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Brief Communication

Microscopical analysis of explanted Titanium alloy customised meshes for bone augmentation: a case series study

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1 Introduction

The use of dental implants is a very common procedure [1]. For ideal prosthetic design, implants must be inserted in a correct 3D position [2]. Patients may present alveolar ridge defects as a consequence of periodontal disease, dental trauma, traumatic extraction, or genetic anomalies, which do not allow the correct implant position [3, 4].

Different treatment options have been described to reconstruct these defects, which may include inlay and onlay block bone grafts, crestal splitting, osteogenetic distraction, and guided bone regeneration (GBR) using resorbable and non-resorbable barrier membranes [5]. Of these, GBR seems to be the most reliable and predictable, providing excellent long-term stability

The basic principle of GBR involves placing a mechanical barrier to protect the blood clot and to isolate the bony defect from the surrounding connective and epithelial tissue invasion. This space is needed to allow the osteoblasts to access the space intended for bone regeneration.

Titanium meshes, as an alternative to membranes, have been used for a long time as a predictable technique for bone regeneration and, owing to their rigidity, the adaptation onto the defect and maintenance of their shape can be more stable. To overcome the main drawbacks, which are the remaining sharp margins after cutting and the increased surgical time required for their shaping and fitting, pre-shaping of the mesh on a stereolithographic model (STL) of the patient's jaw can be an alternative to significantly shorten the intraoperative time, but with a significant cost increase [6–8]. More recently, design/computer-aided manufacturing (CAD/CAM) and Direct metal laser sintering (DMLS) have boosted the 3D-printed products and custom-made titanium meshes have been introduced and evaluated for clinical applications [6, 7].

Regardless of the production technique for any implantable devices, it is mandatory to control the characteristics to optimize their biological performance [9]. The stiffness of titanium meshes can damage the soft tissue, and the mechanical strength is related to the thickness of the material and pore dimensions. More specifically, the surface properties direct the cellular interactions [10]. These properties, including surface topography and chemical composition, are usually derived from the surface treatments applied [9].

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Regardless of the manufacturing process, titanium meshes report high percentages of exposure during the healing. Hartmann et al. [10] in a retrospective study conducted on 65 patients and 70 bone augmentations, observed a 37% of mesh exposure and partial loss of the graft. Chiapasco et al. [11] conducted guided bone augmentation with CAD-CAM titanium meshes and after a mean of seven months they observed 11 exposures out of 53 implanted devices (20%). Cucchi et al. [12] also investigated the exposure rates of titanium customized meshes with and without the combination of a collagen membrane and they have found that the non inferiority analysis was inconclusive, despite an apparent better performance of the group where the titanium mesh was covered with the collagen membrane.

In other retrospective studies [13] data were collected after the use of conventional customized titanium meshes. The exposure has been reported as one of the most common complications, with values ranging from 26% up to 58%.

In a more recent article published [14], TiAl6V4 samples fabricated by two different manufacturers (BTK Vicenza, Italy and Bone Easy Lisboa, Portugal) were experimentally compared after being dipped into buffered solutions for 7, 14 and 21 days at different pH (4 and 7) in order to artificially simulate the oral exposure. The effect of the acid solution, although not reproducible in humans, revealed that both samples were extremely resistant, but the surface showed a moderate degree of corrosion.

The purpose of this investigation is to compare if the morphological data observed on the test specimens can be comparable to the explanted specimens, retrieved after twenty weeks of exposure at the oral environment.

2 Materials and methods

2.1 Intervention type and description of the complications

All the surgeries were performed by experienced dentists on medically healthy patients, non smokers with the purpose of vertical and horizontal posterior mandibular augmentations. The exposures were reported in a period of 6 to 8 weeks after the surgeries and were classified as described by Hartmann [10] as type B (dimension as tooth width). The operators reported that the devices where left exposed for a total period of 20 weeks and patients were instructed to apply Chlorexidine gel 3 times a day until the removal.

2.2 Samples preparation

Explanted customised Ti meshes, manufactured by two different companies (BTK-Vicenza Italy and Bone Easy Lisboa Portugal) were received in the laboratory with the indication of the clinician, who reported an exposure occurred after 6–8 weeks post-implantation. Patients included for this procedure were non-smokers and did not show any medical issue and/or previous periodontal history. All the subjects signed an informed consent before the surgery and agreed to the analysis of the explanted material. Explantation of all the samples was done after 12 weeks.

The devices were sterilized at the dental clinic and packed into two different envelopes (the first envelope was previously sterilized). After receipt, careful attention was paid to avoid contamination of the surface by touching with bare hands.

Samples were broken into half and fixed in epoxidic resin; the specimens after 24 hours were removed from the templates and polished with rubber abrasive drills, then washed into saline sterile solution to remove all the debris. The creation of round shapes allowed the analysis under the Scanning Electronic Microscope (SEM) for the surface and the profiles (Fig. 3).

2.3 Samples analysis

A further SEM (Hitachi S-2500 10KV in secondary electron) analysis was done to assess external and internal modifications of the alloy structures and also to analyse the composition of the samples, comparing these with the manufacturer's declarations by means of Specific Energy-dispersive X-ray spectroscopy (Phenom ProX 800).

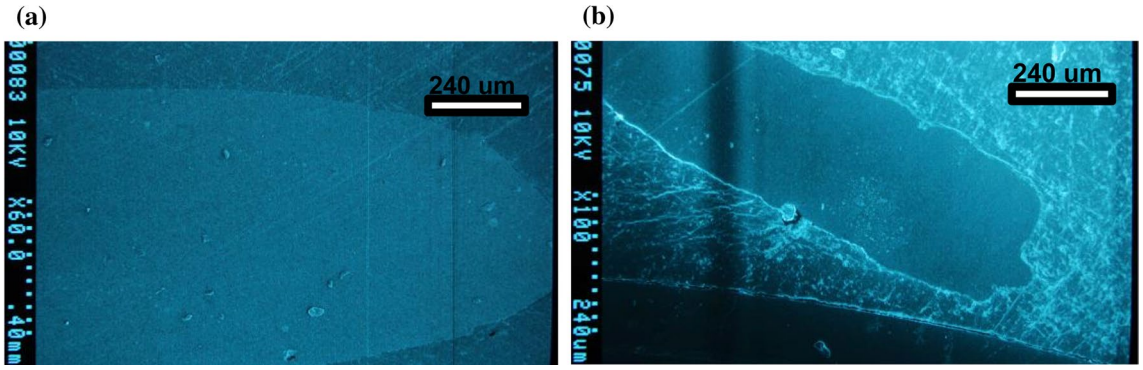

Fig. 1 SEM analysis of the surface of **a** Bone Easy samples and **b** BTK samples. Small internal defects can be observed, more evident in the internal part of the device (**a**), while the device (**b**) shows a more regular surface and a rougher profile

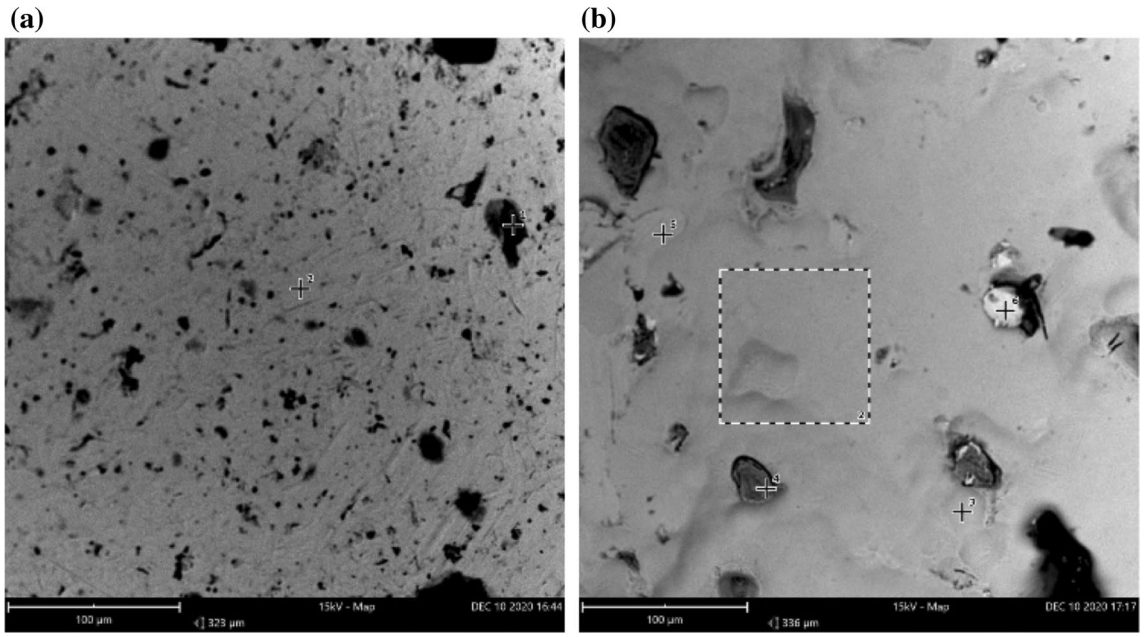

Fig. 2 Images under a different Scanning Electronic Microscope which reveal internal defects for Bone Easy (**a**) and BTK (**b**) meshes. In particular the device **a** shows numerous small defects (ranging between 2 µm and 15 µm), while the device **b** presents less defects with an average diameter of 20 µm

2.4 Samples surface roughness charateristics

Images of samples profiles were analyzed by two different softwares (Image J and MATLAB software) in order to determine the roughness parameters.

3 Results

The analysis was conducted on a total of sixteen samples (8 from BTK- 8 from Bone Easy). The external surface analysis revealed a regular morphology on all the examined samples, but some internal defects were seen in the Bone Easy samples, more than the BTK ones (Figs. 1, 2). In particular the device from Bone Easy (Fig. 2a) shows numerous small defects, ranging between 2 µm and 15 µm, while the device from BTK (Fig. 2b) presents less and more regular defects with an average diameter of 20 µm.

Roughness parameters are reported in Tables 1 and 2, where Ra is the roughness average, Rq the root mean square and Sigma is the standard deviation.

The profile analysis of the upper and lower faces revealed that the superficial defects extended inside the device which may interfere with the mechanical properties of the device. The internal structure was also investigated by means of Specific Energy-dispersive X-ray spectroscopy where the defects were even more emphasized, and the chemical composition of the alloy was observed to be different from the one declared by the two manufacturers. Moreover, 2.76% and 3.18% of carbon was detected in the BTK and Bone Easy samples, respectively. No other elements and contaminants can be observed from the spectra (Figs. 3, 4) and Table 3.

4 Discussion

Direct metal laser sintering (DMLS) is widely applied in the medical field and it is becoming popular in oral surgery. However, only a few studies have analyzed the effect of the laser melting and sintering process (defined as additive manufacturing techniques) on the metal alloys in terms of mechanical and chemical properties [15–17].

AM technology offers some advantages compared to conventional techniques [18], such as digital planning and design of the customized mesh, shorter surgical times, and easy adaptation of the device to the bone defect [19].

Partial exposure of the mesh is one of the most common complications and it has been demonstrated by several studies that it may average from 0 to 66%, regardless of the site and the extension of the bone augmentation [20].

The existing evidence does not report whether the part exposed to the oral cavity and, thus, to contaminants such as food and beverages but also to sudden and extremely variable chemical conditions, may influence or not the surface of the device, affecting the bone response.

Table 1 Roughness parameters on lower faces of both samples

LOWER FACE	BTK µm	BE µm
Ra	17,683	15,636
Rq	21,553	19,683
Sigma	21,555	19,685

Table 2 Roughness parameters on upper faces of both samples

UPPER FACE	BTK µm	BE µm
Ra	12,125	7,601
Rq	13,754	9,072
Sigma	13,756	9,073

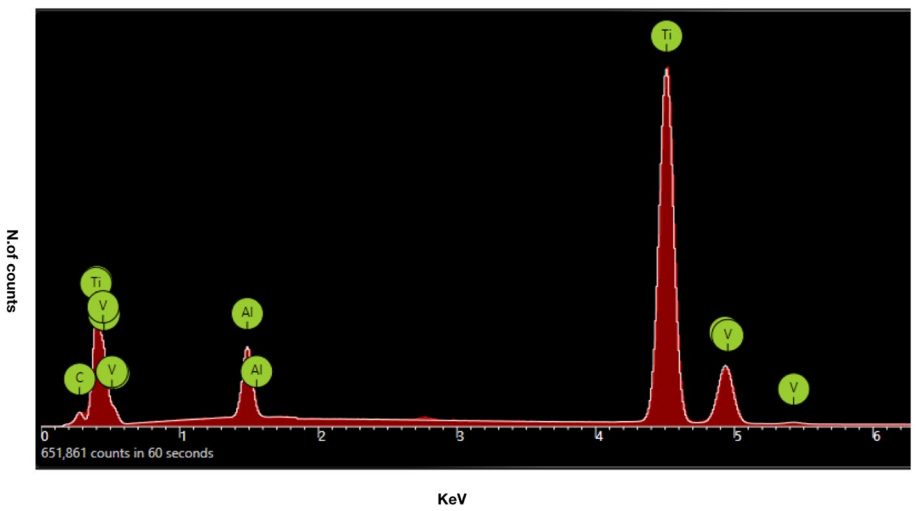

Fig. 3 Chemical composition per number of counts of Bone Easy mesh. As it was expected Titanium; Aluminium and Vanadium are present in the samples but Carbon is 3.18%. No other elements and contaminants can be observed in the spectrum

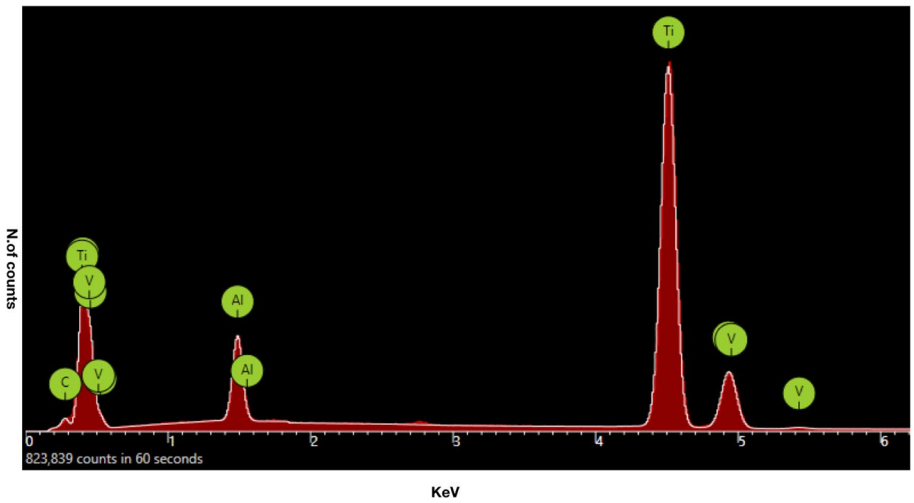

Fig. 4 Chemical composition per number of counts of BTK mesh. As it was expected Titanium; Aluminium and Vanadium are present in the samples but Carbon is 2.76%. No other elements and contaminants can be observed in the spectrum

Table 3 Element weight percentage on the two examined samples

Element weight percentage	Bone easy sample	BTK sample
Titanium	74.76%	75.34%
Oxygen	13.16%	12.52%
Aluminium	5.76%	6.85%
Carbon	**3.18%**	**2.76%**
Vanadium	3.14%	2.53%

The bold is significant because the Carbon % is far away from the standards (Carbon should be < 0.08%)

In a previous study [14] the analysis revealed the presence of external and internal defects after the exposure to acid solutions, but it was expected that on human devices like those examined in this study, the findings would have been different, especially because the exposure to the oral cavity is less aggressive than a pH 4 laboratory solution.

In a systematic review published in 2013 [18] the authors report an average exposure rate of 16.1% with the use of traditional non-customised Ti-meshes. The titanium alloy used for the production of the micro meshes is Grade 4, which has a different composition compared to the Grade 5 alloys, used for customised devices. In more recent human retrospective clinical studies [16] the authors report 21% of exposures of customised titanium meshes used for vertical bone augmentation. This value compared to the one given from the systematic review seems to be suggestive of a higher incidence of complications on customised devices.

Therefore, it might be assumed that this difference could be related to the different chemical composition in conjunction with a thicker profile and an increased roughness.

The presence of this dishomogenous structure, more evident on explanted Bone Easy meshes, could interfere with the mechanical properties of the device, such as resistance to compression and/or flexural strength. Furthermore, it could also be possible that the superficial corrosion may have released contaminants/ions into the patient, but no clinical evidence for that was retrieved from the clinician.

Another aspect to be underlined is the presence of carbon, which was found on both BTK and Bone Easy devices. The same finding was also discussed in our study of the samples and it might be suggestive of external contamination of the alloy powder used for the SLM manufacturing process or connected with the AM procedure, but no technical data (printing temperature, speed and layer thickness) were given from the two Companies, as they are considered intellectual properties.

The average presence of carbon in a grade 5 Ti alloy should be at least 0.08%. In this study the percentage is much higher than the accepted standards and several reasons can be addressed to explain this finding. The devices were received into the laboratory sealed in double envelopes and sterilized, but the presence of carbon was detected not only on the surface of the device because the compositional analysis with Electronic Dispersive X-ray was conducted on the margin after the rupture of the device, in order to investigate the internal composition around the structural defects.

In a recent human clinical and histological case series [21] zirconia was tested as an alternative to the titanium alloy. The reported results seem to be promising (only one device was exposed after the surgery) but numbers are still very limited to draw solid conclusions.

5 Conclusions

In this study the presence of carbon was observed inside the devices together with several internal structural defects on all the examined samples. Based on these preliminary findings, it can be concluded that some issues are referred to the alloy powder composition as well as to the additive manufacturing fabrication process.

The number of examined devices is limited and these aspects should be further investigated in a larger number of samples obtained from different manufacturers and different dental facilities. Nevertheless, these devices should be carefully evaluated by the clinicians and until more evidence is available, they should be considered with precautions.

Author contributions Conceptualisation, NDA and FB; methodology, LS, LA.; software, LA, CP; validation, NDA,AL and FB; formal analysis, LA; investigation, LA; resources, NDA; data curation, NDA;writing—original draft preparation, NDA; writing—review and editing, NDA.; visualisation, CP; supervision, A-L; project administration, FB. All authors read and approved the final manuscript.

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Data availability The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Competing interests The authors declare no conflict of interest.

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