

Final report of the BDIZ EDI implant study 2014/15

SEM surface analyses of 120 sterile-packed implants

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EDI Journal 1/2015 contained an interim report presenting the results for 65 implant systems from the 2014/15 BDIZ EDI implant study. This interim report had focused on notable analytical results for titanium implants and on the presentation of various surface structures of popular implant systems in titanium and its alloys [1]. The present report now also presents implants made of zirconia, tantalum and PEEK. Now that this study has been completed, a total of 120 different systems from 83 suppliers in 16 countries have been examined by scanning electron microscopy, doubling the number of implant systems analyzed by the BDIZ EDI Quality and Research Committee since the first study in 2008 [2,3]. In cooperation with the University of Cologne, extensive material contrast images were obtained and qualitative and quantitative elemental analyses performed on each of the implants examined, using the same study protocol.

Dental implants are an integral part of the therapeutic armamentarium of contemporary dental practices. With their excellent success rates, they have 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 emphasized in advertising as significant advantages to distinguish a given system from its many competitors. According to the Association of German Dental Manufacturers (VDDI), more than 1,300 different implant systems

are currently available worldwide. Northern Italy alone probably has a hundred micro-enterprises that manufacture implants, primarily for regional dentists. But even though only a fraction, namely 120, of all the implant systems available in Europe could be included in this study, these represent the most important brands or major suppliers of implants.

Background and objectives

There is commonly a significant discrepancy between the responsibility treatment providers must assume for the materials they use vis-a-vis their patients and their knowledge regarding the quality of these materials as confirmed by neutral and scientific sources. As stated in the interim report in the

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OK to use in patients – but apparently not always OK to take a closer look

The great majority of manufacturers responded positively to the requests by the University of Cologne. Nevertheless, some manufacturers declared that they had no interest in this study. Not even the proclaimed fact that the present study did not primarily emphasize the producers' interests but rather those of the users caused them to reconsider. In a few cases, orders for implants to be used for the purposes of this study were not filled and delivery was refused – even though these implants are used by several hundred practitioners throughout Europe (see box "Appeal to readers"). Especially noteworthy was the response from one manufacturer stating that one could not remember ever having received requests from users for SEM images or EDX results. Dentists, the statement continued, assumed that these results were good as a matter of course. Or else they were not interested in this information. And even if they were, they would not know how to interpret the data correctly anyway. Less favourable results could be surpassed by the competition; and even good results were no "seller", because they were not properly understood by the reader. Thus, the risk of misinterpretation far outweighed any benefits of the study. All relevant information and a variety of studies on the requested implant system, they concluded, could be downloaded from the company's website. In fact, the website offered no evidence on the safety of the chromium-nickel-steel particles that were found en masse in this study on an implant by that manufacturer. Unsurprisingly, therefore, the sterile-packed implant analyzed in this study was not provided by the manufacturer.

Another manufacturer explicitly did not want to participate in the study, but had then decided to fill the order for a sample implant and not to participate in any boycott. However, the shipment contained an invoice and an explicit note to the effect that the implant was not to be named in any publication related to the present study. We acknowledged that desire, but we did not want to deprive our implantological colleagues of the results. Because if the implants are good enough to be used in patients, they should be good enough to present in an SEM image.

Are we implantologists really not interested in the quality of the systems we use? Are we unable to evaluate the results of this study? Do some manufacturers have to "protect" us from scientific studies because we cannot interpret them correctly anyway? Users will be able to answer these questions readily after reading this report.

previous issue, CE marks do not protect the market, or rather the patient, from substandard quality in medical devices [4]. An international group headed by the University of Geneva School of Dental Medicine has embarked on the highly commendable quest to characterize, classify and code dental implants starting in 2010 – the so-called Implant Surface Identification Standard (ISIS) that might facilitate the future introduction of a possible ISO standard for dental implants [5,6].

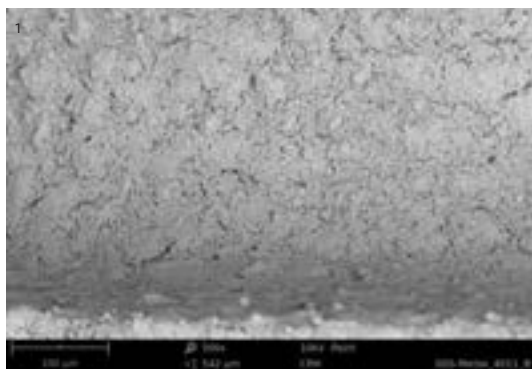
The surface quality of implants depends on a number of different factors. Once the titanium implant blank has been CNC-machined, it is further processed using different techniques that ultimately result in the product's specific surface structure. The various processes used for titanium implants were discussed in the first part of the report. Various production processes ultimately contribute to product quality: the production itself, the cleaning steps, post-production handling (i.e., quality control), packaging and sterilization processes and the packaging itself.

A striking feature of this study has been the many different types of sterile packaging that sometimes go to considerable lengths to prevent any kind of contact of the implant with the packaging. In fact,

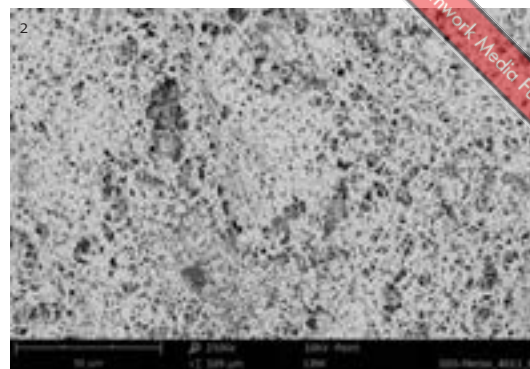
several implants in the study that did not feature contact-free packaging but were delivered in soft sealed polyethylene bags exhibited various amounts of organic contaminants or plastic residue, depending on their surface roughness.

As described in the interim report, even a well-structured implant surface proven in clinical practice for many years may accumulate not insignificant amounts of organic contaminants or plastic particles through abrasion, unless the implant was delivered in non-contact packaging. There have been reports in the literature that these organic contaminants are associated with early implant loss or with peri-implantitis [7]. The documented amounts of carbon in the regions that are already obvious on the material contrast images are considerably higher than the minor amounts of carbon adsorbed from ambient carbon dioxide as present on any titanium implant. The more or less sophisticated technical implementation of the sterile packaging has no direct relation to the price of the implants. But how far can we let manufacturers go in their drive to save cost if the result is sharp-edged cover screws that damage, and thereby breach, the simple sterile packaging even before they are used (see the text box on sterile packaging on page 75)?

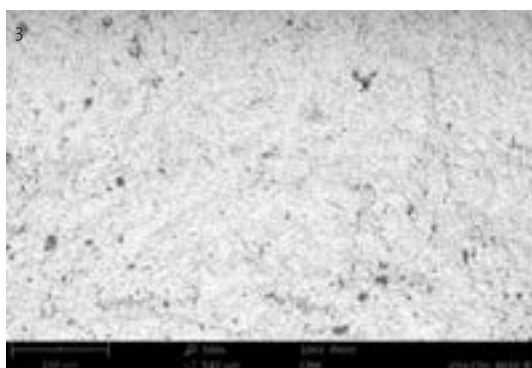
1 I
SDS – Metoxit
(x500).



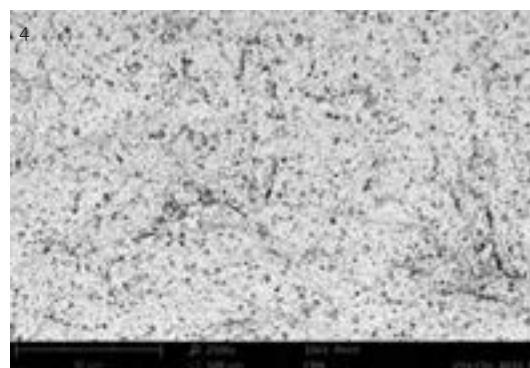
2 I
SDS – Metoxit
(x2,500).



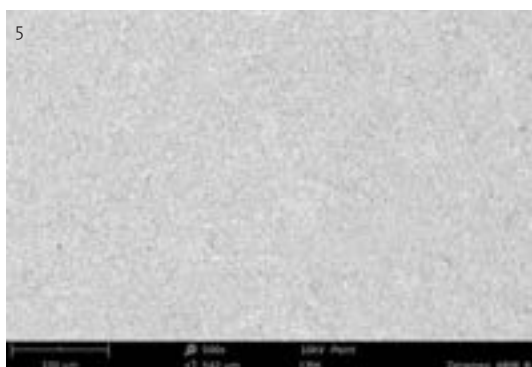
3 I
vitaclinical
(x500).



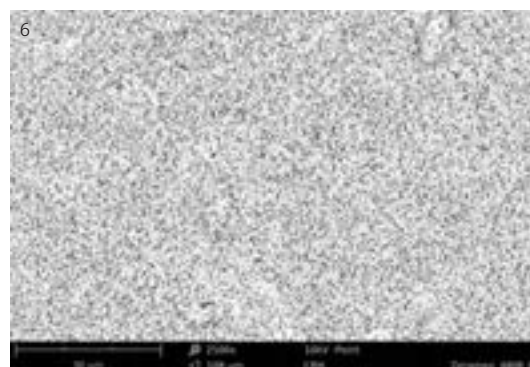
4 I
vitaclinical
(x2,500).



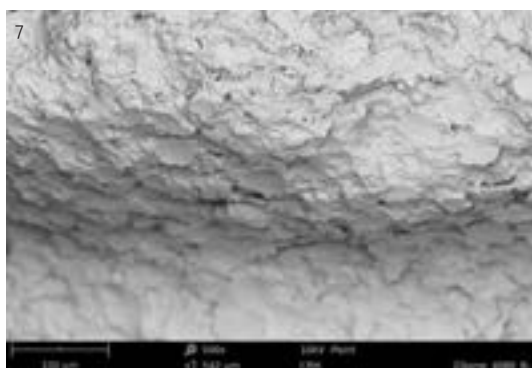
5 I
Dentalpoint –
Zeramex (x500).



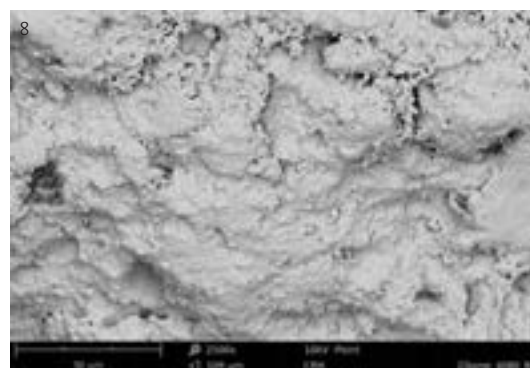
6 I
Dentalpoint –
Zeramex (x2,500).



7 I
Zibone – Coho
(x500).



8 I
Zibone – Coho
(x2,500).

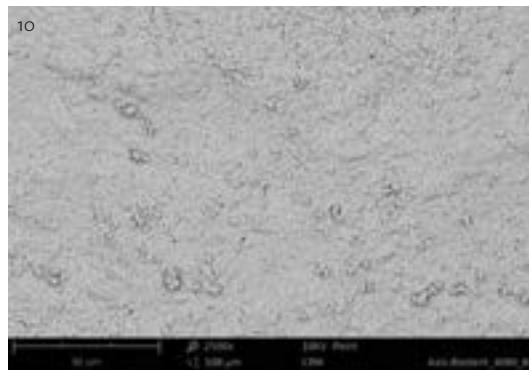
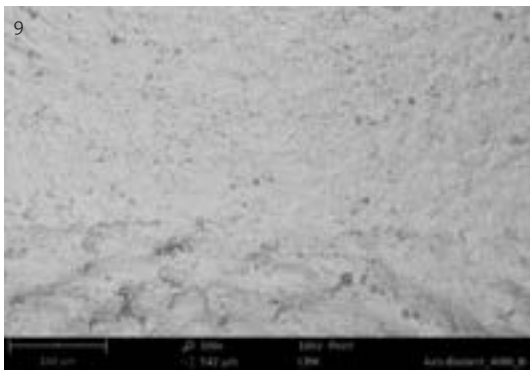


In addition to the previously presented implant systems made of titanium and titanium alloys, implants made of zirconia, tantalum and polyether ether ketone (PEEK) were also studied.

Zirconia as an implant material has been proven for many years. It is probably in no way inferior to titanium or titanium oxide in terms of its osseo-

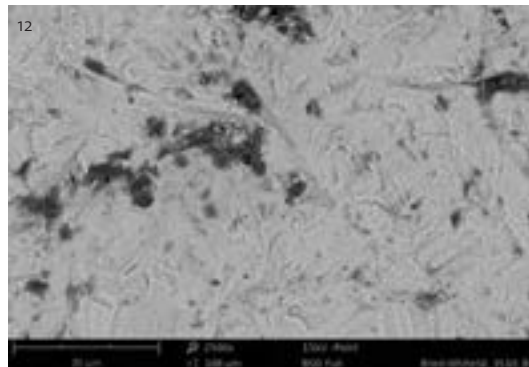
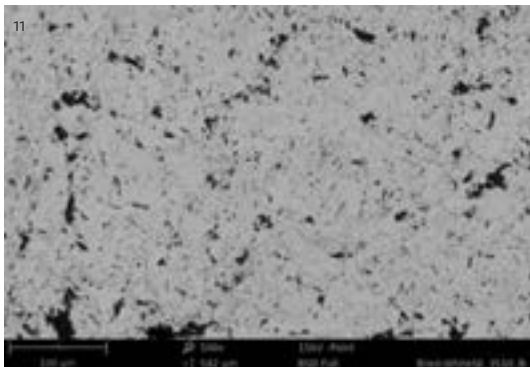
integration potential [8]. The surfaces exhibit different levels of roughness (Figs. 1 to 16).

The specific removal torques – the forces necessary to split up the bone-implant interface by unscrewing the implant once osseointegration has taken place – do not differ between zirconia implants and titanium implants of similar rough-



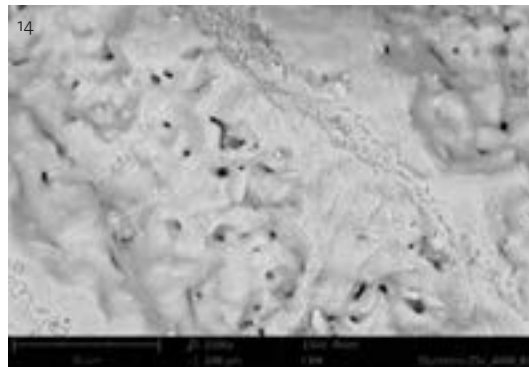
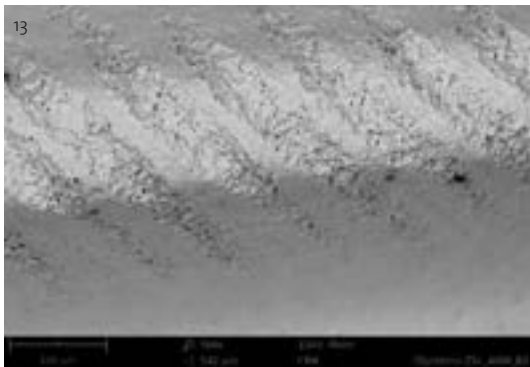
9 |
Axis – biodental
(x500).

10 |
Axis – biodental
(x2,500).



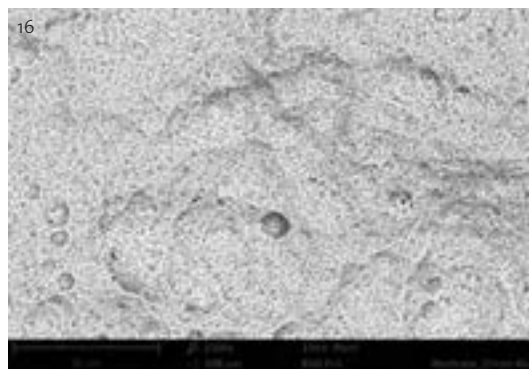
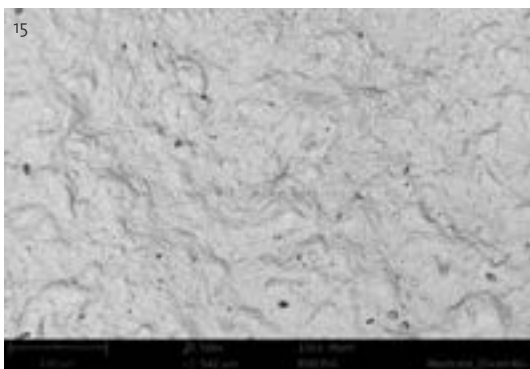
11 |
Bredent – WhiteSky
(x500).

12 |
Bredent – WhiteSky
(x2,500).



13 |
Z-Systems –
Zirkolith (x500).

14 |
Z-Systems –
Zirkolith (x2,500).

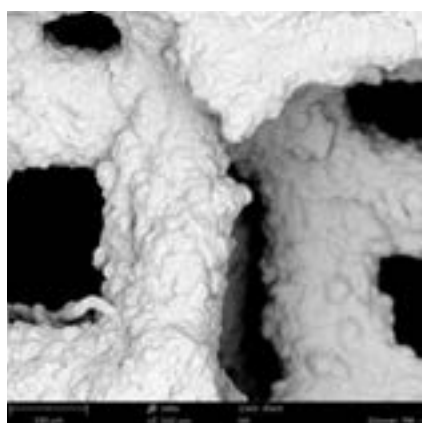


15 |
Natural Dental
Implants – root-
analogue replicate
made entirely of
zirconia (x500).

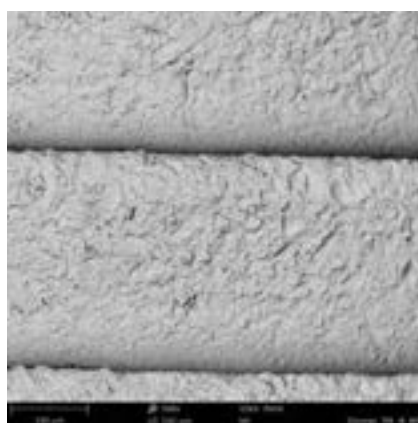
16 |
Natural Dental
Implants – root-
analogue replicate
made entirely of
zirconia (x2,500).

ness [9]. Occasionally observed cases of lost zirconia implants may not be solely due to the surface properties of these implants. One possible cause of early implant loss may be the low thermal conductivity of zirconia. Thus, the thermal conductivity of yttrium-stabilized zirconia, at approximately $2.2 \text{ Wm}^{-1}\text{K}^{-1}$, is nearly ten times lower than that

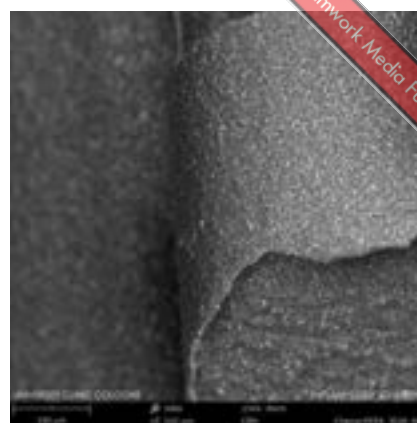
of grade 4 titanium ($22 \text{ Wm}^{-1}\text{K}^{-1}$) and three times lower than that of grade 5 titanium (Ti-6Al-4V) at $6.7 \text{ Wm}^{-1}\text{K}^{-1}$. Inserting zirconia implants at the torques commonly used for titanium implants might result in temperature peaks, especially in high-density bone, that could cause thermal bone damage. In-vitro studies have shown that elevated



17 | Trabecular midsection made of tantalum (Zimmer Trabecular Metal implant, x500).



18 | The shoulder and apex of the same implant are made of titanium (Zimmer Trabecular Metal implant, x500).



19 | Implant made of polyether ether ketone (Champions WIN! PEEK implant, x500).

insertion torques lead to a significant temperature increase, especially in the first few millimetres of the prepared implant site [10].

One tantalum-titanium hybrid implant in this study exhibited a rather particular surface topography. While the titanium surface of the implant shoulder and its apical region had been blasted with hydroxyapatite, the middle segment of the implant, marketed by the manufacturer as “trabecular metal”, had a porous structure not unlike cancellous bone. This three-dimensional structure is based on a glassy carbon framework completely coated with tantalum. The corrosion-resistant tantalum [11] has been successfully used as an orthopaedic implant material for many years. Now also used in dental implants, the special surface texture is designed to allow the ingrowth of bone cells into the depth of the structure [12,13]. The term “osseoincorporation” has been coined in the literature in an attempt to add a third dimension to *Brånemark's* definition of osseointegration [14]. Prospective multicentre studies at 22 locations in five European countries have shown that the clinical success rates of hybrid implants made of titanium and tantalum were similar to those of pure titanium implants [15]. The only representative of this class of materials in the cur-

rent study was the tantalum-titanium hybrid implant by Zimmer (Figs. 17 and 18).

Polyether ether ketone (PEEK) has more recently been used as a new material for dental implants (Fig. 19). As the material has only been used for dental implants for a rather short time, only few reports are extant. In-vitro trials suggest that the mechanical properties of PEEK might optimize the distribution of masticatory forces through the implant's surroundings [16,17]. Here we will have to wait for long-term clinical results. Only one implant made of PEEK was included in the study; a second manufacturer had not responded to our enquiries.

Materials and methods

A total of 120 different implant systems from 83 manufacturers and 16 countries were analyzed by scanning electron microscopy (Table 1). The SEM device used for the acquisition of the surface topography (Phenom proX, Phenom-World, Eindhoven, Netherlands) has a highly sensitive detector for backscattered electrons (BSE) that facilitates inferences about the composition of the examined material as the so-called material contrast image emerges. Elements with a low atomic number, i.e. with fewer electrons, such as carbon or aluminium are shown as relatively dark areas, while elements with high atomic numbers such as titanium or zirconium appear relatively bright.

For testing, the implants were taken out of their packaging using a sterile forceps and attached to the sample holder before being introduced into the vacuum chamber. Because zirconia implants are more easily electrically charged than titanium implants, a so-called charge-reduction sample holder was used that largely attenuates this charging phenomenon, which would otherwise lead to artefacts.

20 | 3D roughness reconstruction (Bredent WhiteSKY, x2,500).

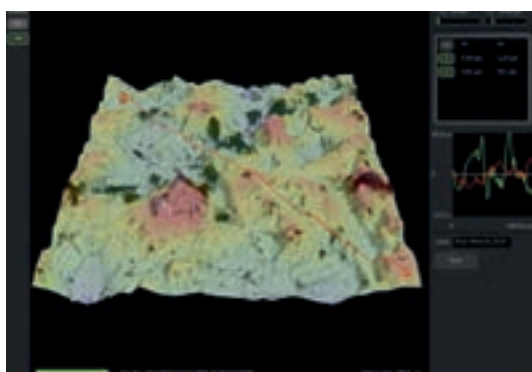


Table 1: List of implant manufacturers participating in the 2014/15 implant study (as per 30 April 2015)

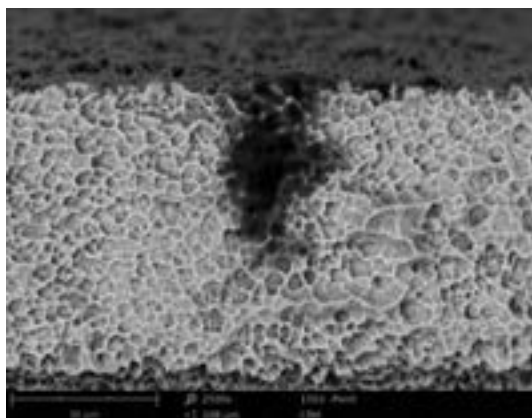
Manufacturer	Country	Manufacturer	Country	Manufacturer	Country
AB	Israel	Dentatus – Loser	Sweden	NBM	Switzerland
3M Espe	Germany/USA	Dentaurum	Germany	Neoss	United Kingdom
Adin	Israel	Dentegris	Germany	Nobel Biocare	Sweden
AGS Implants	Turkey	Dentium	Korea	Nucleoss	Turkey
Alpha-Bio Tec	Israel	Dentsply Implants	Sweden/Germany	OCO Biomedical	USA
Alpha Dent	United Kingdom	Dio	Korea	Osstem	Korea
Alphatech (Henry Schein)	Germany	FairImplant	Germany	OT medical	Germany
Anthogyr	France	General Implants	Germany	Paltop	Israel
Argon Medical	Germany	Glidewell	USA	Phibo	Spain
Avinent	Spain	Hi-Tec	Israel	Phoenix	Germany
Axis biodental	Switzerland	IDI	France	Prowital	Germany
Bego	Germany	Implant Direct	Switzerland	Schütz	Germany
Bio3	Germany	ImplantSwiss	Switzerland	SDS/Metoxit	Switzerland
Biodenta	Switzerland	JDental Care	Italy	SGS	Hungary
Biohorizons	USA	JMP	Germany	SIC	Switzerland
Biomet 3i	USA	Keystone	USA	Southern	South Africa
Biotek BTK	Italy	Klockner	Andorra	Straumann	Switzerland
BlueSkyBio	USA	KSI Bauer	Germany	Sweden Martina	Italy
Bredent	Germany	Lasak	Czechia	TA-Dental	Germany
BTI	Spain	m+k	Germany	Thommen	Switzerland
C-Tech	Italy	Medentika	Germany	TRI	Switzerland
Camlog	Germany/ Switzerland	Medentis	Germany	Trinon	Germany
Champions	Germany	Medical Instinct	Germany	VI-STOM	Italy
Clinical House	Switzerland	Megagen	Korea	vitaclinical	Germany
Cortex	Israel	MIS	Israel	Z-Systems	Switzerland
Cumdente	Germany	Natural Dental Implants	Germany	Zibone/Coho	Taiwan
DENTAL RATIO	Germany	Nature Implants	Germany	Zimmer	USA
Dentalpoint	Switzerland			ZL-Microdent	Germany

An updated list of all investigated implants and comprehensive reports on individual implants (up to three reports per request) are available to BDIZ EDI members by contacting the association office (office@bdizedi.org).

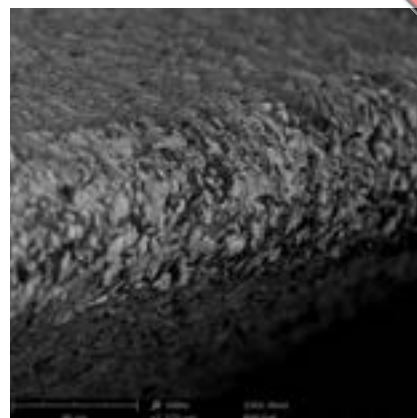
Qualitative and quantitative elemental analysis of the implant surfaces was performed using energy-dispersive X-ray spectroscopy (EDX). Here, the electron beam causes the primary electrons emitted to interact with the atoms of the specimen surface, releasing electrons of the inner shell as “secondary electrons”. The resulting gaps are immediately filled by electrons from a higher orbital. The difference in energy is emitted as an X-ray quantum and detected by a thermoelectrically cooled detector, measuring both the elemental compositions and their con-

centrations. An areal analysis and one or more spot analyses (in case of irregularities) were performed for each implant.

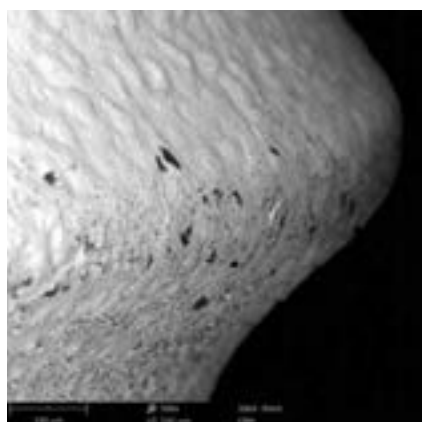
To document the surface roughness of each of the investigated implant systems, a so-called 3D roughness reconstruction was performed that allows a visual comparison of the respective surface structures. During the imaging process, the three-dimensional shape of the object is calculated from the brightness distribution in the grid of the four quadrants of the backscattered electron detector (Fig. 20).



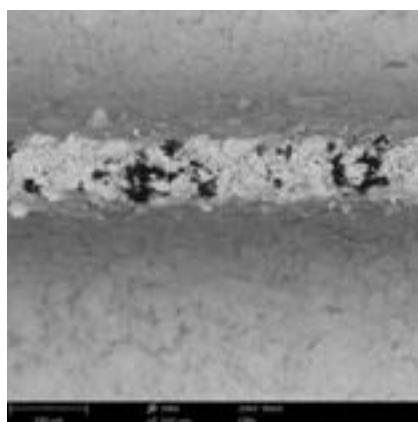
21 | "Single spot", individual organic contaminant (x2,500).



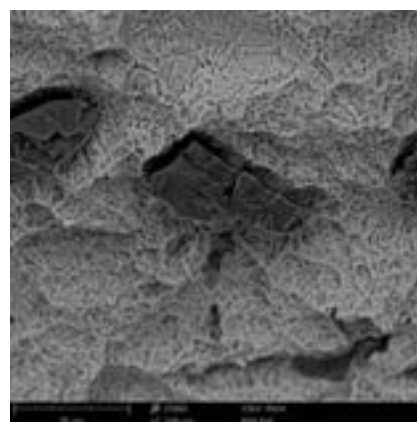
22 | Circumferential organic residue on a titanium implant (x500).



23 | Organic residue on the outer thread structures (zirconia, x500).



24 | Superficial organic particles (zirconia, x500).



25 | Individual inclusions of sandblasting material (titanium, x2,500).

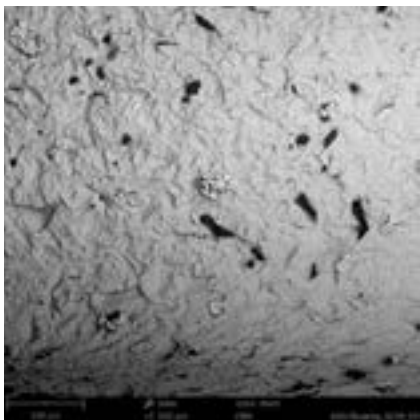
Results

Minor amounts of carbonaceous residue remaining on the implant after the cleaning process are a not infrequent finding. Organic residue appears darker in the material contrast image than titanium or zirconia because carbon atoms have fewer electrons and therefore create fewer backscattered electrons in a SEM than atoms of higher atomic numbers. Soft, sometimes jagged edges are typical of organic contaminants. If there are only a few isolated spots like that, they will make up only a very small part of the total area, being of little consequence and no clinical relevance (Fig. 21). The figure shows a single organic impurity 10 to 20 µm in size on an otherwise largely residue-free implant. More conspicuous were systematically distributed organic residues on several implants that are in contact with their outer packaging. These typically featured circumferential organic contamination occurring only at the outer edge of the thread (Figs. 22 to 24),

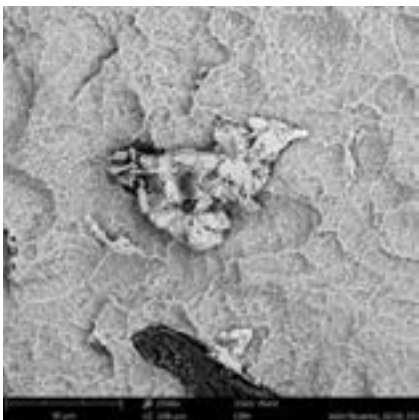
which suggests that contact with the packaging could be responsible.

Some isolated implants exhibited inorganic residue from the sandblasting process, namely alumina particles 20 to 30 µm in size (Fig. 25), but in quantities of presumably limited clinical relevance.

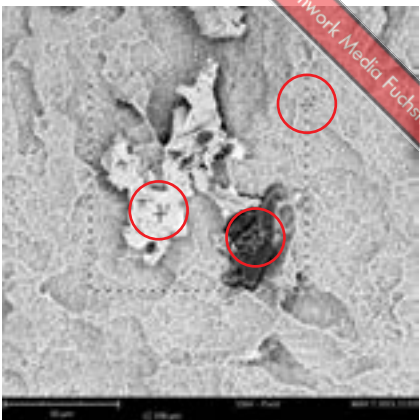
Unexpected inorganic residue findings included, in addition to the iron-copper-chromium particles described in the first part of the report, larger areas with intermittent chromium-nickel-steel particles 4 to 30 µm in size on one of the implants studied. The material contrast image had already presented them as strikingly bright and well-defined structures. These metallic particles might have originated as impurities within the blasting material or as abrasion residue from the CNC cutting tools that were subsequently embedded in the implant surface to the point where cleaning could not remove them (Figs. 26 and 27). Three spot analyses were carried out as part of the qualitative and quantitative elemental



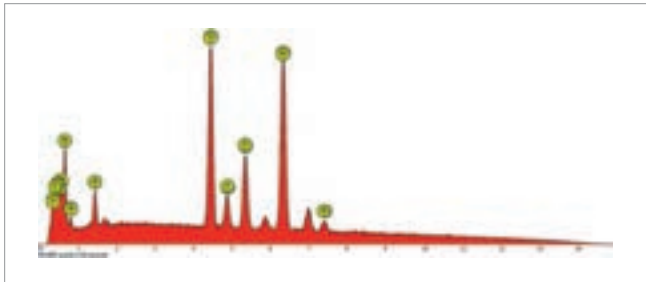
26 | Implant surface (Adin Touareg) with notable light and dark particles (x500).



27 | Same implant surface (Adin Touareg): bright chromium-nickel-iron particle, dark aluminium oxide particle (x2,500).



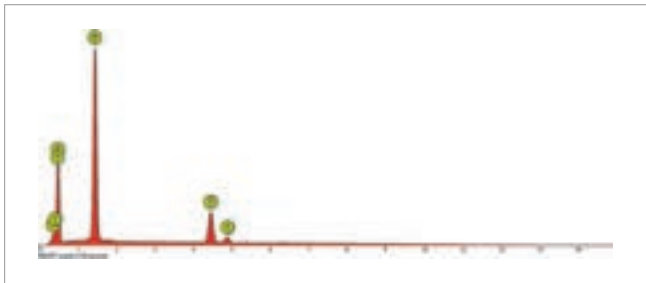
28 | Marks for EDX spot analysis and EDX mapping area (Adin Touareg; x2,500).



29 | Qualitative elemental analysis, spot no. 2 (bright chromium-nickel-iron particle).

Atomic percentage		Certainty
Fe	49.8%	0.99
Ti	24.5%	0.99
Cr	13.6%	0.99
Al	5.6%	0.97
Ni	5.2%	0.96
V	1.3%	0.94

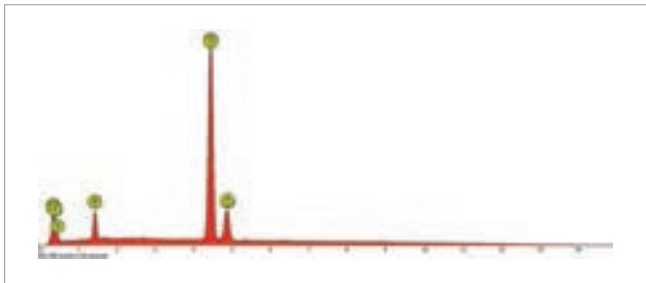
Table 2 | Quantitative elemental analysis – Element distribution, spot no. 2.



30 | Qualitative elemental analysis, spot no. 3 (bright aluminium oxide particle; sandblasting residue).

Atomic percentage		Certainty
O	68.2%	0.99
Al	25.3%	1.00
Ti	6.1%	0.99
V	0.4%	0.93

Table 3 | Quantitative elemental analysis – Element distribution, spot no. 3.



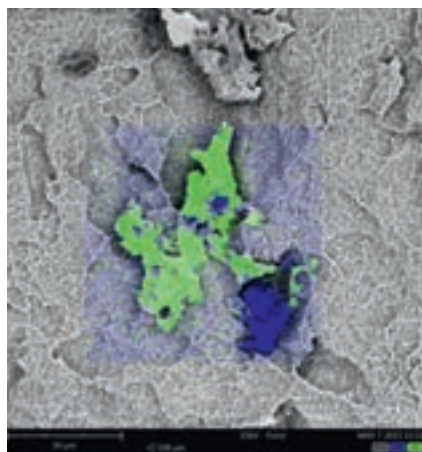
31 | Qualitative elemental analysis, spot no. 4 (particle-free implant surface, grade 5 titanium).

Atomic percentage		Certainty
Ti	85.7%	1.00
Al	11.5%	0.99
V	2.8%	0.94

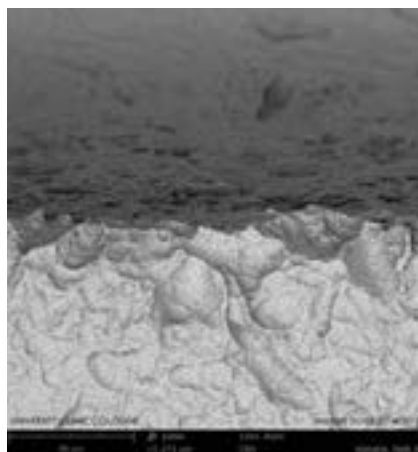
Table 4 | Quantitative elemental analysis – Element distribution, spot no. 4.

analysis (Fig. 28). The analysis of the chromium-nickel-steel particle (spot no. 2) has typical “fingerprints” for the elements iron, nickel and chromium (Fig. 29 and Table 2). As expected, the dark particle turns out

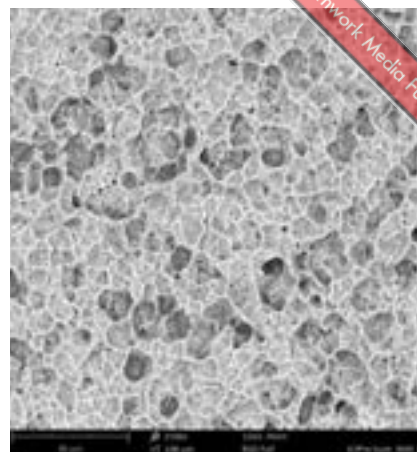
to be alumina (Fig. 30 and Table 3), while the control area outside the two particles (spot no. 4) shows only the typical signs for grade 5 titanium (titanium, aluminium and vanadium) (Fig. 31 and Table 4).



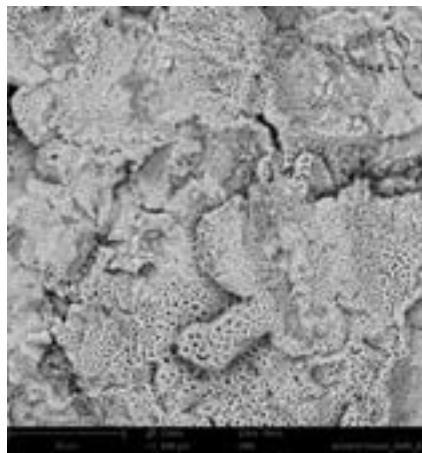
32 | Example of EDX mapping: green = chrome; blue = aluminium (Adin Touareg; $\times 2,500$).



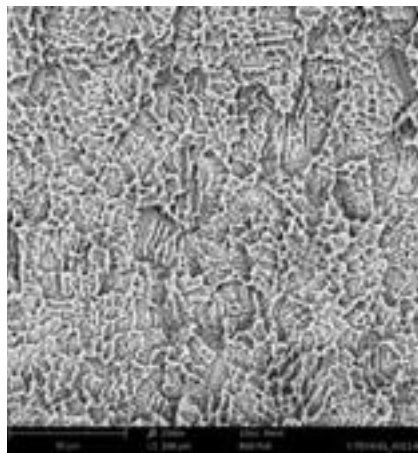
33 | AlphaBio – SPI Spiral Implant ($\times 2,500$).



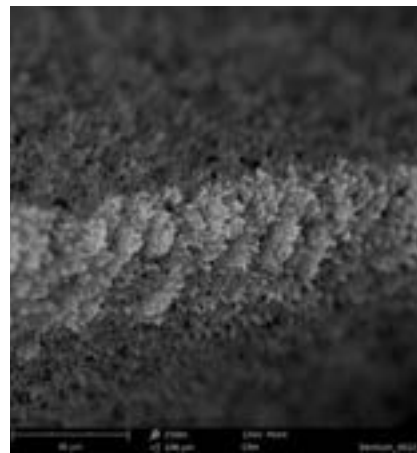
34 | Argon Medical – K3Pro Sure ($\times 2,500$).



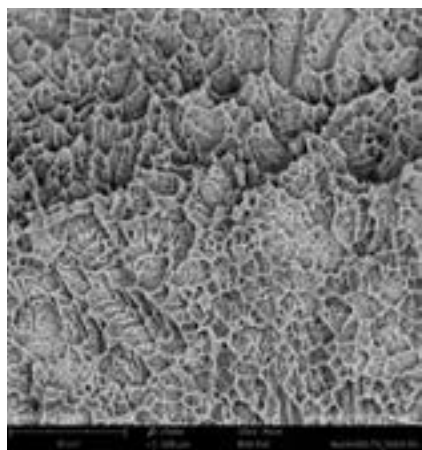
35 | Avinent – Ocean ($\times 2,500$).



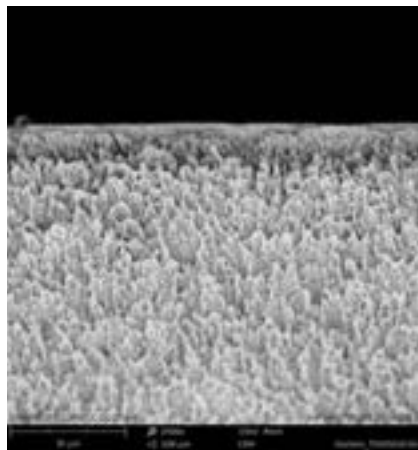
36 | C-Tech – Esthetic Line ($\times 2,500$).



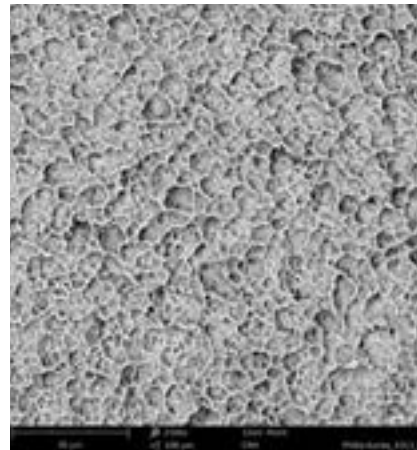
37 | Dentium – Superline ($\times 2,500$).



38 | Nucleoss – T4 Implant ($\times 2,500$).



39 | Osstem – TS III ($\times 2,500$).



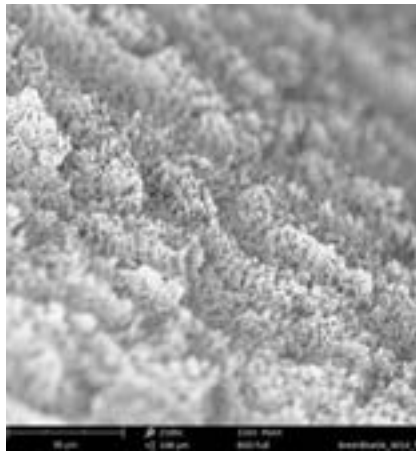
40 | Phibo – Aurea ($\times 2,500$).

The so-called EDX mapping assigns each elemental signal its own colour, which can then be superimposed on the SEM image as a coloured overlay. Figure 32 shows the detected chromium in green and aluminium in blue.

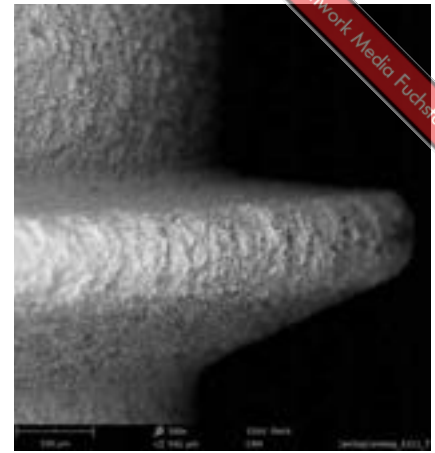
Fortunately, the vast majority of the studied implants exhibited no significant contamination. By way of example, the surfaces of titanium implants by some manufacturers (Alpha-Bio, Argon Medical, Avinent, C-Tech, Dentium, Nucleoss, Osstem, Phibo,



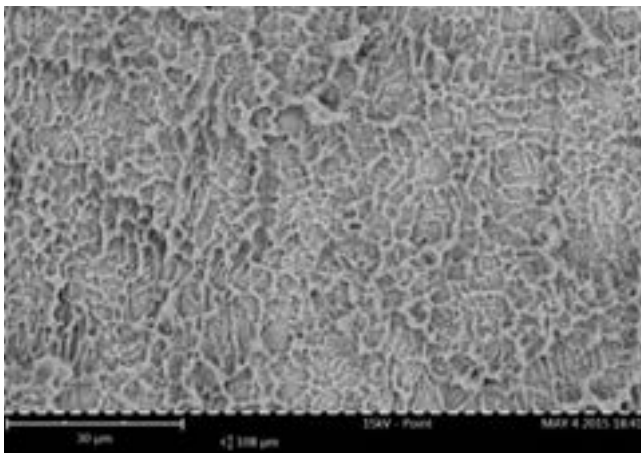
41 | SGS – Pi (x2,500).



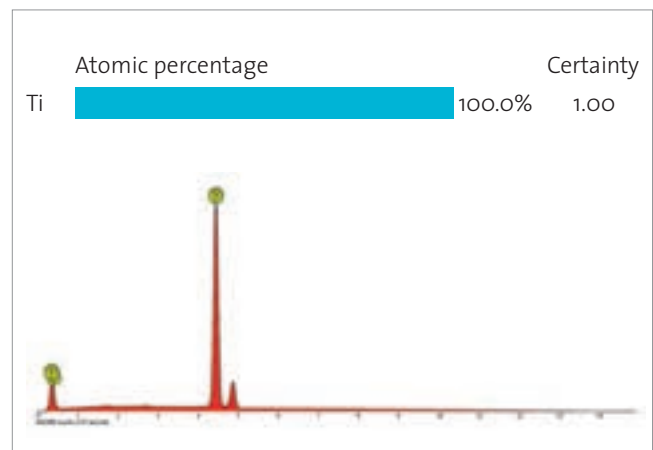
42 | Bredent – BlueSky (x2,500).



43 | Camlog – Conelog (x500).



44 | Camlog – Conelog, EDX area analysis (x2,500).



45 | Quantitative and qualitative elemental analysis of the Camlog Conelog implant surface (pure titanium).

SGS and Bredent) are presented at comparable magnification in Figures 33 to 42. The continuous improvement process in Camlog implants deserves special mention. While the samples analyzed in 2008 showed residues of blasting material on up to ten per cent of the total surface, the figure for 2011 was less than three per cent for the same implant type. In the current study, all three implant models (Camlog, Conelog and iSy) exhibited completely residue-free surfaces in the elemental analysis. Thus, the spectrum of the EDX analysis of the Conelog implant surface indicates only titanium (Figs. 43 to 45).

Discussion

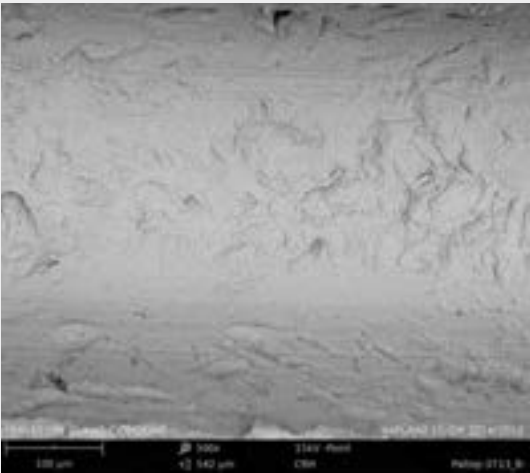
The clinical relevance of minuscule particles and contaminants on dental implants is a matter of debate. Even the manufacturers of implants on whose implants more or less large amounts of organic or inorganic contaminants were found in tests have reported statistical success rates that are not dif-

ferent from those of other implants, proving their point with specially conducted studies.

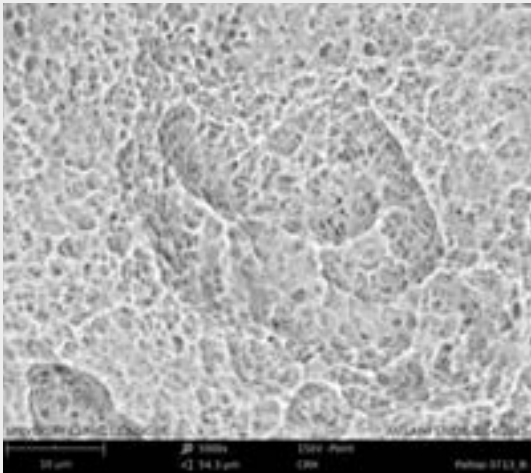
Up to a point, biocompatible aluminium oxide residues are unlikely to affect the bone-implant contact (BIC) [18,19]. But how does the human body handle polyethylene or chromium-nickel-steel particles? Even if these particles are relatively firmly attached to the implant surface, they are likely to become 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 [20], so that questions related to the clinical relevance of such impurities cannot simply be brushed aside. From orthopaedics it is known that particle-induced macrophage activation is associated with an increased osteoclastogenesis and may therefore cause increased bone resorption [21].

Limitations of SEM resolution –
Or: How clean would you like it?



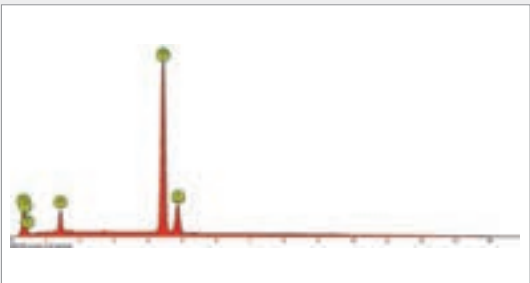
46 | Paltop Advanced Dental Implant (x500).



47 | Paltop Advanced Dental Implant (x5,000).

The scope of elemental analysis by energy-dispersive X-ray spectroscopy (EDX) as used in this study is limited because it does not detect superficial contaminations on the nanoscale. As the electron beam impacts the implant, it is scattered in the sample, so that the emitted X-rays form a pear-shaped volume having a diameter of 0.1 to 2 µm. Thus, signals originating in the top few nanometres of an implant surface are extinguished by deeper signals.

Only X-ray photoelectron spectroscopy (XPS) can produce such sensitive evidence in layers 5 to 10 nm in thickness. The kinetic energy of the photoelectrons of an atom is measured to determine its binding energy, which is characteristic of the atom from which the electron emanates. This can be used to determine whether the cleaning process after acid etching of the implant surface has left traces of acid or if the water used for the cleaning itself was clean enough. An Israeli manufacturer (Paltop) has decided to consistently clean their products with ultra-pure water (UPW), which is rather expensive to produce compared to regular demineralized water and is otherwise mostly employed by the semiconductor industry. XPS analyses of the implant surfaces thus cleaned show no traces of sulphur, silicon, zinc or chlorine, inorganic impurities not infrequently found in the XPS analyses of the sandblasted and acid-etched surfaces of implants by other manufacturers investigated in 2014 as the corresponding ISIS identification cards were prepared [22]. The material contrast image showed no residue on the Ti-6Al-4V ELI implant (Figs. 46 and 47). The corresponding EDX analysis shows only the typical elements for grade 5 titanium (Fig. 48 and Table 5).



48 | EDX spectrum for the Paltop implant.

Atomic percentage		Certainty
Ti	65.6%	1.00
O	24.4%	0.96
Al	7.3%	0.99
V	2.7%	0.96

Table 5 | Quantitative elemental analysis of the Ti-6Al-4V ELI implant surface (Paltop).

One point of criticism that has been repeatedly expressed by some manufacturers in the context of the present study has already been responded to in the published report on the 2011/12 implant trial.

The criticism goes roughly like this: The implant specimen used in this study patterns are only ran-

dom samples. A scientific study requires at least five to seven implants of each implant type to make statistically valid statements about a quality standard.

But the reply can only be that those implants are medical devices where – unlike with general technical goods – defects cannot be remedied or “repaired”

Sterile packaging – bedchamber of implants: from simple and non-sterile to elaborately protected

While a limited number of technologies has now taken over the manufacturing of implants, the ingenuity of manufacturers in packaging their implants apparently knows no limits. The studied implants represented a wide variety of designs, where aspects such as ease of use, safe transport, contamination-free storage and production costs appeared to be in competition.

On the one hand, there are uncompromising elaborate constructions that offer safe handling and are sure to eat into the manufacturer's profit margin (Fig. 49). The illustration shows a complex packaging design where the implant is inserted in a separate sleeve made of the same material (grade 5 titanium) as the implant itself to reduce the influence of other materials to a minimum.

On the other hand, there are simple packaging solutions where the implant is simply sealed in a double plastic bag and the manufacturer seems to have deemed even a stabilizing outer wrapper such as a blister pack to be too costly. Figure 50 shows a sterile package compromised by a sharp-edged cover screw.



49 | Example of elaborate sterile packaging, longitudinal section (Paltop).



50 | Sterile packaging compromised by a sharp-edged cover screw (BlueSkyBio).

once inserted. Each of the implants examined was sterile-packed and intended for use in patients.

One might therefore counter by asking why the manufacturers' quality management is obviously subject to daily fluctuations and why implants are released which yield suboptimal results in individual testing.

Each day we are tasked with winning the trust of our patients, and each time we perform an implantological treatment we are trying to prove worthy of this trust. For individual manufacturers to reject studies like the present one or to allege image manipulation is not particularly helpful in this endeavour. But the vast majority of the studied implants presents an encouraging picture. By far most manufacturers are aware of their responsibility and provide implantologists in Europe with solidly made systems. ■

To find the list of references visit the web (www.teamwork-media.de). Follow the link "Literaturverzeichnis" in the left sidebar.

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Appeal to readers

We would have liked to be able to present results for implants by the following manufacturers:

- Ihde Dental (Switzerland)
- MozoGrau (Spain)
- SHINHUNG (Korea)
- Etgar Implants (Israel)
- Signo Vincos (Portugal/Brazil)

Despite several reminders or placement of a regular order, these implants could not be analyzed.

If you are a user of implants by these manufacturers and as interested as we are in the results, please mail us at duddeck@bdizedi.org.

