Quality assessment of dental implants by SEM and EDX analysis

A comparison of five one-piece implants

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Dental implants are supposed to be clean when delivered in a sterile packaging. Implant surface pollution with organic particles and/or major inorganic residues originating from the production process are suspected to cause insufficient or missing osseointegration of dental implants. Unintended micrometer-scale particles may induce a foreign-body reaction with a loss of bone in the early stages of osseointegration. In cooperation with the University of Cologne and the Charité-University Medicine Berlin, the Medical Materials Research Institute Berlin analysed the quality of dental implants in three consecutive studies since 2008.[1,2] In 2015, extensive material contrast images were obtained and qualitative and quantitative elemental analyses were performed on 135 dental implants using the same study protocol. Results of the recent study and comparison with previous analyses showed an increasing spread of quality in the market.

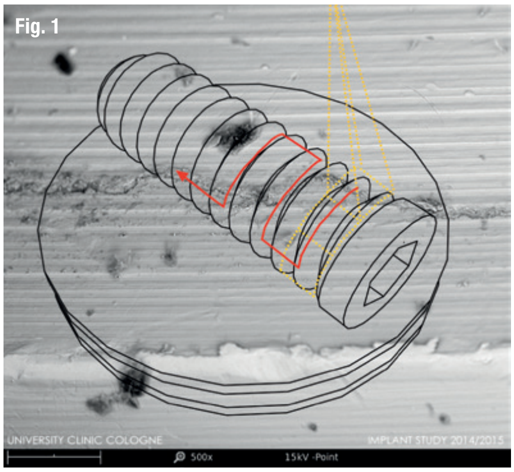

Fig. 1: Systematic scanning of the sample reaching approx. one third of the implants surface in the SEM. Organic contaminants appear darker than titanium.
Fig. 2: MDI (3M ESPE), x500.
Fig. 3: MDI (3M ESPE), x2,500.
Fig. 4: Qualitative elemental area analysis at x2,500.

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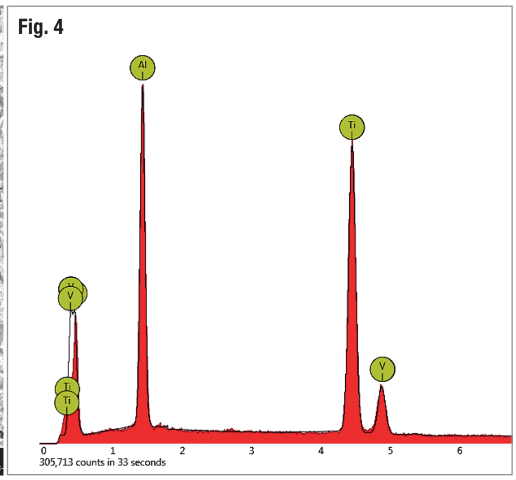

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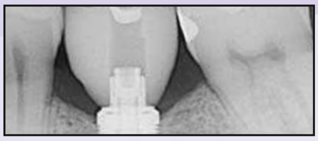
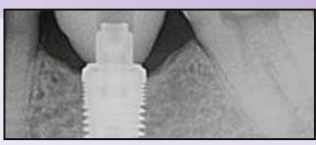


Six months after implant placement



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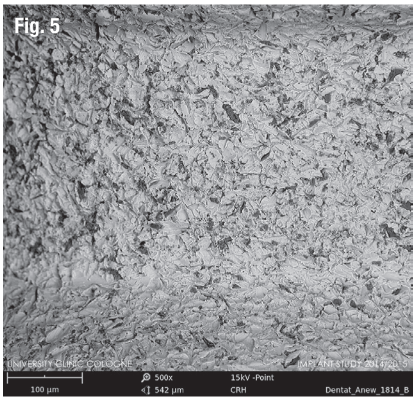
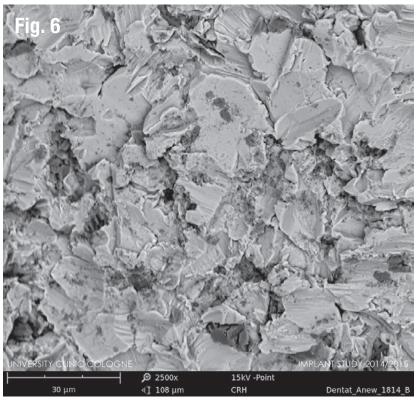
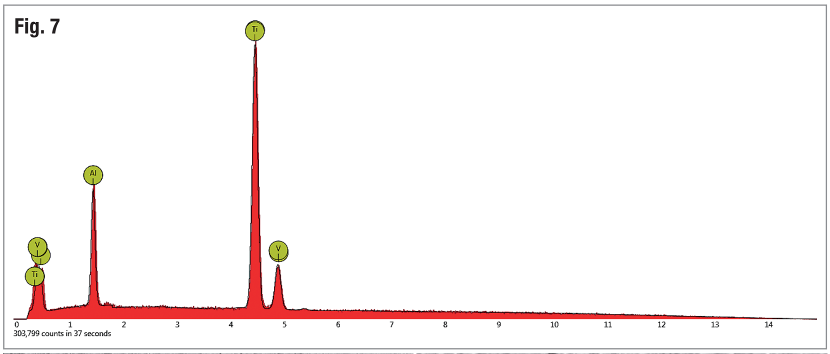
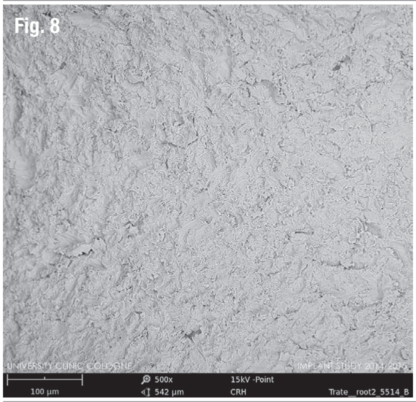
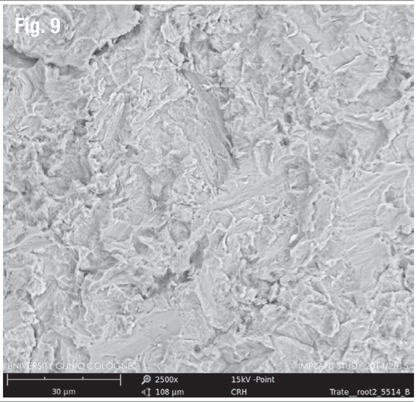










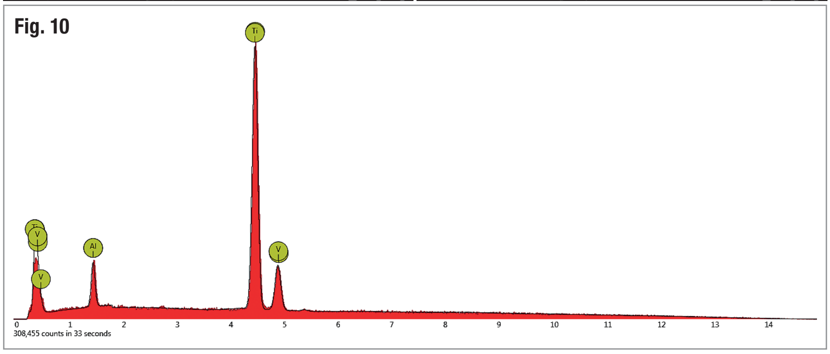


Fig. 5: ANEW (Dentatus), x500. – **Fig. 6:** ANEW (Dentatus), x2,500. – **Fig. 7:** Qualitative elemental area analysis at x2,500. – **Fig. 8:** ROOTT (TRATE), x500. – **Fig. 9:** ROOTT (TRATE), x2,500. – **Fig. 10:** Qualitative elemental area analysis at x2,500.

become the globally established treatment alternative to purely prosthetic solutions for tooth loss. And with the variety of implant systems offered, it has become ever more difficult for the dentist to choose just the right system for his or her practice and patients. Specific surface topographies, material properties that promote osseointegration or surface treatments are often emphasised in advertising as significant advantages to distinguish a given system from its many competitors.

Background and aim

The surface of a dental implant determines the initial phases of the biological response to the implant and affects its ability to integrate into the surrounding tissue.[3] The surface structure should support the process of osseointegration, especially when using highly sophisticated surgical augmentation techniques such as those required in the highly atrophic maxilla.

In recent years, therefore, several working groups and implant manufacturers have presented a multitude of techniques for micromorphological structuring of implant surfaces in order to improve success rates.[4–6] To a large extent, osteoblast proliferation and differentiation at the implant surface will depend on the microstructure of that surface.[7,8] Surface modifications are realised through additive or subtractive treatment of the titanium-implants. Sandblasting and etching procedures in combination or as a single treatment are established as state-of-the-art manufacturing processes. Since the early 1990s, endosseous titanium implants have been examined for residue[9] that may be related to the manufacturing process or to product-specific handling subsequent to the production process.[10] The aim of this study was to present topographic effects of the different manufacturing processes and to analyse potential impurities on implants made of titanium and its alloys.

Methods and materials

Among the group of 135 implants from 95 different manufacturers and suppliers, a few samples were one-piece implants which set the focus on this article. All implants were analysed by means of different techniques: Scanning electron microscopy (SEM) enabled topical evaluation, backscattered electron imaging (BSE) allows the drawing of conclusions about the chemical nature (density) and allocation of the different residues and contaminations on the sample material. Elements with an atomic number lower than that of titanium (and, hence, less electron backscattering) appear darker in the material contrast image (Fig. 1). The qualitative and quantitative elemental analysis of the implant surfaces, the energy-dispersive X-ray spectroscopy (EDX), uses the X-rays emitted by a sample to determine its elemental composition. The implants were fixed on the sample holder to allow a systematic scan reaching approximately one third of the implants surface in a viewing angle of 120 degrees (Fig.1).

A surface-area analysis and one or more spot analyses were performed for each implant.

Results

The implants MDI (3M ESPE) and ANEW (Dentatus) showed a homogenous distribution pattern of numerous aluminium oxide particles (Al_2O_3) as remnants of the blasting process. These aluminium oxide particles appear in the material contrast image darker than titanium which can be seen in Figs. 2–3 and 5–6. The MDI sample showed very rare additional organic particles (10–50 µm), partly with embedded metal particles (500 nm) containing traces of iron and chromium. The ANEW implant showed up to three organic particles (30–40 µm) and traces of silicon (6–8 µm).

The implant ROOTT (TRATE) was the only one-piece implant in the sample group with no organic contaminants or inorganic residues (Figs. 8–10, Tab. 3). The blasting material HA/TCP left no measurable traces on the implant. All three implants as mentioned above are made of titanium grade 5, which is an alloy of titanium, aluminium and vanadium. The higher concentration of aluminium in the elemental analysis of the implants MDI and ANEW (Tab. 1 and 2) is probably a consequence of the blasting material, which remains mechanically interlocked on the implants surface.

	Atomic percentage	Certainty
Ti	51.5 %	1.00
Al	46.3 %	0.99
V	2.1 %	0.96

Tab. 1

	Atomic percentage	Certainty
Ti	70.2 %	1.00
Al	26.6 %	0.99
V	3.2 %	0.97

Tab. 2

	Atomic percentage	Certainty
Ti	83.1 %	1.00
Al	13.0 %	0.99
V	3.9 %	0.95

Tab. 3

Fig. 11

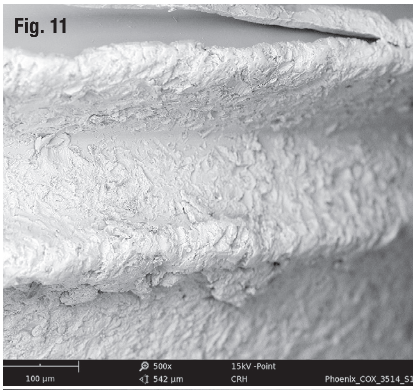


Fig. 12

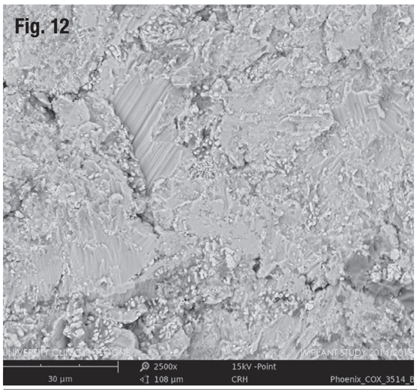
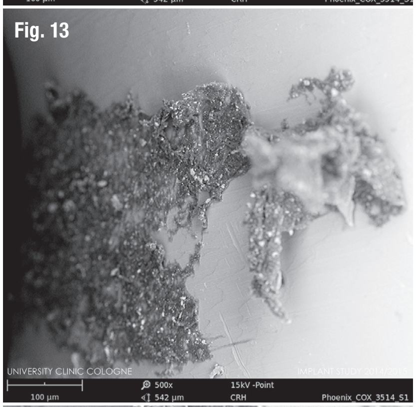


Fig. 13



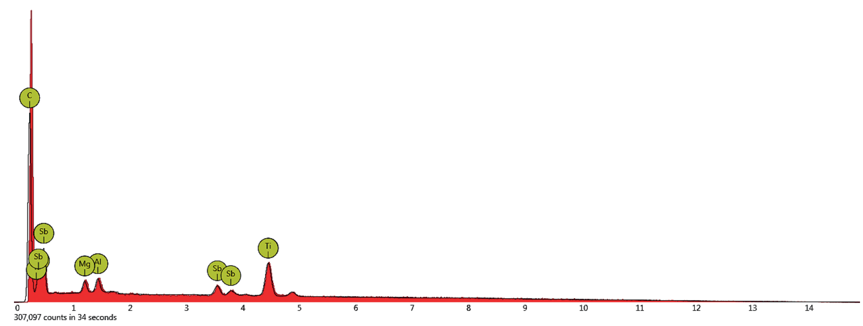
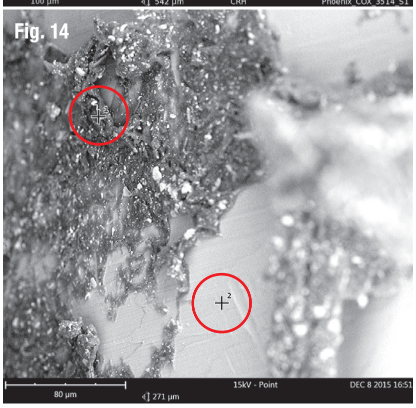


Fig. 15

Fig. 14



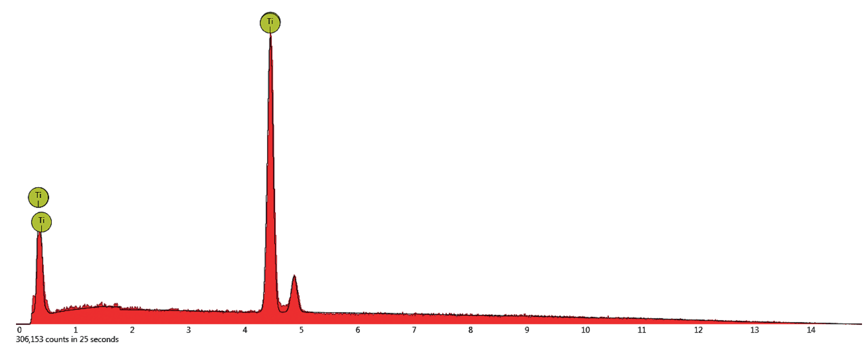


Fig. 16

Tab. 1: Quantitative elemental analysis (titanium grade 5). – **Tab. 2:** Quantitative elemental analysis (titanium grade 5). – **Tab. 3:** Quantitative elemental analysis (titanium grade 5). – **Fig. 11:** CO-XG (PHOENIX) titanium bur, x500. – **Fig. 12:** CO-XG (PHOENIX), x2,500. – **Fig. 13:** CO-XG (PHOENIX) implant neck, x500. – **Fig. 14:** Major organic contamination, x1,000. – **Fig. 15:** Qualitative elemental analysis of spot # 1 in Fig. 14. – **Fig. 16:** Qualitative elemental analysis of spot # 2 in Fig. 14.

	Atomic percentage	Certainty
C	69.2 %	0.99
O	25.3 %	0.99
Ti	3.0 %	0.99
Mg	0.9 %	0.97
Al	0.8 %	0.97
Sb	0.8 %	0.97

Tab. 4

Tab. 4: Quantitative elemental analysis of spot # 1 in Fig. 14.

	Atomic percentage	Certainty
Ti	100.0 %	1.00

Tab. 5

Tab. 5: Quantitative elemental analysis of spot # 2 in Fig. 14.

The titanium grade 4 implant CO-XG (PHOENIX) had a rough implant body and a machined implant neck. In contrast to all other one-piece implants in the cohort, the CO-CG showed large burrs on some outer threads that may lose the remaining contact with the implant during insertion (Fig. 11). Whereas the implant body was mainly free of residues (Figs. 12 and 16), the machined area of the implant neck revealed a massive organic contamination with large particles (100–300 µm) containing not only carbon, but also significant traces of magnesium, aluminium and antimony (Figs. 13–15, Tabs. 4 and 5).

The implant Allfit KOS presented an inhomogeneous distribution pattern of remaining aluminium oxide particles on the rough implant body as remnants of the blasting material with different sizes from 5 to 50 µm (Figs. 17–18). The machined threads at the implants neck that are exposed to the cortical bone showed organic material in the narrow grooves (Figs. 19–20). The correspondent EDX analysis revealed a significant amount of carbon inside these gaps (Fig. 21, Tab. 6) and showed the typical signals of titanium grade 5 in the neighbourhood of these contaminants (Fig. 22, Tab. 7).

Discussion

There is an ongoing discussion, as to whether organic residues or major amounts of blasting material have a clinical impact on the process of osseointegration.[11,12] Even the manufacturers of implants on whose implants more or less large amounts of organic or inorganic contaminants were found in our analyses have reported statistical success rates that are not different from those of other implants, proving their point with specially conducted studies.

But how does the human body handle organic particles or minor particles with traces of iron, chromium, nickel or even antimony? This question should actually not arise in the first place, because impurities are preventable, as this study clearly shows. Even if these particles are relatively firmly attached to the implant surface, they are likely to become detached by the resulting frictional forces in the bone bed as the implants are inserted at torques in the double digits to achieve the desired level of primary stability. Particles with a diameter of less than 10 µm are susceptible to uptake by macrophages through phagocytosis,[13] so that questions related to the clinical relevance of such impurities cannot simply be brushed aside.

If we follow the shift in paradigm and understand that osseointegration is the consequence of a dynamic foreign body equilibrium, rather than a static situation, every additional and avoidable foreign body on a sterile packed implant renders activation of the immune system and may be the reason for a periimplantitis.[14,15] Especially in the early phase of osseointegration, a particle-induced macrophage activation is associated with an increased osteoclastogenesis and may therefore cause increased bone resorption.[16]

According to Albrektsson, we should abide by his fundamental guiding principle that we have to know, not to believe, that a specific implant will do no harm to our patients.[17] To cut a long story short: Concern-

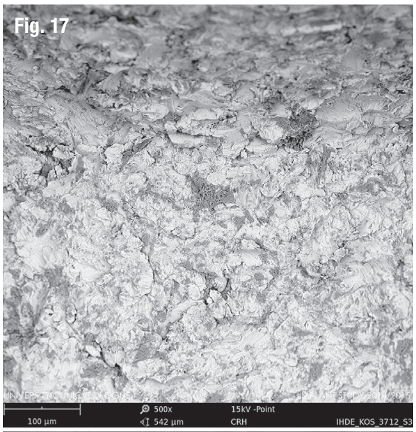


Fig. 17

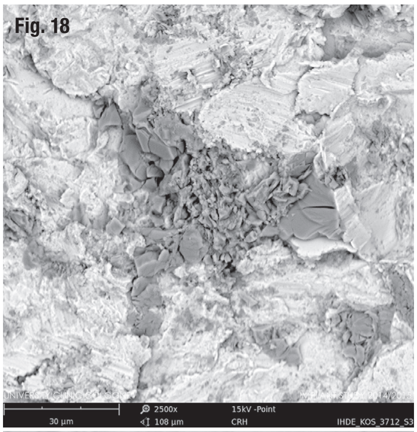


Fig. 18

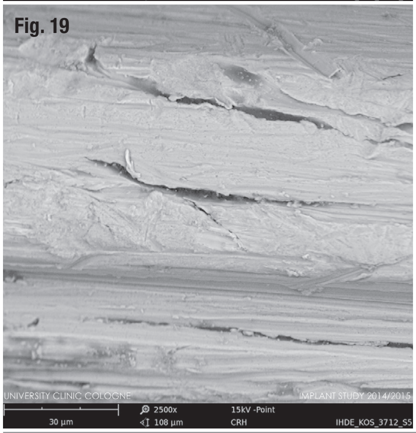


Fig. 19

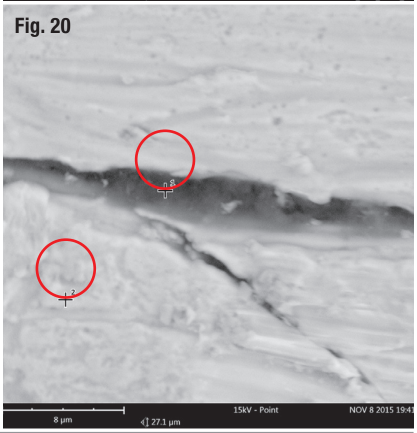


Fig. 20

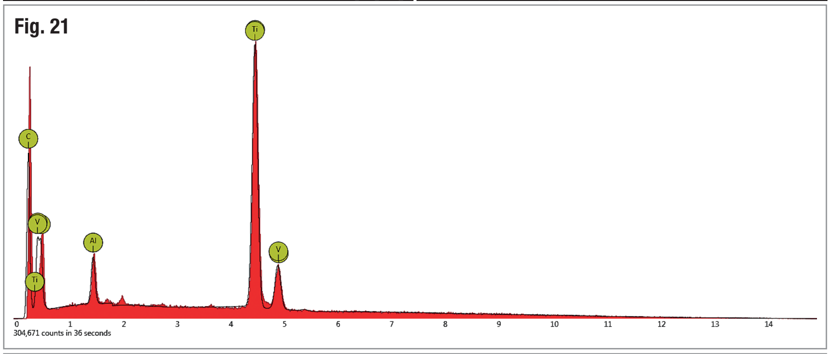


Fig. 21

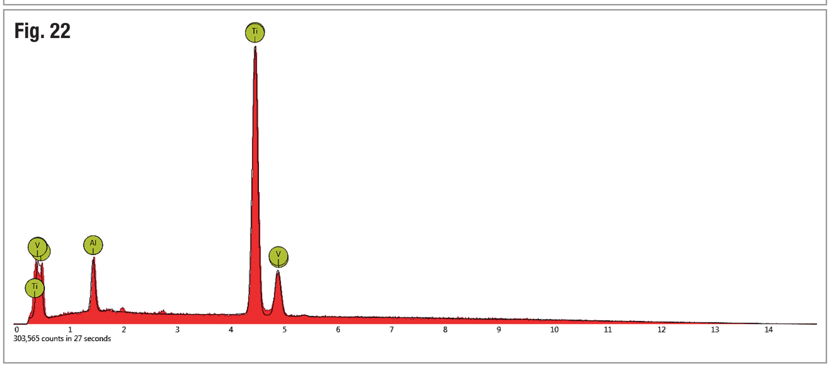


Fig. 22

	Atomic percentage	Certainty
C	74.4 %	0.99
Ti	21.8 %	1.00
Al	2.9 %	0.98
V	0.9 %	0.97

Tab. 6

	Atomic percentage	Certainty
Ti	81.7 %	1.00
Al	14.5 %	0.99
V	3.8 %	0.95

Tab. 7

Fig. 17: Allfit KOS, x500. – **Fig. 18:** Major aluminum oxide particle, x2,500. – **Fig. 19:** Allfit KOS, machined thread, x2,500. – **Fig. 20:** EDX analysis of organic material, x10,000. – **Fig. 21:** Qualitative elemental analysis of spot # 1 in Fig. 20. – **Fig. 22:** Qualitative elemental analysis of spot # 2 in Fig. 20. – **Tab. 6:** Quantitative elemental analysis of spot # 1 in Fig. 20. – **Tab. 7**: Quantitative elemental analysis of spot # 2 in Fig. 20.

ing dental implants, dentists, not only in Europe, should act in accordance with what is said to be a Lenin citation which claims that trust is good, but control is a lot better.

The CleanImplant Foundation, an international non-profit organisation, will continue and extend the periodic analyses of dental implants all over the globe in order to provide dentists with independent research results and evaluate improvements in the manufacturing process of previously analysed implants. More information and a correspondent newsletter is available at the project´s homepage www.cleanimplant.com_

Literature available from the author.

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