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The fate of titanium miniplates and screws used in maxillofacial surgery: A 10 year retrospective study

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Abstract. The objective of this 10 year, retrospective study is to evaluate the indications for the removal of titanium miniplates following osteosynthesis in maxillofacial trauma and orthognathic surgery. All patients who had miniplates placed in a Regional Oral and Maxillofacial Department between January 1998 and October 2007 were included. The following variables were recorded: patient gender and age, number of plates inserted, indications for plate placement, location of plates, number and location of plates removed, indications for plate removal, time between insertion and removal, medical co-morbidities, and the follow-up period. During the 10 years of the study, 1247 titanium miniplates were placed in 535 patients. A total of 32 (3%) plates were removed from 30 patients. Superficial infection accounted for 41% of all plates removed. All complications were minor and most plates were removed within the first year of insertion. A low removal rate of 3% suggests that the routine removal of asymptomatic titanium miniplates is not indicated.

Keywords: titanium miniplates; removal; osteosynthesis; trauma; orthognathic.

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Monocortical miniplate fixation is an accepted and reliable method of fixation for patients with maxillofacial trauma undergoing orthognathic surgery[13]. Luhr[20], Schilli[28], Spiessl[30], Michelet et al[23] and Champy et al[7] developed internal fixation systems that were designed to replace or supplement maxillo-mandibular fixation in the treatment of maxillofacial injuries and deformities. Titanium miniplates have superseded vitallium and stainless-steel plates because they are reliable, and appear clinically inert, causing little or no local reaction. Despite their excellent clinical performance, doubts have emerged about their long-term behaviour in tissues and their potential local and systemic side effects[19].

There is agreement that symptomatic plates should be removed, but there is no consensus among maxillofacial surgeons on the need for routine removal of asymptomatic plates. Some authors recommend removal[1,6,23,30], while others recommend retention unless clinically indicated[3,5,17,22]. In 1991, the Strasbourg Osteosynthesis Research Group (SORG) produced the following recommendations: 'A plate which is intended to assist the healing of bone becomes a non-functional implant once this role is completed. It may then be regarded as a foreign body'. There is no clear evidence that a plate causes harm, but knowledge remains incomplete so it is impossible to say that an otherwise

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symptom-less plate left in situ, is harmless.

SORG states that the removal of a non-functioning plate is desirable 'provided that the procedure does not cause undue risk to the patient'[31]. Ward Booth[33] states that interpretation of these recommendations means that for most patients there is less risk in leaving symptom-less plates in situ than removing them.

Alpert and Seligson[1] advocate the removal of asymptomatic bone plates following fracture repair, stating that they then become a useless foreign body and a potential source of problems once healing has occurred. In1996, Haug[17] reported that there was no association between tumour formation or allergic reactions and commercially pure titanium.

Katou et al[18] studied immuno-inflammatory responses to titanium miniplates used in the treatment of mandibular fractures and found that titanium particles released from miniplates induce and maintain chronic inflammation and fibrous encapsulation. They suggest that non-functioning plates and screws should be removed after healing.

Weingart et al[34], in a study on titanium deposition in regional lymph nodes after insertion of titanium screw implants in the maxillofacial region, found a raised titanium level in some regional lymph nodes, but no foreign body or toxic reaction was observed in the histological sections. In 1991, Tomazic et al[32] found an association between titanium particles and monocyte and macrophage activation with release of bone resorbing mediators, fibroblast stimulation, impaired bone healing and impaired immune responses.

Langford and Frame[19], in a controlled human plate retrieval study, found no signs of corrosion or surface deterioration on the retrieved plates and screws that had been in the tissues for between 1 month and 13 years. They found no evidence to support the routine removal of titanium miniplates due to corrosion up to 13 years after insertion.

Rosenberg et al[26] showed the amount of titanium deposition from miniplates was small and pigmentation was asymptomatic. There was no relation between complications and pigmentation. It is their opinion that changes in soft tissues near titanium miniplates should not be interpreted as an indication to remove the plates.

Branemark et al[4], in numerous long-term studies, showed that titanium dioxide did not produce any toxic side effects. Eppley et al[12] state that titanium does not contraindicate the use of MRI, produces no high density scatter in CT, offers no interference with complex three-dimensional CT reconstruction, and is compatible with radiography. Alpert and Seligson[1], state that the potential for artefacts remains as long as a plate remains in place.

In common with other maxillofacial units[5,6,21,22], it is the policy at the authors' hospital to remove titanium bone plates only if they become symptomatic, in response to patients' requests, if they impede further surgery or if they have the potential to interfere with facial growth. The purpose of this study is to evaluate the incidence and reasons for plate removal following the placement of plates during maxillofacial trauma and orthognathic surgery.

Patients and methods

This is a 10-year, retrospective study of patients who had titanium bone plates (Stryker Liebinger Micro Implants, Freiburg, Germany) placed in the Department of Oral and Maxillofacial Surgery, Mid Western Regional Hospital, Limerick, Ireland, between January 1998 and October 2007. The following variables were recorded: patient gender and age, number of plates inserted, indications for plate placement, location of plates, number and location of plates removed, indications for plate removal, time between insertion and removal, medical co-morbidities, and the follow-up period. The specific medical comorbidities noted were immunosuppressive conditions that may predispose to infection and the need for bone plate removal, diabetes, HIV disease, steroid medication, chemotherapy or neoplastic disease. The reason for removal was based on the surgeon's clinical and radiographic assessment, and the patient's symptoms. All information was obtained from patient medical records and operation reports. The indications for plate insertion were: maxillofacial fractures and orthognathic surgery (Le Fort I and mandibular sagittal split osteotomy, and genioplasty).

All patients admitted with maxillofacial trauma were treated using the same antibiotic and dietary protocol.

Patients with mandibular or maxillary (Le Fort I and II) fractures are admitted for surgery under general anaesthesia. The interval between admission and definitive fracture treatment is variable and based on clinical presentation and other ongoing hospital emergency surgical activity. All patients are administered intravenous antibiotics on admission (amoxycillin/clavulanic acid 1.2 g or clindamycin 600 mg 8 hourly if penicillin allergic) and throughout the hospital stay. Patients complete a 5-day course of oral antibiotics on discharge.

Patients with isolated and minimally displaced orbitozygomatic complex fracture are assessed in the Accident and Emergency Department and in most cases discharged with oral antibiotics (amoxycillin/clavulanic acid 325 mg 8 hourly, clindamycin 150 mg 8 hourly if penicillin allergic). These patients are readmitted 5 days later for definitive fracture treatment when the facial swelling has reduced.

Orbitozygomatic complex fracture patients are admitted, if the facial fractures are associated with other significant associated injuries such as head injury, cervical spine injury, orthopaedic or abdominal injuries, or with clinically relevant ocular findings such as reduced visual acuity, disabling diplopia. Occasionally, social circumstances necessitate hospital admission. On admission, patients are administered intravenous antibiotics (amoxycillin/clavulanic acid 1.2 g 8 hourly or clindamycin 600 mg 8 hourly if penicillin allergic) that are continued during the hospital stay. They are prescribed oral antibiotics for 5 days following discharge.

Patients attending for orthognathic surgery are admitted on the day of surgery and treated with prophylactic intravenous antibiotics at induction of general anaesthesia (amoxycillin/clavulanic acid or clindamycin as above). Intravenous antibiotics are continued during the hospital stay and a 5-day course of oral antibiotics is completed on discharge.

All patients follow a similar postoperative dietary regimen. In the presence of intra-oral wounds, patients fast for 6 h postoperatively followed by a period of clear liquids for 48 h and advanced to a soft diet, which continues for 6 weeks postoperatively. All patients have a consultation with a dietician during their hospital stay.

Results

The results are outlined in Tables 1 and 2 and Fig. 1. During the 10-year period of this study, 1247 titanium miniplates were placed in 535 patients **(**428 (80%) were male and 107 (20%) female**).** In total, 30 patients underwent plate removal; 26 (87%) were male and 4 (13%) female, their mean age was 29 years (range 3–72 years).

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