Release of elements from retrieved maxillofacial plates and screws

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Vitallium appliances and surrounding tissues were investigated to evaluate the release and accumulation of elements.

Four microplates, sixteen screws and surrounding tissues were removed from three patients presenting inflammation 4 to 6 years after surgery and were submitted to SEM and X-ray microprobe analysis. Histology was performed on paraffin or PMMA sections of tissues.

A continuous release of elements from metallic appliances into soft tissues was observed. Cobalt, chromium, and nickel were detected in soft and boney tissues in close proximity to the appliance. Aluminium, as a component of screw coatings, accumulated in soft tissues, and a remarkable amount of aluminium was detected in the dense lamella of lamellar bone.

The results suggest that coatings containing aluminium should be avoided and the time these appliances are allowed to remain in patients should be shortened. Further studies on element release and the fate of aluminium in bone are warranted.

1. Introduction

It is not uncommon for active elders to seek maxillofacial treatments, but in this population, the side effects produced by appliances may be more pronounced than in the younger cohort. The side effects of implants can be traced back to the composition of the appliances. Metallic appliances made of Ni, Cr/Co and Ti alloys are known to produce inflammatory responses in *in-vitro* studies [1–3]. Metal elements are capable of triggering inflammation and allergic reactions *in-vivo* [4, 5]. Metallic wear debris [6] can trigger inflammation and may also lead to a periprosthetic fibrous-tissue disease known as metallosis [7]. Several studies point out that elements can leach out of appliances and accumulate in oral tissues [8–10]. Optical (OM) and scanning electron (SEM) microscopy [11] or ultrastructural analysis of tissues and analysis of metal elements [12–14] have been used to analyze opaque particles in oral surgery.

Dental alloys may undergo galvanic corrosion [15], releasing elements and producing inflammation of the gingiva and mucosa, without evidence of metallosis. Few reports have analyzed the release of elements from appliances and their fate in surrounding tissues [10,16] and subsequent outcomes.

This study was performed on patients presenting with a remarkable degree of inflammation of the mucosa covering pre-prosthetic bone grafts performed for implant based-prostheses. The morphology of soft and hard oral tissues was studied by light microscopy and SEM, whereas elemental analyze was investigated by Energy Dispersive X-ray analysis (EDAX). The aim of this work was to explore the intricate relationships between composition and structure of periprosthetic tissues and element diffusion from appliances.

2. Materials and methods

The study was performed on vitallium plates and screws removed from patients (ranging in age from 47 to 68 years) who had undergone pre-prosthetic bone grafts for implant based-prostheses. Metallic devices and surrounding tissue were harvested from selected patients who presented a high degree of local inflammation without dark pigmentation of the gingiva and mucosa, excluding exposed devices or those producing metallic particles causing mucosal pigmentation. Four microplates and 16 vitallium screws (removed 4 to 6 years after surgery) and the surrounding soft and hard tissues were fixed in 4% paraformaldehyde in 0.1M phosphate buffer, pH 7.2 for 4 h at room temperature and dehydrated through an ethanol series.

Part of the mucosa was separated from the soft tissue adjacent to the device and embedded in paraffin. Microplates, screws and the adjacent soft tissue were desiccated in a critical point dryer (CPD030, Bal-Tec, FL) at 40 °C and pressure of 7.4 MPa, using CO_2 as intermediate agent. Bone and a part of soft tissue were embedded in methyl-methacrylate (PMMA) without decalcification. After EDAX, microplates and screws were also embedded in PMMA and sectioned to study their composition.

The PMMA blocks containing soft tissues or bone were sectioned using a bone microtome (Autocut1150, Reichert-Jung, D) to obtain 5 micron-thick sections. Sections were stained with Hematoxylin-Eosin or Toluidine Blue. The remaining part of the PMMA block containing bone and microplates or screws were cut into 1 millimeter-thick slices using a diamond saw microtome (1600, Leica, D). The surface of each section was then polished with sandpaper and diamond compound (3 μm). The polished sections and appliances surrounded by fibrous tissue were gold sputtered (SCD004, Bal-Tec), examined by SEM using the back-scattered electron detector (XL40, Philips, NL) and analyzed with an X-ray microprobe (EDAX9900, Philips) at 25 kV, 0° Tilt, 31° take-off, 0.08 μm spot. Each specimen was submitted to 10 to 30 X-ray analyses at different sites. X-ray mappings (128 × 100 pixel) were drawn up under the same analysis conditions but with 0.1 μm spot and 0.2 sec dwell-time.

3. Results

Histology of the mucosa revealed a feeble lymphoplasmacytic reaction and polymorphonuclear infiltrate with many mast cells. Bone growth was adequate in all patients after oral surgery. Fibrous tissue did not invade the area between the vitallium microplates and bone. Bone grew over the microplates in two vitallium microplates; this bone was surgically removed and then embedded. Connective tissue, rich in collagen fibers with scanty cellular elements, surrounded the parts of the microplates not covered by bone. Scattered mastocytes were found inside the fibrous tissue. SEM revealed a smooth surface of microplates and screws with no scratches or other alterations.

At the time of manufacture, presiding regulations did not require producers to declare the exact composition of devices but only the trade name (i.e. Vitallium); thus, we do not know the exact composition of the alloy prior to explantation.

EDAX revealed the composition of the vitallium alloy (Fig. 1(B)) as W/Cr/Fe/Co/Ni at 18.8/19.9/2.4/48.3/10.6 wt% (quantitative analysis, after Z.A.F. correction). SEM analysis of the sections of embedded vitallium microplates (Figs. 1(B) and 2(C)) pointed out a non-homogeneous composition of the alloy. Several lighter spherical portions were engulfed by a homogeneous darker matrix (Fig. 2(C)), whose EDAX spectrum (Fig. 3, lower spectrum ➊) was the same as that referred above. The spherical portions had the same W/Cr/Fe/Co/Ni composition (Fig. 3, lower spectrum ➋) but a different content (64.7/12.3/0.6/19.2/3.2 wt%).

Cobalt, chromium, wolfram and sometimes aluminium, were detected by EDAX in the fibrous tissue surrounding vitallium microplates. Small and scanty vitallium fragments were found almost completely surrounded by bone in the removed tissue (Fig. 2(A)). Cobalt and chromium were detected both in bone surrounding these fragments but also in bone growing around the microplate (Fig. 2(B) and Fig. 3, upper spectrum). This interfacial bone also contained aluminium (Fig. 3, upper spectrum).

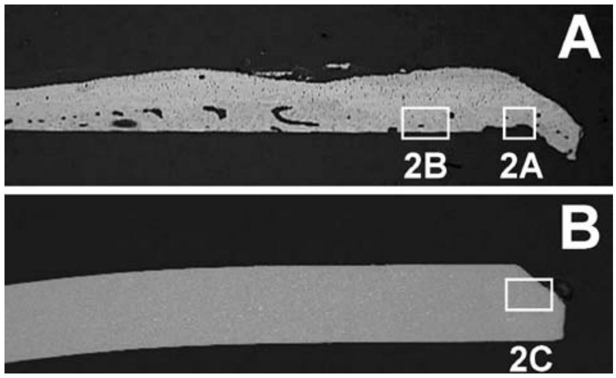

Figure 1 Back-scattered SEM images of sections of a vitallium microplate (B) and of its bone cover (A). The boxed-in areas correspond to the higher magnification images reported in Fig. 2. Field width: $A =$ 8 mm; $B = 5$ mm.

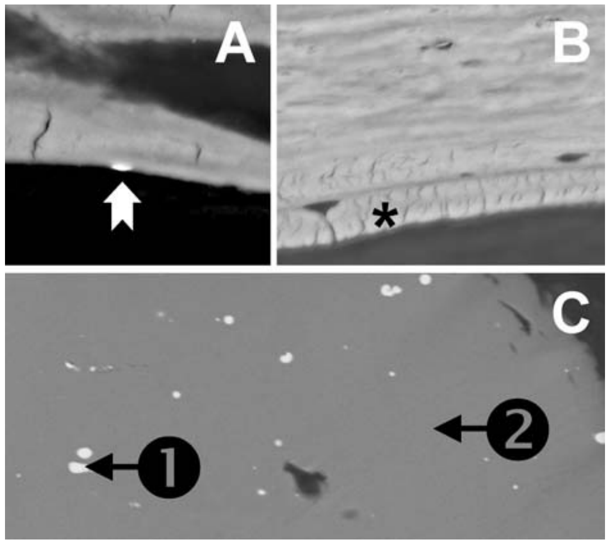

Figure 2 The arrow in A indicates a luminescent granule, almost completely integrated in bone, which was found to be a microplate fragment at EDAX. The asterisk in B corresponds to the site where EDAX of interfacial bone was performed. In C note the microplate of spherical portions displaying a high X-ray emission ➊ surrounded by a homogeneous matrix ➋. Field width: A = 50 μm; B = 100 μm; C = 125 μm.

EDAX analysis revealed aluminium in the lamellar bone formed at a distance from the microplate surface. A very high aluminium content was found in the dense lamella (Figs. 4-Al and 5, d.l. spectrum) whereas only traces of aluminium were detected in the loose lamella (Figs. 4-Al and 5, l.l. spectrum). No aluminium was detected in woven bone.

Very high amounts of cobalt, chromium and aluminium (Wt rates: Cr/Co = 0.48 and Al/Co 0.32) were detected in soft tissue surrounding vitallium screws (Figs. 6(A) and 7, upper spectrum). X-ray mapping of the screw surfaces highlighted an irregular aluminium distribution. Analysis of sections of embedded screws (Figs. 6(B), (D) and 7, lower spectra) showed a composition of 28.9/0.5/70.6 wt% Cr/Fe/Co. SEM analy-

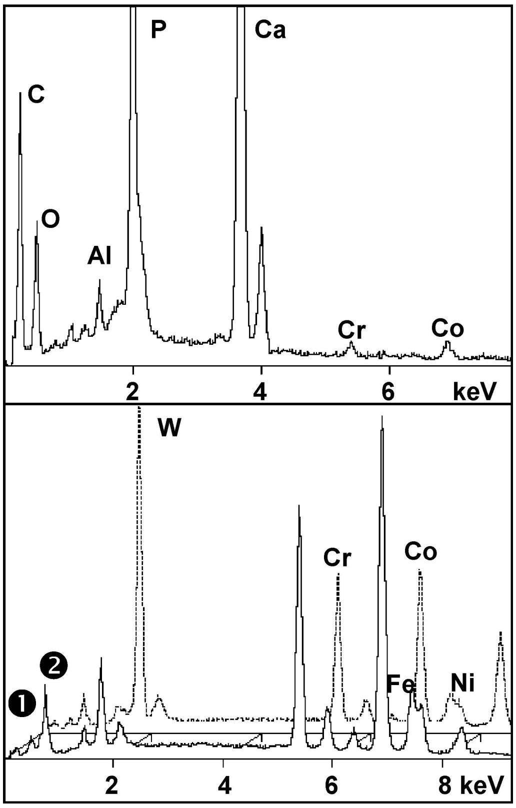

Figure 3 Graphs showing the EDAX of the interfacial bone of Fig. 2(B) and of the two sites indicated in Fig. 2(C). Cr and Co, in addition to Al, are present in bone facing the vitallium plate (upper spectrum). Note (lower spectra) the higher content of W of the spherules ❷ and the higher content of Cr, Fe, Co and Ni of the matrix ❶ of the vitallium plate.

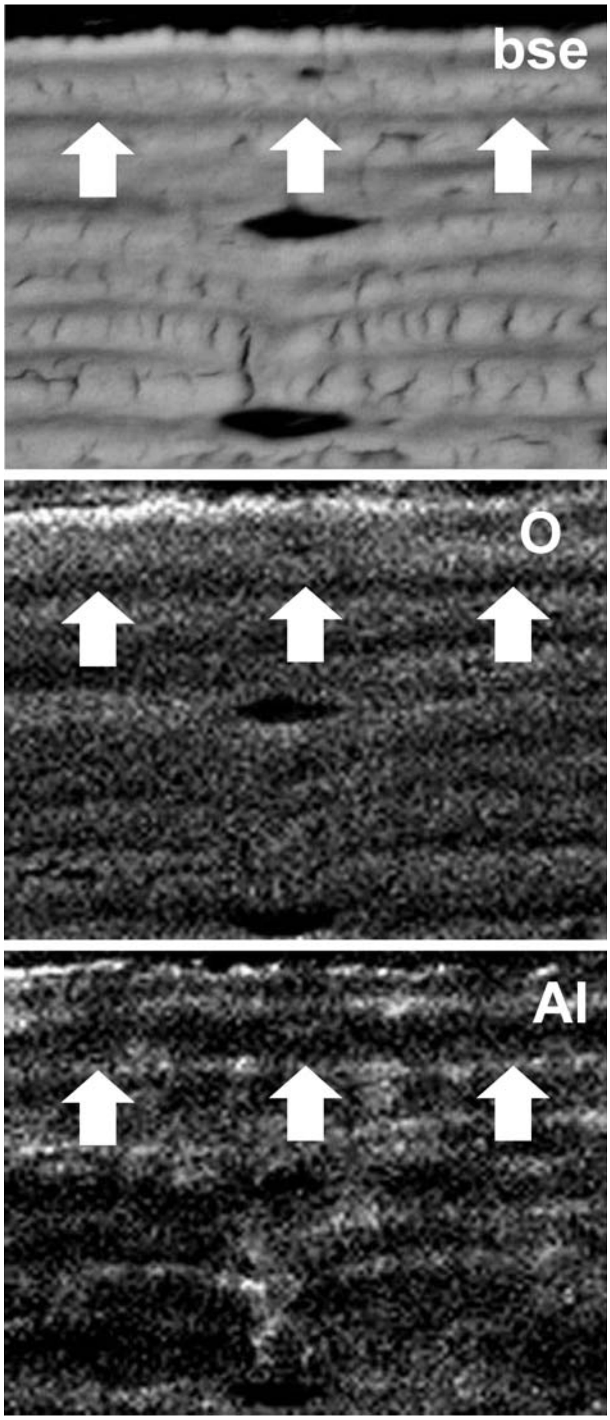

Figure 4 Back-scattered image (bse) and X-ray maps for oxygen (O) and aluminium (Al) of lamellar bone surrounding the vitallium microplate. The arrows point to the same dense lamella in the three images. Note how the dense lamellae (darker in bse) show a higher Al content (X-ray map for Al), whereas the more mineralized loose lamellae (lighter in bse) have a higher content of Ca, P and O (X-ray map for O). Field width 100 μm.

sis also revealed surface degradation both at the head, enveloped by fibrous tissue (Fig. 6(B)), and the apex, enveloped by bone (Fig. 6(D)). The composition of the degraded material (❷ in Figs. 6(C) and 7, lower spectrum ❷) was similar (Cr/Co = 0.38) to that of the screw (❶ in Fig. 6(C) and Fig. 7, lower spectrum ❶), but it also had an appreciable aluminium content (Al/Co = 0.18).

4. Discussion

Energy dispersive X-ray analyses (EDAX) showed a strong release of elements from the examined appliances and an irregular distribution of these elements in both soft and hard oral tissues.

The vitallium microplates examined had a composition similar to that first used in dentistry about seventy years ago [17]. Cobalt/Chromium alloys are particularly suited to orthopedic practice because they have good mechanical properties [18] and corrosion resistance [17]. We found leaching of cobalt, chromium and nickel, but a scanty local accumulation of microplate components. This may signify that biological fluids are capable of draining these elements from the tissue surrounding the microplate, in a way similar to what occurs with commercially pure (c.p.) titanium [19]. In a longitudinal study Jacobs *et al.* [20] found an eightfold increase in the concentration of chromium in the serum and urine of patients with Co/Cr-alloy femoral prosthesis. The diffusion of cobalt, chromium and nickel ions, first into soft tissues and then systemically, must be kept in mind given their propensity to produce severe inflammatory and allergic reactions.

Particular attention seems warranted for aluminium. Aluminium is currently regarded as a putative risk factor for severe neurological disorders, including Alzheimer's disease [21], and metabolic bone diseases, such as osteomalacia [22]. Aluminium can potentiate oxidative and inflammatory events, including iron-induced oxidative events [23, 24].

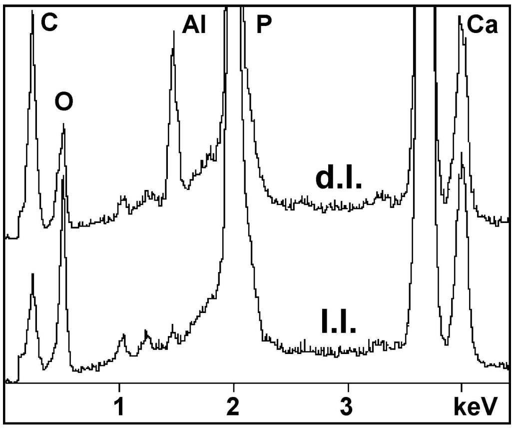

Figure 5 Graphs showing the EDAX of the dense (d.l.) and loose (l.l.) lamella (upper left). Note how the dense lamella (darker in Fig. 4 -bse) shows a higher Al content (upper spectrum).

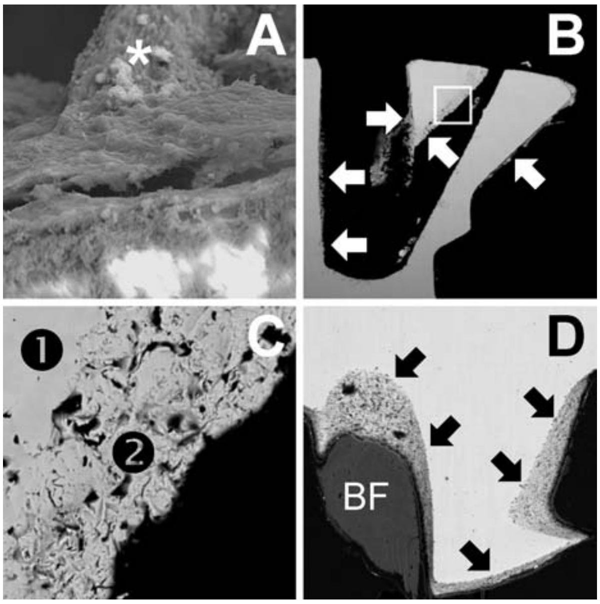

Figure 6 Back-scattered images of the fibrous tissue (A) bound to a vitallium screw, and sections of the external part (B) and apex (D) of a vitallium screw. The boxed inset in B corresponds to image C at higher magnification. The arrows in B and D point to the external degraded parts. In D note how the external degraded part of the apex appears partially adhered to a bone fragment (BF). The asterisk (∗) in A corresponds to the site where EDAX of fibrous tissue (upper graph of Fig. 7) was performed. Field width: A = 160 μm; B = 2.5 mm; C = 400 μm; D = 1000 μm.

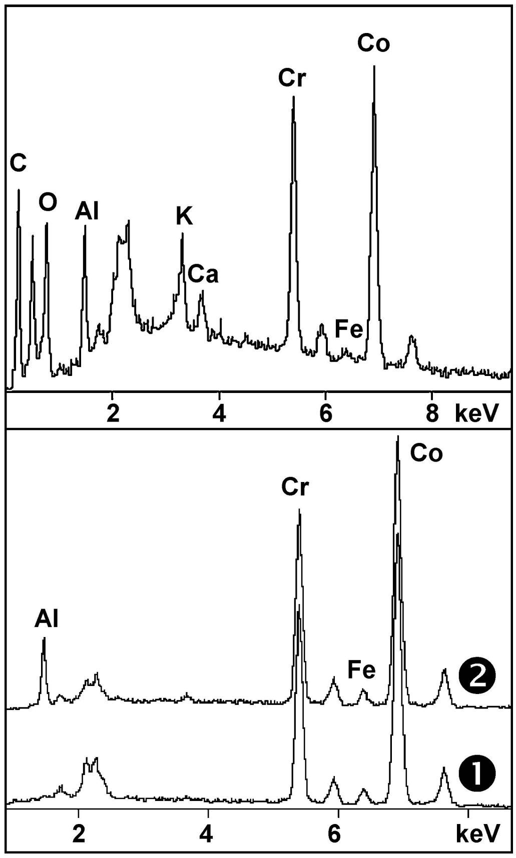

Figure 7 The upper graph shows the high content of foreign elements such as Cr, Fe, Co, Al, but not Ni and W in fibrous tissue. The two spectra on the lower graph, related to the EDAX of ❶ and ❷ sites of Fig. 6C, show an almost similar composition, but with aluminium in ❷.

The coating of the examined screws contained aluminium, which was released and passed into the soft tissue. In line with Shahgaldi *et al.* [25], our results indicate a local accumulation of aluminium in soft tissue. The aluminium content of connective tissue surrounding metal implants may reach high values, and a very high rate of aluminium accumulation was found in the dense lamella of bone [26, 27].

In speculation, accumulation of aluminium in the dense lamella may be accounted for by two possibilities: (1) aluminium-collagen affinity, since the dense lamella is rich in collagen fibers [26, 27]; (2) dilution of aluminium content when large amounts of bone matrix is synthesized, such as in loose lamellae rich in bone matrix [26, 27]. Further studies will be necessary to untangle these relationships.

When the implanted appliances have ceased to leach aluminium *per se*, a secondary release from aluminium stores may continue to propagate the dangerous side effects of this element [21]. Indeed, aluminium build up in bone buffers soft tissue deprivation and bone remodeling produces a further release of this element.

A relationship seems to emerge between tissue reactivity and element release. Besides composition, vitallium appliances have a limited element release, and they do not seem responsible for the observed tissue reaction. Nevertheless, particularly in elderly patients, appliance should be removed as soon as possible. Moreover, marked release of elements occurs with coated appliances, and this may be ascribed to the aluminium content of the coating or to enhanced corrosion, or both. The findings suggest that the use of aluminium-containing coatings on appliances targeted for use in the oral compartment should be avoided, in particular on cobalt/chromium alloy appliances, even to the detriment of their mechanical properties. Strong element release is associated with soft tissue reactivity and with the possible involvement of bone tissue. Particularly in patients with bone disease, these side effects could undermine the stability of implant-based prostheses. Larger studies are warranted to corroborate or refute the impact of element release from appliances, both in terms of alloy components and potentially dangerous elements such as aluminium and their interactions.

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