Contaminants on ceramic implants: Do manufacturing deficits compromise their value?

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With new developments in biomaterials science and industrial technology, the profession has recognised that the long-term success of zirconium dioxide implants is demonstrably comparable to that of titanium. However, despite best manufacturing and packaging practices, the presence of contaminants and pollutants at the bone–implant interface of any implant material can initiate an inflammatory response with consequential bone resorption. There is a pressing need for the industry to recognise the inherent value of screening dental implant devices for these toxic compounds to obviate the bio-interface reactions they can cause in the early phase of osseointegration (Figs. 1 & 2).

Particulate and thin film contaminants on the implant surface are identified by using a unique combination of analytic techniques. The precise location of impurities is detected using a scanning electron microscope (SEM) with additional elemental analyses by energy dispersive X-ray spectroscopy (EDS) performed in a particle-free cleanroom. The chemical compound of these contaminants is identified by subsequent time-of-flight secondary ion mass spectrometry (ToF-SIMS). Both analytical tasks are performed in officially accredited testing laboratories according to DIN EN ISO/IEC 17025:2018, thereby ensuring that all analyses are precise and unbiased.

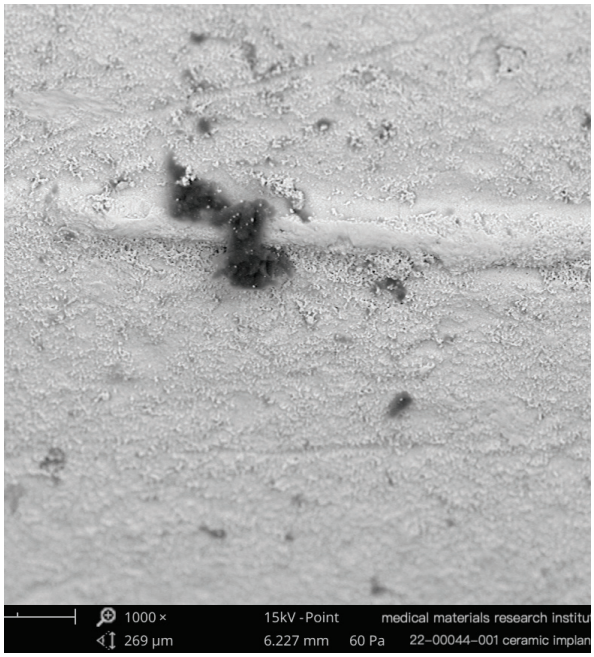

Fig. 1: SEM image revealing significant carbonaceous contaminants on the shoulder of a sterile packaged ceramic implant.

The identification of Didecyldimethylammonium chloride (DDAC) on a sterile packaged ceramic implant, as shown in Figure 1, is alarming. DDAC is a cell-toxic quaternary ammonium compound used as a biocide and pesticide. It causes the disruption of intermolecular interactions and the dissociation of lipid bilayers. This ceramic implant type is claimed to be “innovative and safe” by the responsible provider and legal manufacturer.

For the past eight years, the CleanImplant Foundation has worked with a growing group of industry partners to ensure particle-free implant production. It has introduced a quality seal for tested, verified clean implants, the “Trusted Quality Mark” (www.cleanimplant.org), an acknowledgement of these manufacturers’ tireless efforts on behalf of the profession. The criteria for implants that are largely free of foreign particles were defined in guidelines published in a 2017 consensus paper. The renowned scientists of the Foundation’s Scientific Advisory Board decide on the receipt of the quality seal through a peer-reviewed process. To sustain the use of the Trusted Quality seal, a random selection of five samples of the implant system is subjected to a rigorous, independent analysis every two years.

The demand for implant dentistry continues unabated. It has long been understood that the wear, friction, and biofilm formation in the corrosive oral environment associated with titanium can promote inflammatory reactions and bone destruction in the surrounding tissues, the very essence of why the transition to ceramic implants. However, ceramic implants compromised with plastic residues and cell-toxic biocides are no less a danger.

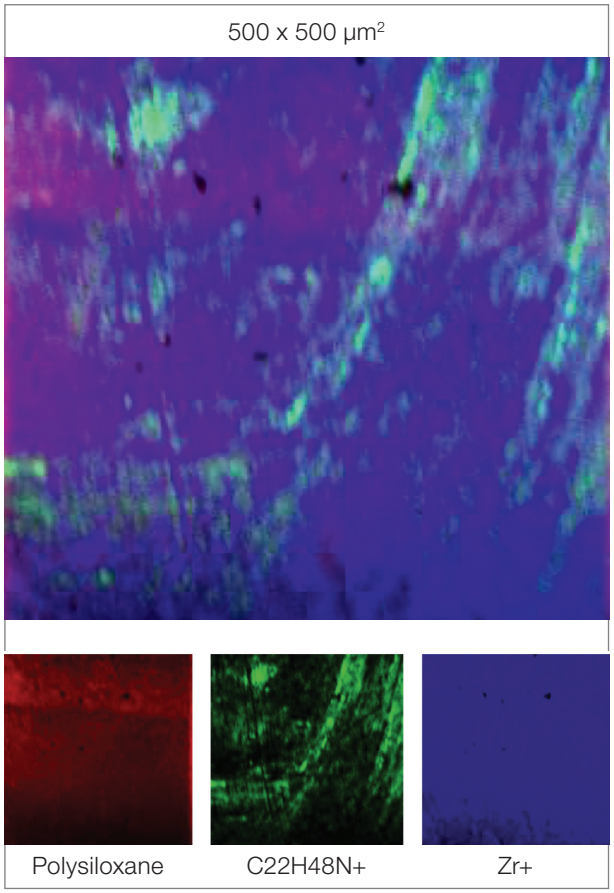

Fig. 2: ToF-SIMS visualisation of plastic residues (Polysiloxane) and a quaternary ammonium compound (C22H48N+) on the ceramic implant shown in Figure 1.

There is no ethical conundrum in dentistry. Contaminants on the surface of an implant constitute a contaminated implant. This is not a difficult puzzle or problem to solve. We have the means to prevent this; it can be done, it must be done, and there is no excuse for it not being done. Companies owe this to clinicians, patients, and to themselves. We are a health science profession; the health of our patients and the science behind the materials we use warrant unprecedented and unimpeachable quality standards. There must be trust within the circle of care giving, that is the ultimate reward of service.

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