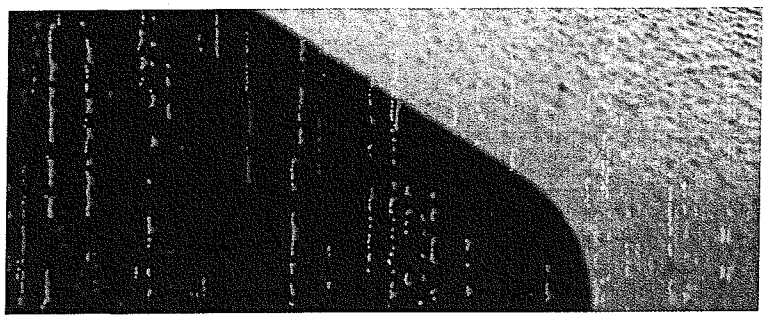
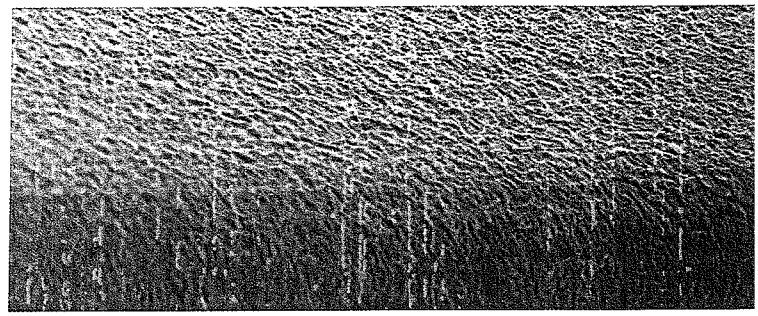
BDIZ EDI

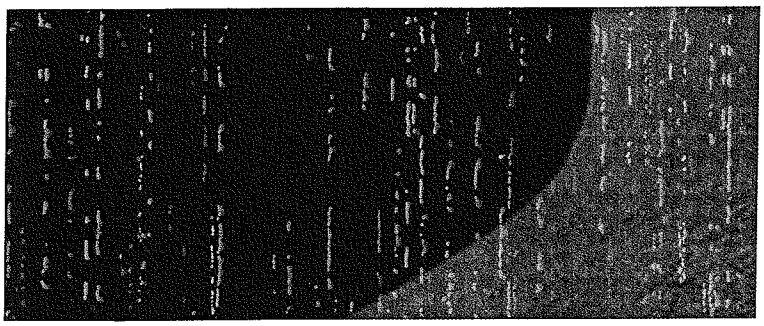
Bundesverband der implantologisch tätigen Zahnärzte in Europa e.V.
European Association of Dental Implantologists

EDI Journal

European Journal for Dental Implantologists

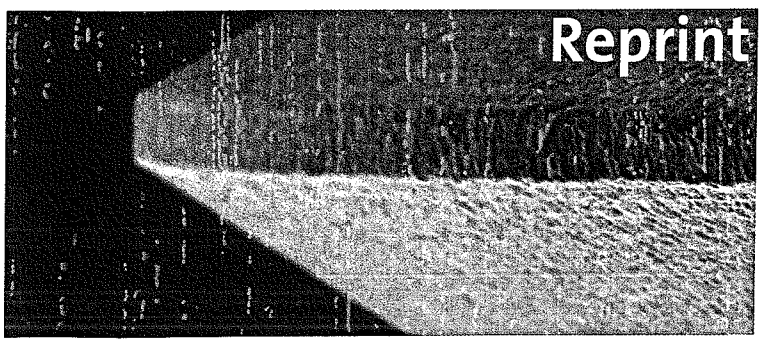


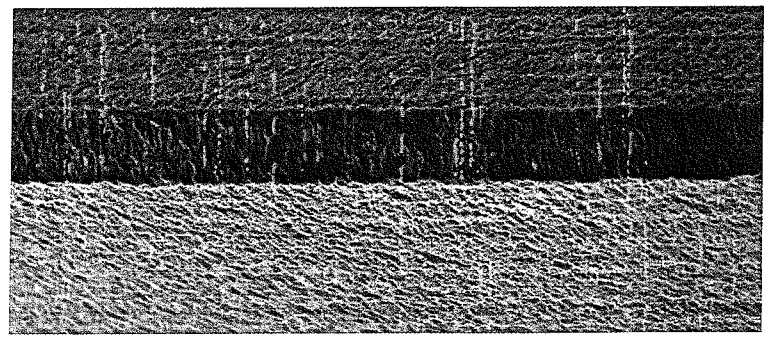


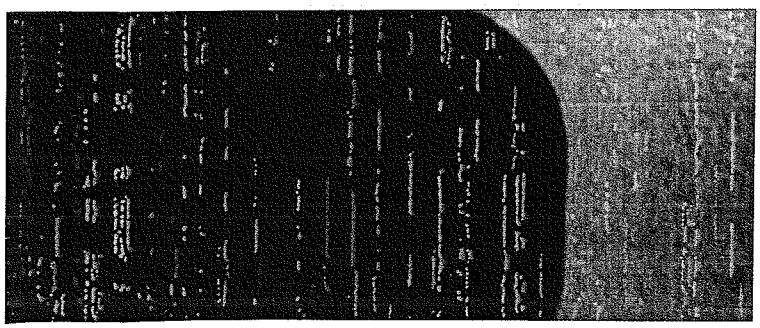


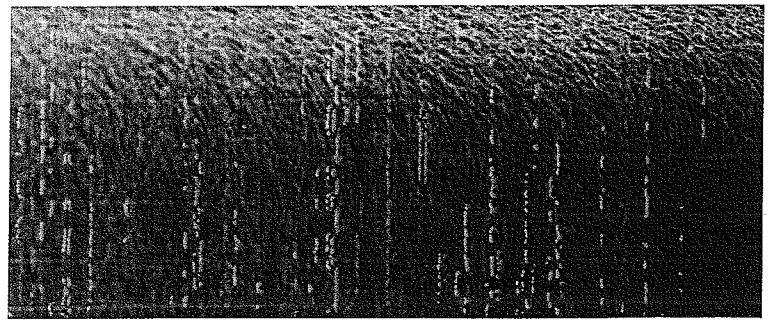
Surface characteristics and quality of implants in sterile packaging

SEM examination and qualitative and quantitative elemental analysis of 54 implants









European Association
of Dental Implantologists (BDIZ EDI)

Lipowskystr. 12 · 81373 Munich · Germany
Phone +49 89 720 69-888 · Fax +49 89 720 69-023
office-munich@bdizedi.org · www.bdizedi.org

SEM examination and qualitative and quantitative elemental analysis of 54 implants

Surface characteristics and quality of implants in sterile packaging

Dr Dirk Duddeck[1,2], Schaghajegh Iranpour[1], Mehmet Ali Derman[1], Dr Jörg Neugebauer[1,3] and Professor Joachim E. Zöller[1]

As a part of the activities of the Qualification and Registration Committee – Scientific Research of the BDIZ EDI (Quality and Research Committee), the material of numerous failed implants had been examined over many years. But equally interesting is the question of the process quality of implants in sterile packaging. In 2008, BDIZ EDI had commissioned its first study on the topic, examining the surfaces of 23 sterile-wrapped implants from nine countries with a scanning electron microscope and subjecting them to a qualitative and quantitative elemental analysis. That study had yielded unexpected results such as significant residue of the aluminium oxide abrasive as well as organic contaminants and imprecise thread structures on the implants of certain manufacturers [7].

On behalf of BDIZ EDI, an extensive follow-up study was conducted from 2010 to 2012, examining and comparing 57 different implants by 44 manufacturers in 13 countries (Table 1). Not only implants made of titanium and its alloys, but also implants made of zirconia and tantalum as well as temporary implants were studied. Compared to the previous study, the current analysis showed significantly fewer implants with systematic organic impurities originating in the manufacturing and/or packaging process, and some manufacturers have made significant improvements in reducing abrasive residues (aluminium oxide) on the sterile implants. What role do these residues play clinically? And how can oral implantologists be sure that their implants of choice have been subjected to an adequate quality control? These are the questions this paper strives to answer.

Implant surface affects biologic response

The surface of a dental implant significantly determines the initial phase of the biological response to the inserted implant and therefore has a great influence on its integration into the surrounding tissues [6]. Osteoblast proliferation and osteoblast differentiation on the implant surface depend critically on the microstructure of that surface [10]. Rough implant surfaces can therefore greatly support the process of osseointegration, particularly in the context of concomitant augmentation measures.

In recent years, many research groups and implant manufacturers have developed techniques to improve the micromorphological structure of implant surfaces with the aim of further increasing success rates or facilitating earlier loading of the inserted implants [2,8,12,14,16].

Background and objectives

Surface enlargement in titanium implants can be achieved by additive or subtractive methods. Sandblasted implant surfaces (Figs. 1 and 2), etched implant surfaces (Figs. 3 and 4) or the so-called SLA surfaces (sandblasted with large-grit particles and then acid-etched; Figs. 5 and 6) have also been established as state-of-the-art techniques, just like anodic oxidation (Figs. 7 and 8). The abrasive agents used were mainly corundum (aluminium oxide), calcium phosphate compounds or titanium oxide. Sintered implant surfaces (Figs. 9 and 10) have the advantage of significantly increasing the surface area, but they are found only on continuous level surfaces, i.e. not on

[1] *Interdisciplinary Policlinic for Oral Surgery and Implantology, Department of Oral and Maxillofacial Plastic Surgery, University of Cologne, Germany*
[2] *Dentalforum Berlin, Berlin, Germany*
[3] *Zahnärztliche Gemeinschaftspraxis Dres. Bayer, Kistler, Elbertzhagen und Kollegen, Landsberg am Lech, Germany*

Table 1, part 1
Implants examined, 2010–2012.

Manufacturer	Country	Type	Surface treatment	Material
3M Espe	Germany	MDI MAX	Sandblasted/etched	Grade 5 titanium
Alphatech (Henry Schein)	Germany	BoniTex	Sandblasted (HA), etched, CaP-coated	Grade 4 titanium
Alphatech (Henry Schein)	Germany	DuoTex	Sandblasted (HA)/etched	Grade 4 titanium
Alphatech (Henry Schein)	Germany	VTPS	Titanium plasma spray	Grade 4 titanium
Alpha Bio	Israel	SPI Spiral Implant	Sandblasted/etched	Grade 5 titanium
Anthogyr	France	Axiom	Sandblasted (BCP)/etched	Grade 5 titanium
Astra Tech (Dentsply Implants)	Sweden	OsseoSpeed	Sandblasted (TiO_2)	Grade 4 titanium
Bego	Germany	Semados	Sandblasted/etched	Grade 4 titanium
Bicon	USA	Integra-CP	Double sandblasted (HA)	Grade 5 titanium
Biomet 3i	USA/Spain	Osseotite Certain Prevail 2	Double-etched	Grade 4 titanium
BpiSystems	Germany	Classic	Sandblasted/etched	Grade 4 titanium
BpiSystems	Germany	Ceramic	Sandblasted	Zirconium oxide
Bredent	Germany	Blue Sky	Sandblasted/etched	Grade 4 titanium
Bredent	Germany	White Sky	Sandblasted	Zirconium oxide
BTI	Spain	Interna	Etched	Grade 4 titanium*
C. Hafner	Germany	i-Plant	Machined	Grade 5 titanium
Camlog	Switzerland	Conelog Screw-Line Promote Plus	Sandblasted/etched	Grade 4 titanium
Camlog	Switzerland	Camlog Screw-Line Promote Plus	Sandblasted/etched	Grade 4 titanium
Champions	Germany	Tulip	Sandblasted/etched	Grade 4 titanium
Clinical House	Switzerland	Perio Type	Anodically oxidized and CaP-coated	Grade 4 titanium
Creamed	Germany	Omnis	Etched	Zirconium oxide
Cumdente	Germany	Click Implant	Sandblasted	Grade 5 titanium
Dentalpoint	Switzerland	Zeramex	Sandblasted/etched	Zirconium oxide
Dentegris	Germany	Straight	Sandblasted/etched	Grade 4 titanium
Dentegris	Germany	Tapered	Sandblasted/etched	Grade 4 titanium
Dentegris	Germany	Sinus Lift (SL)	Sandblasted/etched	Grade 4 titanium
Dentsply Friadent (Dentsply Implants)	Germany	Xive	Sandblasted/etched	Grade 2 titanium
Dentsply Friadent (Dentsply Implants)	Germany	Ankylos	Sandblasted/etched	Grade 2 titanium
DRS	Germany	Octagon	Sandblasted/etched	Grade 4 titanium

Sandblasted = *With Al_2O_3 (unless otherwise noted)*
BCP = *Biphasic calcium phosphate (BCP), 60% hydroxyapatite (HA) and 40% tricalcium phosphate (TCP)*
CaP = *Calcium phosphate*
HA = *Hydroxyapatite*
* = *Manufacturer reports using "special" titanium (grade 4) with better mechanical properties than regular grade 4 titanium*

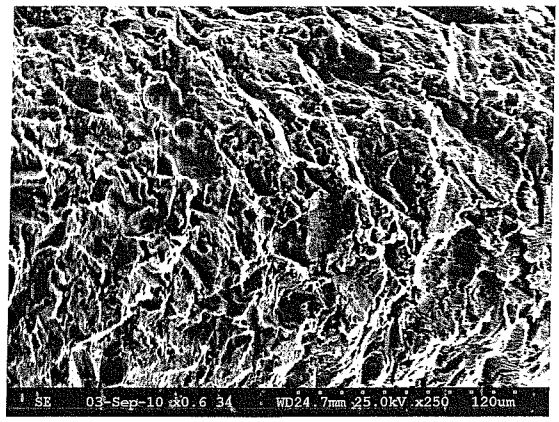


Fig. 1 Sandblasted implant Astra OsseoSpeed, SE x250.

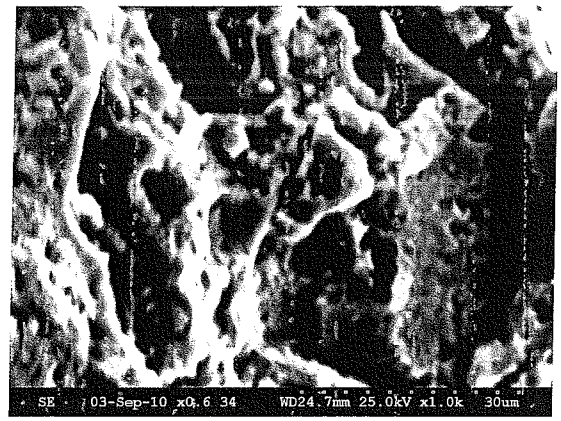


Fig. 2 Sandblasted implant Astra OsseoSpeed, SE x1000.

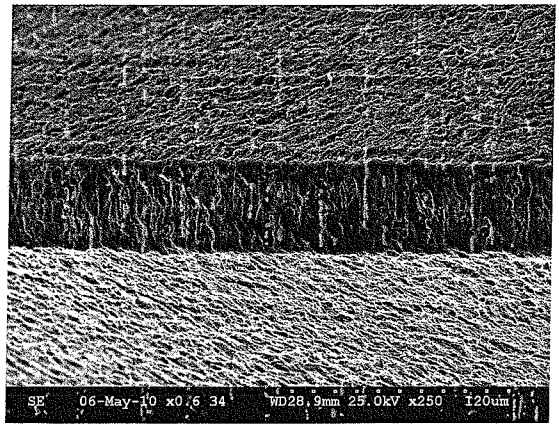


Fig. 3 Etched implant BTI Interna, SE x250.

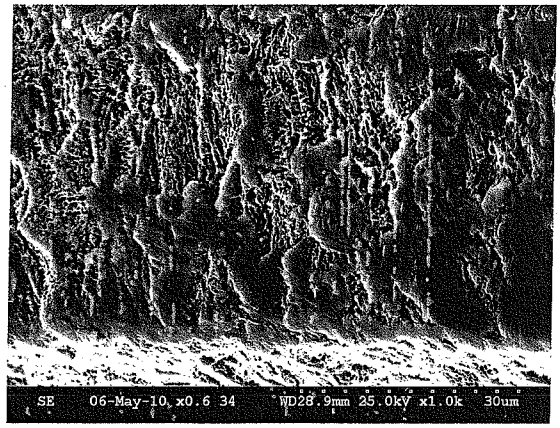


Fig. 4 Etched implant BTI Interna, SE x1000.

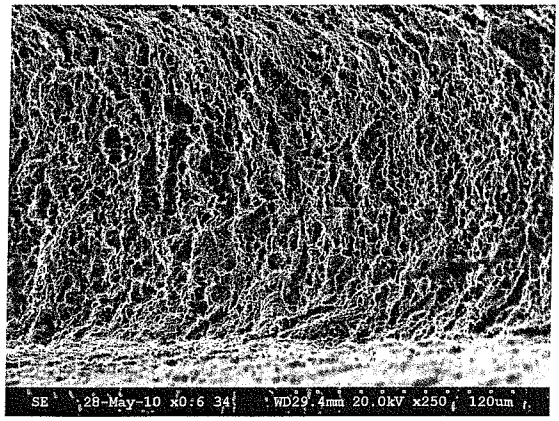


Fig. 5 Sandblasted/etched implant Camlog Conelog, SE x250.

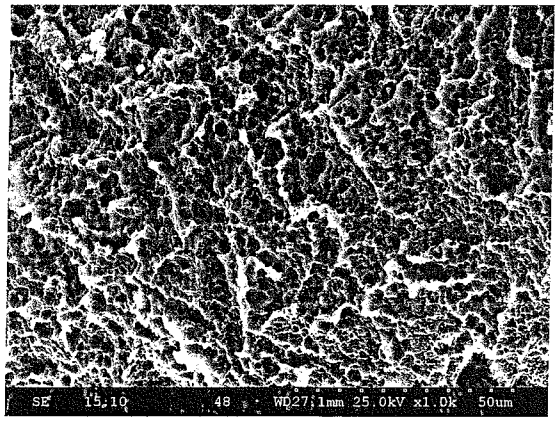


Fig. 6 Sandblasted/etched implant Camlog Conelog, SE x1000.

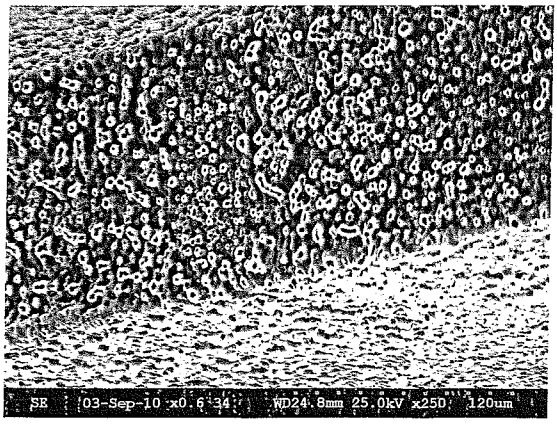


Fig. 7 Anodically oxidized implant NobelActive, SE x250.

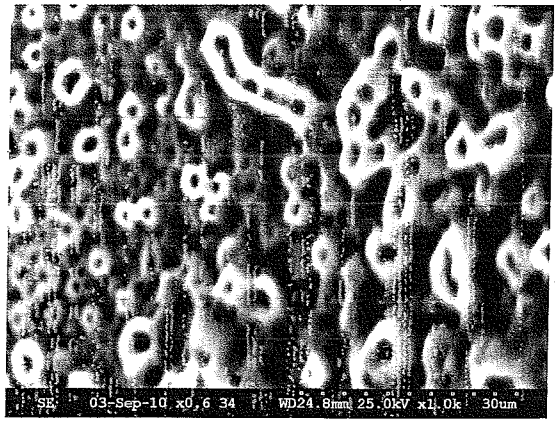


Fig. 8 Anodically oxidized implant NobelActive, SE x1000.

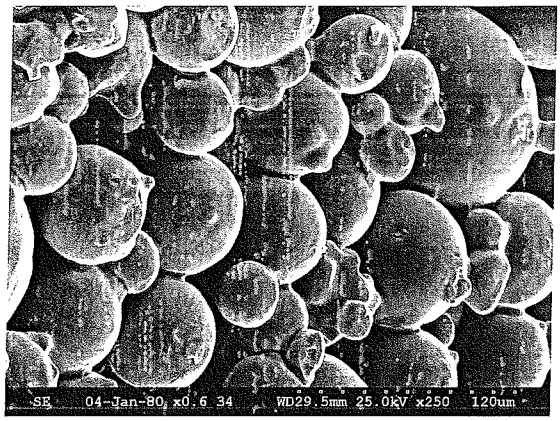


Fig. 9 Sintered implant OT Medical OT F3, SE x250.

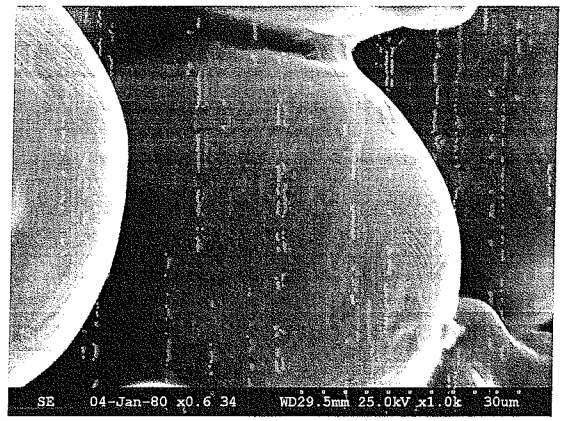


Fig. 10 Sintered implant OT Medical OT F3, SE x1000.

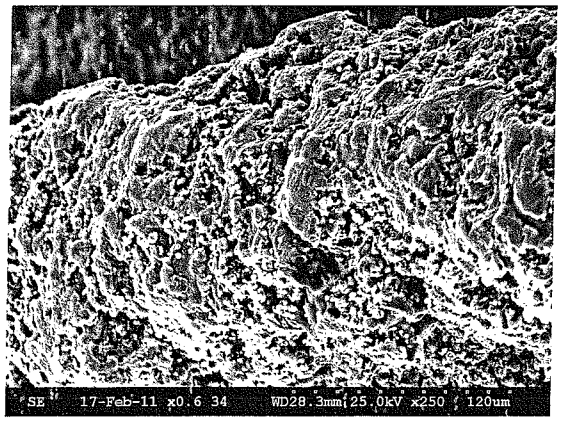


Fig. 11 Titanium plasma spray implant Alphatech VTPS, SE x250.

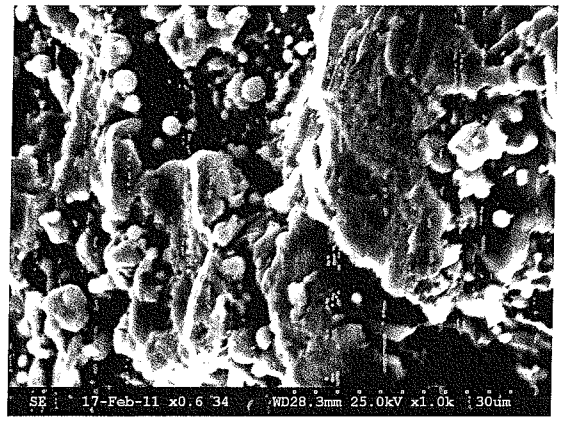


Fig. 12 Titanium plasma spray implant Alphatech VTPS, SE x1000.

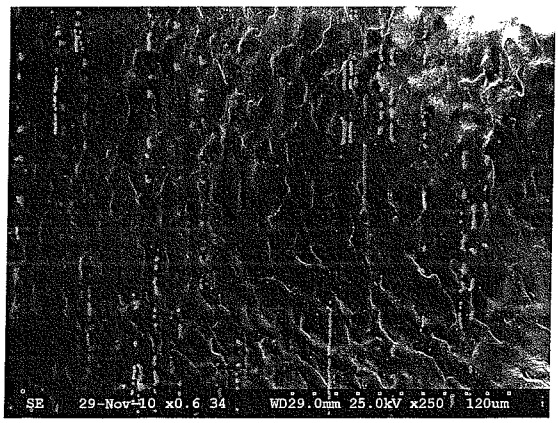


Fig. 13 Zirconia implant Creamed Omnis, SE x250.

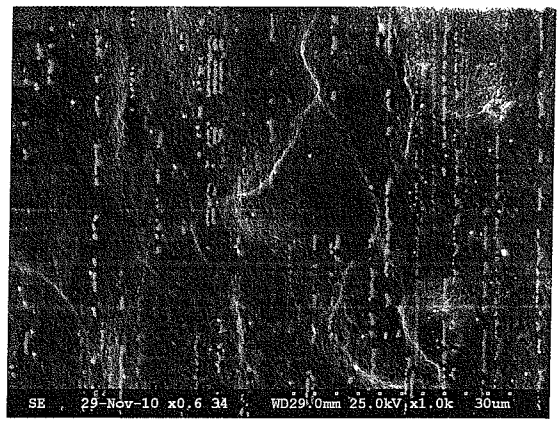


Fig. 14 Zirconia implant Creamed Omnis, SE x1000.

screw-type implants. Additive processes such as coating with titanium plasma spray (Figs. 11 and 12) are now used only rarely. By contrast, recent years have seen an increase in the number of implant systems made of zirconia (Figs. 13 and 14), which have significant benefits in terms of aesthetics as well as for soft-tissue apposition. But compared to titanium implants, there are still relatively few long-term studies on zirconia implants. Two-piece zirconia implants today allow submerged healing. Implants made of alloys of titanium and zirconia (Figs. 15 and 16) as well as new hybrid implants consisting of titanium with a central part made of tantalum (Figs. 17 and 18) add to the variety of available systems.

Different surface treatments for titanium performed during the industrial implant production process not only influence the surface characteristics of the implants but also may leave residues on the implants themselves. Since the early 1990s, implants have been tested for residue [11] originat-

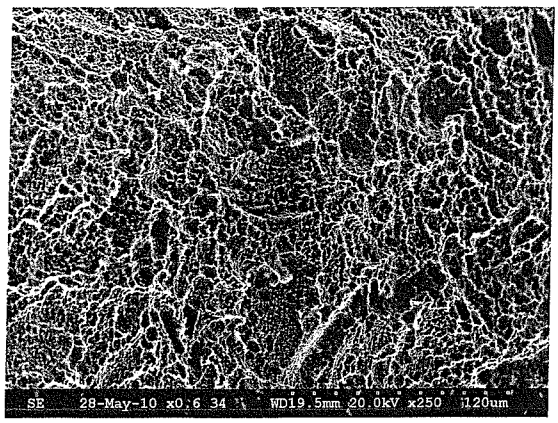


Fig. 15 Alloy of titanium and zirconium (Straumann Roxolid SLActive), SE x250.

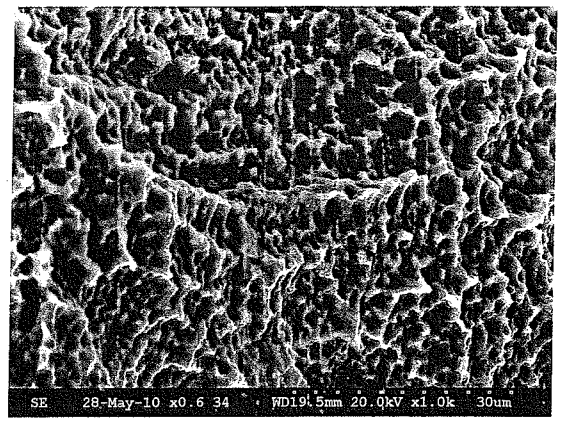


Fig. 16 Alloy of titanium and zirconium (Straumann Roxolid SLActive), SE x1000.

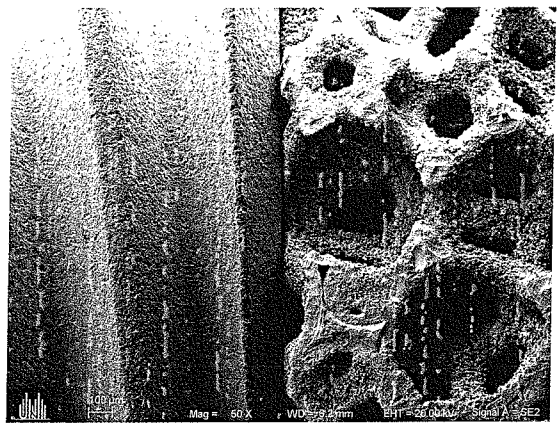


Fig. 17 Hybrid implant Zimmer Trabecular Metal, SE x50, MTX tantalum.

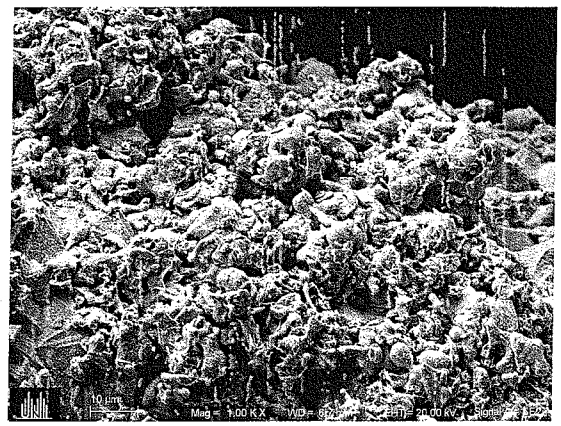


Fig. 18 Hybrid implant Zimmer Trabecular Metal, SE x1000, tantalum.

ing both in the actual production process and in the subsequent sterilization and packaging process [1]. The objective of the present follow-up study was to detect and identify process-related residue and handling-specific contamination on various implant systems and to compare the results with those of the previous study. In doing so, generalized residue distributed across the entire implant surface was distinguished from random local contamination; in either case, the findings were to be subjected to subsequent measurements and qualitative and quantitative elemental analysis.

Materials and methods

In the current study, conducted from 2010 to 2012, a total of 54 different implant systems by 44 implant manufacturers were examined by scanning electron microscopy. The study protocol called for three distinct study phases:

- The SEM material contrast image allowed conclusions to be drawn on (1) the chemical nature of the target material and (2) the distribution of different materials across the depicted surface. Elements with an atomic number lower than that of titanium (and, hence, less electron backscatter) appear darker in the material contrast image.
- The qualitative and quantitative analysis of the implant surfaces, the so-called energy-dispersive x-ray spectroscopy (EDS), uses the x-rays emitted by a sample to determine its elemental composition. An areal analysis and one or more spot analyses were performed for each implant.
- In the third and final phase of the study protocol, those implants exhibiting interesting findings on the material contrast image that were not only local but also distributed across most of the implant surface were topographically surveyed to identify the average area affected as a percentage of the total area.

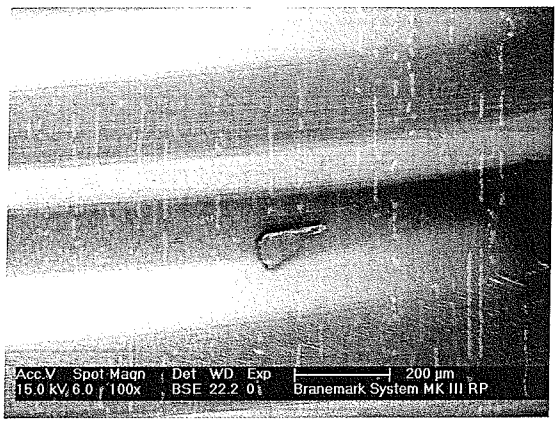


Fig. 19 Machined implant Brånemark MKIII, SE x100 (study 2008).

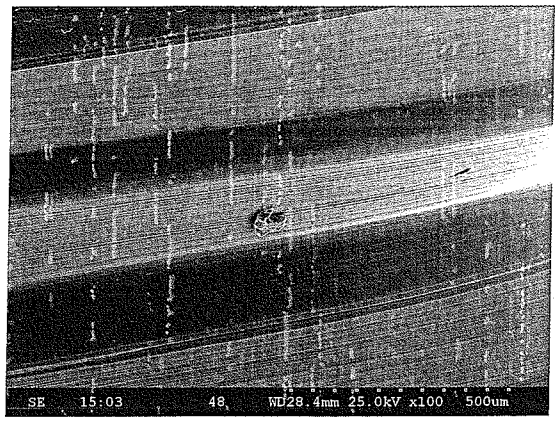


Fig. 20 Machined implant Nobel Biocare MKIII, SE x100 (study 2010–2012).

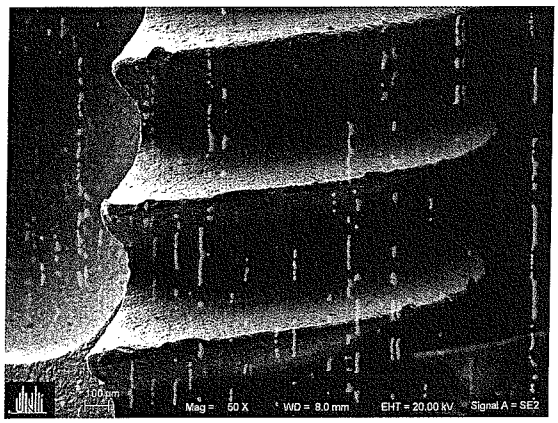


Fig. 21 Irregular outer thread edges, Tri Dental Implants Tri Vent implant, SE x50.

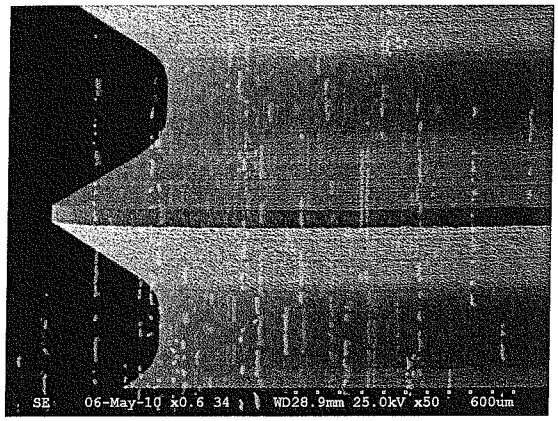


Fig. 22 Precise thread structure, BTI Interna, SE x50.

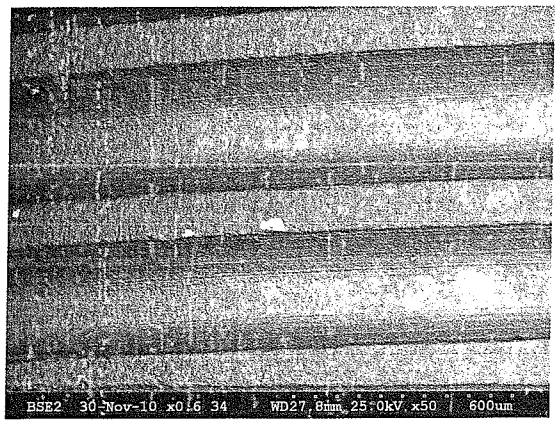


Fig. 23 Clinical House Perio Type, BSE x50.

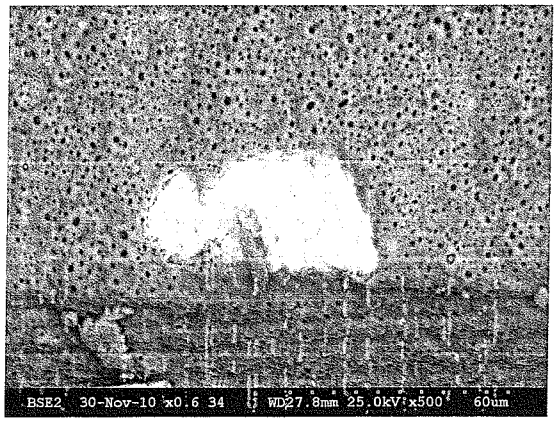


Fig. 24 Clinical House Perio Type, BSE x500.

Results

Like its predecessor study in 2008, this study also found topographic irregularities, contaminants and residue on some implants.

Topographic irregularities

As in 2008, one machined implant had residual titanium filings on the thread surface (Figs. 19 and 20). One implant had irregularly threaded outer thread edges (Fig. 21), but the vast majority of the implants analyzed were precisely threaded (Fig. 22). In one implant the anodized boundary layer was incomplete (Figs. 23 and 24).

Localized organic contamination

16 implants exhibited localized areas of dot-shaped organic impurities (carbon), which were analyzed quantitatively and qualitatively (for examples see Figs. 25 to 28, Tables 2 and 3).

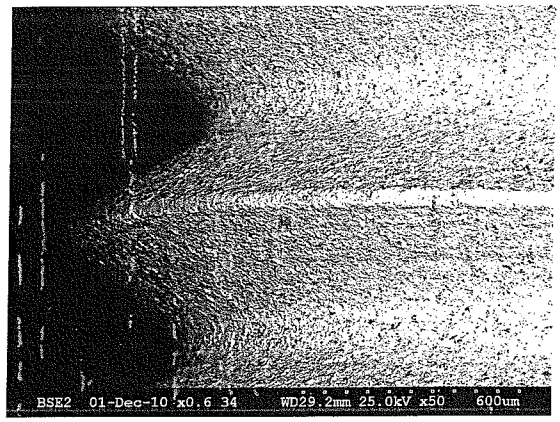


Fig. 25 Southern IBi, BSE x50.

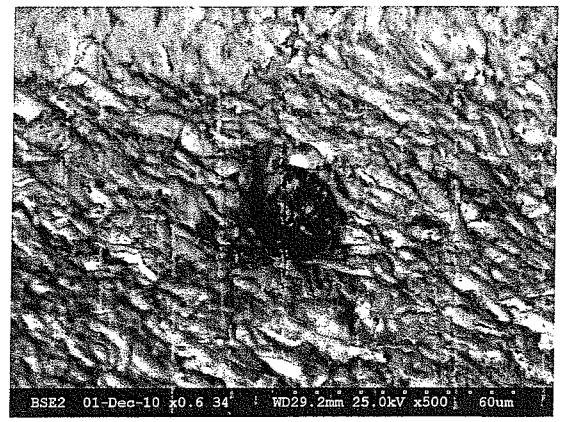


Fig. 26 Southern IBi, BSE x500.

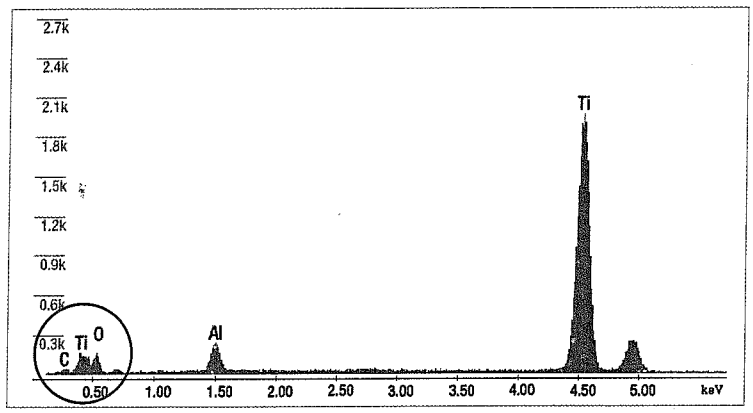


Fig. 27 Southern EDX, qualitative elemental analysis, implant surface.

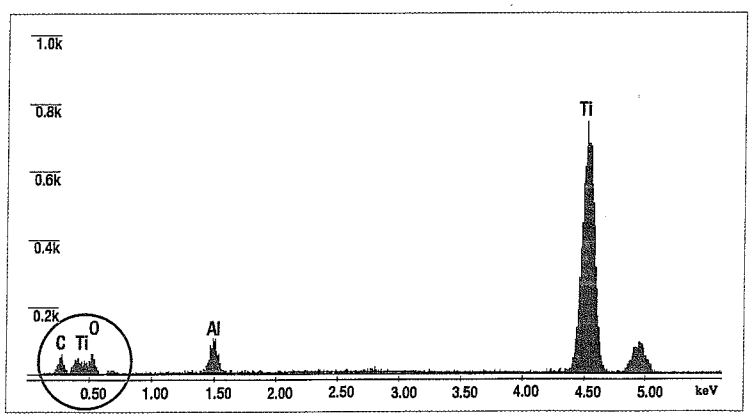


Fig. 28 Southern EDX, qualitative elemental analysis, spot analysis.

Table 2 Southern IBi, quantitative elemental analysis.

Element	Wt%	At%
CK	6.64	15.56
OK	22.98	40.48
AlK	6.26	6.54
TiK	64.29	37.82
Total	100.00	100.00

Element	Wt%	At%
CK	17.20	35.19
OK	19.70	30.25
AlK	5.52	5.03
TiK	57.58	29.54
Total	100.00	100.00

Table 3 Southern IBi, quantitative elemental analysis, spot.

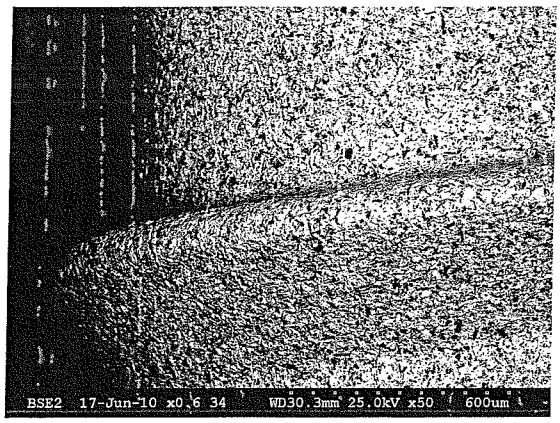


Fig. 29 3M Espe MDI MAX implant, BSE x50.

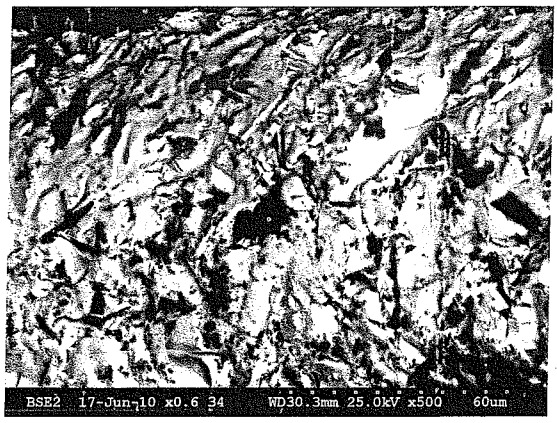


Fig. 30 3M Espe MDI MAX implant, BSE x500.

Fig. 31 Part of spot, BSE x500.

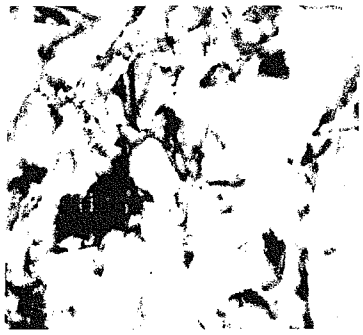


Fig. 32 Reduced colour depth to determine the area ratio.

Channel:	
	Greyscale
Value(s):	254
96 in range:	0,0 (50)
96 below:	17,2
96 above:	82,8
Mean:	211
Median:	255

Fig. 33 Black area ratio (= Al_2O_3 particles) up to 17.2 per cent.

Generalized inorganic residue from the manufacturing process

Generalized inorganic residue from the manufacturing process as well as carbon appeared in the SEM material contrast image as dark light elements in seven implants (for examples see Figs. 29 and 30). Up to 17.2 per cent by area of aluminium oxide residue from sandblasting was found on some surfaces (Figs. 31 to 33).

Comparing the results of the current study with those of 2008, some manufacturers have been able to significantly reduce the aluminium oxide residue. In the case of Bego, the manufacturing process was substantively changed from a purely sandblasted to a sandblasted and etched surface (Figs. 34 and 35).

In the case of Camlog, the average amount of aluminium oxide residue was reduced from 10 per cent in 2008 to 2 per cent in the present study while retaining the same general manufacturing process (Figs. 36 and 37).

The implant of the Korean manufacturer Osstem (Osstem GS II) had shown a significant thread deformation in 2008 as a result of sandblasting with hydroxyapatite (Fig. 38). The current implant by the same manufacturer (Osstem TS III SA) no longer exhibits any such deformation (Fig. 39).

Discussion

The significance of the Al_2O_3 residue found in more than half of the sandblasted and etched implants examined has been the subject of controversy. For example, *Piatelli* and *Degidi* (2003) showed in an in-vivo study that traces of aluminium oxide have no statistically significant effect on osseointegration [13]. *Ruger* and *Gonsior* (2010) came to the opposite conclusion, namely that reducing the aluminium oxide residue on hip implants made of titanium to below 4 per cent resulted in significantly higher

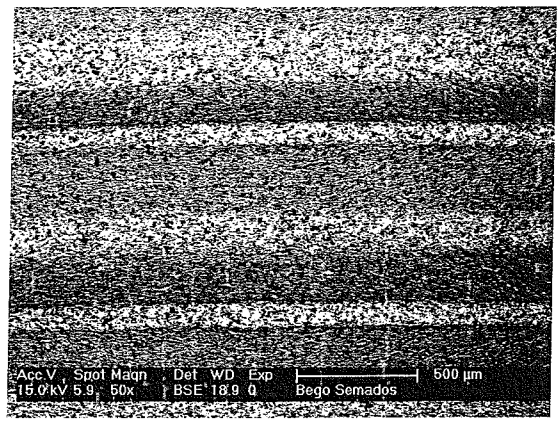


Fig. 34 Bego Semados (2008), BSE x50.

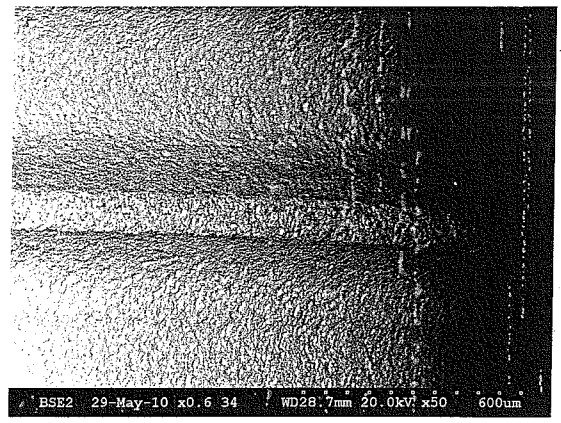


Fig. 35 Bego Semados (current), BSE x50.

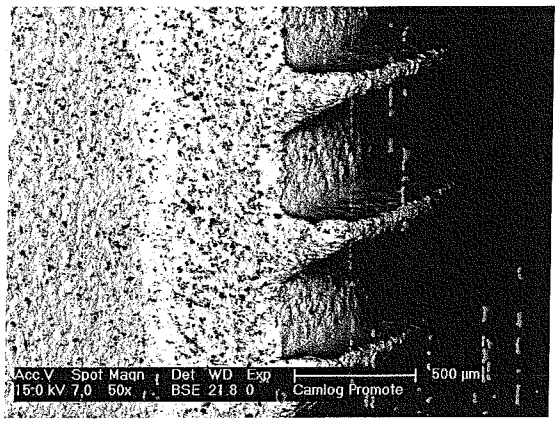


Fig. 36 Camlog (2008), BSE x50.

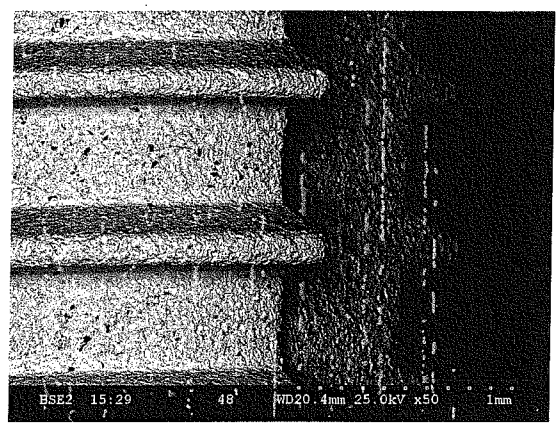


Fig. 37 Camlog (current), BSE x50.

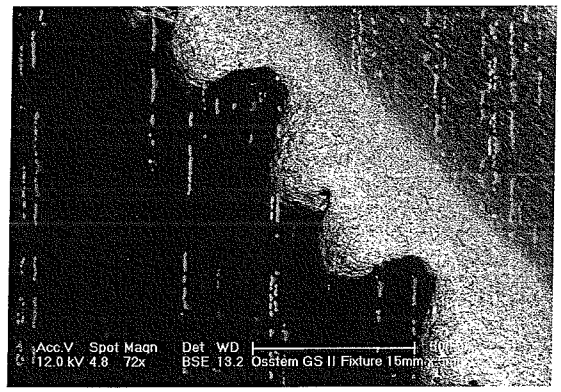


Fig. 38 Osstem (2008), SE x50.

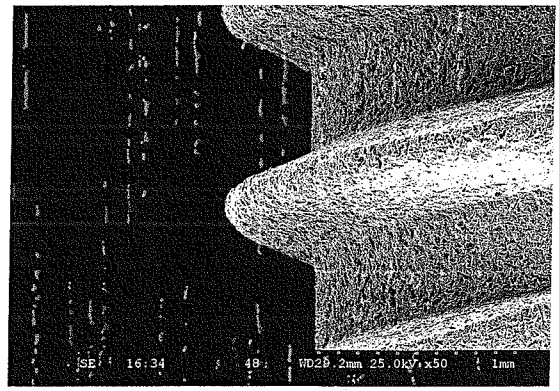


Fig. 39 Osstem (current), SE x50.

bone-to-implant contact (BIC) and, hence, more bone apposition [15]. This was confirmed by a study of *Canabarro* and coworkers (2008), who showed that high concentrations of Al_2O_3 on the titanium surface impeded mineralization of the extracellular matrix [3]. The fact remains that it is technically feasible to reduce the amount of Al_2O_3 on sandblasted implants and that this is likely to benefit the osseointegration result.

Unlike its predecessor in 2008, the present study did not show any significant, systematically occurring organic contaminants covering extended surfaces. For the more common selectively occurring spots of organic contaminants, such as might be taken up by macrophages immediately after insertion of the implant, there are currently no studies that show any effect of this on osseointegration. Further studies are needed.

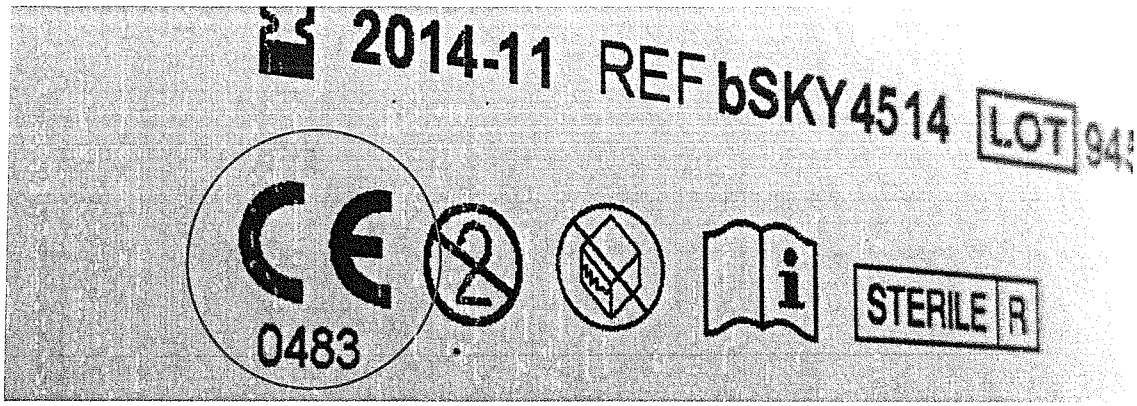


Fig. 40 CE mark on implant package.

Can we trust the CE mark on implants?

If you ask our dental colleagues what the CE mark (Fig. 40) means, an overwhelming majority believes that this mark implies that the quality of the respective medical device has been verified.

The manufacturer of a medical device must demonstrate, in the so-called EC Declaration of Conformity Process, that the product to be marketed is safe and that its medical and technical performance matches the medical indication claims in the product's labelling and advertising. External certified proof of the safety and performance of medical devices by a so-called "Notified Body" is required for manufacturers to be authorized to affix the CE mark to their products.

But the external Notified Bodies are the weak links in this chain. In general, these institutions possess high levels of professional competence in carrying out their duties. Reputable manufacturers are required to submit complete and diligently prepared documentation for the certification, which is created at considerable expense before launching a product. A report published in the British Medical Journal in October 2012, however, raises the question whether this system can protect the European market against grey imports [4]. Medical journalists applied for the CE mark for a fictional hip implant by an equally fictional Chinese manufacturer, which according to the (fictitious) documentation submitted releases toxic metal ions and causes fractures of the acetabulum, where the hip joint rests. The proceedings were filmed with hidden camera (viewable at the BMJ website: www.bmj.com/content/345/bmj.e7163). The result: On payment of the stipulated fee, that highly questionable implant received the coveted CE mark as a ticket for entry into the European market – from five Notified Bodies. The question remains: Quis custodiet ipsos custodes? Who watches the guards? Who audits the auditors?

We will gladly assume that the reputable manufacturers on the large European market have submitted reliable documents for the CE mark. But the procedure itself provides no protection against manipulation or criminal activity. Reason enough to consider a possible BDIZ EDI certificate for dental implants, to protect both patients and honest manufacturers from unsafe, carelessly produced grey imports on the market.

Summary

Many studies have confirmed that the treatment of implants to increase the biologically active surface supports and accelerates the process of osseointegration [5,9]. However, the manufacturing of implants requires an adequate system of quality controls. Although some manufacturers have made substantial improvements since our first survey in 2008, the current study again singles out a few implants with larger areas of surface blasting residue and selective organic impurities. BDIZ EDI will continue to examine the implants available on the European market at regular intervals. ■

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

Contact address

Dr Dirk Duddeck
Interdisciplinary Policlinic for Oral Surgery and Implantology
Department of Oral and Maxillofacial Plastic Surgery
University of Cologne
Director: Professor Joachim E. Zöller
Kerpener Straße 62
50937 Köln
Germany
dirk.duddeck@gmx.de