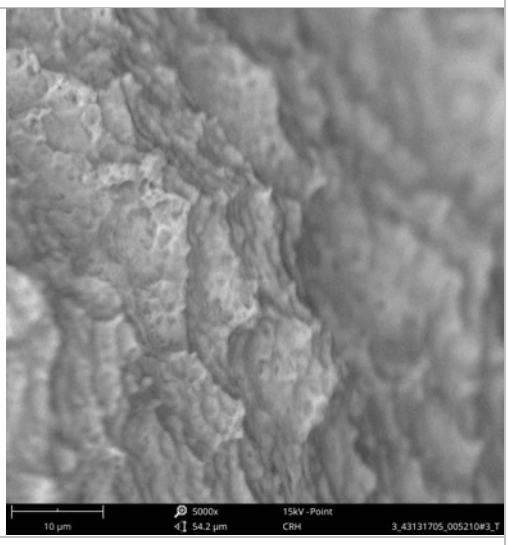
500x



1.000x



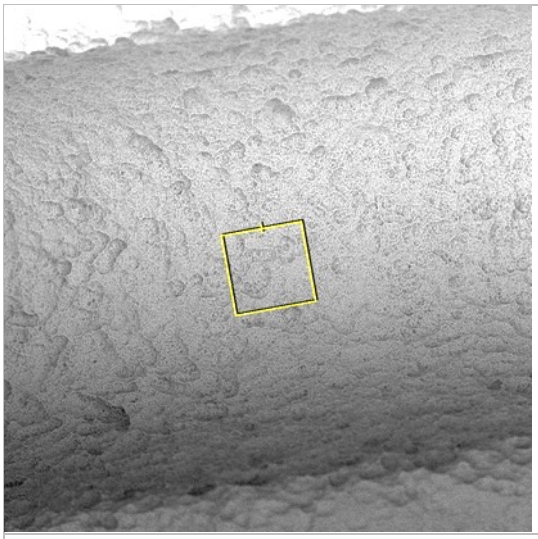
2.500x



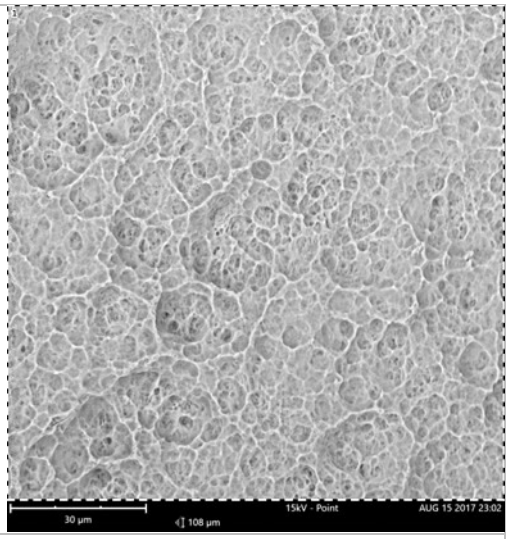
5.000x

5.3 Elemental Analysis (EDS) Sample #3

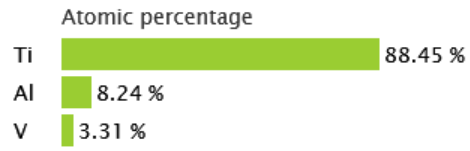
5.3.1 EDS Area Analysis



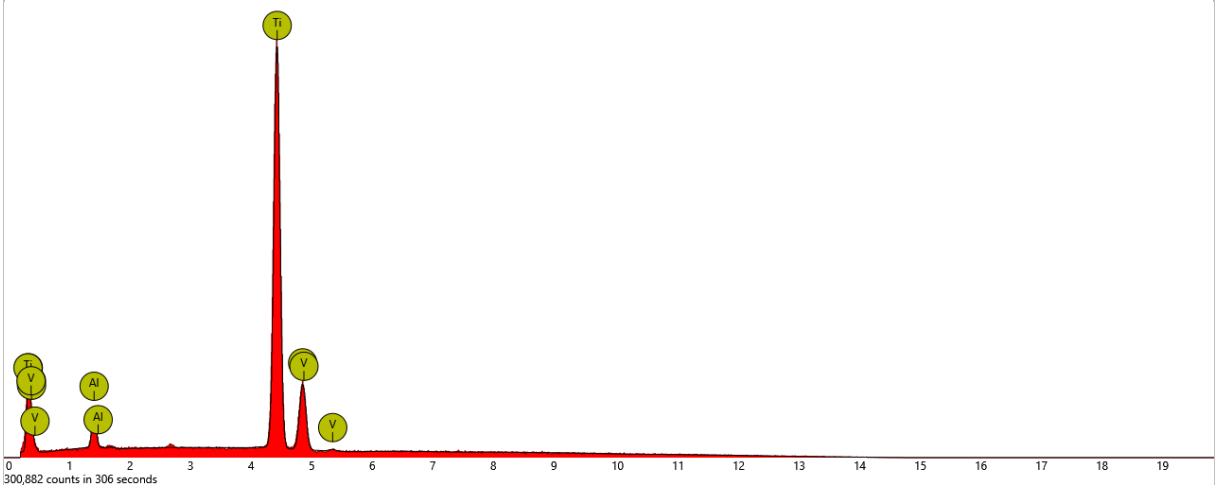
Field of view



Area analysis



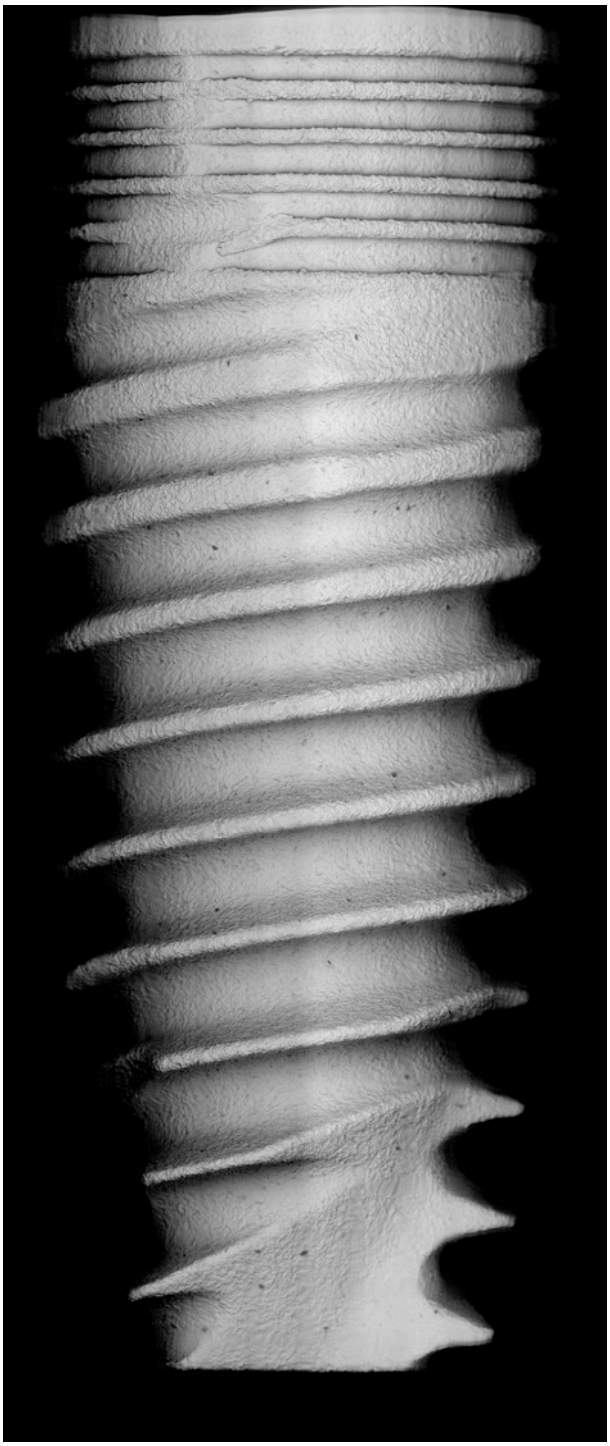
Quantitative elemental analysis

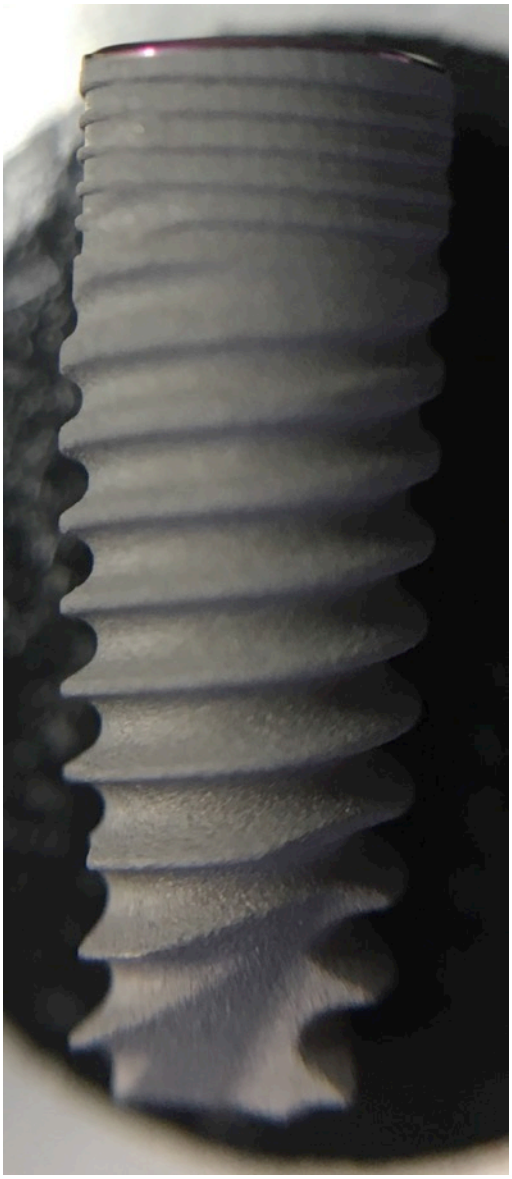


Qualitative elemental analysis

6 Sample #4: V3 D3.9 L10 LOT W16012292

6.1 Full-Size High-Resolution SEM Image

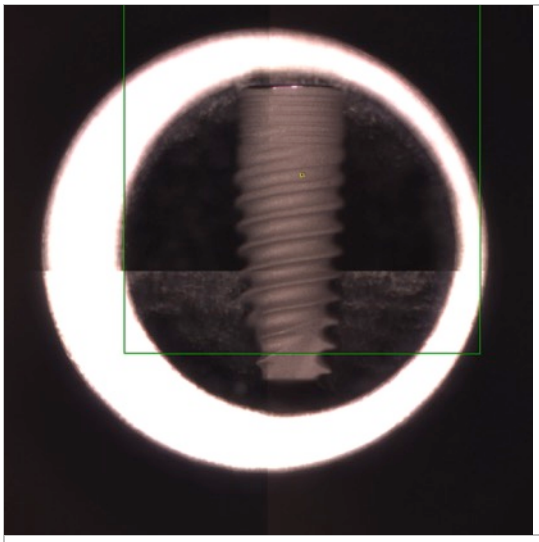




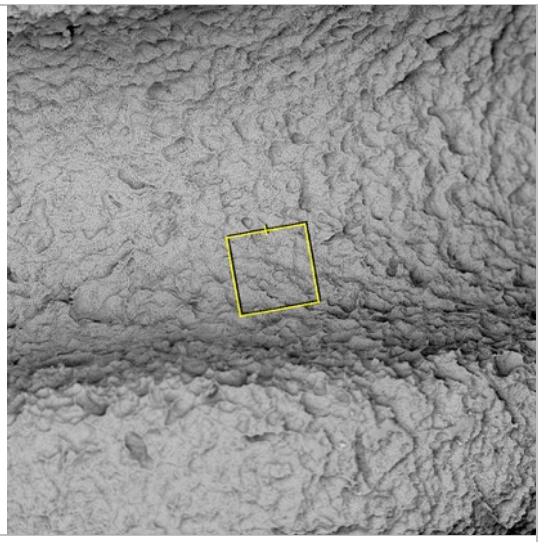
FSHR-SEM image (digitally composed, approx. 500x)

6.2 SEM Imaging Sample #4

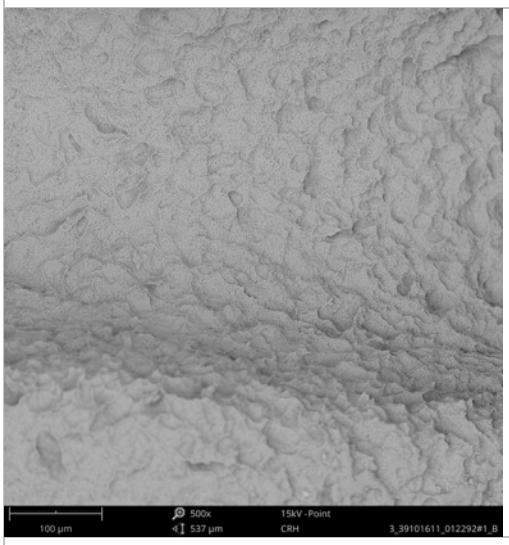
6.2.1 SEM Images Implant Body



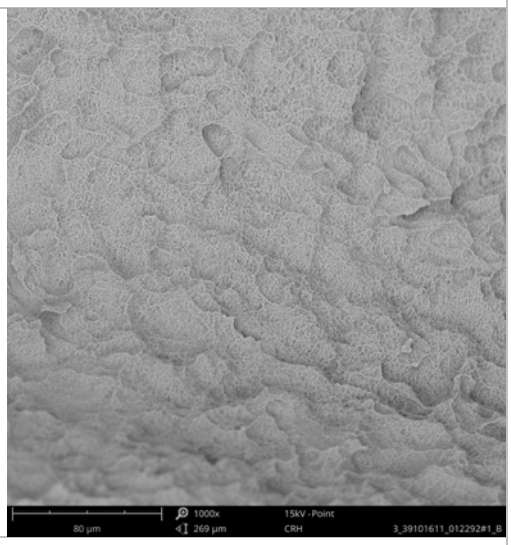
Phenom camera



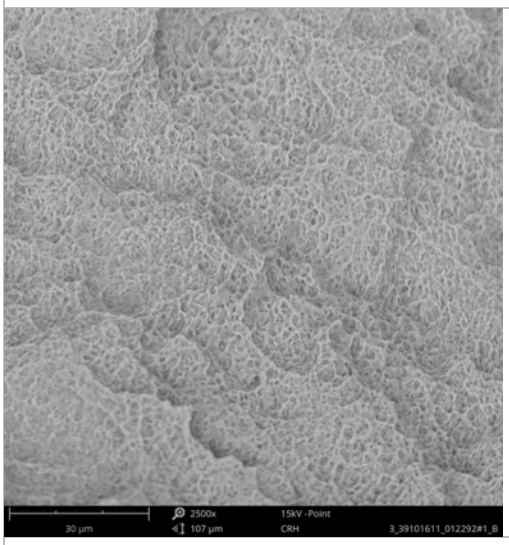
Field of view



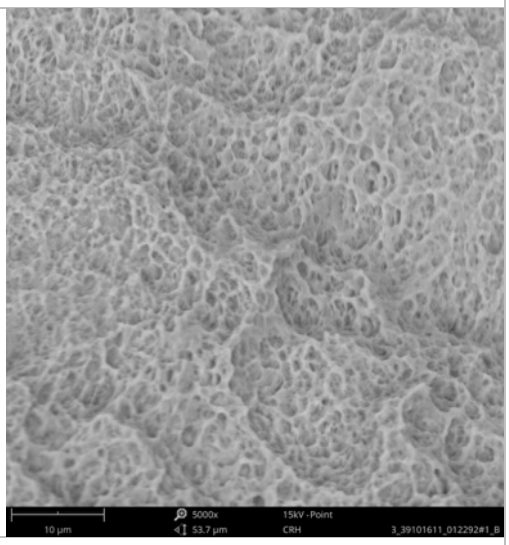
500x



1.000x

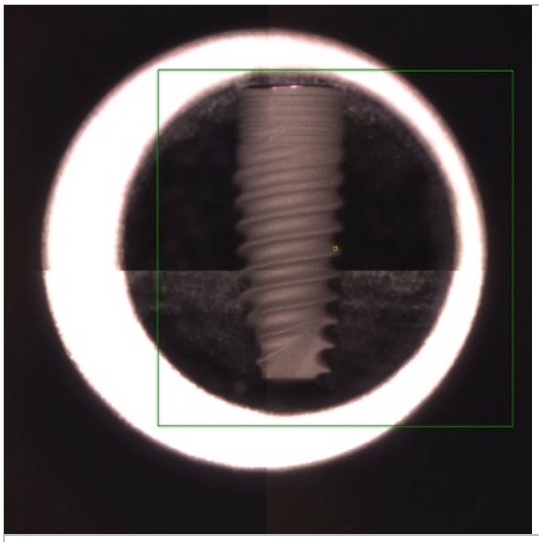


2.500x

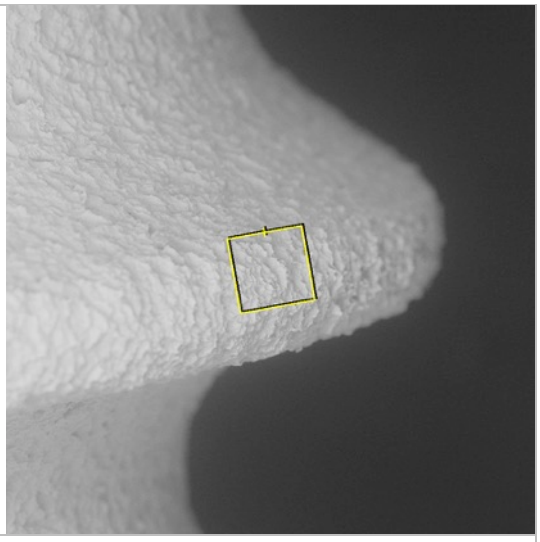


5.000x

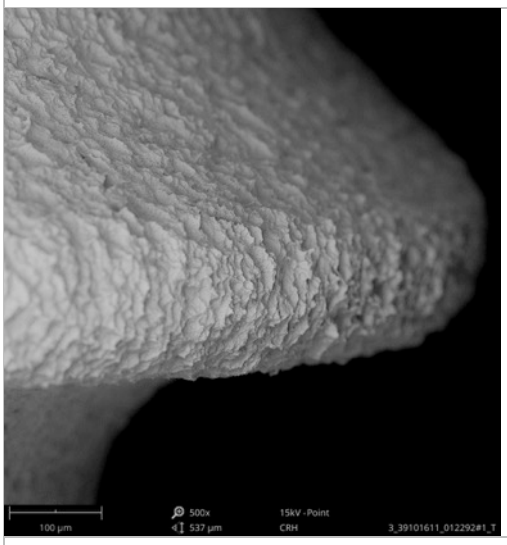
6.2.2 SEM Images Implant Thread



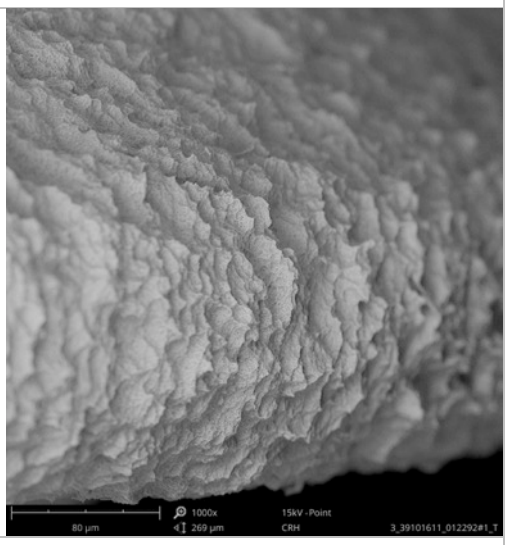
Phenom camera



Field of view



500x



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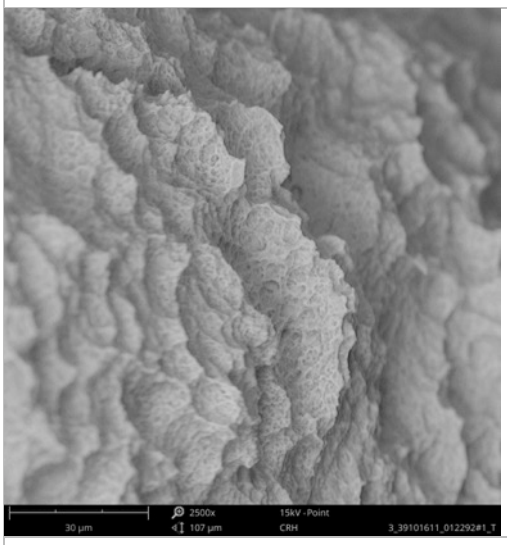
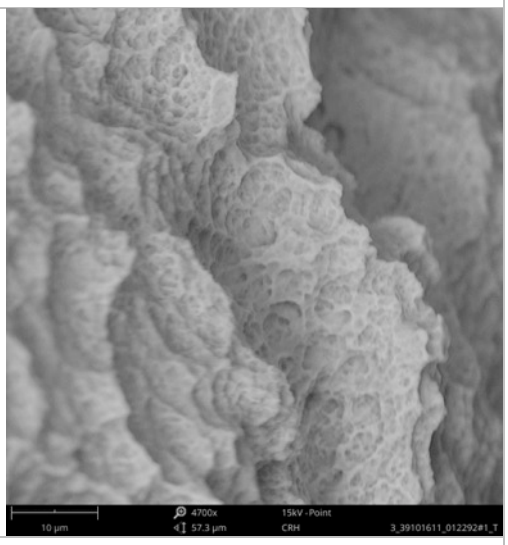
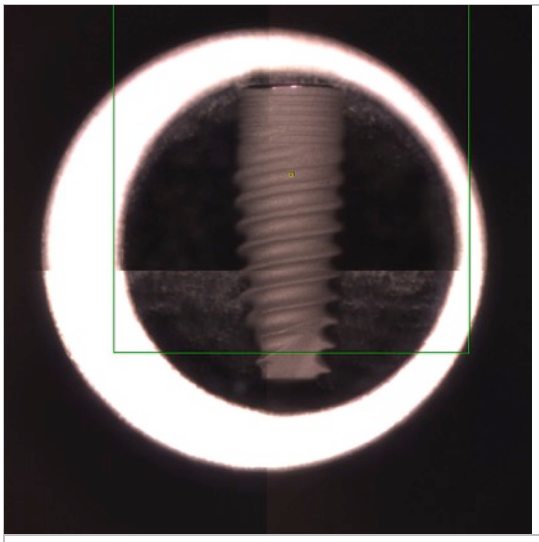


2.500x

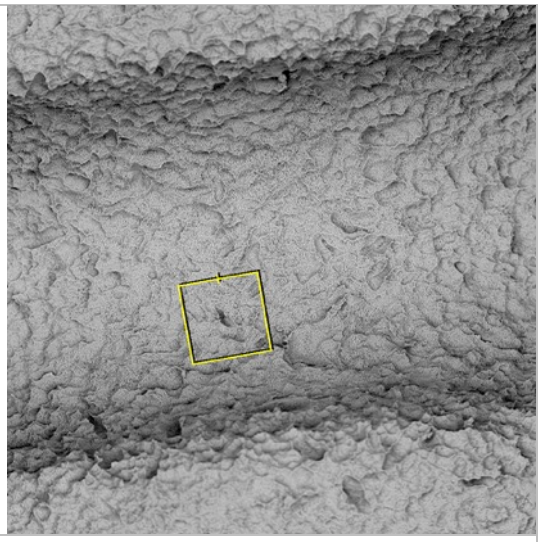


5.000x

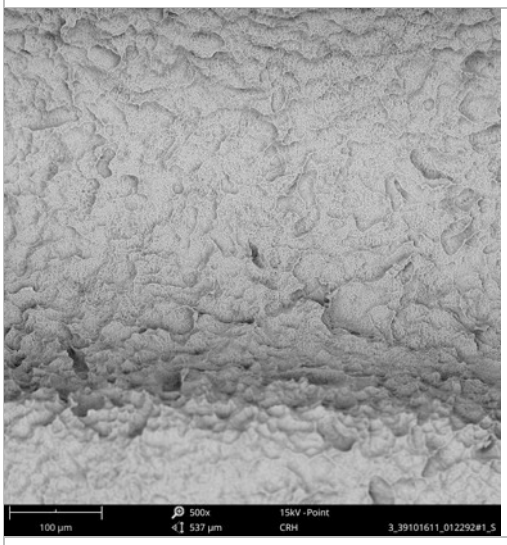
6.2.3 SEM Images Spot_1



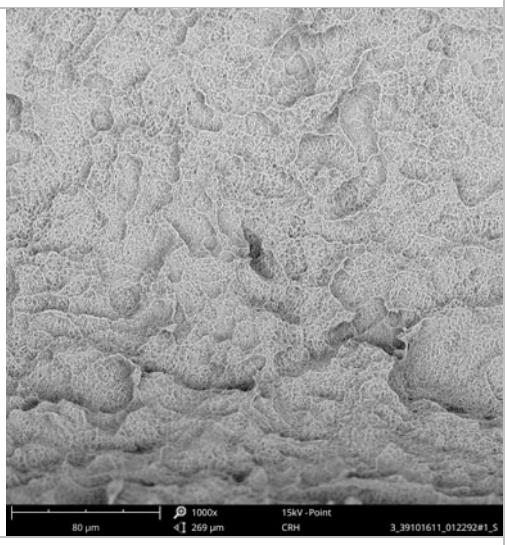
Phenom camera



Field of view



500x



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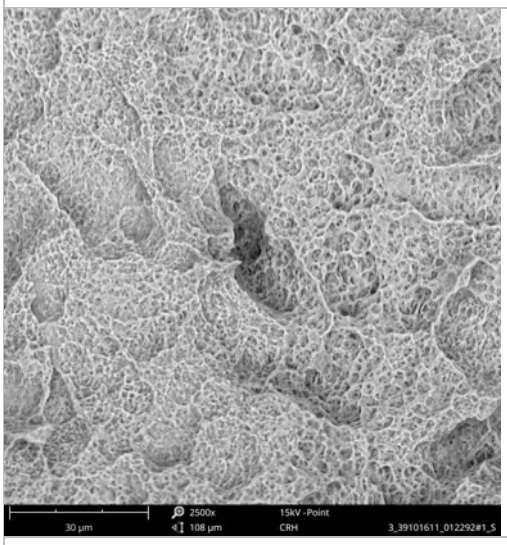
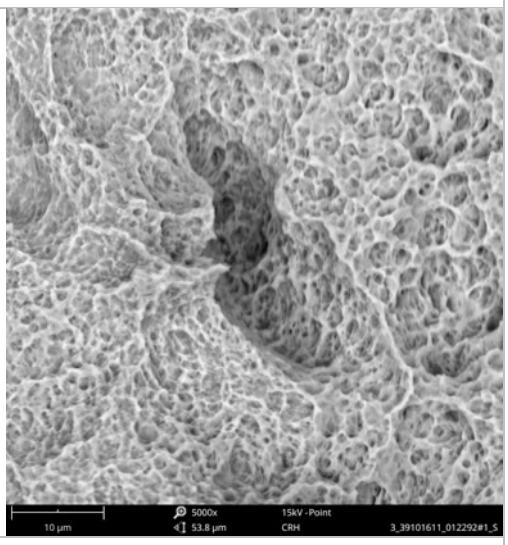
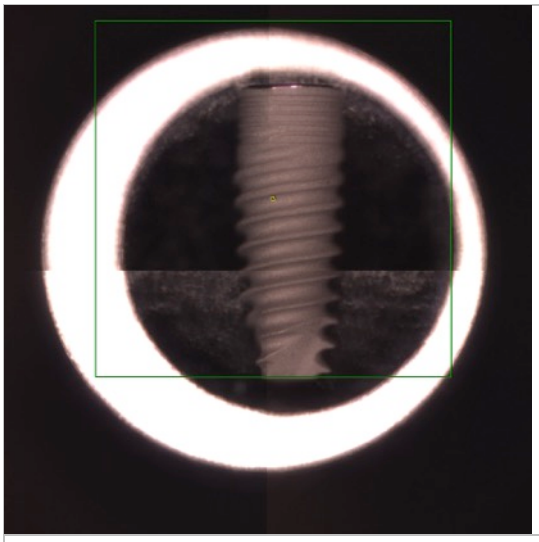


2.500x

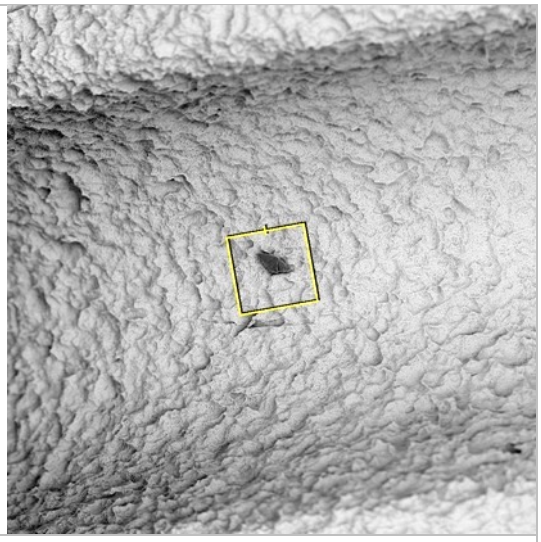


5.000x

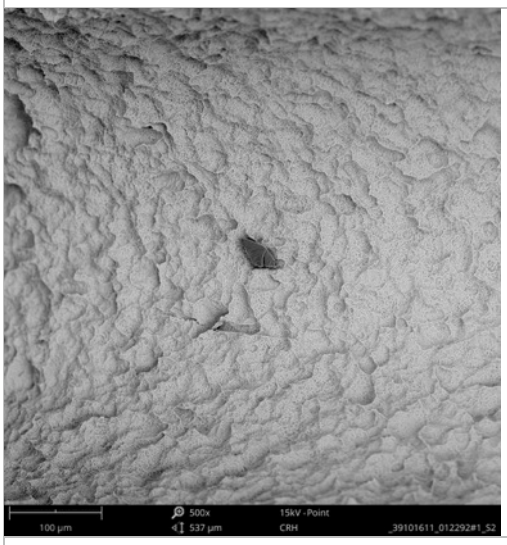
6.2.4 SEM Images Spot_2



Phenom camera



Field of view



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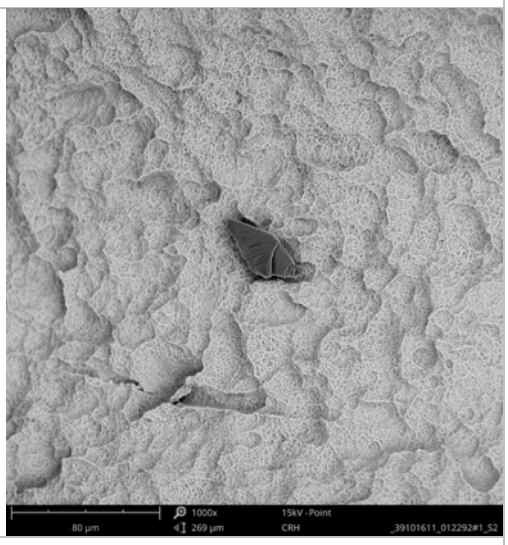

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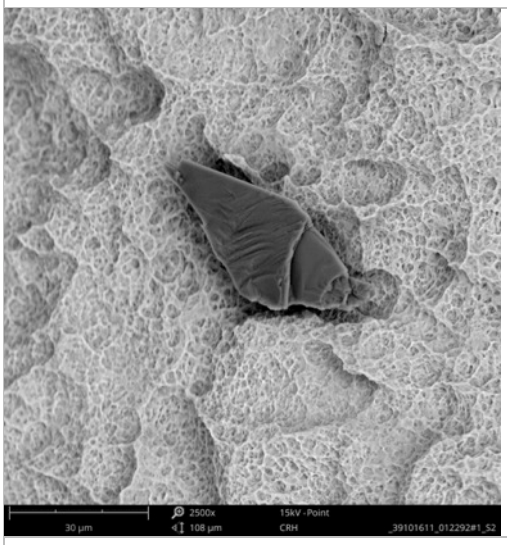

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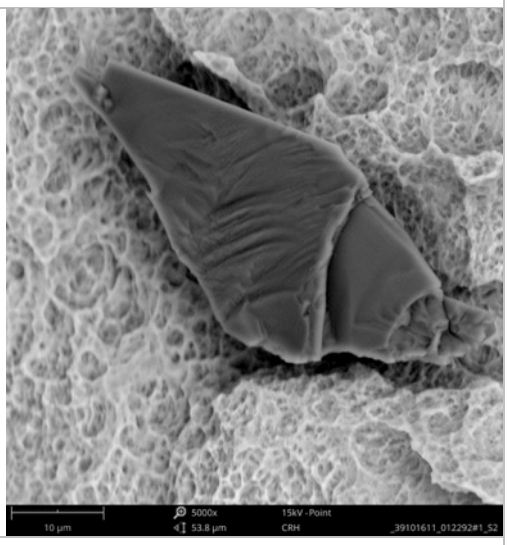
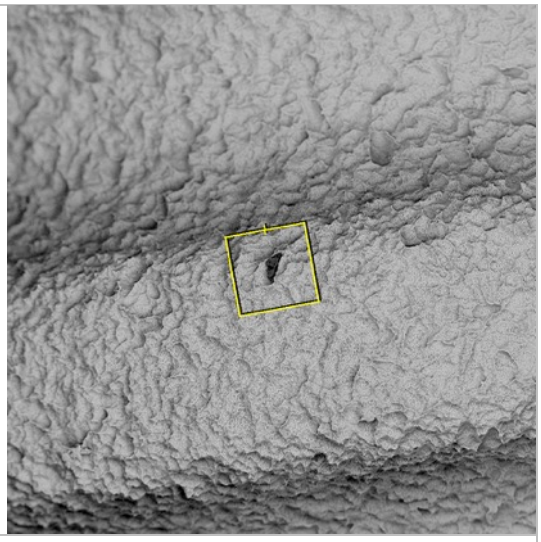
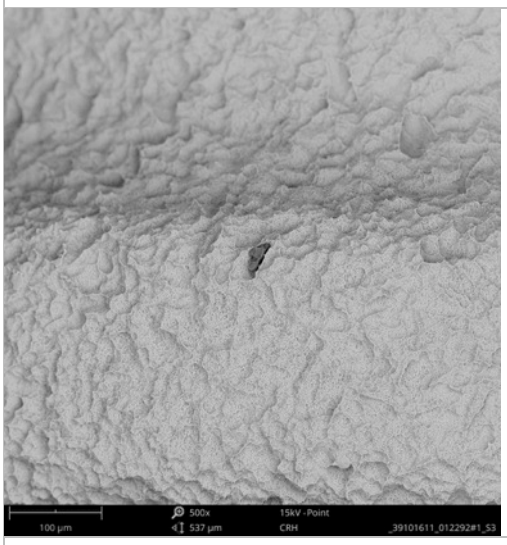
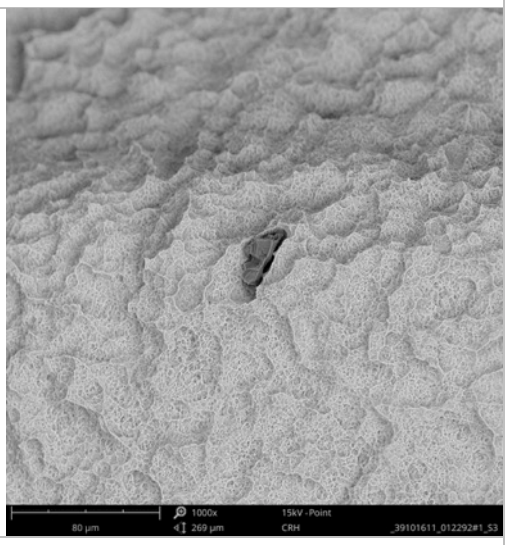


5.000x

6.2.5 SEM Images Spot_3

Camera image not accessable	
Phenom camera	Field of view
	
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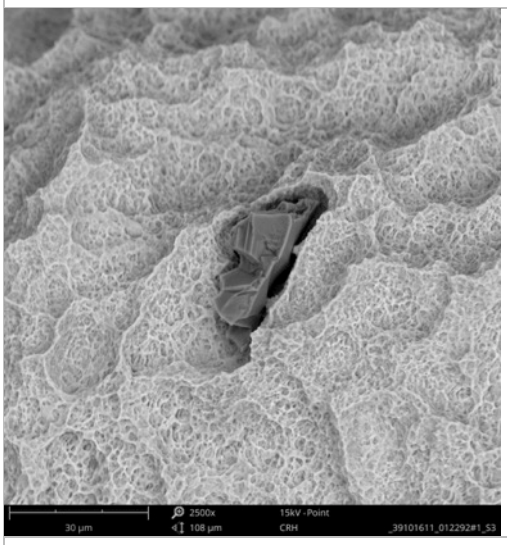	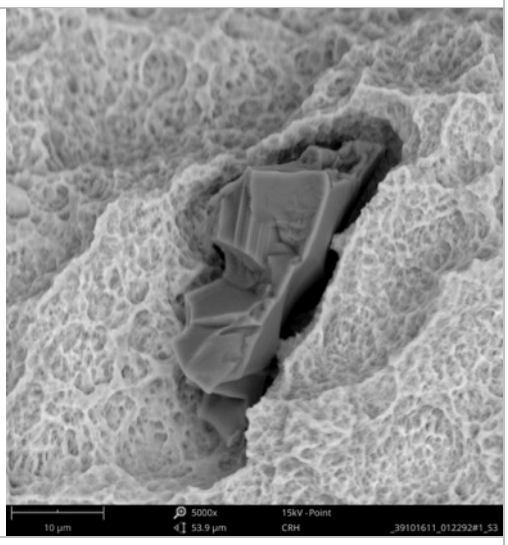
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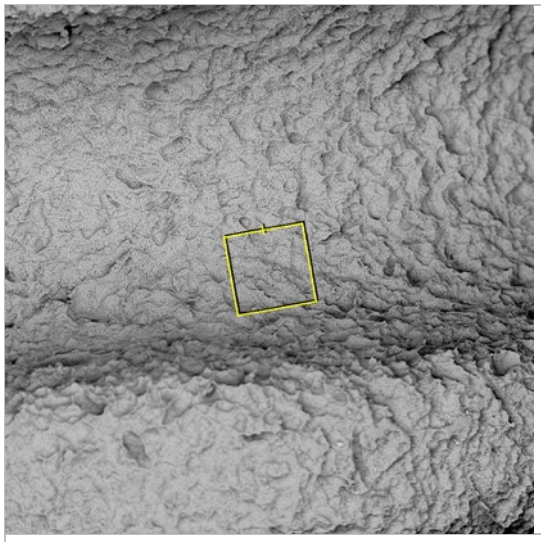
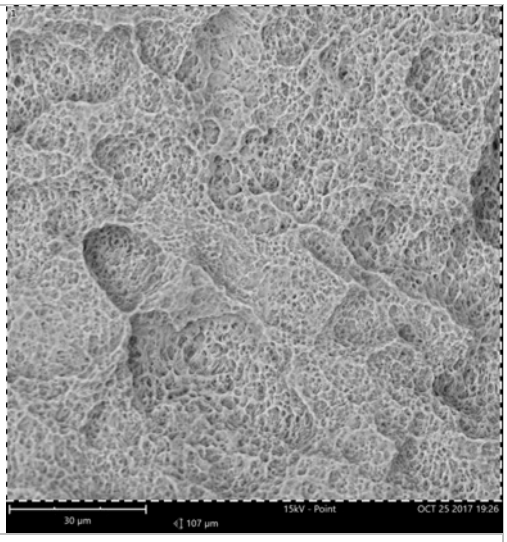
6.3 Elemental Analysis (EDS) Sample #4

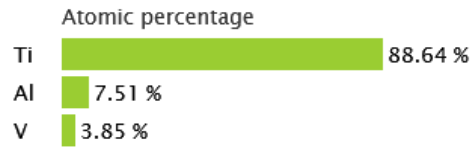
6.3.1 EDS Area Analysis



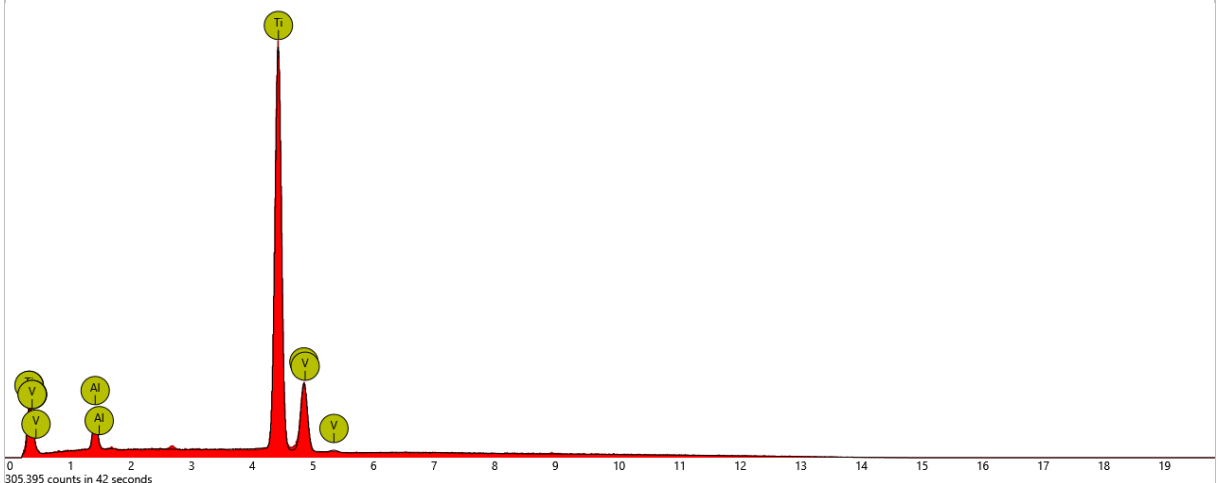
Field of view



Area analysis

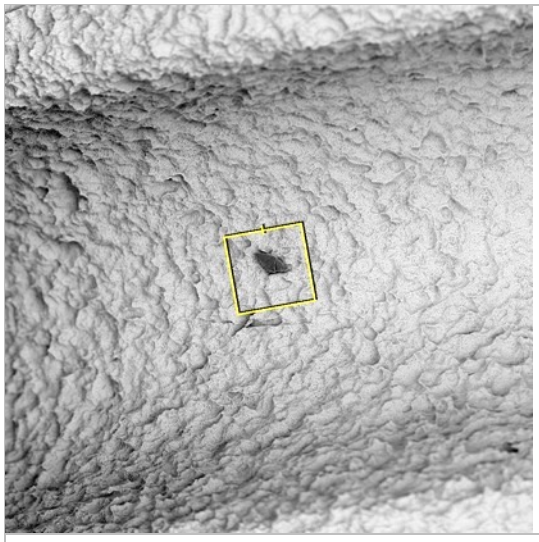


Quantitative elemental analysis

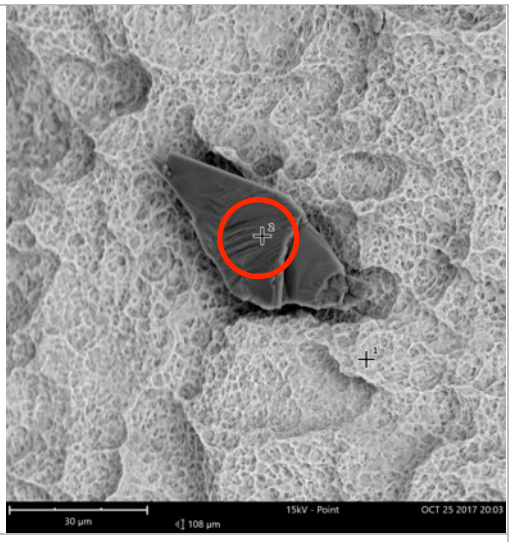


Qualitative elemental analysis

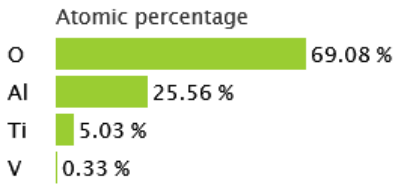
6.3.2 EDS Analysis Spot_2



Field of view

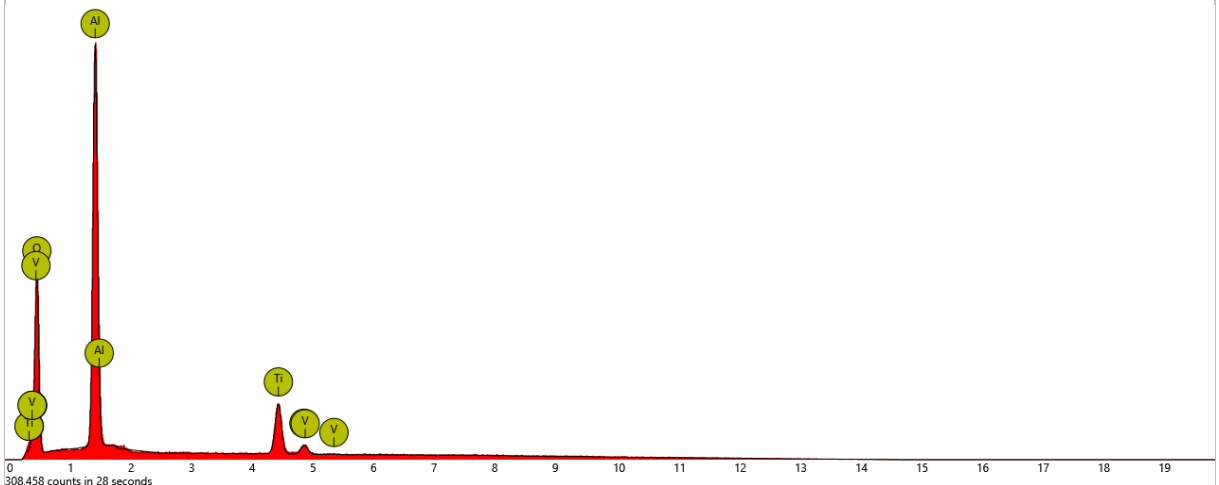


Spot reading #2



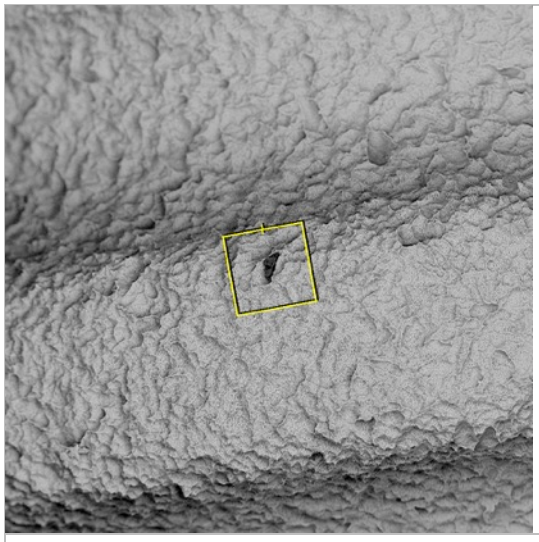
Note: Particle of Al_2O_3 as remnant from the blasting process

Quantitative elemental analysis

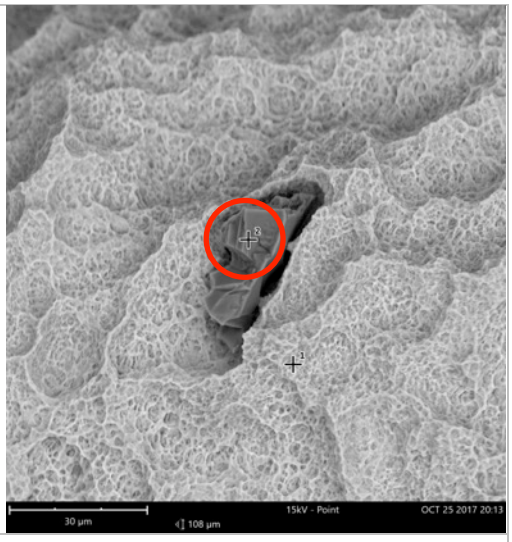


Qualitative elemental analysis

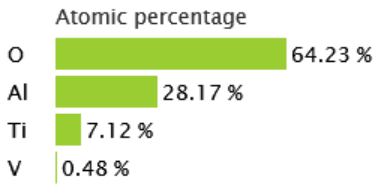
6.3.3 EDS Analysis Spot_3



Field of view

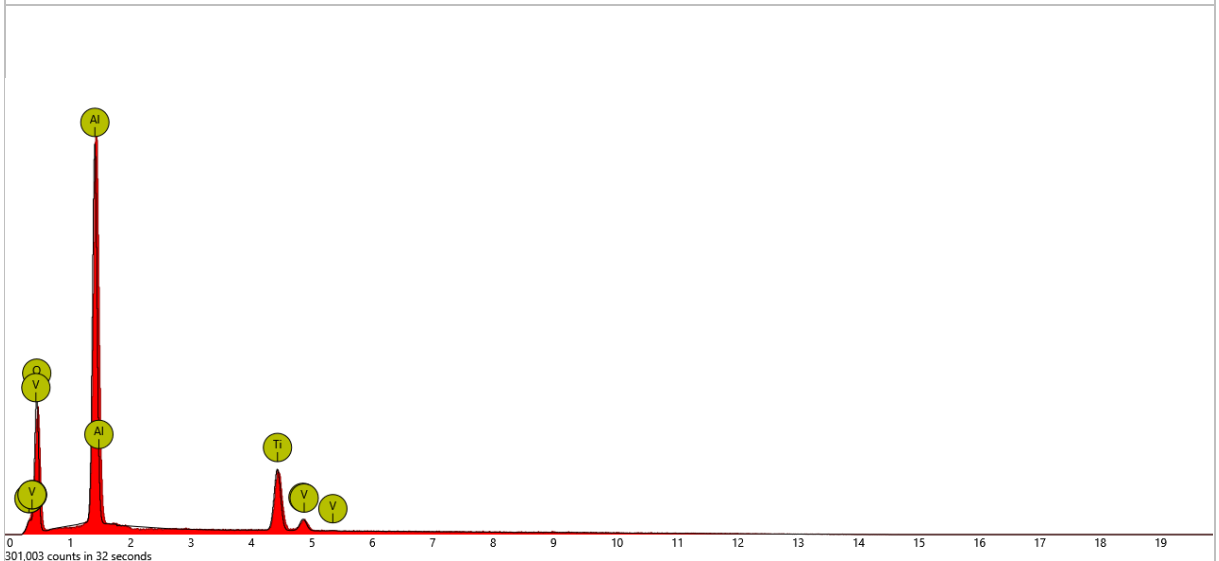


Spot reading #2



Note: Particle of Al_2O_3 as remnant from the blasting process

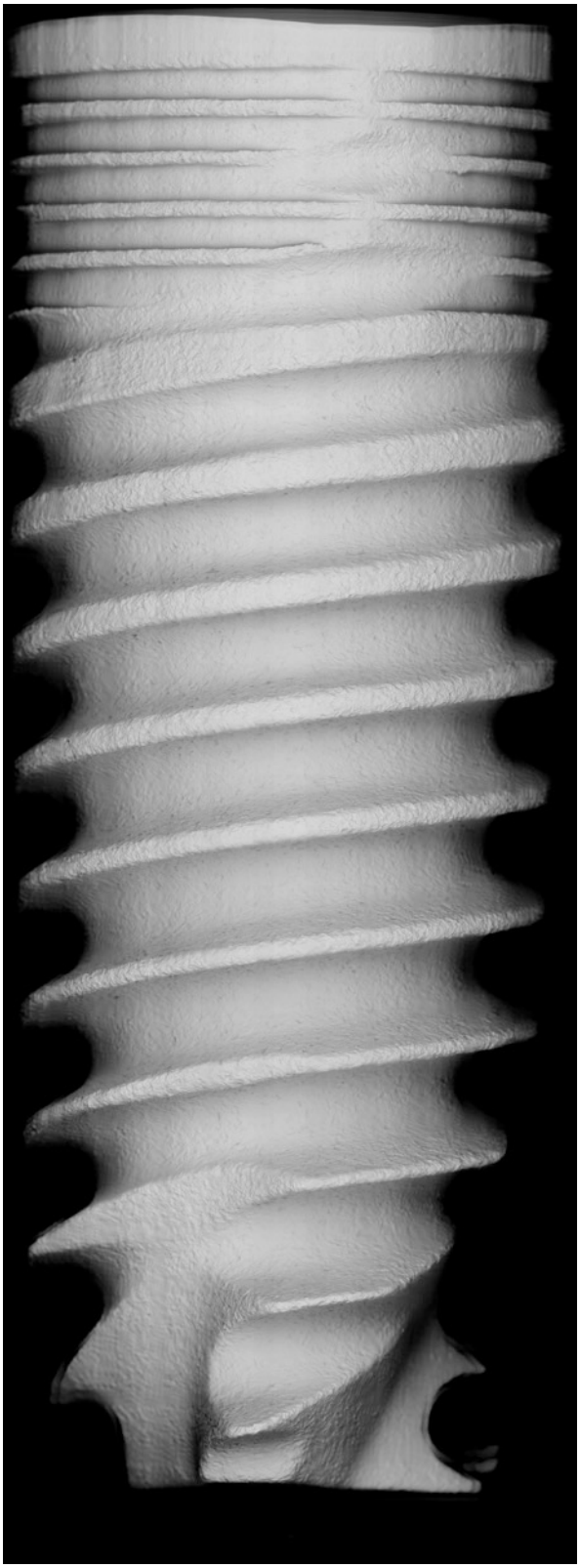
Quantitative elemental analysis



Qualitative elemental analysis

7 Sample #5: V3 D3.9 L10 LOT W17004237

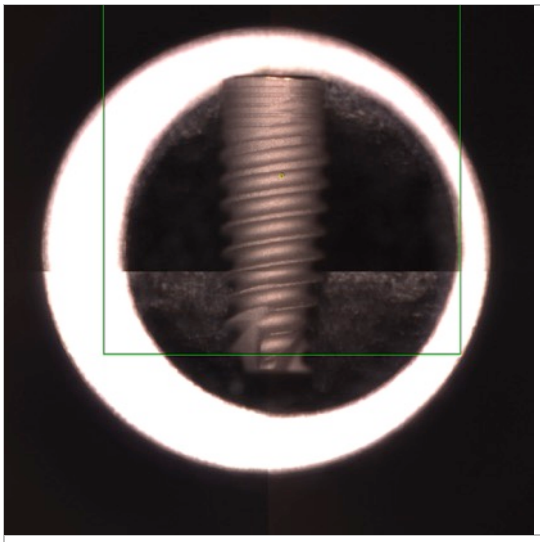
7.1 Full-Size High-Resolution SEM Image



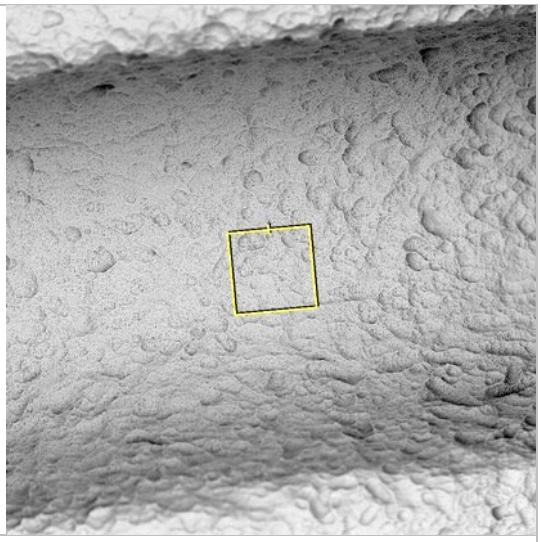
FSHR-SEM image (digitally composed, approx. 500x)

7.2 SEM Imaging Sample #5

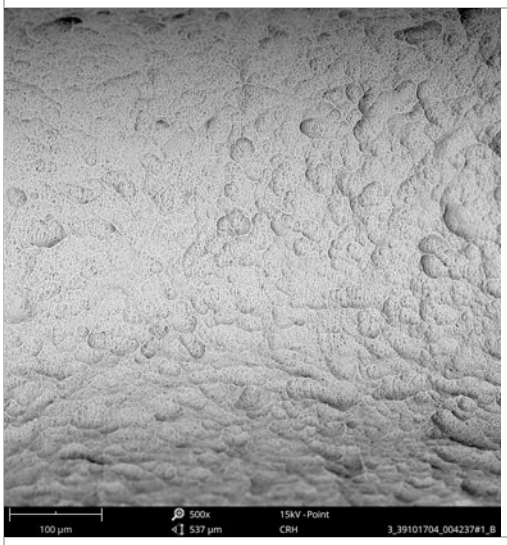
7.2.1 SEM Images Implant Body



Phenom camera

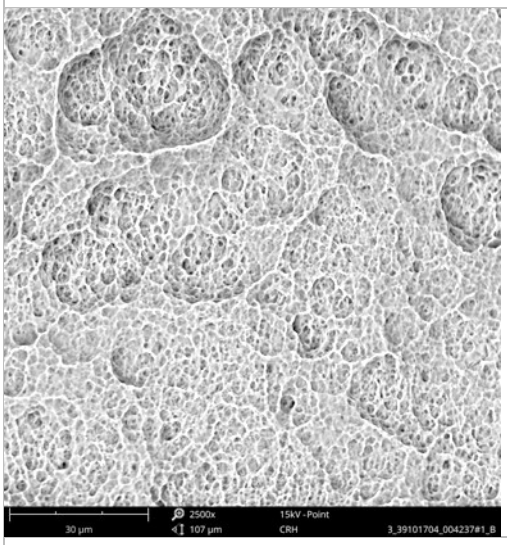


Field of view



500x

1.000x



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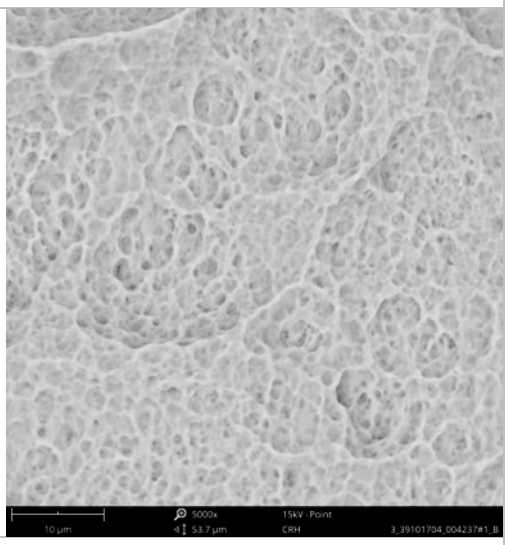
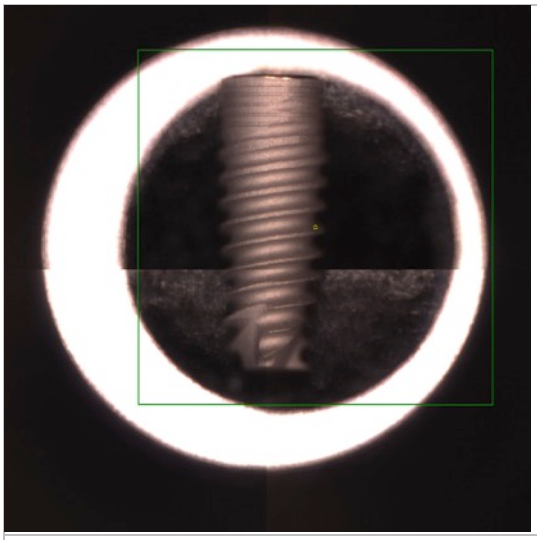
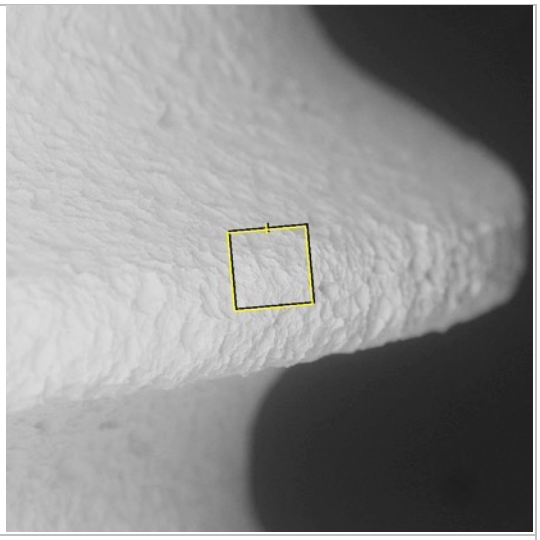


5.000x

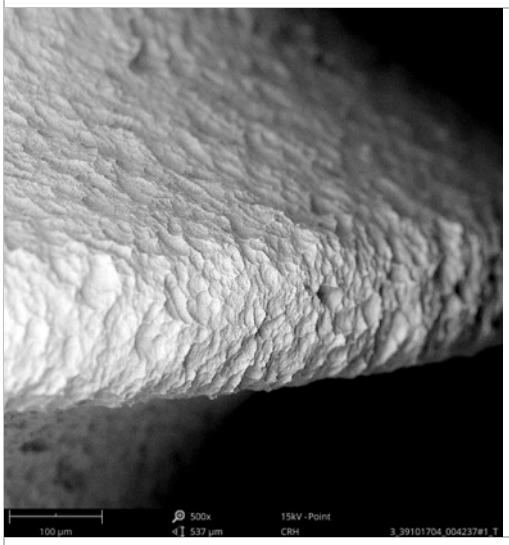
7.2.2 SEM Images Implant Thread



Phenom camera



Field of view



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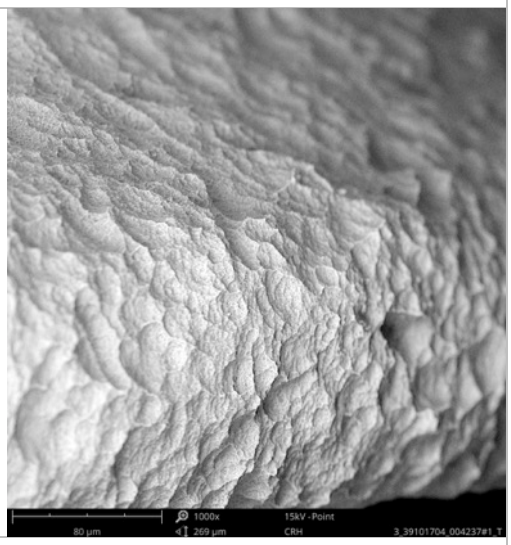

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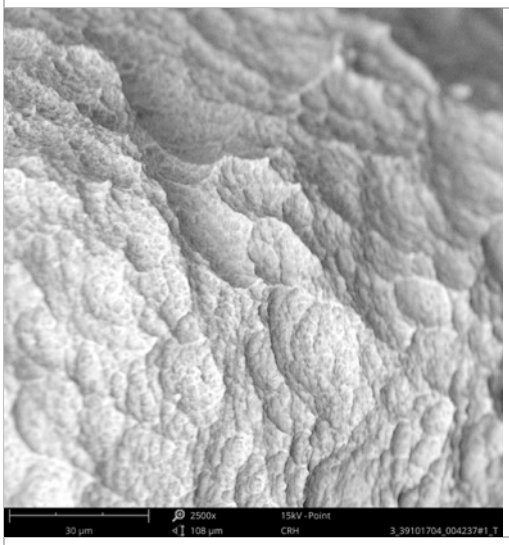

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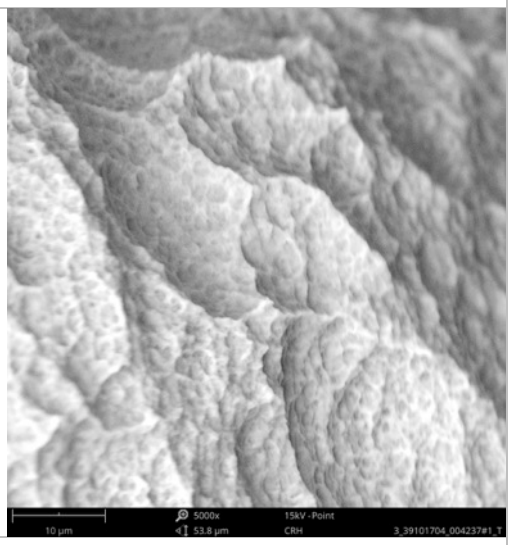

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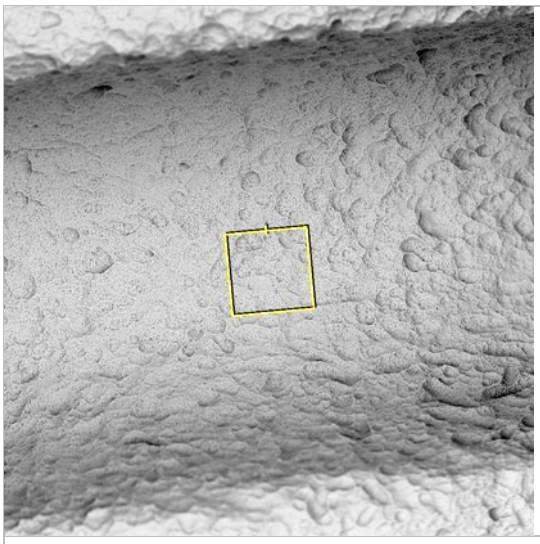
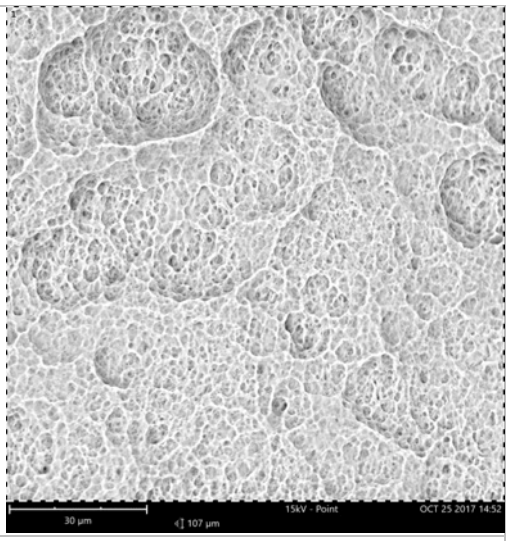
Elemental Analysis (EDS) Sample #5

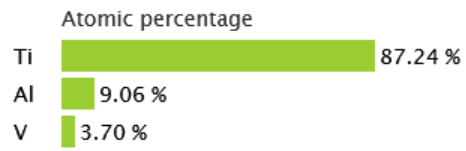
7.2.3 EDS Area Analysis



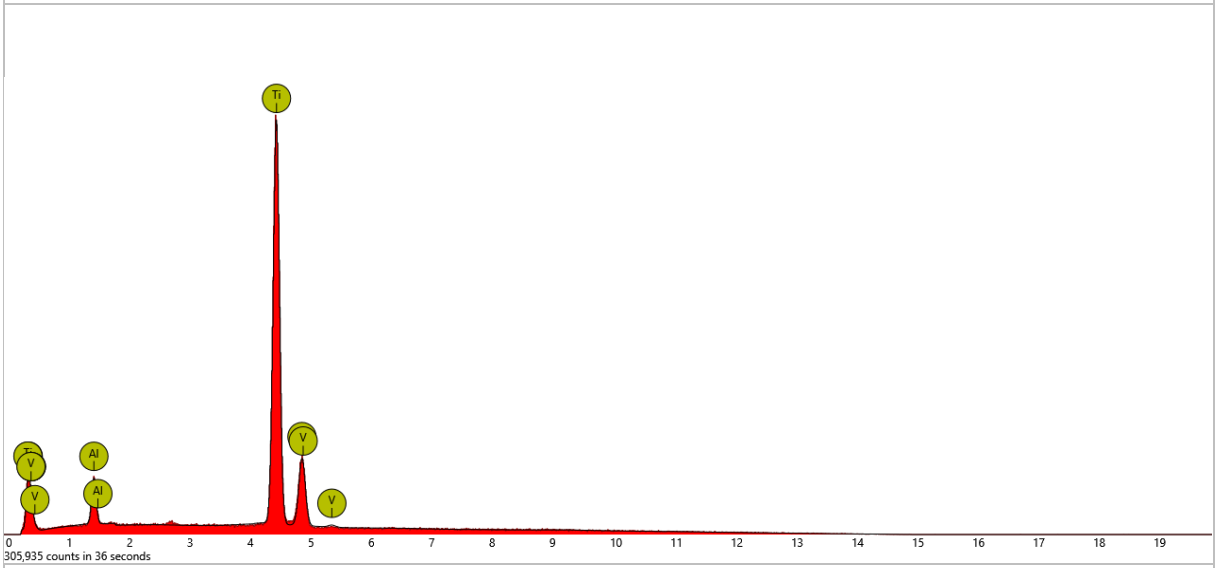
Field of view



Area analysis



Quantitative elemental analysis



Qualitative elemental analysis

8 Synopsis

Name of Manufacturer:	MIS Implants Technologies
Analyzed Product(s):	V3 D4.3 L13 LOT W17005210 (ex factory) V3 D4.3 L13 LOT W17005210 (ex factory) V3 D4.3 L13 LOT W17005210 (ex factory) V3 D3.9 L10 LOT W16012292 V3 D3.9 L10 LOT W17004237
Investigator/s:	Dr. Dirk U. Duddeck
Analyses carried out by:	mmri.berlin - medical materials research institute berlin
Analysis period:	August - November 2017
Methodology:	Phenom proX Scanning Electron Microscope, equipped with high-sensitivity backscattered electron detector; EDS Analysis detector type: Silicon Drift Detector (SDD) Thermoelectrically cooled (LN_2 free), Detector active area: 25 mm^2, Ultra-thin Silicon Nitride (Si_3N_4) X-ray window allowing detection of elements C to Am, Energy resolution Mn Kα ≤ 140 eV, Max. Input count rate: 300,000 cps
Summary/Conclusions:	Organic particles were not found. Only one implant (sample #4) showed aluminum-oxide particles (20-30µm, random distribution) as remnants of the blasting process. Requested clinical documentation of implants from the device family was provided. Two peer-reviewed publications with 14 months follow-up of 112 implants (JOMI, 2014) and 24 months follow-up of 33 implants (JOURNAL OF OSSEOINTEGRATION, 2016) showed survival rates of 100 percent (see summary of articles in the appendix). Conclusion: **The implant "V3" from MIS Implants Technologies meets the criteria for the CleanImplant Trusted Quality Mark 2017-2018 (standard version).**

9 COORDINATING INVESTIGATOR(S) SIGNATURE(S)

TITLE: Report of Analysis for the “CleanImplant Trusted Quality Mark 2017-2018”

AUTHOR OF REPORT: Dr. Dirk U. Duddeck

Principal Investigator and Managing Director CleanImplant Foundation
Guest researcher at the Charité University Medicine Berlin - Campus Benjamin Franklin
Department of Prosthodontics, Head: Prof. Dr. Florian Beuer

eMail: duddeck@cleanimplant.com

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

PRINCIPAL INVESTIGATOR: Dr. Dirk U. Duddeck

DATE: November 23, 2017

10 PEER REVIEW SIGNATURES

We confirm that the information provided in this report meets the Criteria for the CleanImplant Trusted Quality Mark 2017-2018.

December 1, 2017
Prof. Dr. Ann Wennerberg
CleanImplant Scientific Advisory Board

December 1, 2017
Univ.-Prof. Dr. Florian Beuer MME
CleanImplant Scientific Advisory Board

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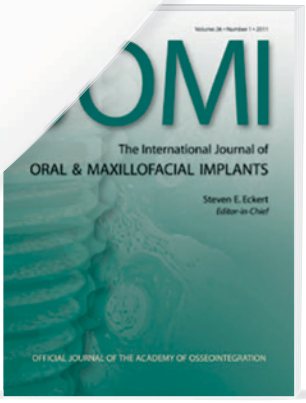
November/December 2014 | Published in: JOMI

Implant Survival Rate and Marginal Bone Loss of 6-mm Short Implants: A 2-Year Clinical Report.”*

Emanuel Bratu, PhD, DMD; Hsun-Liang Chan, MS, DDS; Sorin Mihali, DMD; Olimpiu Karancsi, DMD; Dana Christina Bratu, PhD, DMD; Jia-Hui Fu, MS, BDS; Hom-Lay Wang, PhD, MS, DDS



*Bratu E, Chan HL, Mihali S, Karancsi O, Bratu DC, Fu JH, Wang HL. Implant survival rate and marginal bone loss of 6-mm short implants: a 2-year clinical report. Int J Oral Maxillofac Implants. 2014 Nov-Dec;29(6):1425-8. doi: 10.11607/jomi.3729

[1]Emanuel Bratu
[2]Hsun-Liang Chan
[3]Sorin Mihali
[4]Olimpiu Karancsi
[5]Dana Christina Bratu
[6]Jia-Hui Fu
[7]Hom-Lay Wang

"Implant Survival Rate and Marginal Bone Loss of 6-mm Short Implants: A 2-Year Clinical Report."

SUMMARY.

Purpose

This study aimed to evaluate (1) the association between implant diameter and marginal bone loss (MBL) of short (6 mm) implants and (2) the survival rates of short implants.

Materials and methods

Thirty-three 6-mm implants (SEVEN®) were placed in the mandibles of 16 qualified patients. The selected sites had > 5 mm ridge width and < 9 mm bone height. None of the implant sites required bone augmentation procedures. All implants were uncovered 3 months after placement, and all patients were rehabilitated with 2- or 3-unit implant-supported fixed partial dentures. Standardized periapical films were taken after 24 months of function. Radiographs were digitalized, and MBL was assessed.

Results

For all implants, the mean MBL was 0.17 mm at the point of uncovering. At the 2-year follow-up, all implants were immobile and functional. Implants with 4.2-mm diameters had significantly more MBL (1.95 mm) than wider implants (0.47 mm and 0.35 mm for 5.0-mm and 6.0-mm implants, respectively).

Conclusion

This 2-year study illustrated that short implants are a viable option in selected clinical scenarios. Short implants with wider diameters are preferred because they have less marginal implant bone loss.

Summary of Mean Marginal Bone Loss (In mm)* Arond 6-mm-Long Implants at Different Time Periods

Implant diameter (mm)	4.2	5.0	6.0
No. implants	9	14	10
Insertion	0	0	0
Stage-two surgery	0.22±0.13	0.12±0.05	0.17±0.04
3m**	0.75±0.12	0.34±0.13	0.26±0.15
6m**	0.95±0.25	0.44±0.22	0.30±0.17
12m**	1.79±0.31	0.47±0.15	0.35±0.13
24m**	1.95±0.24	0.47±0.16	0.35±0.14

*Measured from the platform level to the first radiographic bone-to implant contact. **After functional loading.

Authors' affiliations

[1] Professor and head, Department of implant-supported restorations, Victor-Babes University of Medicine and Pharmacy, School of Dentistry, Timisoara, Romania.

[2]Adjunct Clinical Assistant Professor, Department of Periodontics and Oral Medicine, School of Dentistry, University of Michigan, Ann Arbor, Michigan, USA.

[3]Associate Assistant Professor, Department of Prosthodontics, Victor-Babes University of Medicine and Pharmacy, School of Dentistry, Timisoara, Romania.

[4]Assistant Professor ,Department of Implant – Supported Restorations, Victor-Babes University of Medicine and Pharmacy, School of Dentistry, Timisoara, Romania.

[5]Assistant Professor, Department of orthodontics and Pedodontics, Victor-Babes University of Medicine and Pharmacy, School of Dentistry, Timisoara, Romania.

[6] Assistant Professor, Discipline of Periodontology, Faculty of Dentistry, National University of Singapore, Singapore.

[7]Professor and Director of Graduate Periodontics, Department of Periodontics and Oral Medicine , School of Dentistry, University of Michigan, Ann Arbor, Michigan, USA.

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April
2016

JO JOURNAL OF OSSEOINTEGRATION

Marginal Bone Level Around Conical Connection Tapered Implants with Platform Switching: A Multicenter Retrospective Study at 14 Months Follow-Up"

J. Ekstein; M. Tandelich; J. Nart;
J.L. Calvo Guirado; L. Shapira

Ekstein J, Tandelich M, Nart J, Calvo Guirado JL, Shapira L Marginal bone level around conical connection tapered implants with platform switching: A multicenter retrospective study at 14 months follow-up. Journal Osseointegr, August 2016. DOI: 10.4081/jo.2016.6922

[1] J. Ekstein
[1] M. Tandelich
[2] J. Nart
[3] J.L. Calvo Guirado
[4] L. Shapira

"Marginal Bone Level Around Conical Connection Tapered Implants with Platform Switching: A Multicenter Retrospective Study at 14 Months Follow-Up"

SUMMARY.

Aim

The long-term success of dental implants mainly depends on marginal bone stability around the fixtures. The development of prosthetic abutments with reduced width in relation to the implant prosthetic platform (platform switching) and/or tighter implant/abutment connections seem to have a potential in reducing crestal bone resorption. The aim of the present study was to examine the effect of platform switching and conical connection design, on marginal bone loss around newly designed dental implants.

Methods

Subjects who underwent implant therapy in three different centers, were enrolled in the present retrospective study. Patients were rehabilitated with tapered platform-switched dental implants. To evaluate marginal bone level changes over time, the mesial and distal bone height was radiographically evaluated on the day of implant placement (baseline) and 14 months post-implantation.

Results

One hundred and twelve conical tapered platform-switched implants (C1, MIS Implants Technologies Ltd.) were placed in three different centers in 37 patients, with mean age of 53 years. The survival rate was 100% after an average follow-up of 14 months. During the first year, marginal bone loss was 0.67±0.45mm. No statistically significant differences were recorded between the different centers.

Conclusions

Within the limitations of the present retrospective study, limited marginal bone loss and 100% implant survival rate were observed over 14 months of follow-up. The results showed high crestal bone stability around the newly designed conical tapered platform-switched implants.

1.

2.

Fig.1. Periapical X-rays – day of stage 2 surgery.

Fig.2. Periapical X-rays – 1 year results.

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[1] Department of Periodontology, the Hebrew University – Hadassah Faculty of Dental Medicine, Jerusalem, Israel

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