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Research Paper
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Chemical and structural analyses of titanium plates retrieved from patients

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Abstract. The aim of this study was to evaluate the microscopic structure and chemical composition of titanium bone plates and screws retrieved from patients with a clinical indication and to relate the results to the clinical conditions associated with the removal of these devices. Osteosynthesis plates and screws retrieved from 30 patients between January 2010 and September 2013 were studied by metallographic, gas, and energy dispersive X-ray (EDX) analyses and the medical records of these patients were reviewed. Forty-eight plates and 238 screws were retrieved. The time elapsed between plate and screw insertion and removal ranged between 11 days and 10 years. Metallographic analysis revealed that all the plates were manufactured from commercially pure titanium (CP-Ti). The screw samples analyzed consisted of Ti–6Al–4V alloy, except four samples, which consisted of CP-Ti. Titanium plates studied by EDX analysis presented greater than 99.7% titanium by mass. On gas analysis of Ti–6Al–4V screws, three samples were outside the standard values. One CP-Ti screw sample and one plate sample also presented an oxygen analysis value above the standard. The results indicated that the physical properties and chemical compositions of the plates and screws did not correspond with the need to remove these devices or the time of retention.

Keywords: titanium; fracture fixation – internal; fixation devices – internal; orthognathic surgery; bone plates; bone screws.

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Bone plates have been used for osteosynthesis in the oral and maxillofacial region since the late 19th century, although modern internal fixation devices have gained popularity since the report by Champy et al. in 1978.[1] Nowadays, titanium bone plates are an important part of the management of facial bone trauma and orthognathic, craniofacial, and maxillofacial reconstructive surgery.[2,3] It has been suggested that they are suitable as permanent implants because the biological compatibility of titanium is superior to that of other materials such as stainless steel.[4]

There is, however, no consensus in the oral and maxillofacial surgery literature regarding the removal of bone plates, hence their long-term management remains somewhat controversial.[2] Early systems were generally large, bulky, and fabricated of stainless steel or cobalt chrome, and as part of the overall treatment plan it was advocated that these fixation devices be removed after they ceased to function.[1]

Despite the excellent clinical performance presented by titanium plates, doubts have emerged about their long-term behaviour in tissues and their potential local and systemic side effects. There is agreement that in symptomatic cases, plates should be removed, but there is no consensus among maxillofacial surgeons regarding the need for routine plate removal in asymptomatic cases.[5] Most reports do not suggest bone plate removal and this is generally

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undertaken only when there are associated symptoms.[6–8]

Adverse outcomes of bone plates requiring removal include prominence and palpability, infection, plate migration, exposure, and temperature intolerance. Infection and exposure are the most common reasons for the removal of plates associated with fractures of the jaws, while prominence and pain are the main reasons for bone plate removal in the midface.[9]

One concern related to leaving metal plates and screws in the tissues is the possibility of corrosion.[10] Pigmented deposits in the tissues adjacent to maxillofacial plates have been described in different studies and have been reported to be titanium particles.[11–13] Various mechanisms, including mechanical wear, electrochemical corrosion, and mechanical disruption during either insertion or removal, may account for such local metal release and potential dissemination.[10,14]

The aim of the present study was to evaluate the microscopic structure and chemical composition of titanium bone plates and screws retrieved from patients with a clinical indication and to relate the results to the clinical conditions associated with the removal of these devices.

Materials and methods

This study was approved by the research ethics committee and informed patient consent was obtained from all patients.

The experimental population comprised 30 patients from whom plates and associated screws were removed between January 2010 and September 2013. For two of these patients, only screws were removed. The devices were removed due to clinical indications including infection, exposure, pain, screw loosening, palpability, and elective secondary procedures in the same area. After removal, plates and screws were stored in a sterile container and identified with a number corresponding to the individual patient.

The patient medical records were examined and the following data were recorded: age, gender, type of surgical procedure that led to plate and screw insertion, time between insertion and removal of these devices (retention period), indication for plate and screw removal, site of removal, and general medical condition.

The evaluation of plate and screw samples was performed by metallographic, gas, and energy dispersive X-ray (EDX) analyses. The preparation and analyses of samples were done in accordance with the American Society for Testing and Materials (ASTM) specifications.[15–19]

The samples used for metallographic and EDX analyses consisted of part of each bone plate retrieved and one of the associated screws. The metallographic analysis was performed for all of the samples. The EDX analysis was performed for 13 plate samples and 12 screw samples. For gas analysis, the samples consisted of bone plate fragments and associated screws. This analysis was performed for 12 patients. One unused titanium plate and titanium screws that had not been retrieved from a patient were also analyzed by metallographic, gas, and EDX analyses and served as controls.

After preparation, the samples were subjected to metallographic analysis by use of an optical microscope (Olympus Model BX51M) at magnifications of 200× and 500×, and the microstructure of each plate and screw sample was determined.

The EDX analysis was used to confirm the chemical composition of the samples. For this analysis, the samples were evaluated using an energy dispersive X-ray spectrometer (Shimadzu Model EDX-720), and it was possible to determine the mass percentage of titanium and iron in samples of commercially pure titanium (CP-Ti) and the mass percentage of the constituent elements of the Ti alloy (Ti, Fe, Al, and V) for Ti–6Al–4V alloy samples.

To perform the gas analysis, a sufficient sample weight and size is necessary, since the fusion process requires similar dimensions and weights for the segments of the samples; these are subjected to two to three different analysis processes to determine the mean values for each element.

Only some of the plates and screws had enough material to allow for this analysis, and the evaluation and determination of the elements hydrogen (H), oxygen (O), and nitrogen (N) were prioritized; an Oxygen Nitrogen Hydrogen Analyzer was used (ONH-2000; ELTRA GmbH, Haan, Germany). Likewise, only a small portion of plates and screws were also subjected to analysis and determination of carbon (C), using a Carbon Sulfur Analyzer (CS-2000; ELTRA).

The results obtained by metallographic, EDX, and gas analyses were compared with ASTM standard specifications. The ASTM F67 Designation[15] was applied for CP-Ti samples and the ASTM F136 Designation[19] was applied for Ti–6Al–4V alloy samples.

To evaluate the clinical factors associated with the plates and screws removed, a descriptive analysis was performed of the data collected from the medical records; the χ^2 test was applied. The results were considered statistically significant at $P < 0.05$.

Results

During the 4-year study period, 30 patients underwent plate removal; 22 (73.3%) were male and eight (26.7%) female. Their average age was 34.7 ± 13.8 years (range 13–70 years) at the time of plate and screw removal. The mean time elapsed between insertion and removal was 23.1 ± 29.6 months (range 11 days–10 years). Forty-eight plates and 238 screws were retrieved.

Patients had undergone osteosynthesis for fracture repair in the maxillofacial area in 18 cases (60.0%), for orthognathic surgery in eight cases (26.7%), and during reconstructive surgery due to maxillofacial tumours and other lesions in four cases (13.3%).

The site of plate and screw removal was the mandible in 20 patients (66.7%) and the maxilla/middle third of the face in 10 patients (33.3%). No statistical significance was observed when the variables gender and site of plate/screw removal were related ($\chi^2 = 0.34$; $P = 0.56$).

The indication for plate/screw removal was infection in 13 cases (43.3%), pain in four cases (13.3%), second surgical procedure (i.e., reconstructive procedures, dental implant insertion) in 11 cases (36.7%), screw loosening in one case (3.3%), and dehiscence and intraoral exposure of the device in one case (3.3%). Six patients (20.0%) presented medical diseases (i.e., hypertension, diabetes, hypothyroidism).

Metallographic analysis revealed that all of the plates were manufactured from CP-Ti. All the plates studied by EDX analysis presented greater than 99.7% titanium by mass. The screw samples analyzed consisted of Ti–6Al–4V alloy, except for four samples, which consisted of CP-Ti. All samples were within ASTM F67[15] and F136[19] specifications according to the metallographic and EDX analyses. At metallographic analysis, all plate and screw samples manufactured from CP-Ti presented a microscopically uniform appearance, with no 'alpha case' (Fig. 1A). All the screw samples manufactured from Ti–6Al–4V alloy were composed of finely dispersed globular α + β phases, with no 'alpha case' (Fig. 1B).

For the Ti–6Al–4V screw samples, hydrogen (H) analysis revealed one sample with a value above that of the ASTM specifications (0.037%; ASTM standard 0.012%), while oxygen (O) analysis

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