Contaminated implants raise global concern among dentists

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There is a problem that many implantologists are not aware of: recent analyses of dental implants using scanning electron microscopy indicate that an alarming number of sterile-packaged implants are contaminated. In addition, the number of manufacturers affected is increasing, which is a major cause for concern. The placement of contaminated implants can lead to a decline in the quality of clinical outcomes and, as a result, possibly lead to an increase in malpractice cases and thus compensations claims.

In this regard, the organisers of a study currently being conducted in collaboration with the Charité–University Medicine Berlin in Germany are approached by concerned dentists almost daily. Compared with three previous studies over the last ten years,[1–3] this new study indicates a concerning increase in contaminations of implants due to production, such as metallic particles (including residues of stainless-steel particles, tungsten and tin bronze from the blasting process). Moreover, the study has found large amounts of organic particles originating either from handling and packaging processes, or from rough implant surfaces coming into direct contact with the packaging. The discussion about the clinical consequences of such contaminations is as old as the discipline of implant dentistry itself. For instance, in implants that had not successfully osseointegrated, Büsing and Donath both found significant foreign body giant cells in the areas surrounding foreign material residue.[4,5] The authors assumed that either foreign particles had found their way into the osseous bed during the implant placement procedure or the implant material itself was contaminated.

Sterile debris

In the 1980s, Prof. Gerhard Wahl examined dental implants under a scanning electron microscope. In his findings, published in 1987, he states that an alarming number of contaminated implants were found using this

Fig. 1: Implant analysis by an accredited laboratory.

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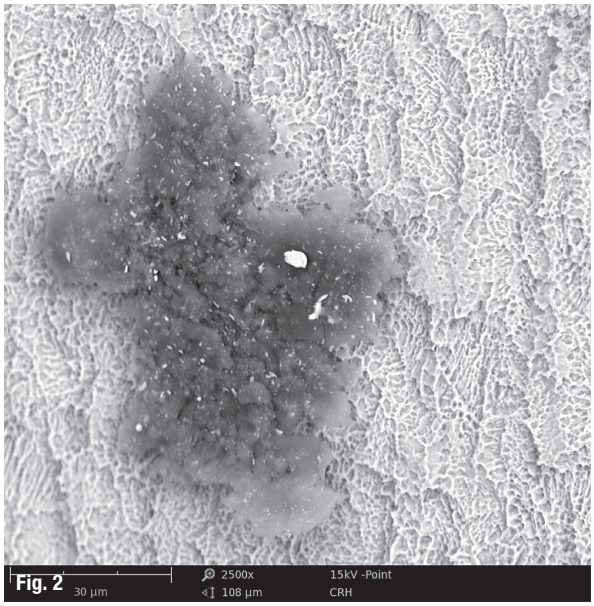

Fig. 2: Tin bronze particles (light) on organic contamination (dark) – SEM 2,500x.

method.[6] Yet, it seemed at that time that most manufacturers did not care a great deal about these issues or about quality management in general.

Today—more than 30 years later—there is no longer any need for dentists to extensively sterilise implants at their dental practices. However, in light of the most recent scientific findings, the following statement by Prof. Wahl can be considered more topical than ever: "We need to admit that, for a long time, 'sterile debris' has found its way into the bodies of patients during implant placement procedures, and such contamination was difficult to detect preoperatively owing to a very small particle size."[6]

Plaque-like contaminations that are larger in size are most likely to be encapsulated in soft tissue, whereas particles smaller than 10 µm tend to be absorbed by the body through phagocytosis. Considering the absorption of these foreign materials by the patient's body, the question needs to be raised of whether the problem of incompletely osseointegrated, contaminated implants and contaminated implants with low bone–implant contact values can be solved within the context of an academic discussion. It becomes obvious that—even after 30 years—many manufacturers apparently still do not think it is worth ensuring that their implants are as sterile and clean as they can possibly be according to state-of-the-art technology, and without foreign particle contaminations of any kind. This is where dental practitioners come into play: if not even existing CE marking certification can guarantee the cleanliness of implant surfaces, how are dental clinicians supposed to know which systems are safe to use in clinical procedures in their practices? After all, providing patients with the best possible medical devices and thus the best possible treatment should be a goal worth aiming for.

Trusted Quality Mark

By introducing a global quality label for clean implants, the CleanImplant Foundation, a non-profit organisation located in Berlin, is addressing the issue of contaminated implants. Supported by numerous renowned scientists, the organisation has released a consensus paper which stipulates specific criteria implants have to meet in order to be considered clean. Most importantly, these criteria include being free of foreign particles, as well as long-term clinical documentation. Last year, implant systems from MIS Implants Technologies (V3), bredent (blueSKY), NucleOSS (T6), BTI (UnicCa), MegaGen (AnyRidge) and NDI (REPLICATE) were awarded the Trusted Quality Mark according to a strict peer-review process. In a comprehensive analysis at a testing laboratory accredited according to DIN EN ISO/IEC also implants from Straumann (SLA Standard) and Nobel Biocare (NobelActive), met the strict testing criteria of this international quality label in 2019.

Transparent testing conditions

At this year's IDS, to be held from 12 to 16 March in Cologne in Germany, dentists can form their own opinions on their preferred implant systems. Implants can be checked on-site by means of a scanning electron microscope at the CleanImplant Foundation's booth. Those who are not able to attend the trade fair in Cologne this spring can register as a member of the CleanImplant Community online. For the annual membership fee, equivalent to the cost of one implant, members receive professional support in the case of legal disputes, as well as a certificate to display in the waiting room of their dental practice that states that the implants used by the dentist are certified to be free of contamination. This serves as an indicator for patients and referral practices alike. For further information, visit CleanImplant at IDS in Hall 11.1 at Booth B020.

Editorial note: A list of references can be obtained from the author.

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