

“All that glitters ain’t gold”

Can ceramic implants meet higher expectations?

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When Prince wrote his song “Gold”, of which the headline of this article quotes the refrain, he tried to explain the problem of having exaggerated expectations in a relationship. Presumably, he was not thinking about an ideal material for dental implants. Zirconium dioxide may have some advantages in comparison with titanium or titanium alloys. Better aesthetic appearance in case of significant bone loss and low plaque affinity are benefits of this material. As the production process differs from titanium implants, one might expect that the surface cleanliness of zirconia implants further makes a difference.

Implant surfaces determine the initial phase of the biological response to the inserted implant and affect its ability to integrate into the surrounding tissue. Unfortunately, the majority of dental practitioners only receive limited non-biased information about the surface qual-

ity of implants used in their daily practice. Impurities on sterile-packaged implants, in particular organic particles from the production or packaging process, are highly suspected of being responsible for incomplete osseointegration of dental implants, inducing a foreign-body reaction, leading to early peri-implantitis or even loss of bone in the initial healing period.

Four consecutive studies over a period of more than ten years, conducted in close cooperation with the University of Cologne and the Charité–University Medicine Berlin, both in Germany, have shown that neither the CE (French: Conformité Européenne) marking nor U.S. Food and Drug Administration clearance can provide a reliable indication of the cleanliness of zirconia or titanium implants. Scanning electron microscopy (SEM) imaging and elemental analysis (EDS) revealed an increas-

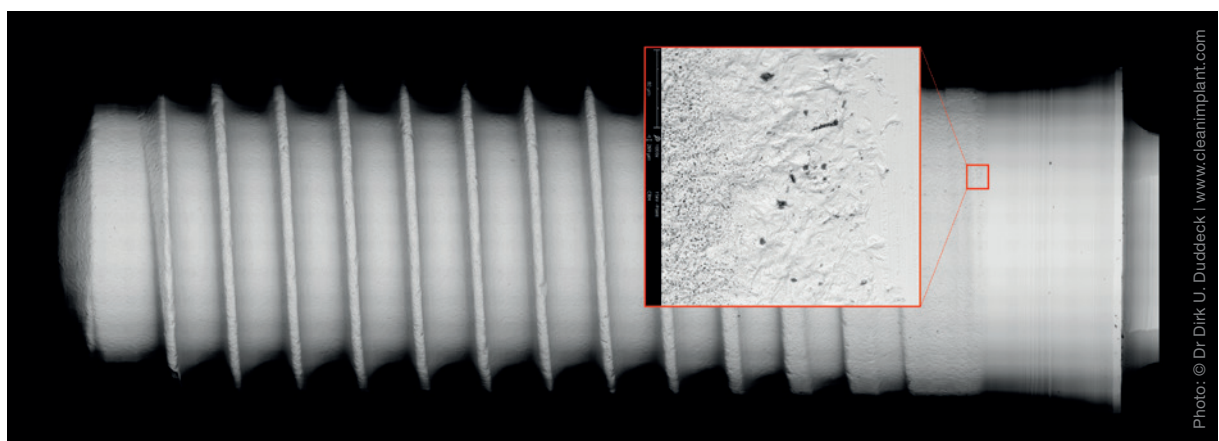
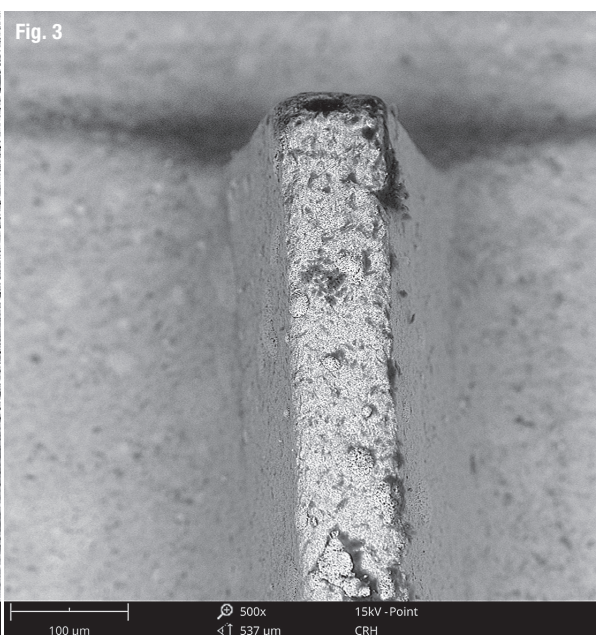
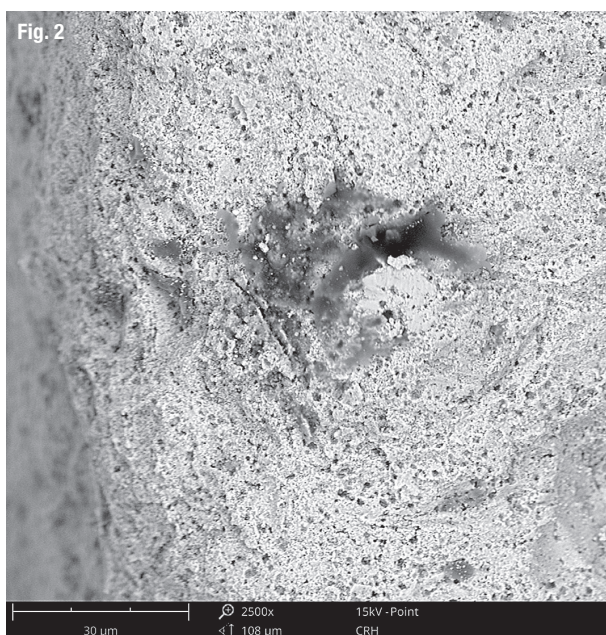


Fig. 1: Mapping image of a zirconia implant (assembled from 546 SEM images at 500x, detail enlargement at 1,000x).

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Fig. 2: Organic contamination on zirconia implant (SEM image at 2,500x). **Fig. 3:** Organic particles on outer thread of zirconia implant (SEM image at 500x).

ing number of dental implants with impurities. Intermediate results of the current Implant Study 2017–2018, performed by the CleanImplant Foundation and Charité, have given cause for concern. The study showed zirconia implants with clean surfaces, as well as others with remnants of aluminium oxide (Fig. 1) and samples with significant organic impurities (Figs. 2 & 3), thus indicating that any expectations of superior cleanliness of all zirconia implant systems may not be fulfilled.

CleanImplant, an independent non-profit organisation, carries out periodical quality assessments and is supported by a scientific advisory board. The board is chaired by renowned scientists and practitioners, such as Prof. Tomas Albrektsson (Sweden), Prof. Ann Wennerberg (Sweden), Dr Michael Norton (UK), Prof. Hugo de Bruyn (Netherlands), Prof. Florian Beuer (Germany), Dr Scott D. Ganz (US), Dr Jaafar Mouhyi (Morocco) and Dr Luigi Canullo (Italy).

The foundation established a thorough and accredited testing procedure that not only is being used for the Implant Study 2017–2018, but also builds the basis for a new, globally accepted quality seal for dental implants: the Trusted Quality Mark. All implants have to be unpacked and analysed by SEM under cleanroom conditions according to ISO Class 5 (DIN EN ISO 14644-1). The testing laboratory is accredited for this analysis according to DIN EN ISO/IEC 17025 and audited regularly by external, independent accreditation bodies. To avoid any possible cherry-picking, up to 600 single SEM images of each implant are digitally composed to one large image with an extremely high resolution, providing a perfect overview of the implant cleanliness.

The final results of the comprehensive Implant Study 2017–2018 with SEM/EDS data on zirconia and titanium implants will be presented at the 2019 IAOCI (International Academy of Ceramic Implantology) World Congress in Tampa, Florida, USA. The comparison regarding the cleanliness of titanium and ceramic implants may probably surprise some participants and may show, that “all that glitters ain’t gold”; that is, all that is white, is not necessarily clean. In other words, dentists should not only rely on the given marketing information to make a conscientious decision on a titanium or zirconia implant system.

When it comes to the question of implant production quality, we all should act according to a Lenin quote: “Trust is good, but control is better.”

More information and a corresponding newsletter can be found on the project’s website www.cleanimplant.com.

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