Quality deficiencies of sterile packaged implants

Sterile and yet dirty?

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In 2019, the FDA released two decades of previously unpublished data and 2.1 million reports of failed dental implants from which more than 100,000 reports referred to 2018 alone. Most of these failures related to a lack of osseointegration, raising major concerns among dentists in the US and abroad as the number of additional unreported losses is likely to be much higher. Comments made by manufacturers, regarding these figures, focus on patients with unfavourable clinical preconditions and even blame dentists for their lack of experience and training. Is this the whole truth?

Alarming results—also for ceramic implants

In a recent study, conducted by the non-profit CleanImplant Foundation in collaboration with the Charitè–University Medicine Berlin, more than 100 different sterile-packaged implants—including ceramic and titanium implants—from 80 implant brands were analysed. SEM imaging and elemental analysis (EDS) were performed in an officially accredited testing laboratory, according to DIN EN ISO/IEC 17025. Almost every second implant sample that was unpacked under cleanroom conditions and analysed in the SEM showed considerable contamination, i.e. unwanted particles originating from the manufacturing, handling or packaging of the implant. These contaminants on sterile packaged implants, especially organic particles from the manufacturing or packaging process, can cause an uncontrolled foreign body reaction resulting in osteoclastogenesis, leaving rough areas of the implant surface exposed to bacterial colonisation.[1,2] Significant amounts of foreign particles were detected on the sterile implant surfaces, with not only iron, chromium, molybdenum, copper, tin, tungsten and nickel but also major organic contamination.

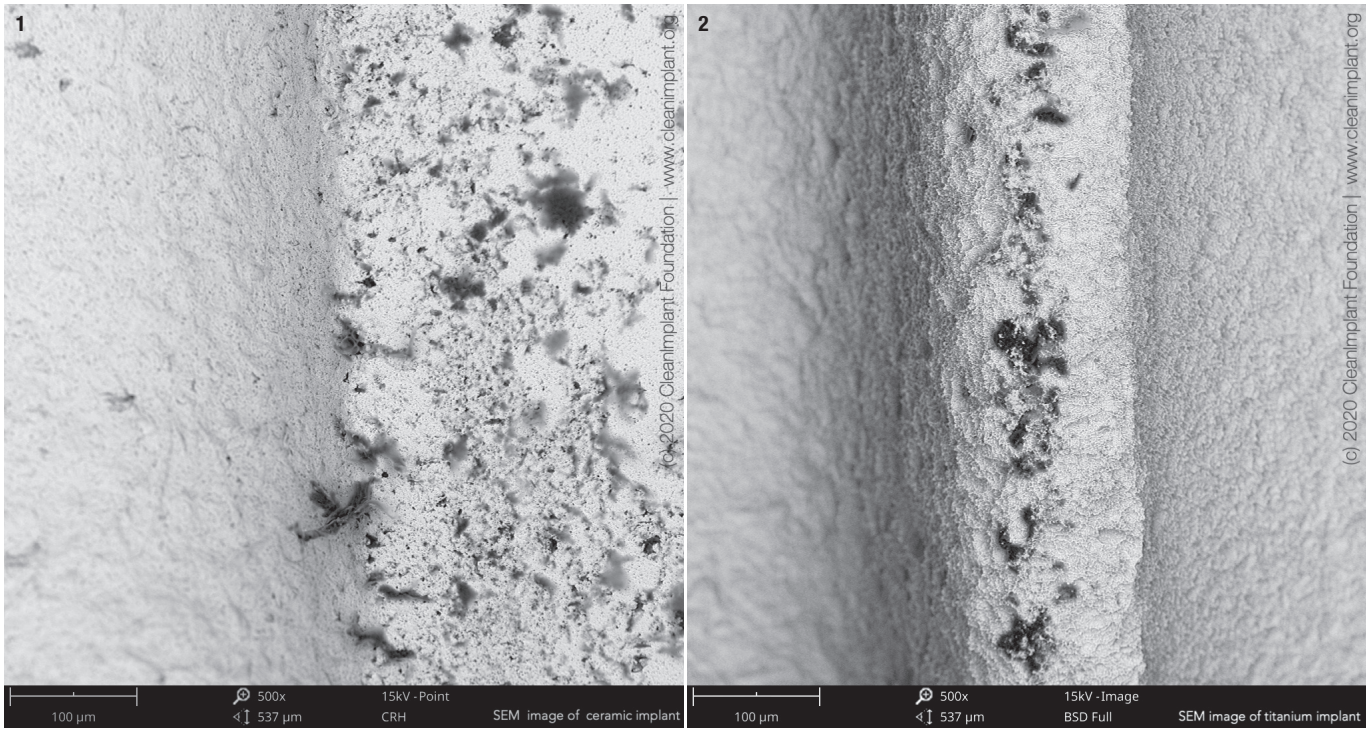

Fig. 1: Numerous organic particles (black) on a ceramic implant (SEM 500 x). **Fig. 2:** Organic particles (black) on outer thread of titanium implant (SEM 500 x).

Additional analysis of these organic contaminants, using time-of-flight secondary ion mass spectrometry (ToF-SIMS), revealed thermoplastic materials, synthetic polymers, polysiloxanes and even dodecylbenzene sulfonic acid (DBSA). DBSA is found in washing detergents and is a hazardous surfactant, according to the United States Environmental Protection Agency (EPA). It is noteworthy that all implants analysed carried the FDA label or CE mark. The results showed that neither the national label for market approval nor the size or name of a manufacturer could guarantee that implant surfaces are free of significant impurities. Clinicians should think twice before considering adding zirconia implants to their portfolio just because they are white and promised to be biologically beneficial. Organic particles from 1 to 100 µm in diameter were also found on ceramic implant samples (Fig. 1).

Instead of only blaming inexperienced clinicians or patients with unfavourable preconditions for the high number of FDA-documented implant losses, it should be considered that contaminants on sterile packaged implants—in other words a lack of quality and "sterile dirt" that is technically avoidable—may also play a significant role in the incomplete osseointegration of dental implants, bone loss in the early healing phase and even the failure of implants.

Quality seal creates safety

As a consequence of the obvious lack of quality control in implant manufacturing, the CleanImplant Foundation introduced a globally recognised test procedure in 2017. The independent organisation published a consensus-based guideline with thresholds leading to the award of the "Trusted Quality Mark" (the consensus paper is available at www.cleanimplant.org). This test procedure and process of analysis always requires the testing of five implant samples of the same type. At least two of these implants are obtained directly from dental practices on a random basis, so that factory manipulation or the dispatch of particularly clean test samples can be ruled out.

Before the seal of approval can be awarded, two members of CleanImplant's Scientific Advisory Board independently review the results of the technical analysis that have to meet the current criteria as well as the clinical documentation of the implant system that has to give proof of a survival rate of at least 95 per cent over more than two years.[3,4] Profs. Tomas Albrektsson, Ann Wennerberg, Florian Beuer, Jaafar Mouhyi, Hugo de Bruyn and Drs Luigi Cannulo and Michael Norton, past president of the AO, form the Scientific Advisory Board that is responsible for the peer-review process. Their signatures on the final CleanImplant Trusted Quality seal guarantee an unbiased quality assessment.

Time to avoid risks and build trust

In these extraordinary times when patients avoid medical treatments due to possible infection and many dentists even fear for their economic existence, it is more important than ever for practitioners to give their patients the confidence that only safe and high-quality medical products are used. Within a few months, more than 80,000 dentists have joined the CleanImplant Foundation's quality initiative on Facebook alone. Every month, well over 1,000 users search for reliable information on clean implant systems on the project's website. Dentists and implantologists, who want to build trust and inform their patients about the cleanliness of implants in use in their clinic, can join the project and request a personalised certificate—a convincing sign that conveys confidence in the waiting room or even on the clinic's website.

The current alarming situation of factory-made contaminated dental implants presents two different risks. For the patient, contaminants can induce an uncontrolled foreign body reaction with peri-implantitis, bone loss or even the failure of an implant, thus compromising the clinical outcome and the patient's expectation. On the other hand, practitioners unknowingly using dirty implants have to deal with the risk of patient lawsuits for dental malpractice. Both risks are avoidable.

Literature

about the author

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