Impurities on Sterile Packaged Implants: Is the Rise of Cheap Copy-Cat Products a Danger for our Patients?

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Background & Aim

Residues on sterile-packaged implants, in particular, organic particles originating in the production or packaging process, are suspected to be responsible for cases of incomplete osseo-integration or early bone loss. Three consecutive studies in the last 10 years performing SEM imaging and elemental analysis of 250 different dental implants have shown that neither the CE mark nor the FDA clearance is a reliable indicator for the purity of dental implants. What are the potential risks and how can we protect ourselves and our patients from implants of inferior quality?

Methods

In order to avoid artifacts, implant samples were unpacked and analyzed in the scanning electron microscope (Phenom ProX) under cleanroom conditions according to ISO class 5. With a special mapping technique, more than 360 single high-resolution SEM images of each implant were digitally composed to one large SEM image of extremely high resolution. Additional spot analyses of impurities using Energy Dispersive X-ray Spectroscopy (EDS) showed the chemical nature of the foreign material. Analyses were performed according to DIN EN ISO/IEC 17025.

Results

In 2017 a catalog of criteria for cleanliness of dental implants was agreed in a consensus process* of renowned scientists and board members of the independent non-profit Clean-Implant Foundation. According to this criteria, a series of more than 50 implants have been analyzed in the SEM. Results showed very clean implants but also implants with severe organic and/or inorganic contaminations containing e.g. tungsten, copper, chromium, iron, nickel and even PTFE.

Conclusion

30 years after the first SEM research about contaminations on dental implants by Wahl et al., we still can find major impurities on many sterile implants today. Not only clinical1,2 but also legal implications may occur in the future if practitioners are using implants of inferior quality. The quality of a dental implant is always the result of appropriate quality management. Results of SEM/EDS analyses in 2017 give cause for concern.

*) 20-pages Consensus Paper is available for download at www.cleanimplant.com