

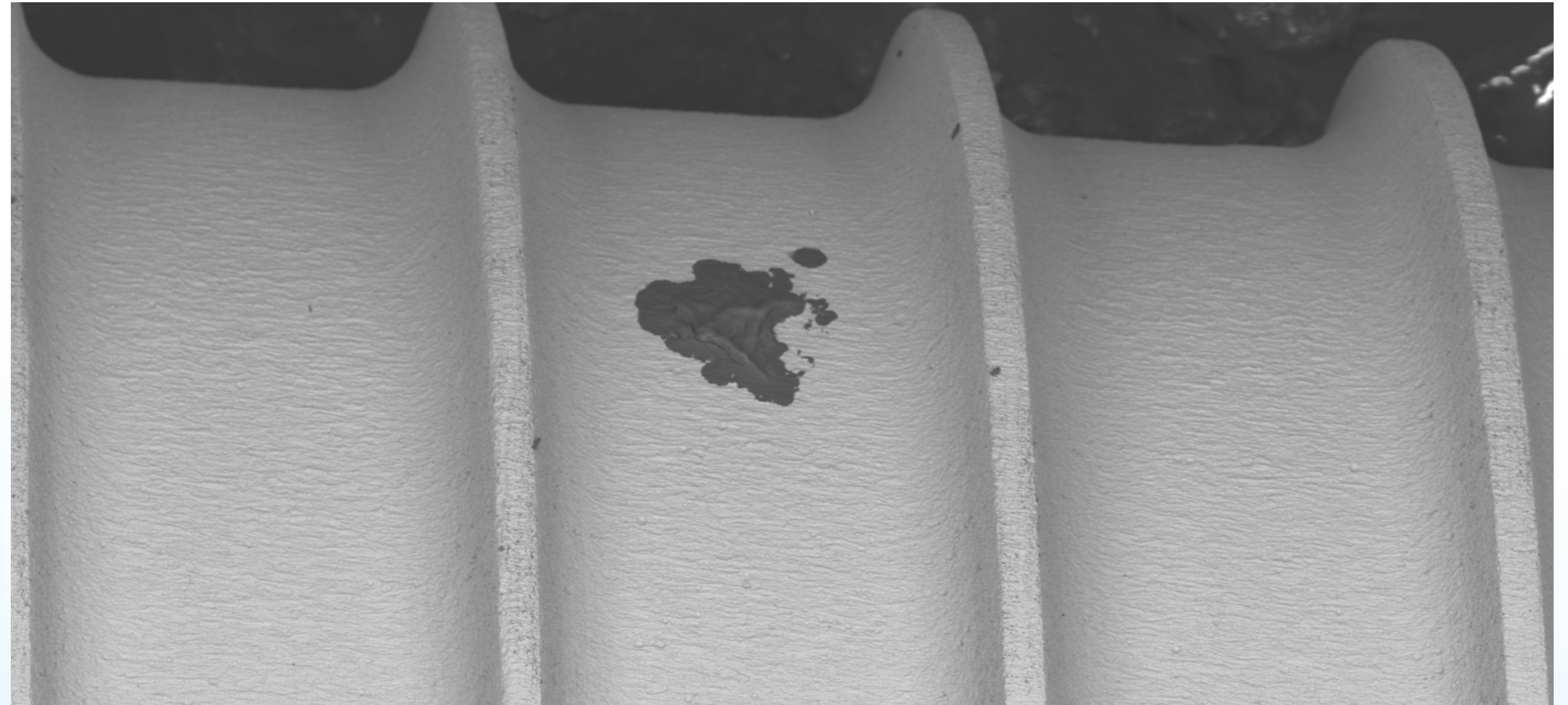
Assessing the cleanliness of dental implants using scanning electron microscope (SEM) and Energy-dispersive X-ray spectroscopy analysis (EDS)

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Aim

To assess contamination of different implant systems.
To evaluate the effect of exposing the implants prematurely
during surgery on surface contamination.



Introduction

Cleanliness of the dental implant surface is one of the factors affecting osteointegration. The cleanliness of the surface may be jeopardized during the many steps of manufacturing.

Materials and Methods

Three systems were evaluated. Fifteen implants per system were examined with 30x, 100x , and 200x magnification using a scanning electron microscope (SEM) to identify and count foreign particles.

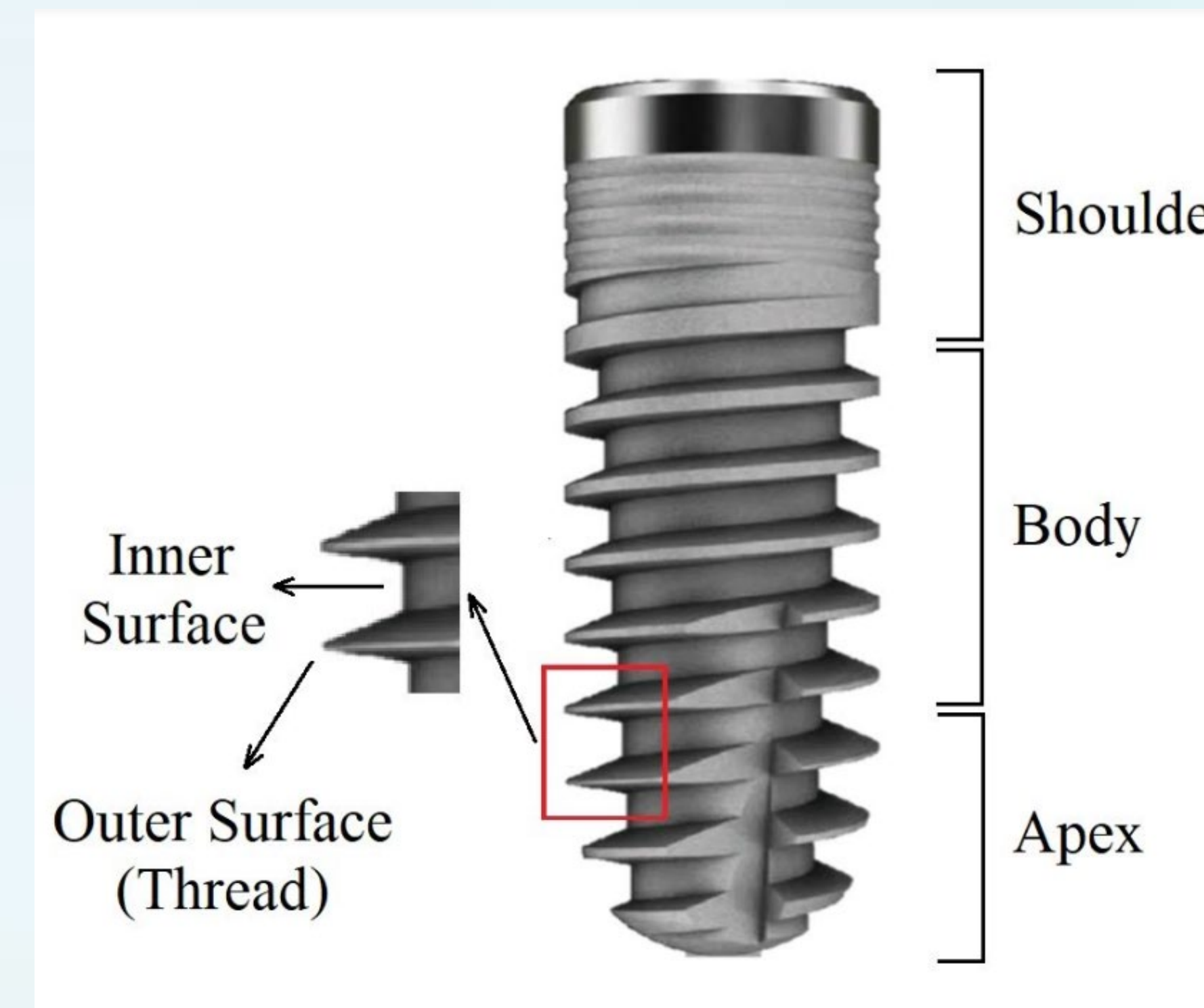
The chemical composition was analyzed using energy-dispersive X-ray spectroscopy (EDS) at 400x magnification.

Companies

1. Cortex, Dental Implants Industries, LTD, Israel.
2. Keystone Dental, Inc, USA.
3. Zimmer Biomet Holdings, Inc, USA.

Area of interest

1. Shoulder (Sh)
2. Body (B)
3. Apex (A)



Statistical power

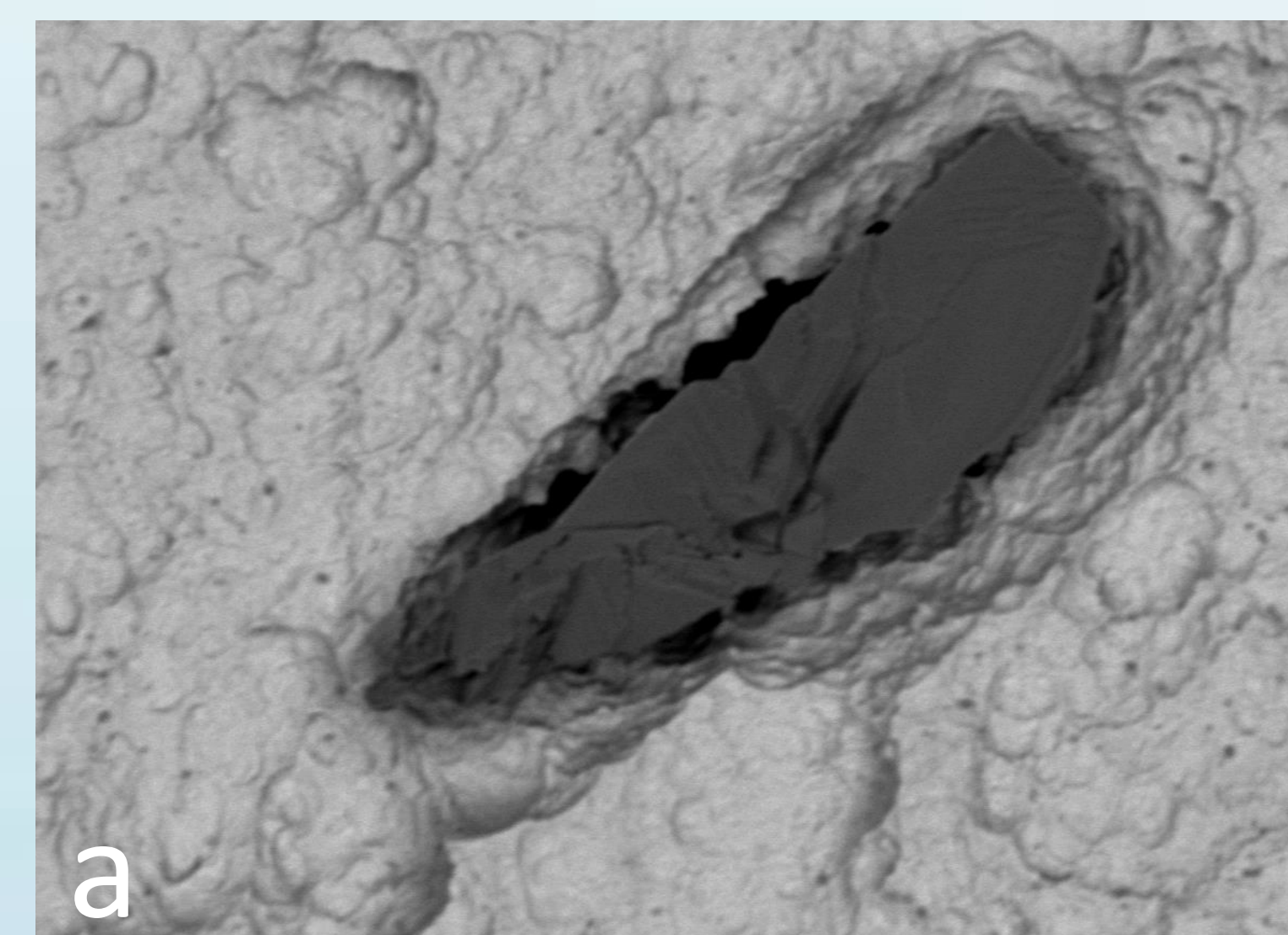
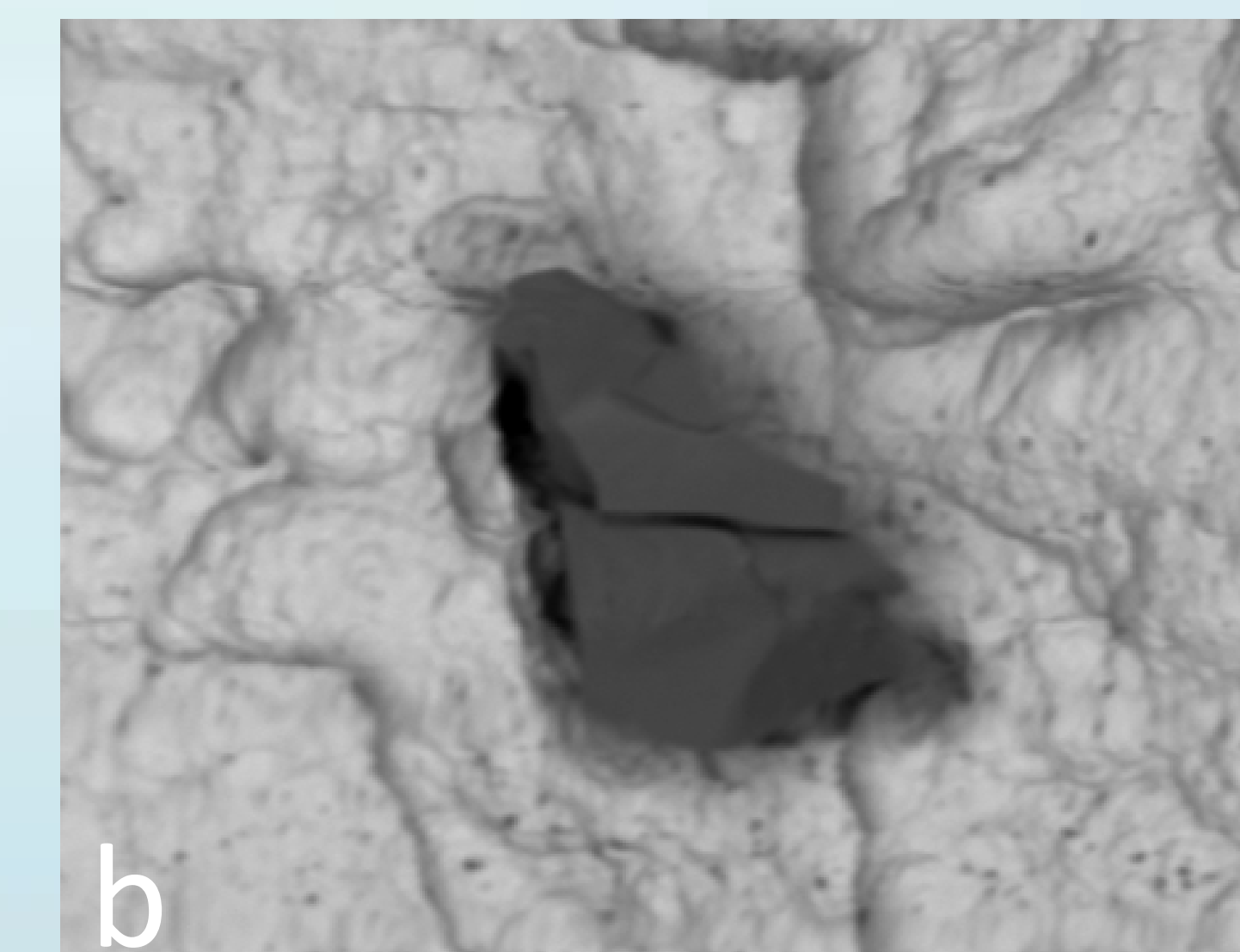
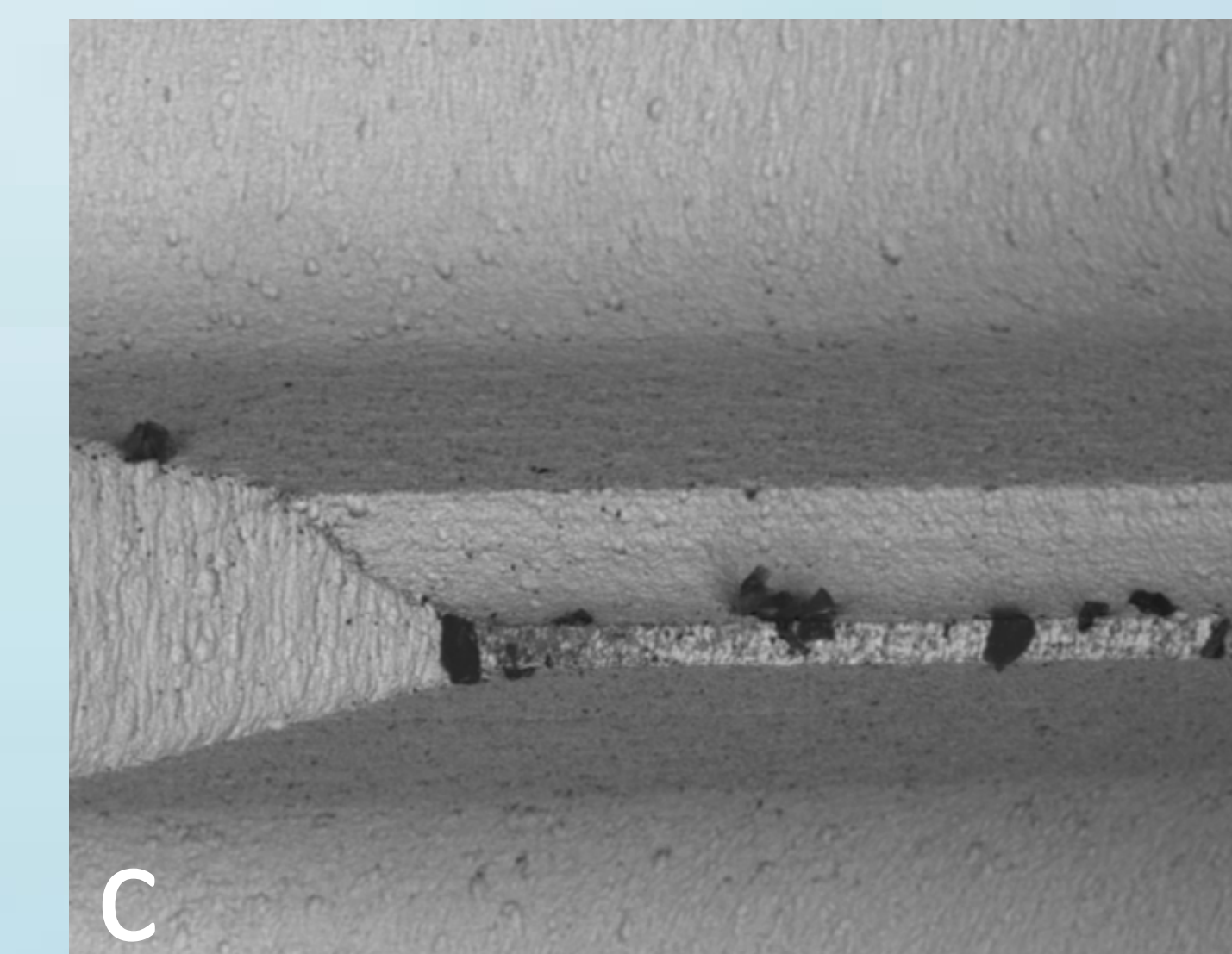
- 15 Implants per company.
- 3 Areas evaluated separately.
- Particles size subdivision:
 - Small $< 8 \mu\text{m}$
 - Large $> 20 \mu\text{m}$
 - Medium $> 8 \mu\text{m}$ and $< 20 \mu\text{m}$
- Quantitative comparison in-between the different areas.
- Quantitative comparison between the companies.
- Quantitative comparison between the inner and outer surface of each area.
- EDS analysis on one particle found in each area.
- A second scan after exposing the implants to rooms air for 10 minutes.

SEM

Back scattered electron (BSE) provides compositional image
Black particle = Organic contamination.

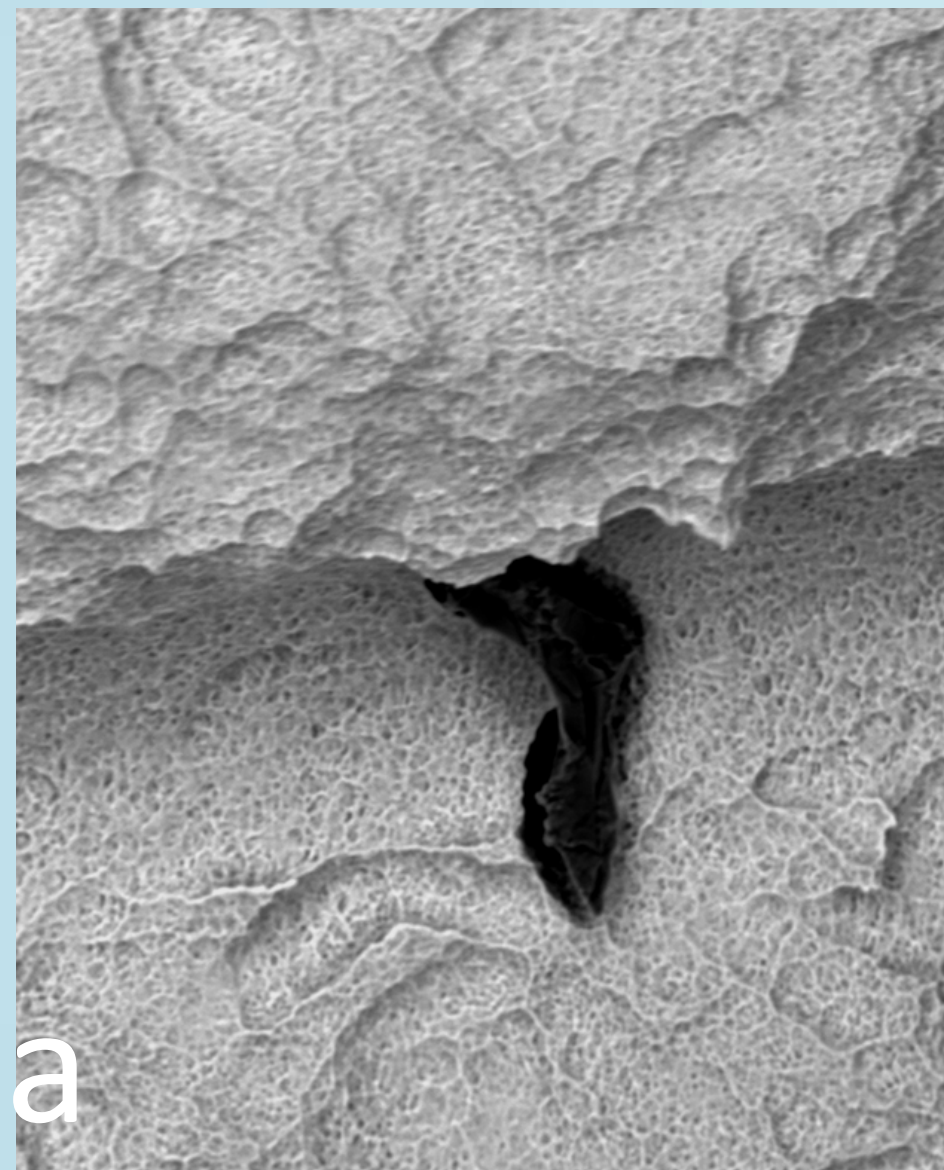
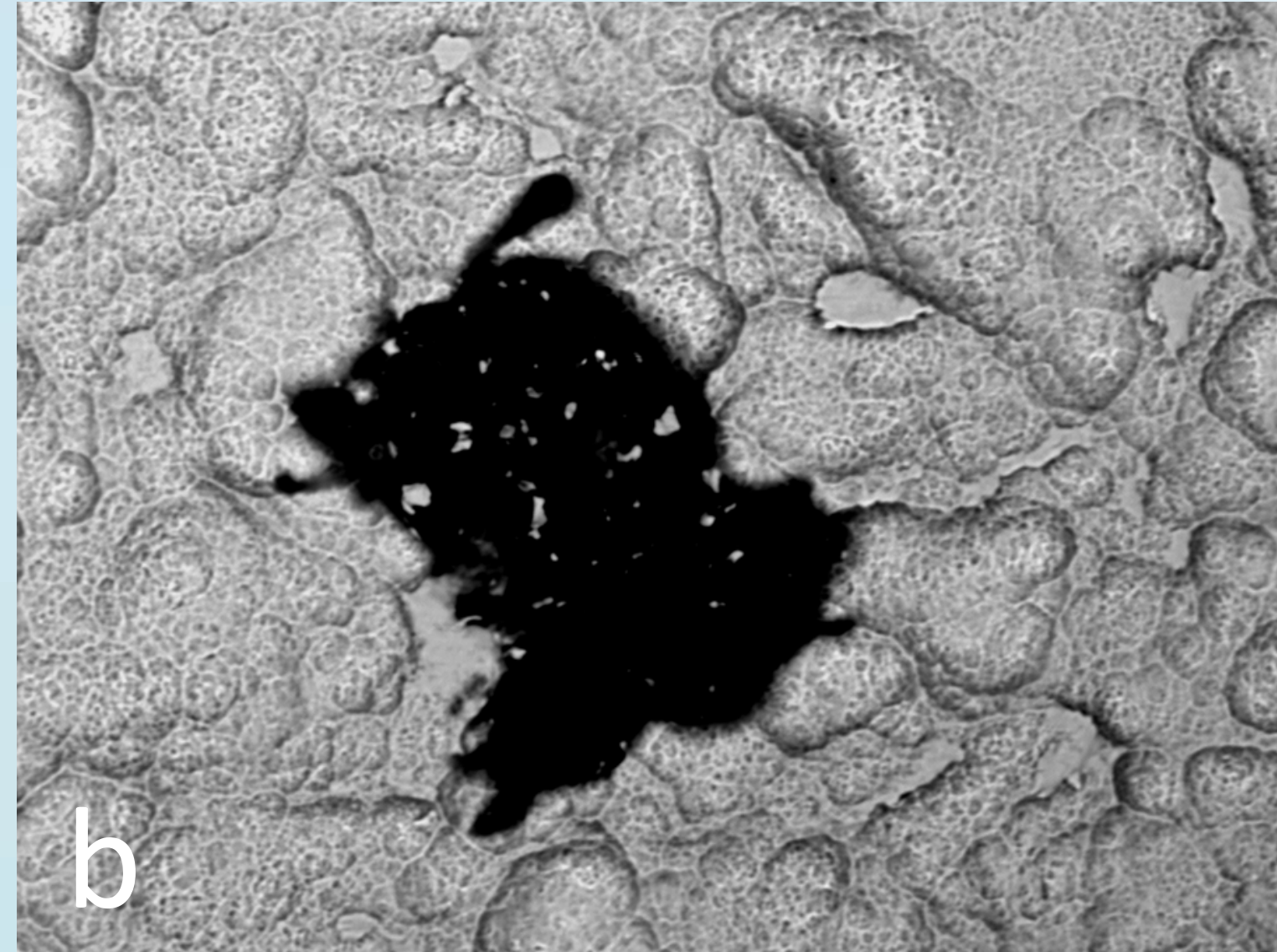
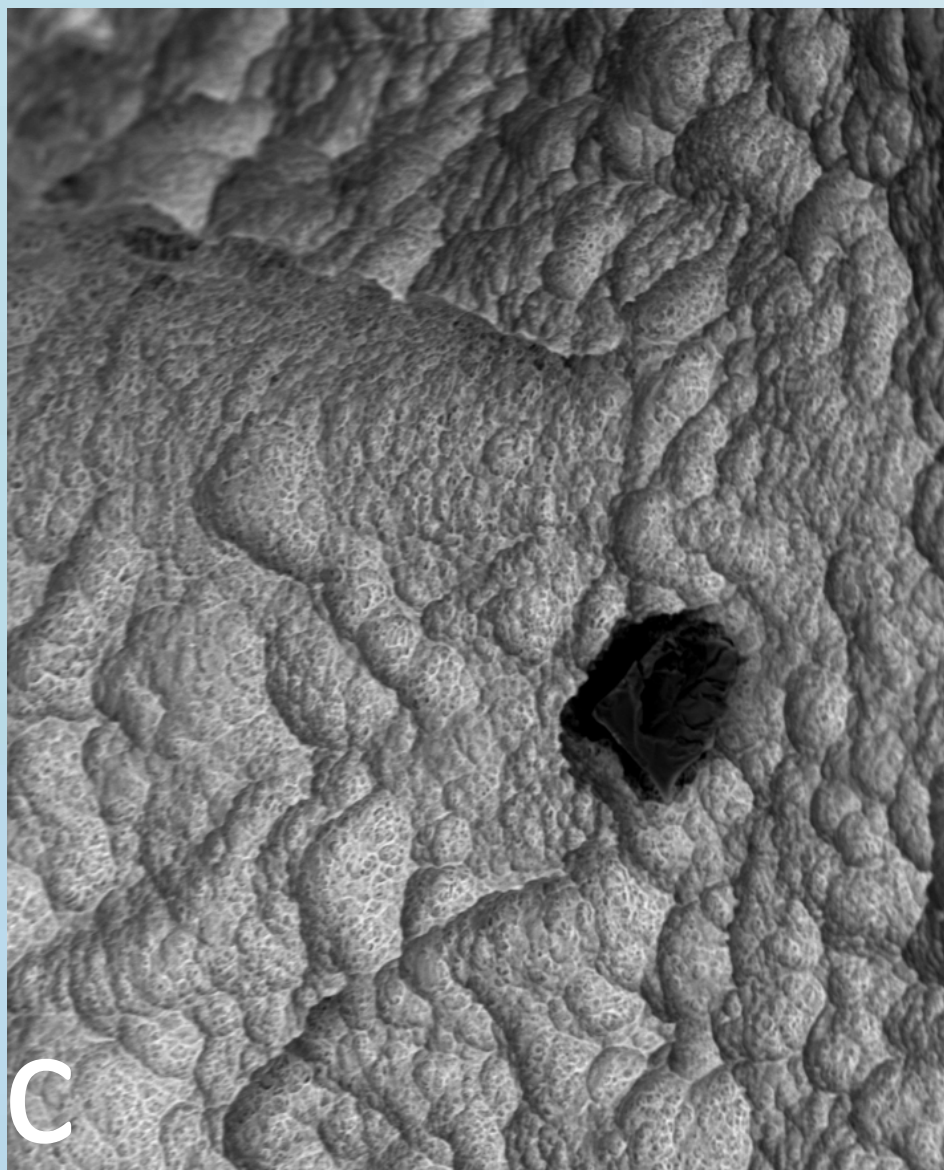
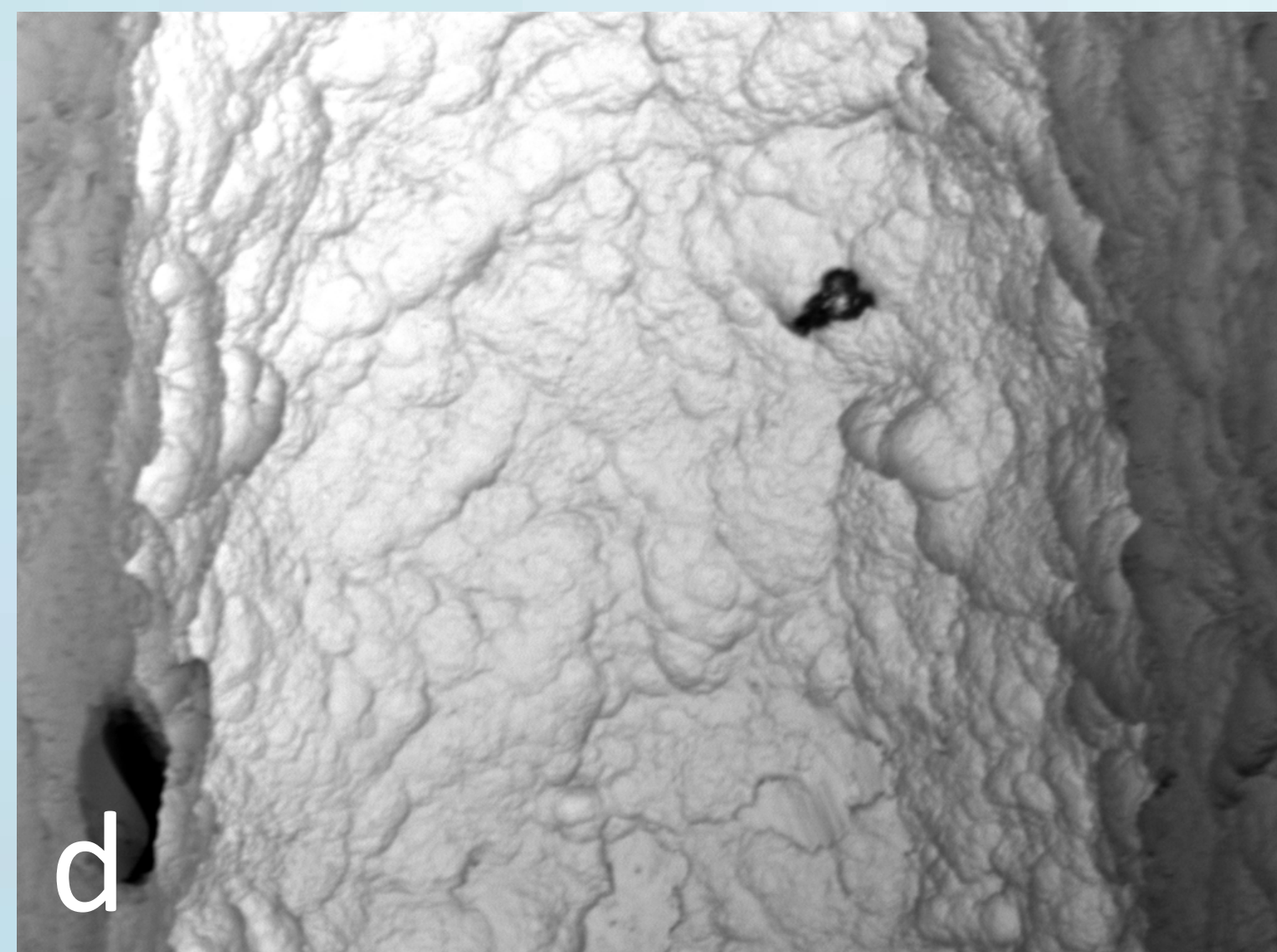
Low accelerating voltage (5kV) provides higher sensitivity for detecting organic contaminations.

Particles found on different implants and companies. Single well-defined particles (a+b).
Several particle on the outer surface of the implant(c).



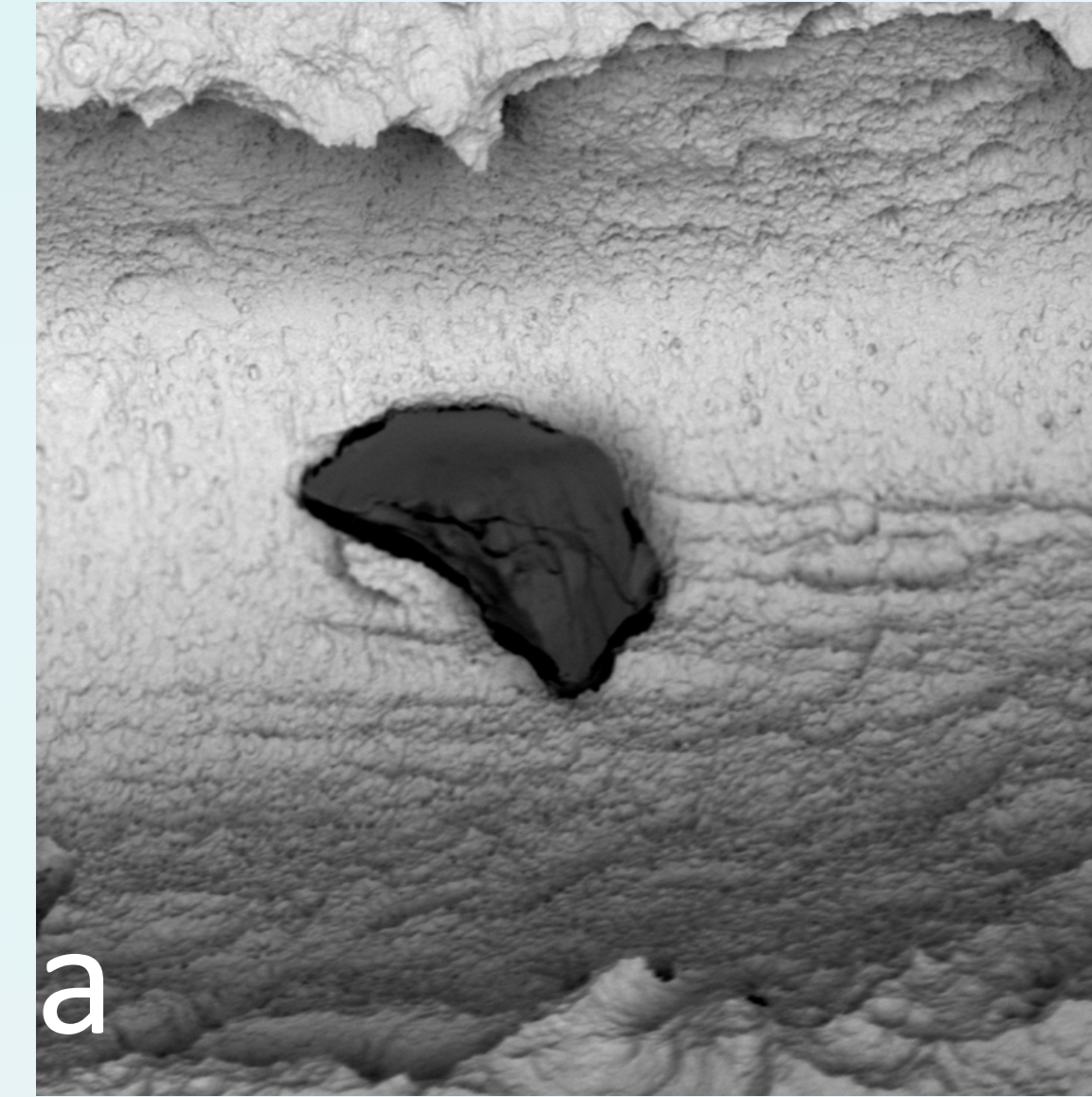
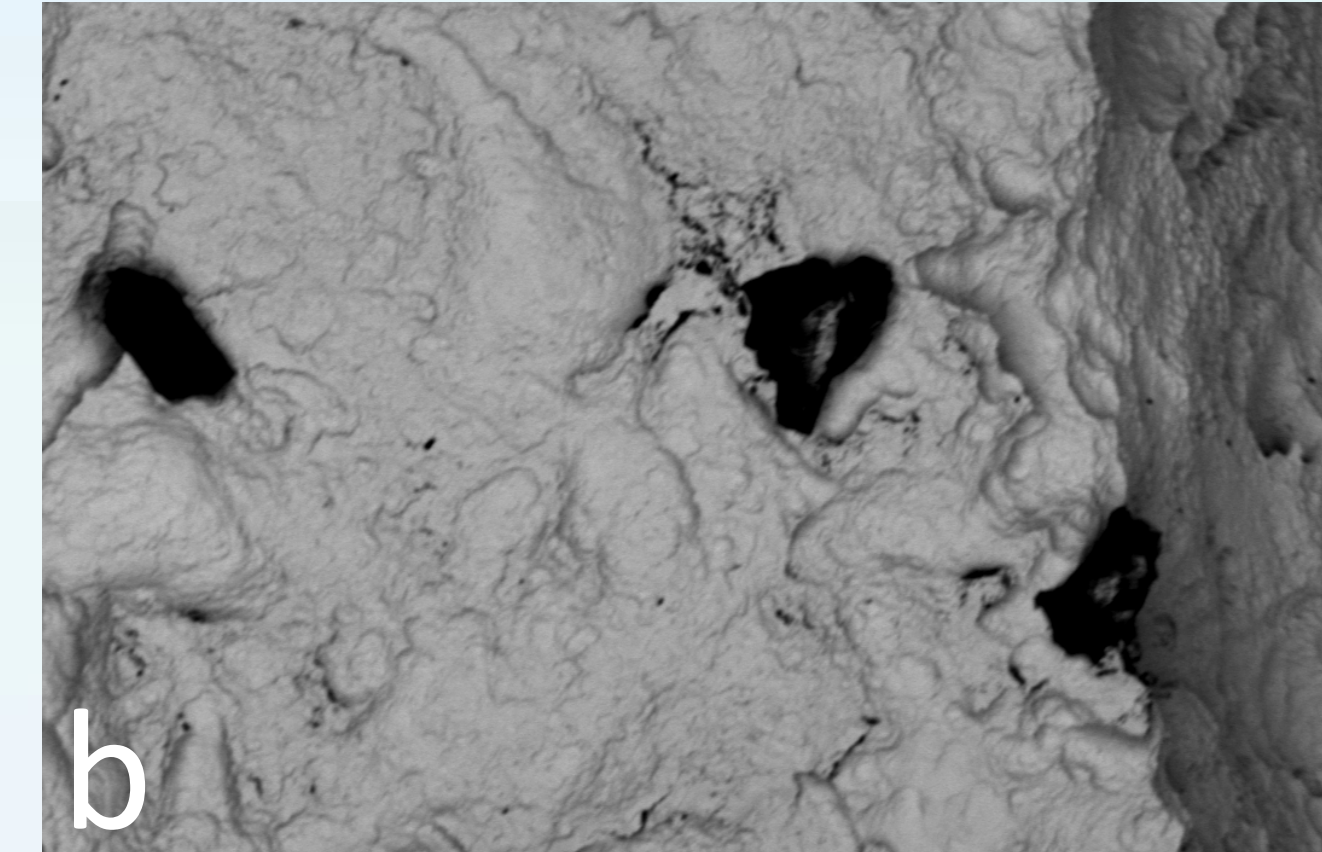
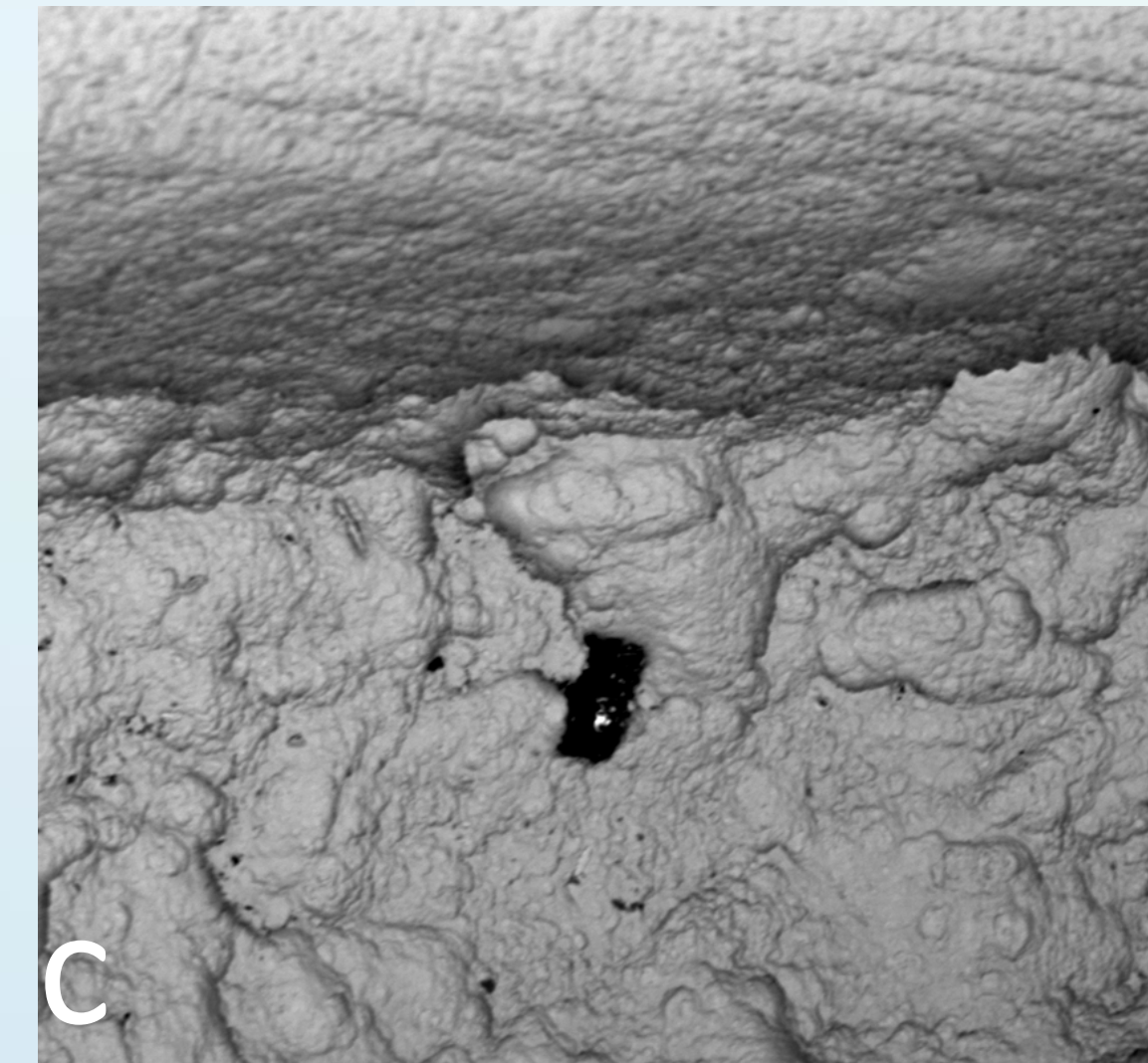
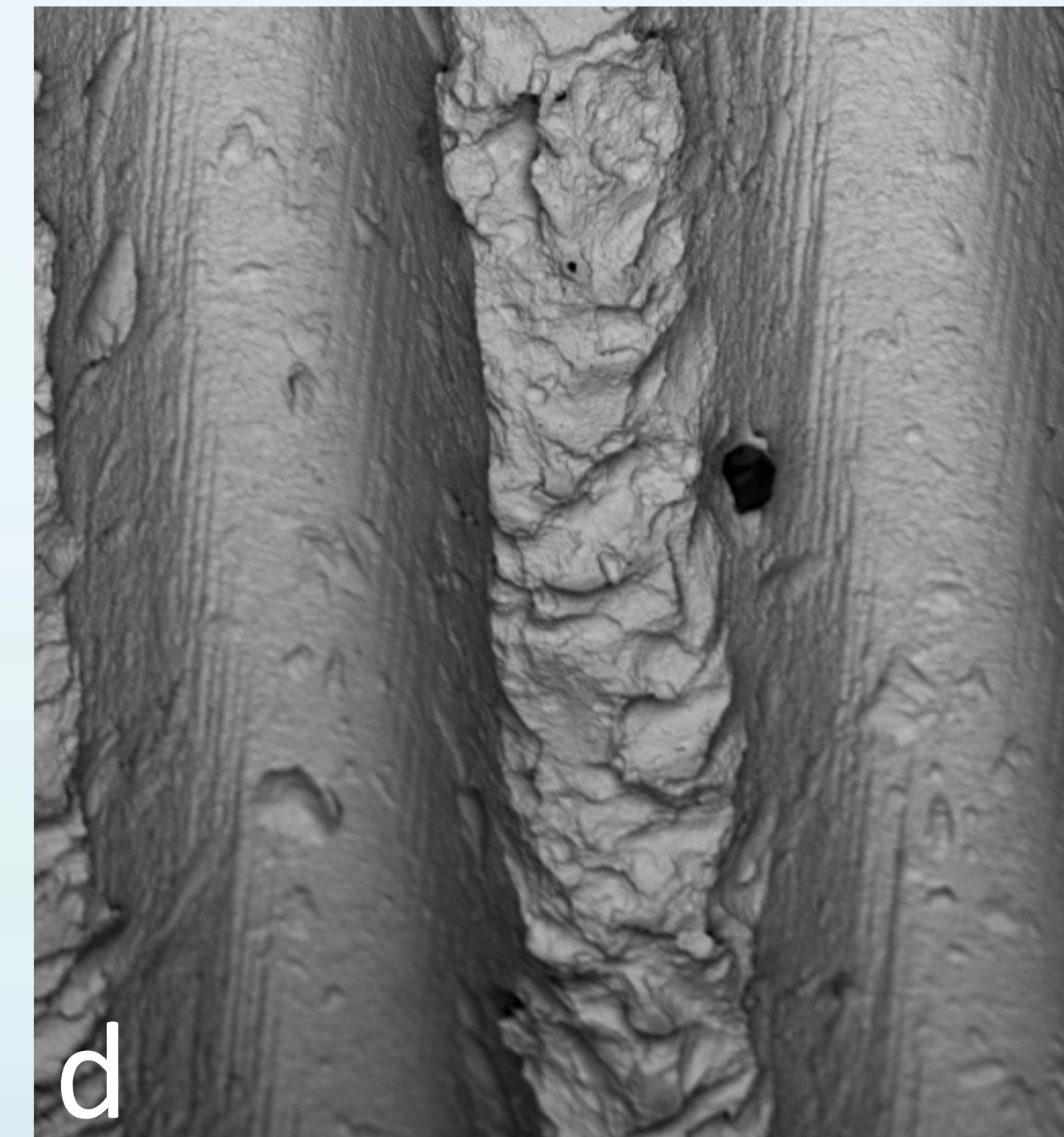
Cortex

SEM images (400x) on Cortex dental implants. Oblong well-defined particle(a). Large irregular particle with smaller particles on its surface (b). Square like particle with a rounded side(c). Two separated particles with different size (d).



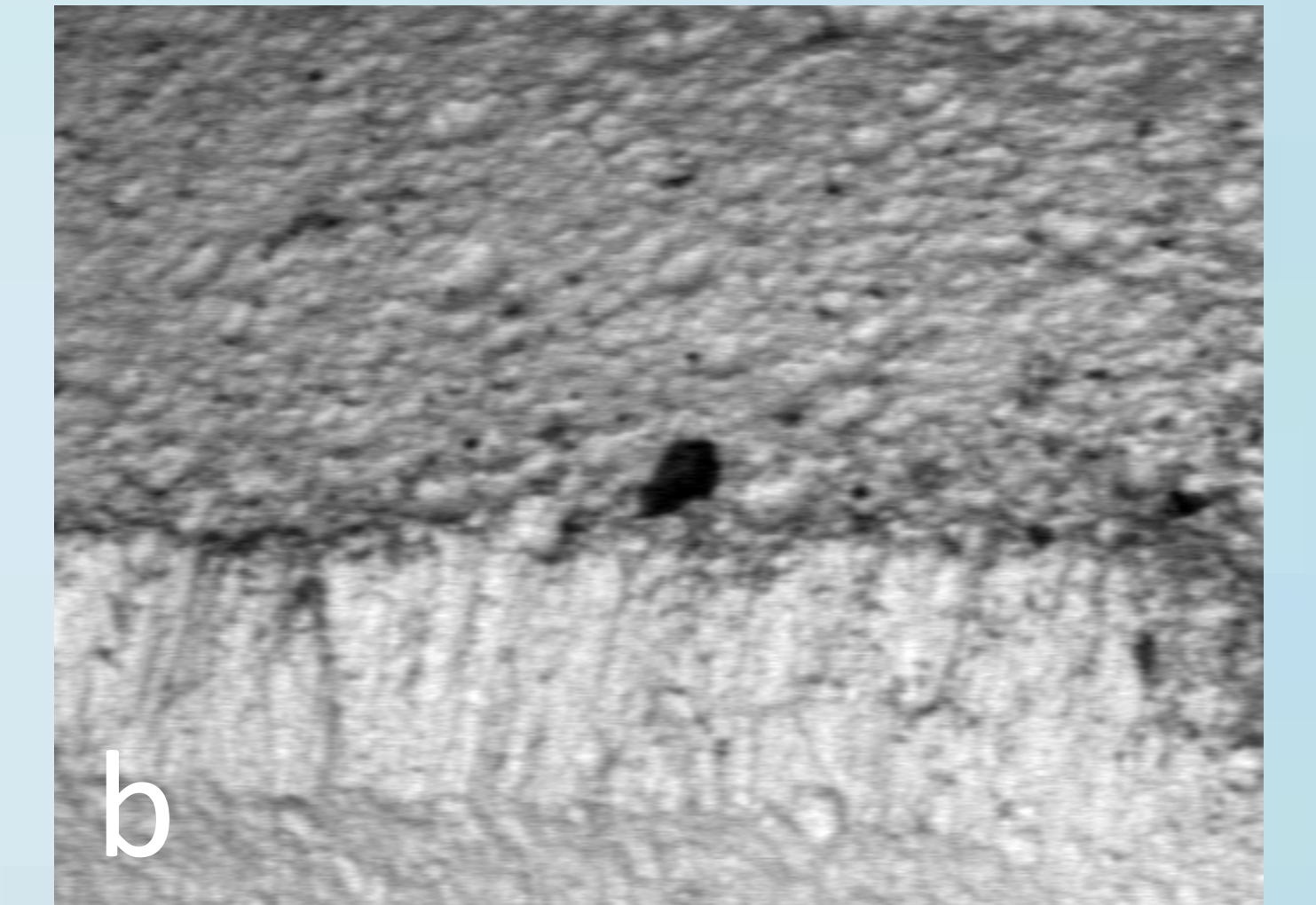
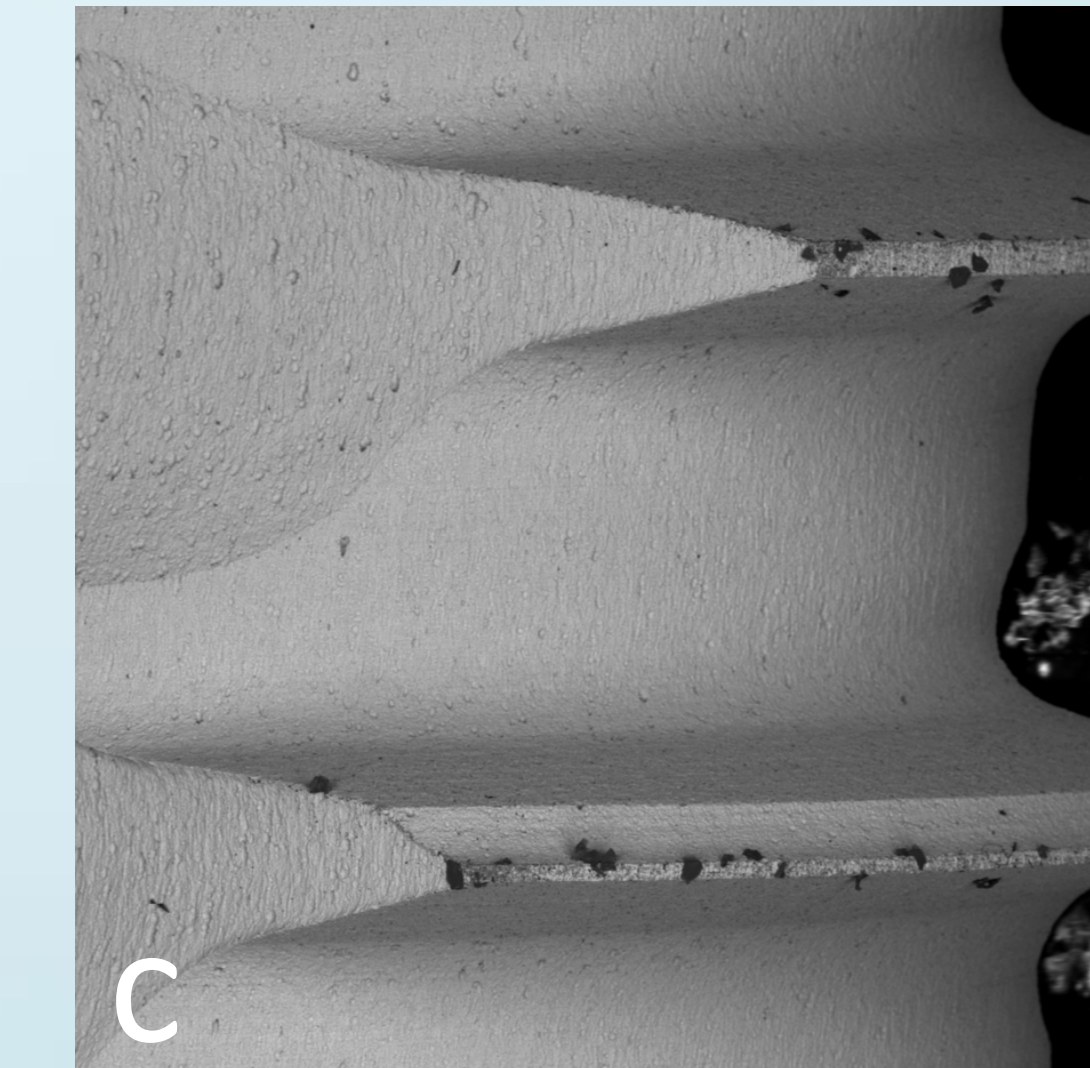
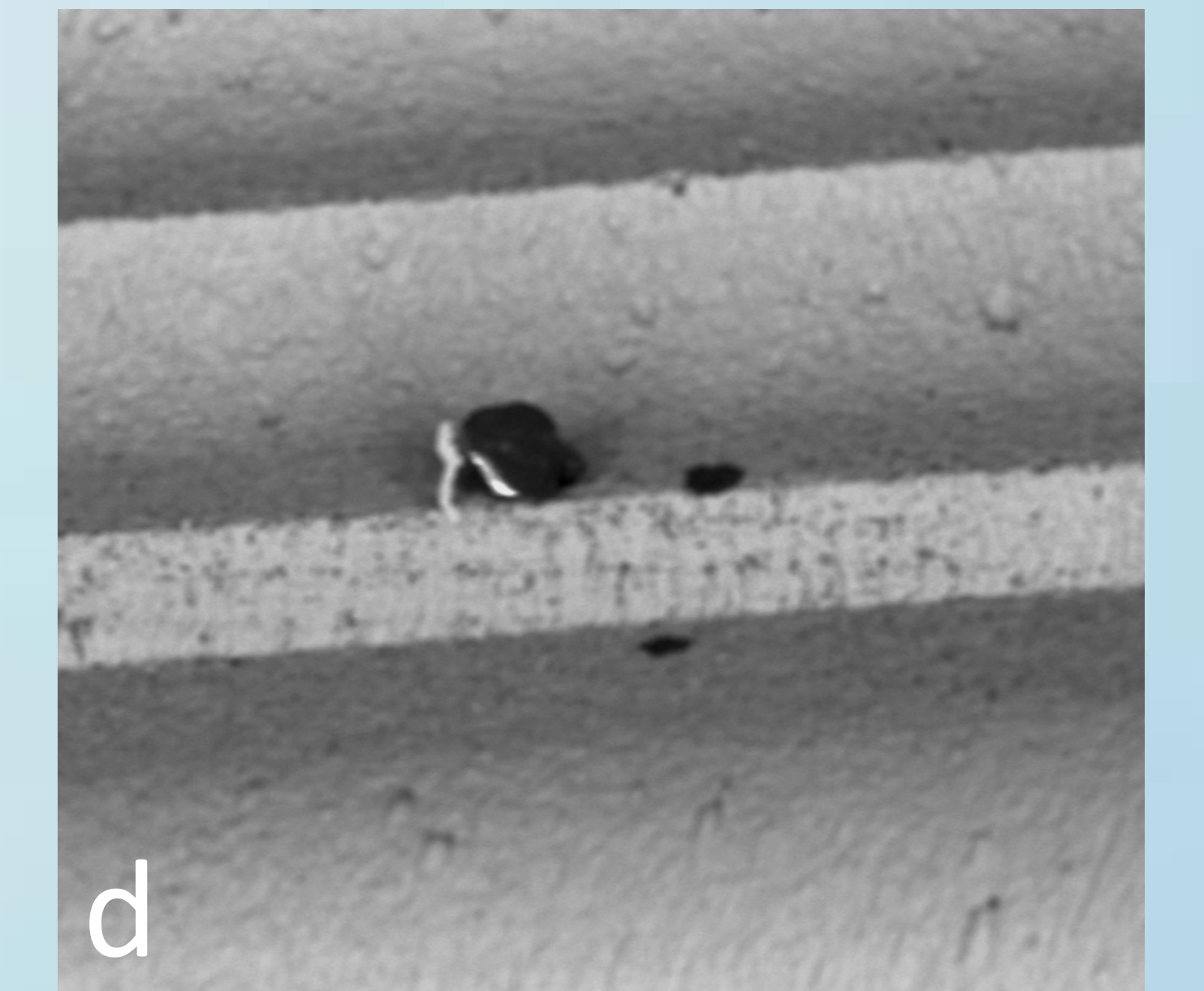
Keystone

SEM images (400x) on Keystone dental implants. Bended rectangular particle (a). Three large particles surrounded by smaller particles (b). Rectangular particle with nonorganic elements on its surface(c). Single particle imbedded in the thread(d).



Zimmer

SEM images Zimmer Biomet dental implants. Very large irregular particle(a). a "touch-like" contamination at the apex(b). Several particles on the outer surface area(c). A large particle with two adjacent flat particles (d).



Company Elements	Cortex			Keystone			Zimmer		
	Mean%	SD	(n)	Mean%	SD	(n)	Mean%	SD	(n)
C	57.3	±31.62	13	42.94	±19.71	15	37.52	±12.18	15
N	44.51	25.75 ±	13	40.32	±13.03	13	49	±13.76	15
Al	19.47	14.3 ±	14	24.23	±14.77	13	35.62	±42.85	3
O	27.27	±15.76	14	27.67	±12.53	15	21.15	±10.15	14
Ti	87.21	±3.91	5	9.09	-	1	86.1	±3.13	2
Si	6.33	9.3 ±	3	5.07	±4.5	5	7.18	±11.5	5
S	0.76	-	1	0.89	±0.39	5	0.64	±0.2	9
Ca	0	-	0	14.6	-	1	10.09	±5.37	8
Na	0.95	±0.6	2	1.33	±1.05	3	0.68	±0.27	6
Mg	2.84	-	1	9.11	±11.06	2	8.89	±9.5	2
Cu	0	-	0	2.5	±0.03	2	0	-	0
F	0	-	0	5.77	-	1	0	-	0
Cl	0	-	0	0.28	-	1	12.16	-	1
Fe	20.67	-	1	0	-	0	5.31	-	1
P	1.2	0.45 ±	4	0	-	0	2.1	-	1
V	66.61	-	1	0	-	0	0	-	0

Elements distribution on implants (n) and their concentration by mass (wt%) in the particles found on the dental implants with EDS. Four elements dominated on most implants: carbon, nitrogen, aluminum, oxygen. Zimmer had aluminum on 3 implants only. other foreign elements were detected in small amounts and in a few implants. It is suggested that the origin of **Oxygen** could be the Ti oxide layer, adsorbed water, and organic compounds. **Aluminum** residuals is attributed to sandblasting. **Nitrogen's** origin can be attributed to Ti nitride, ammonium and organic nitrogen-containing species. **Carbon** contamination is attributed to contaminated metals, lubricants, aging, and storage.

The difference in particles area mean between implant's brands. Significantly more L and S contaminants on the Zimmer Biomet's dental implants than on the other two brands.

Particle Implant Size Brand	L ¹		M ²		S ³	
	Mean%	SD	Mean%	SD	Mean%	SD
Cortex	1.46	±0.33	0.97	±0.21	1.89	±0.8
Keystone	1.80	±0.38	1.12	±0.3	3.33	±0.5
Zimmer Biomet	3.58	±0.73	1.52	±0.25	5.59	±1.6
P. value	< 0.01		0.052		< 0.01	

1 Large particles > 20 µm

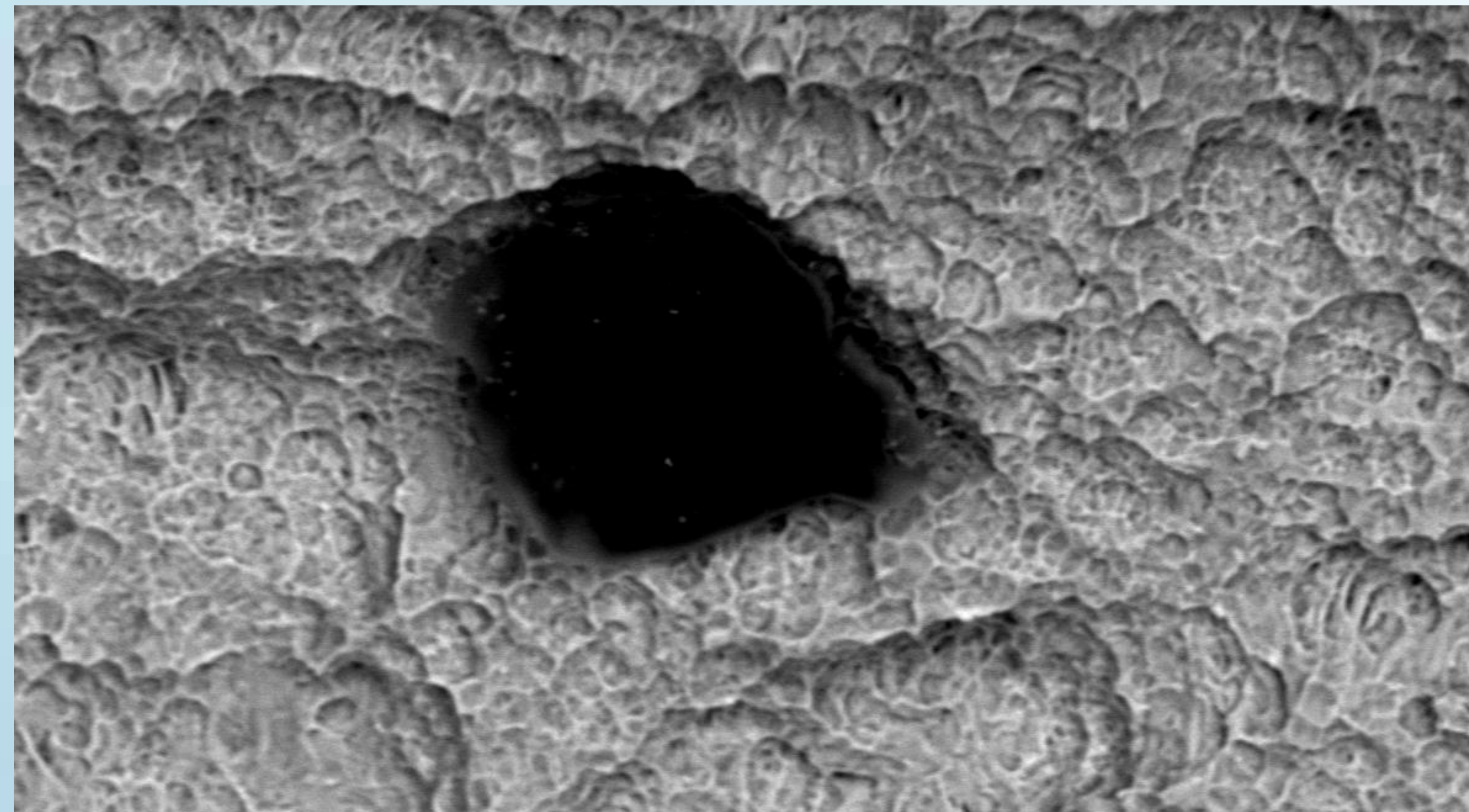
2 Medium particles. Between 8 and 20 µm

3 Small particles < 8µm



Summary of Outcomes

- The apex in Zimmer Biomet's dental implants is more susceptible to contaminations in comparison to the other two areas. Opposite to the other two brands.
- Cortex dental implants had the cleanest surface.
- The implants outer surface is significantly more contaminated than the inner surface ($P < 0.05$).
- No significant difference in the large particles counts after exposing the implants to rooms air ($P > 0.05$).



Conclusions

Within the limitations of this study, it can be concluded that:

- All implants are contaminated to some extent.
- Carbon, oxygen, nitrogen, and aluminum are the most common elements.
- In general, the shoulder and body have the highest contamination counts.
- The outer thread is more prone to contamination.
- Exposing the implant to room air for up to ten minutes during surgery is acceptable but is not recommended.

The importance of the cleanliness of dental implants is gaining more recognition among practitioners and scientists. Simplified and reliable protocols for cleanliness examination need to be developed.

