Surface cleanliness of dental implants: Current insights

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Manufacturing-related contamination of dental implants represents a significant yet under-recognised risk factor for implant failure. This review critically examines the evidence on surface cleanliness, focusing on the analytical protocols and findings of the CleanImplant Foundation. Using scanning electron microscopy and energy-dispersive X-ray spectroscopy, multiple studies have revealed metallic, organic and polymeric residues on sterile implants. Although these impurities can induce foreign body reactions and compromise osseointegration, current standards remain largely consensus-based. This review identifies methodological gaps and proposes a framework for future evidence-based testing to establish reproducible cleanliness thresholds and strengthen patient safety in implantology.

Introduction

Sterility is a regulatory requirement for dental implants, yet cleanliness—the absence of residual material on implant surfaces—remains insufficiently defined. The pioneering work by Duddeck revealed through scanning electron microscopy (SEM) and energy-dispersive X-ray spectroscopy (EDS) that many sterile implants harbour inorganic and organic debris invisible to the naked eye.[1] Recognising this discrepancy, the CleanImplant Foundation (CIF) was founded in 2016 to systematically assess and certify implant cleanliness. By employing ISO-accredited laboratories and transparent evaluation protocols, the CIF provides manufacturers and clinicians with objective data on implant surface quality.[2] Nevertheless, the absence of globally harmonised cleanliness standards means that permissible levels of surface residues vary between manufacturers. Since surface contamination may provoke inflammatory or immune responses that interfere with osseointegration,[3] defining and validating cleanliness thresholds is crucial for consistent clinical outcomes. This review aims to summarise current findings on implant surface contamination, analyse the scientific and procedural framework of the CIF, and outline future directions for evidence-based cleanliness standards in implantology.

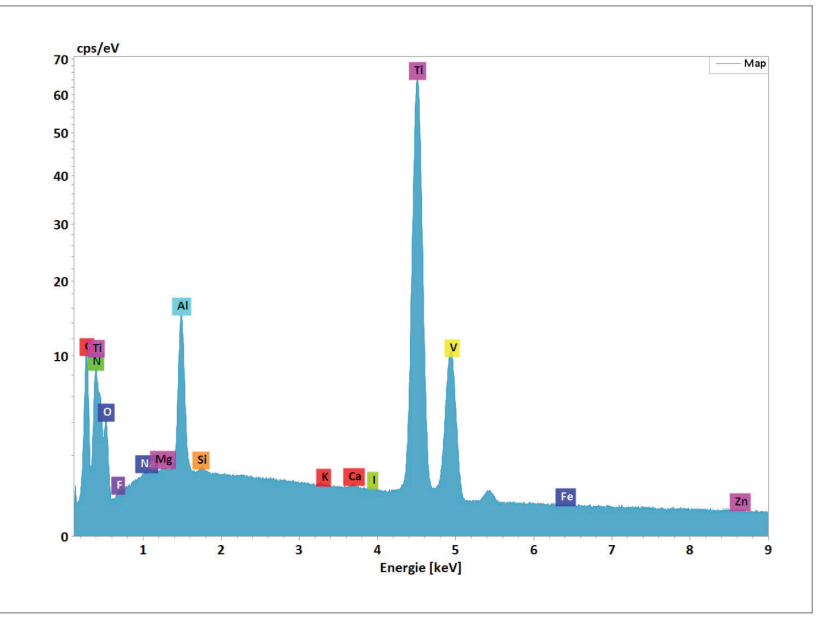


Fig. 1: Integrated spectrum across the entire imaged area. C = carbon; Ti = titanium; N = nitrogen; O = oxygen; F = fluorine; Na = sodium; Mg = magnesium; Al = aluminium; Si = silicone; K = potassium; Ca = calcium; I = iodine; V = vanadium; Fe = iron; Zn = zinc.

Materials and methods

This review was conducted to synthesise and critically analyse the available literature and institutional data concerning surface contamination of dental implants and the methodologies used to evaluate implant cleanliness. The research design followed the general principles of systematic qualitative review.

Relevant publications published between January 2016 and May 2025 were identified through a structured literature search in PubMed, ResearchGate and Google Scholar. The search terms were “CleanImplant Foundation”, “implant surface contamination”, “osseointegration”, “peri-implantitis”, “foreign body reaction”, “scanning electron microscopy (SEM)”, and “energy-dispersive X-ray spectroscopy (EDS)”. Additional material was obtained from the CIF’s official documentation, including its “Trusted Quality” mark reports and technical notes published between 2017 and 2025. The search was supplemented by manual screening of bibliographies from key articles to ensure comprehensive coverage.

Studies were included if they (1) provided analytical data on implant surface composition or contamination, (2) investigated biological or clinical consequences of surface residues, or (3) described standardised laboratory protocols for implant surface evaluation. Studies were excluded if they (1) lacked methodological transparency, (2) focused on non-titanium materials or (3) were unrelated to dental implantology. The final selection encompassed a variety of study types, including experimental *in vitro* analyses, *in vivo* animal models, and clinical or observational studies.

Data extraction focused on identifying the types of contaminants reported—such as metallic, organic and polymeric residues—as well as the analytical methods used for detection. The synthesis process further included comparing methodological frameworks and cleanliness thresholds between studies, particularly with reference to the evaluation procedures of the CIF. These procedures involve high-resolution SEM imaging and EDS compositional analysis under ISO Class 5 clean room conditions in laboratories accredited according to DIN EN ISO/IEC 17025, ensuring both accuracy and reproducibility.

Each study was analysed with respect to the reliability of its analytical procedures, the clarity of its contamination classification criteria, and the presence or absence of clinical correlation. Special attention was given to the distinction between sterility—the absence of living microorganisms—and cleanliness, defined as the absence of non-biological surface residues. This differentiation was essential for interpreting the significance of findings within the context of implant safety.

The results of this synthesis were interpreted descriptively and analytically rather than quantitatively, given the heterogeneity of study designs and outcome parameters. The review thus provides an integrative overview of the state of research, placing emphasis on the scientific basis, reproducibility and clinical relevance of surface cleanliness assessment methods. By aligning and contrasting the laboratory procedures of the CIF with peer-reviewed evidence, this study identifies existing methodological gaps and proposes directions for the establishment of evidence-based cleanliness standards in dental implantology.

Results

Findings of the CIF

The CIF's analytical protocol employs the Phenom ProX scanning electron microscope (Thermo Fisher Scientific), equipped with a high-sensitivity back-scattered electron detector and silicon drift detector for EDS, enabling compositional imaging at nanometre resolution. Implants are unpacked under ISO Class 5 clean room conditions to prevent testing artefacts.[4]

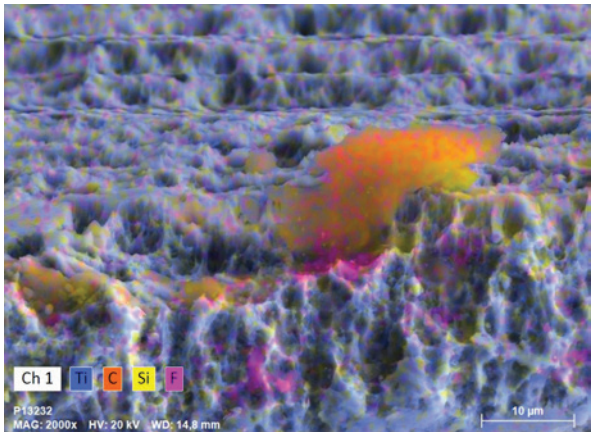


Fig. 2: SEM image and elemental mapping of the implant surface showing a localised contaminant deposit identified by energy-dispersive X-ray spectroscopy. Ti = titanium; C = carbon; Si = silicone; F = fluorine. Imaging parameters: magnification = ×2,000; accelerating voltage = 20 kV; working distance = 14.8 mm; scale bar = 10 µm.

Testing revealed recurring contamination, including iron, nickel, chromium, tungsten, copper, zinc and antimony—elements not native to titanium alloys. In addition, organic residues and PTFE fragments were frequently observed, often embedded in the outer threads and shoulder regions.[5] According Duddeck, the CIF defines tolerable contamination as (1) up to five organic particles smaller than 50 µm and (2) surface alterations due to blasting residues such as aluminium oxide or titanium dioxide.[4] All metallic debris and larger organic residues are considered unacceptable.

Manufacturing and packaging sources of contamination

Surface treatment methods such as sand-blasting and acid etching improve bone–implant contact but risk embedding blasting media.[6] Schupbach and Glauser found aluminium oxide residues on 14.4% of tested implants,[7] and Draenert and Mitov demonstrated successful elimination of residues in Straumann's SLA and SLActive systems, showing that manufacturing optimisation can prevent contamination.[8]

Mechanical machining contributes metallic debris—often stainless steel and tungsten—and packaging processes can introduce microplastic and organic residues.[9] The presence of such contaminants even on sterile implants underscores limitations in current clean room manufacturing protocols.

Clinical implications of contamination

Microscopic contaminants may alter the biological interface by triggering foreign body reactions or influencing peri-implant inflammation. Studies show that foreign materials such as silk ligatures can induce bone loss independent of bacterial infection, demonstrating that inflammation can arise from sterile stimuli.[10]

Albrektsson et al. propose that osseointegration reflects a homeostatic immune balance rather than complete tissue integration.[11] Metallic debris or organic films may disturb macrophage polarisation from M1 (pro-inflammatory) to M2 (anti-inflammatory), leading to chronic inflammation.

Peri-implantitis, once attributed primarily to plaque, is now recognised as multifactorial, involving host immune dysregulation and implant material effects.[12] Despite marginal bone loss being a common indicator, implants can remain functional for decades if immune equilibrium is maintained.[13,14]

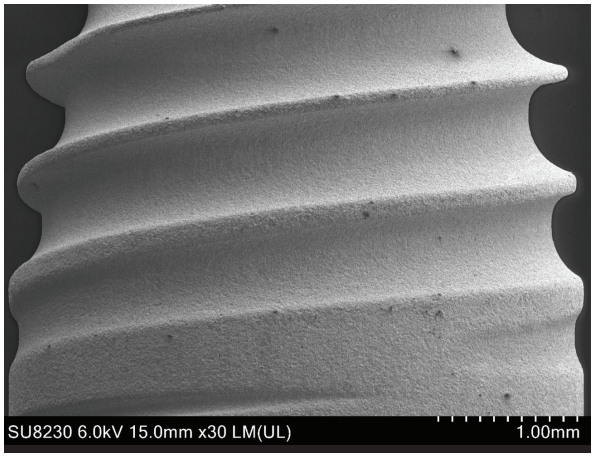


Fig. 3: SEM image of a sand-blasted and acid-etched titanium implant surface showing discrete dark deposits on the threads, indicating the presence of surface contaminants or embedded blasting residues. Imaging parameters: accelerating voltage = 6 kV; working distance = 15 mm; magnification = ×30; scale bar = 1 mm.

Discussion

A discussion of implant surface cleanliness must address both the scientific and practical implications of current analytical protocols, as well as the broader clinical consequences of contamination. The CIF has introduced a standardised analytical framework using SEM and EDS under ISO Class 5 clean room conditions. This represents a significant methodological advancement in the field. These protocols ensure that results are reproducible, traceable and independent of manufacturer influence. The CIF approach has identified a wide range of contaminants—including metallic, organic and polymeric residues—on sterile implants from multiple manufacturers. The foundation's commitment to transparency and peer-reviewed evaluation has undoubtedly elevated the discourse on implant surface quality and patient safety.

However, despite the technical precision of the CIF analytical process, the criteria used to classify implants as "clean" or "contaminated" are not grounded in empirically validated, evidence-based thresholds. Current contamination limits, such as the allowance of up to five organic particles smaller than 50 µm, were derived through expert consensus rather than statistical correlation with clinical outcomes. This limitation reflects a broader challenge in the field: while laboratory data clearly demonstrates the presence of contaminants, the biological significance of these residues remains poorly quantified. It is not yet known which particle types or concentrations might be clinically tolerable and which could trigger inflammatory or immune-mediated complications. The lack of published data linking specific contamination profiles to implant failure rates limits the ability of clinicians and regulatory bodies to distinguish between benign and harmful impurities.

Establishing evidence-based cleanliness standards therefore requires integrating materials science with biological and clinical research. Controlled experimental designs—combining *in vitro*, *in vivo* and clinical studies—are essential to quantify how contaminants influence osseointegration and peri-implant health. *In vitro* studies can provide a valuable first step by enabling the systematic evaluation of cytotoxic and inflammatory responses to defined contaminants. For instance, osteoblast and macrophage cultures exposed to titanium alloys containing iron, nickel or PTFE residues can reveal the degree to which such materials impair cell viability and mineralisation and induce or alter cytokine release.[15,16] Such models can help identify particle size and composition thresholds that disrupt the delicate balance between osteogenesis and immune regulation. *In vivo* animal experiments can then extend these findings by measuring bone–implant contact ratios and histological responses in controlled conditions. Notably, studies on rabbits have demonstrated that non-bacterial ligature materials alone can provoke peri-implant bone loss, illustrating that even sterile foreign bodies can trigger persistent inflammatory reactions.[10] Translating these findings to humans remains challenging, yet long-term clinical registries and cohort studies may provide the statistical power required to assess whether implants bearing the CIF's "Trusted Quality" mark indeed achieve lower rates of peri-implantitis or failure than non-certified systems do.

The absence of such longitudinal data underscores a critical gap between analytical quality assurance and real-world clinical evidence. While the CIF's certification process has a strong signalling effect, encouraging manufacturers to improve production hygiene, it currently serves more as a marker of procedural diligence than as a clinically validated predictor of success. To close this gap, interdisciplinary collaborations between independent research institutions, universities and implant manufacturers are needed. Such partnerships could generate standardised multicentre databases tracking

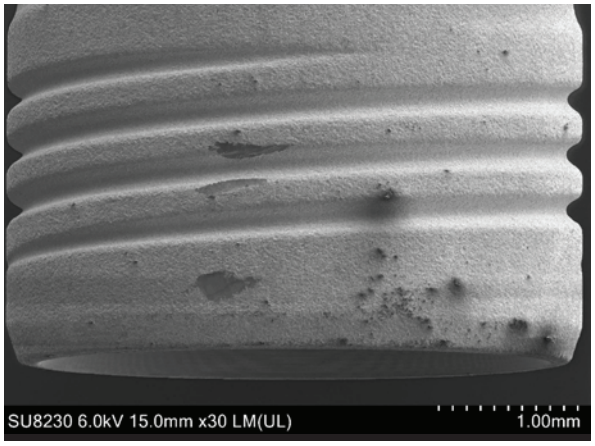


Fig. 4: SEM image of the coronal thread region of a titanium implant showing pronounced surface irregularities and contamination features. Imaging parameters: accelerating voltage = 6 kV; working distance = 15 mm; magnification = ×30; scale bar = 1 mm.

implant performance over time, while preserving data transparency and patient privacy. These registries would allow for correlation analyses between contamination parameters and clinical outcomes such as marginal bone loss, implant survival and patient-reported complications.

Beyond research, regulatory implications must also be considered. Regulation (EU) 2017/745 requires comprehensive safety evaluations of implantable materials, yet no explicit cleanliness criteria are included. Integrating surface cleanliness into these frameworks would shift the paradigm from voluntary certification to mandatory compliance. A harmonised ISO standard defining acceptable contamination levels—analogous to sterility norms—would compel manufacturers to maintain consistent quality across production batches. This would also facilitate more equitable market competition by ensuring that smaller manufacturers adhere to the same analytical rigour as industry leaders do. Moreover, mandating third-party verification could help prevent conflicts of interest and enhance clinician confidence in manufacturer claims.

For dentists and oral surgeons, understanding the potential impact of surface residues on biological integration is increasingly important. Even trace levels of metallic debris or polymeric films may alter protein adsorption, cell adhesion and the early stages of osseointegration. In susceptible patients—particularly those with compromised immune systems or systemic inflammatory conditions—these effects could amplify peri-implant inflammation and contribute to long-term bone loss. Clinical awareness therefore should extend beyond surgical technique to include implant selection and handling. Dentists should prioritise implant systems that have undergone independent cleanliness verification, ensure strict aseptic protocols during unboxing and placement, and avoid contact between the sterile implant and non-sterile instruments.

At a broader level, the CIF's work has already influenced industry behaviour by introducing accountability and transparency into the implant market. Manufacturers are increasingly publishing their analytical reports and adopting advanced cleaning technologies, such as plasma-based surface treatment or solvent-free sterilisation. These innovations are encouraging steps towards minimising particulate residues without compromising implant surface characteristics that promote osseointegration. However, achieving a true zero-contamination objective remains aspirational until there is comprehensive empirical validation of what constitutes a biologically clean implant.

Conclusion

While the CIF has set an invaluable precedent by systematising surface cleanliness evaluation, the field still requires robust scientific evidence linking contamination characteristics to biological and clinical outcomes. Only through coordinated interdisciplinary research and regulatory integration can cleanliness evolve from a conceptual quality mark into a measurable clinical safety standard. Such progress would not only reduce peri-implant complications but also reinforce patient trust in the long-term reliability of dental implants.

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References

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