

Quality of implant surfaces and deficient osseointegration

Part I: Deficient implant surfaces and production processes

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_Implant failures occur regularly and are thus part of everyday practice. Manufacturers claim success rates above 99 per cent. As experience has shown, however, such rates seldom correlate with practice. They are perfect for marketing purposes, but do not give any feedback about the true reason for implant failure. Often, data from independent studies is lacking or analysis from the manufacturer is classified.¹⁻⁹

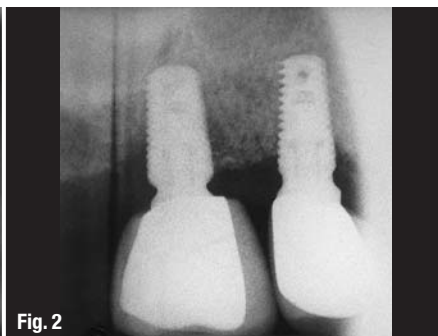
First, it is necessary to define implant failure in therapy. Since the principle of osseointegration has been established for many years, implant healing nowadays is expected to simply be successful. However, implant therapy is only reasonable if it is considered to be superior to conventional therapies, such as bridgework and dentures, in each specific case. Implant therapy should be applied only if long-term stability is guaranteed and higher comfort, as well as superior aesthetics, can be achieved. If we consider which of these factors can be realized in practice, suc-

cess rates of implant therapy are often lower than claimed by manufacturers.

Regarding the success of implant therapy, practitioners bear a major responsibility: tissue quality and quantity, implant positioning, prostheses, surgical protocols, mouth hygiene and surgical techniques endanger the success of therapy if performed wrongly. Besides all these factors, we as practitioners have to trust that the product has been accurately manufactured without deficiencies, impurities or faults. This is exactly the issue we want to control and analyse. As recent studies have shown, numerous implants lack accuracy and harbour surface impurities. Such findings, combined with specific clinical situations, raise the logical questions of if and how failures in production processes influence osseointegration.

Dental implants are manufactured workpieces; thus, faults and defects do occur. Such incidences can

Figs. 1-3_The clinical examination found a mesial rotation of implant #16 of approximately 10 degrees and implant mobility. The radiograph showed bone resorption around implant #16 (4.7 mm × 8 mm) of 2 mm distally and around implant #15 (4.1 mm × 8 mm) of 1 mm mesially.





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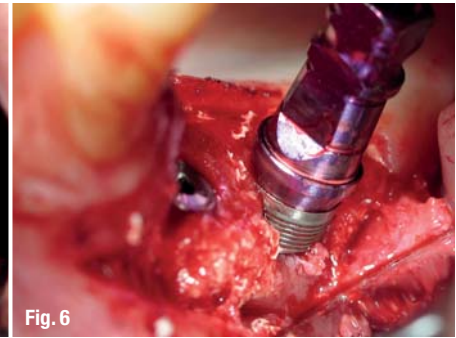
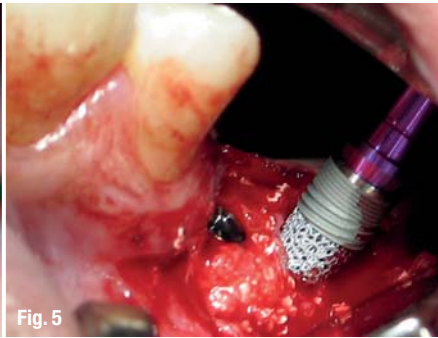
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Figs. 4–7 Insertion of two implants with a modern design and a porous tantalum cylinder, as well as promising osseo-incorporation.

only be avoided by means of a detailed quality control system. Apart from the problems already mentioned, further issues to consider include implant body design, compatibility between thread designs and implant surface treatment, implant cleaning procedure, as well as macro- and micro-roughness.

While many of the production defects lead to implant fracture, surface problems remain initially undetected. Implant surface problems can be observed at re-entry when, for example, the removal of the cover screw leads to implant removal or rotation. Such implants become mobile and fail; if not at this stage, this failure will be seen after several weeks of implant loading at the latest.

Case description

In this case, the clinical situation was similar to that described above. The patient received four implants in the maxillae in regions #15, 16, 24 and 26. Implant placement was delayed for all four implants and bone augmentation with a maxillary sinus lift limited in extent was performed at #16 and 26. The re-entry was performed five months postoperatively and prosthetic treatment two weeks later.

Two weeks after loading, the patient complained about occlusal malfunction in region #16. The clinical examination found a mesial rotation of #16 of approximately 10 degrees. A closer look revealed implant mobility. On the radiograph, we could detect bone resorption around implant #16 (4.7 mm × 8 mm) of 2 mm distally and around implant #15 (4.1 mm × 8 mm) of 1 mm mesially. Nonetheless, these observations were insufficient to explain the clinical findings (Figs. 1–3).

Healing period without complications

The mobility of #16 was identified as rotation. Separating the crowns from each other and the adjacent tooth, #14, led to explantation at zero torque. The macroscopic examination of the implants found a clean implant surface on the coronal half and some indications of tissue on-growth on the apical half. The

osteotomy in the bone showed no signs of soft-tissue ingrowth, as is often seen in cases of implant mobility caused by peri-implantitis. Further signs of inflammation were not evident.

Since we could not explain the reason for this implant failure, we decided against immediate implantation and to allow healing of the sockets. After a collagen fleece had been applied to the sockets, the wound was fixed with single sutures.

Implant #15 was sent back to the manufacturer for reclamation and analysis. Implant #16 was sent to a university for further examination, microscopy and reflection electron microscope morphometry. Our focus was on the analysis of defects and determination of the implant surface roughness in order to compare this analysis with the manufacturer's data.

Three months after the implant failure, the surgical was repeated. Since we had not received a statement from the manufacturer yet, we decided on a different implant type. We inserted two implants with a modern design and a porous tantalum cylinder, as well as promising osseo-incorporation (Figs. 4–7). In order to reduce risk and prevent any further complications, we allowed a healing phase of four months, taking into consideration that the rest of the implant body had shown standard surface characteristics.

During surgery, we determined after raising the flap that no bone loss resulting from the explantation had occurred. Also all of the bone augmented buccally during the first surgery (region #15) remained. These findings solidified our strong suspicion that the first implant probably had surface defects that had influenced osseointegration. Guided bone regeneration at region #16 to ensure 2 mm of bone buccally (sandwich technique with autologous bone, allograft and xenograft; Figs. 8&9) was performed. The implants inserted had a diameter of 4.1 mm and 4.7 mm, respectively.

The implants' healing occurred without any complications. After implant loading, we performed another radiograph to observe peri-implant tissue and

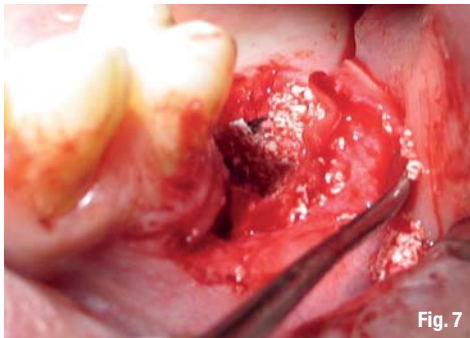


Fig. 7



Fig. 8



Fig. 9

ensure that there was no cement around the emergence profile.

Discussion

In recent decades, numerous reviews have shown how osseointegration works and what roughness and surface characteristics promote the desired tissue response. These studies have also investigated how a suitable microstructure advances bone regeneration around implant surfaces. Furthermore, independent from additive or subtractive production processes, production faults, inaccuracies, impurities, residue, and incompatibility of design and roughness methods do not influence osseointegration positively.¹⁰⁻¹⁶

Findings like the above are currently the subject of controversial debate. Their influence on osseointegration has not been proven yet. Nonetheless, such production issues cannot promote implant healing. As we will see in the next part of this case series, debris and residue on the surface reduce implant-bone contact and thus endanger osseointegration. The same negative progress can be observed when surface roughness is reduced, for example, by an incomplete and inhomogeneous surface treatment.¹⁷⁻²⁰ It would be interesting to investigate how often implant failures can be ascribed to production failures by the manufacturer.

There are numerous steps that performed wrongly could lead to implant failures, from surgery to prostheses, and including mouth hygiene, medicaments and habits. If we eliminate iatrogenic and hygienic factors, dental implants will remain workpieces that are abundantly defective.

Implant manufacturers are responsible for the product they market, just as we bear the responsibility for our treatment of our patients. Good quality control is not random, but deals with each component systematically. In this case, the patient received implants with the same serial number in regions #24 and 26. Implants #15 and 16 were from the same manufacturer but with different serial numbers. A recall of implants with specific serial numbers, three months

postoperatively, was declared a documentation fault. For those implants that had been inserted, operators were recalled, although implants with those specific serial numbers began to fail in succession.

Recalls must be justified honestly, so that imperfections can be corrected. The relationship between manufacturers and users is based on confidence. Openness and frankness solidify this confidence. Visits to the production site and close contact with service staff and colleagues are important utilities for the user.

Finally, it is important to understand that not every surface and surface treatment is compatible with every macro and thread design. Combining good features in a product does not automatically result in a superior product. It is rather the consequence of the underlying research and development that has evolved the product or a feature to a reliably performing workpiece. A deeper understanding of mechanics, physics and material science will allow us to evaluate dental implants and their components during the healing period and in the long term when interacting with the organism and the stomatognathic system.

Conclusion

In Part II of this series, macro-images of various implants that failed and the corresponding sterile-packaged ones will be shown. In Part III, failed and sterile-packaged implants from the various manufacturers will be compared under a scanning electron microscope.

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Figs. 8 & 9 Sandwich technique with autologous bone, allograft and xenograft.