Surface analysis of titanium maxillofacial plates and screws retrieved from patients

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Abstract

Introduction: Miniplate fixation and screws is the method of choice for many surgeons to obtain rigid fixation and promote osteosynthesis within the maxillofacial region. The most common commercially used plates and screws are made up of pure titanium. The popularity of biocompatible devices containing titanium is due to its high resistance to corrosion in physiologic body fluids.

Generally titanium fixation plates are not removed after osteosynthesis because they have high biocompatibility. This study was done to analyze the surface characteristics and changes in retrieved titanium plates and screws by scanning electron microscope (SEM) and stereomicroscope.

Materials and Method: A total of 20 plates were retrieved from 12 patients visiting the department of oral and maxillofacial surgery at our institution over a period of 18months. These samples were studied by stereomicroscopy and scanning electron microscopy. Each plate and one of its screws were examined for evidence of manufacturing defects, surgical damage and corrosion. Particular attention was focused on countersink area of plate and taper of the screw head as these regions were particularly prone to micro movements and subsequent corrosion.

Results: Surface contamination was detected both on retrieved and control plates. Manufacturing defects comprising of rough metal edges and protuberances were identified on the unused controls and surgical damage was evident on retrieved specimens. Two of the retrieved plates and screw showed the presence of corrosion and metal release which had been in the tissues for 14 to 20 months. Rest of the retrieved plates and screws, which had been in the tissues, between 6 months to 48 months showed no signs of corrosion or surface deterioration.

Conclusion: The present study showed that 2 plates and its associated screws had signs of corrosion and metal release; but further long-term follow-up studies are desirable to assess the clinical and toxicological effects of the retention of titanium plates, especially in relation to release of particles to the surrounding tissues. The source of metal release has to be further confirmed by EDX analysis. There was no evidence from this study to support the routine removal of titanium maxillofacial miniplates.

Keywords: Titanium Plates, Corrosion, Metal Release, Retrieved Plates

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Introduction

Miniplate fixation is an accepted and reliable method of fixation for patients with maxillofacial trauma. Titanium is more frequently used for metallic miniplates manufacturing since its well tolerated by living tissue causing minimal local reactions in vivo. Titanium has been used because of its high wear and tear resistance, chemically inert nature i.e. corrosion resistant and absence of metal release. It is available in all sizes and shapes and is easily adaptable. Once implanted these plates are often left in place because of its biocompatible and corrosion resistant nature. These features are the result of the fact that titanium forms a dense, pore free and self-regenerating oxide film on the surface also called passive layer of titanium dioxide. Inspite of their excellent clinical performance doubts have been emerged about their long term behavior in the tissue and about potential local and systemic side effects. A concern about leaving metal plates and screws is the tissues with the possibility of corrosion stays.

The severity of corrosion and the quantity of corrosion products released may depend, not only on the corrosion susceptibility of titanium plates; but it also depends on the tissue response to the titanium plates as well as surgical procedures used during plate fixation. There is very little information available on the release of elements from titanium plates used for immobilization of fractures of maxillofacial skeleton.

There is an agreement that symptomatic plates should be removed, but there is no consensus among the maxillofacial surgeon on the need of routine removal for asymptomatic plates. Some of the authors recommend removal while others recommend retention, unless clinically indicated.

There have been previous plate retrieval studies performed on both patients and animals but few of these studies were flawed because comparison was not made between retrieved and control plates[1,2,3].

The aim of this study is to study the corrosion of titanium metal plates used for immobilization of fractures of maxillofacial region with special emphasis on the release of metal from the plates, to compare the surface characteristics of retrieved titanium miniplates with the unused (control) plates and to study the structural changes of titanium plates and screws.

Materials and Method

A total of 20 plates were retrieved from 12 patients visiting the department of oral and maxillofacial surgery at our institution over a period of 18 months.
The inclusion criteria in the present study were:
1. Patient aged between 15 to 60 years
2. Patient should be medically fit for the surgery
3. Patient willing to give a written consent
4. Cases where the radiographic evidence shows complete healing of the fractured segment or where the signs of infection were present making plate removal mandatory.
5. Cases which can be operated under local anesthesia

The exclusion criteria in the present study were:
1. Patient with systemic co-morbidity
2. Mentally and physically challenged patients
3. Patient requiring general anesthesia for surgery
4. Patient unable to or not willing to give a written consent
5. Radiographs showing evidence of nonunion or malunion

Later the retrieved titanium plates and screws and the control samples of unused plates and screws comprising of 10 titanium plates and screws were taken from the same plating system encountered in the retrieved specimen. All these samples were studied by stereomicroscopy and scanning electron microscope (SEM).

Each plate and one of its screws were examined for evidence of manufacturing defect, surgical damage and corrosion. An initial lower power stereomicroscopy and subsequently high power scanning electron microscopy were performed around the end of screw hole of each plate, on the head and fitting taper of each screw and on any area exhibiting unusual surface characteristics. Particular attention was focused on the counter sink area of the plate and taper of the screw head. These were the regions particularly prone to micro-movements and subsequent corrosion.

Results

SEM Results: All the plates and screws studied under SEM were manufactured from commercially pure titanium consisting of greater than 97% of titanium by weight. Two surface finishes were identified on the specimens. One was plain titanium dioxide and another one was the anodized surface or finish. The plain titanium plate on SEM showed surface characteristics by multiple, randomly arranged polymorphous defects and fine surface scratches. Few scratches were found on plain titanium plates and were covered by electrolytically thickened layer of titanium dioxide. Surface defects were seen on both retrieved and controlled plates.

Retrieved Specimens: Nine plates showed or had an anodized surface finish and the rest of the plates showed plain non anodized surface. Signs of surgical damage were identified on all retrieved plates and screws. Surgical damage was evident as shallow score marks on the plates; and on the screws damage was seen on head of the screws. Two of the plates and screws showed metal release (Aluminum), which has to be further confirmed by Energy Dispersive X-Ray Spectroscopy (EDX) analysis (Fig. 1). Two of the retrieved plates showed pitting corrosion seen as depressions and stress corrosion seen as surface cracks in the area of tensile stress (Fig. 2). One of the plate showed hole like defect which might be due to corrosion. Surface defects and finishing defects were seen. Intrinsic surface irregularities and small number of score marks were visible on surface.

Fig. 1: SEM images showing stress corrosion of titanium plate

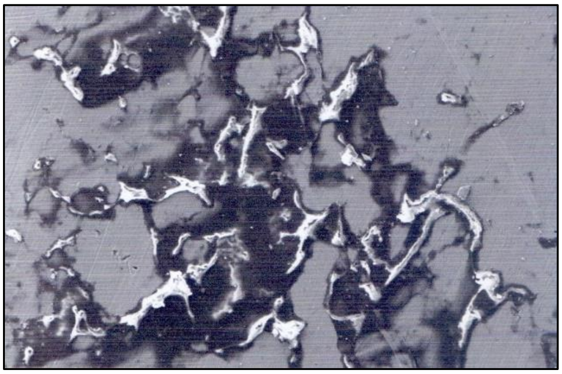

Fig. 2: SEM images showing metal release

Control specimens: Study of control plates and screws revealed mainly manufacturing defects which consisted of round edges. Metal protuberances which were located on plates and screws mainly on head of screws and around rim of screw holes. Dark irregularities with a smooth surface were found on control plates. Group of polymorphous defects were seen interspersed, randomly over the surface, on controlled titanium plates. Depression or defects seen on control pates are shallower than used plates. Linear cracks were seen adjacent to depression on both surfaces of control plates. These cracks measured l -30 um long and I -5 um thick and were randomly distributed parallel to each other. Shallow scratch marks were also apparent on control plates and were oriented randomly (Fig. 3).

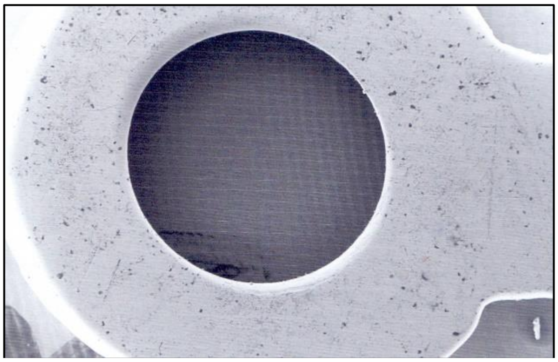

Fig. 3: Control (unused) plate

Stereomicroscopic Results

Results could be classified as mechanical damage, corrosive degradation or combination of two (Fig. 4).

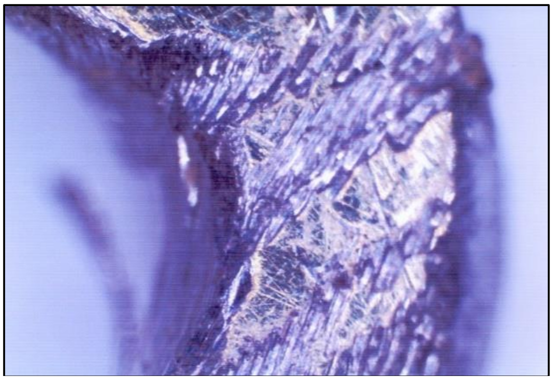

Fig. 4: Stereo microscopic images showing corrosion and metal release of titanium plates

Plates

- Mechanical defects on the surface of majority of plates were observed.
- Handling defects were found on all the plates, however the distribution and severity varied.
- Tool marks on the free surface of the plates had a character of sharp-edged scratches but were not involved by detectable corrosion.
- Mechanical defects in the countersink regions had a similar appearance to those appearing on free surface.
- Typical drilling injuries in the countersink area were common on all the plates.
- In contrast, corrosive degradation was observed in two cases observed in association with ~~the~~ mechanical defects in the countersink region (Corrosion never extended onto the free surface outside the countersink area).
- No relation was found between the frequency of corroded devices and plate removal earlier than 6 months or more than 6 months postoperatively.

Screws

- All screws exhibited handling defects visible as minor scratches on screw heads and along screw threads. In combination with the mechanical defects, minor splints were infrequently observed under screw head (Fig. 5).
- There was no obvious difference regarding the severity of mechanical screw defects.
- Corrosion defect were found on screw head and at the transitional zone of screw head / screw thread.

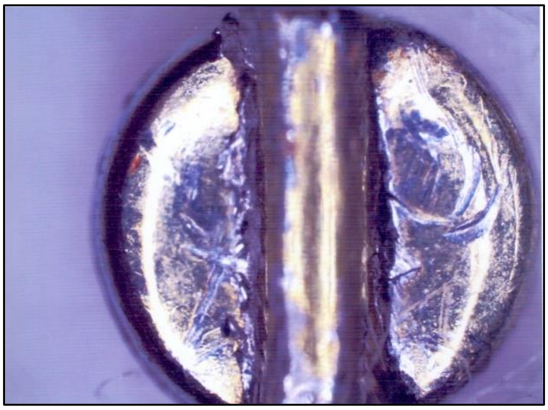

Fig. 5: Stereo microscopic images showing corrosion and metal release of titanium screw head

In this study comprising of 12 patients, 11 (91.6%) were males and 1 (8.4%) was female. The extremes of ages ranged from 15-55 years, with the mean age group of 28.83±10.78 years (Table 1). The maximum number of plates were removed from left parasymphysis [12 plates (60%)] followed by right parasymphysis [4 plates (20%)], then frontozygomatic area [3 plates (15%)] and 1 plate (5%) was removed from right infraorbital region (Table 2). The duration for which the plate was kept in-situ ranged from 6 months to maximum of 37 months with average duration of 15.08±10.5 months (Table 3). Results showed manufacturing defects in 100% cases of both the study and control group, whereas, corrosion and metal release were seen in only 10% cases of the study group (Table 4).

Table 1: Age and Sex wise distribution of cases

Age	Male		Female		Total	
	No	Percentage (%)	No	Percentage (%)	No	Percentage (%)
15-24	4	33.3	0	0	4	33.2
25-34	5	41.5	1	8.4	6	50.0
35-44	1	8.4	0	0	1	8.4
45-54	0	0	0	0	0	0.0
>=55	1	8.4	0	0	1	8.4
Total	11	91.6	1	8.4	12	100.0

Table 2: Location wise removal of plates

Location	Number of cases	Percentage (%)
Left Parasymphysis	12	60
Right parasymphysis	4	20
Frontozygomatic area	3	15
Right infraorbital area	14	5
Total	20	100

Table 3: Duration of plates in-situ

Location	Number of cases	Percentage (%)
6 months to 12 months	7	58.3
12 months to 24 months	4	33.3
25 months to 36 months	0	0.0
>= 37months	1	8.4
Total	12	100

Table 4: Comparison of study group and control group

Analysis	Study group		Control group	
	No.	Percentage (%)	No.	Percentage (%)
Manufacturing	20	100	10	100
Corrosion	2	10	0	0
Metal release	2	10	0	0

Discussion

During last decade, rigid internal fixation with titanium miniplates and screws had gained widespread acceptances in the management of maxillofacial fractures. Titanium and its alloys possess outstanding biocompatibility in human body by virtue of formation of oxide film in minimum time and their corrosion resistance to blood and other body fluids.

Metal miniplates are used to immobilize fractures of facial skeleton but the question arises, whether, nonfunctional miniplates be removed routinely after bone healing or not. The decision to leave miniplates insitu may be influenced by many factors such as the known biocompatibility of the implant, poor access and patient's choice. The financial and resource implications of a second procedure to remove miniplates may also be a constraint, screws may be damaged and may fracture during removal, thus, complicating miniplates retrieval. Therefore, some clinicians thus feel justifiable to leave implants insitu if there have been no clinical symptoms from the fracture site during healing. However, an international study group has recommended that all nonfunctional implants should be evaluated for removal[4].

A major concern about the permanent retention of metal miniplates and screws after osteosynthesis is the effect on the implant surface of general corrosion and fretting corrosion between miniplates and screws. Experimental studies on animals have shown that the surface of implant material may retain their original surface characteristics after a period of implantation. Linder and Lundskog[5] used SEM to study the surface of stainless steel and pure titanium cylindrical implants retrieved from 7 to 10.5 months after implantation into bone defects created in the tibia of rabbits and found that there was no evidence of corrosion. Moberg et al[6] examined miniplates made of cobalt chromium alloy, nickel chromium and titanium retrieved from mandible of monkey upto 6 months after surgery. Using light microscope the authors found no visible corrosion sites or corrosion products on surface of implants. Retrieval studies provide useful information about surface characteristics of miniplates that have been removed from patients after osteosynthesis. There are many retrieval studies that are done on animal but a very few retrieval studies[7] of titanium plates on human beings. However, some of the studies done on animals were flawed because comparison was not made between the retrieved plates and unused control specimens. The importance of this element in any retrieval study has been emphasized by a study on unused titanium plates, showing numerous defects and irregular fragment on the surface.

A controlled retrieval study in animals in which titanium miniplates were used to fix mandibular osteotomies found that there were no significant changes in surface characteristic of miniplates retrieved upto 24 weeks after insertion in comparison with unused controls. Our present study was designed to determine whether these findings were same in humans. The retrieved plates and screws were studied under SEM and Stereo microscope to identify the surface contamination of control and retrieved plates.

The surface characteristics of experimental titanium plates and screws removed from patients were compared with unused control plates and screws. Particulars attention was paid to potential sources of metal release into tissues such as corrosion, wear, manufacturing defects and surgical defects.

The plates most frequently used in oral surgery are made of cobalt-chromium, titanium and nickel-chromium alloys. It has been shown that release of metals occurs in vivo from all types of alloys used in Implantology. The release of Ti from implant in bone has earlier been reported to be low. However, Fergusonet al[8] found a relatively large release of Ti from a Ti alloy. The results of our present study showed metal release from titanium plates and screws used for fracture immobilization procedure. Metal may be released as a result of manufacturing defect, corrosion, surface contamination or mechanical damage which may occur during insertion, removal or due to wear while in-situ.

The long term management of miniplates osteosynthesis remains controversial with some authors recommending routine removal of plates at 3 months (Peterson et al, 1986), while others recommended retention of plates until their removal is clinically indicated[9-11].

The likelihood of infection or pain have been cited as a reason for the routine removal of plates. Other causes of plate removal were palpability, wound dehiscence, sensory disturbances and discomfort. The decision as such to remove maxillofacial miniplates depends upon the presence of signs and symptoms and on consent from the patients.

In this study, out of 20 plates retrieved from 12 patients, only one patient showed signs of infection and pain, which was the cause for the removal of the plates, in other cases plates and screws were removed on a routine basis without any associated signs and symptoms of infection. The reason for low infection rate is due to the reason that patients were managed with strict antibiotic protocol and adherence of the patient to rigorous postoperative dietary instructions leading to reduced mobility at the fracture sites. This does not concur with other authors[1,12,13] who found infection to be the main cause of plate removal.

In one of the study done by Alpert and Seligson[14], they reported that temperature conduction, associated with bone plates, is a significant cause of morbidity and plate removal. In this present study, none of the plates were removed due to temperature sensitivity, which is in line with the other studies[1,15,12,13] in which there were no examples of plate removal due to thermal sensitivity.

In this study 9 of the titanium plates showed anodized surface and rest of the plates showed non anodized surface. Under SEM, the plain plates had a matt grey appearance and anodized surface had a dull gold or colored finish. Anodized surface produce a smoother, scalloped surface whereas, defects and scratches found on non-anodized surface are covered by an electrolytically thickened layer of titanium dioxide. This concurs with the result of the study done by R.J Langford et al[16] in which anodized plates had a smoother more uniform surface with no detectable rough edges or metallic protuberances.

In the present study, all titanium plates were retrieved after complete union of fractured fragments. Two of the plates were retrieved within 7 months of insertion. These findings coincided with the study done by T.Kawai et al and Heppenstall who have found most of the fractures had united 4 months or more after surgery and suggests that favorable time for removal of fixation material is after 5 months of fracture fixation.

In the study, most of the titanium plates (9 plates) were removed from the mandible in the parasymphysis region and rest of the plates were removed from frontozygomatic area. This is not surprising because most of the titanium plates used in trauma cases are placed in parasymphysis region. These findings concur with Mosbashet al[12] where most plates were removed from parasymphysis region.

Mosbal et al in his study showed 75% of the plates placed in trauma patients were removed within 6 months of insertion. But in this study, only two of the plates placed in parasymphysis region were removed within 7 months of insertion, rest most of the plates were removed within one year of insertion, which concurs with the study done by Bhatt et al[1], in which they have demonstrated a removal rate of 72% within first year of placement.

There are studies done on surface analysis of titanium miniplates and stainless steel plates. These plates were analyzed under SEM and EDX analysis. SEM analysis revealed corrosion and metal release only in relation to stainless steel plates, but, these findings were not found in retrieved titanium plates. In this study only titanium maxillofacial plates and screws were studied under SEM, the results of which differ from previous studies as two of titanium plates and associated screws were associated with corrosion and metal release.

In this study, corrosive degradation was observed in association with the mechanical defects in the countersink region of titanium plates and screws as this region is particularly prone to micro movements and subsequent corrosion. The results of this study differs with other studies done by Langford et al[2] and IR Mathew et al[7], in which, there were no signs of corrosive degradation in countersink area of titanium plates and screws.

The results of this study showed surface defects which were present on both control specimen and retrieved specimen and they showed no differences. These surface defects were most likely the results of manufacturing process which involves rolling milling and polishing. These results concur with the study done by I.R. Mathew et al[7] the results of which shows surface detects and handing defects. The surface irregularities of the control specimens appeared to have occurred during implant manufacture. The surface cracks and depression probably arose during production of the sheets from which miniplates are cut. The countersinks for the screw hole had in smooth finish and a consistent bevel angle, indicating that a precision milling apparatus was used to machine the screw holes and the line scratches on the surfaces of all miniplates probably occurred during the final polish. The surface deposits may have been caused by aluminium oxide or silicon carbide abrasives used to polish the miniplates during manufacture.

In this study, signs of surgical damage were evident but there was no indication that this leads to corrosion. Previous in-vivo retrieval studies done by Mathew IR et al[17] and Torgersen et al[4,18] have shown no evidence of titanium corrosion. But these results differ from the studies done by Acero J et al[19], who have claimed to have identified areas of corrosion and metal loss from titanium plates in both experimental and clinical situations. But these studies were flawed due to lack of suitable controls. In this present study, surface analysis of both retrieved and control groups were done under SEM and stereomicroscope.

In this present study, surface deposits of aluminum were identified on retrieved specimens on SEM analysis, which has to be further confirmed by EDX-analysis. This contamination was found embedded in the surface irregularities and may have occurred during manufacturing .Other possible sources of aluminum contamination are from atmospheric dust or from autoclaving the plates prior to clinical use. These findings concurs with previous studies done by 1.R Mathew et al[7] who have identified aluminum and silica on the surfaces of titanium plates and in the soft tissues adjacent to titanium miniplates. The cellular toxicity caused by aluminum has been associated with Alzheimer's disease, Parkinsonism and osteomalacia.

In our study two of the retrieved plate showed pitting corrosion which was seen as depression and stress corrosion seen as surface cracks in the areas of tensile stress. One of plate showed hole like defect which might he due to corrosion or the defects might be representative of the manufacturing process or due to surgical manipulation. This finding concurs with the results of study done by Acero et al[19], in which, hole like defects were identified in 35% of the plates supposed to be due to corrosion.

In this present investigation there were signs of titanium corrosion and metal release. Surgical manipulation and manufacturing defects are probably more important sources of particulate metal release when maxillofacial osteosynthesis plates are used. The source of surface contamination with aluminum should he determined and appropriate action taken to minimize the problems. Anodizing does appear to reduce the presence of surface contamination with aluminum.

Further, long term follow-up studies are desirable to assess the clinical and toxicological effects of retention of titanium plates especially in relation to release of particles into surrounding tissues.

Conclusion

To conclude for retrieval studies to be informative a control group of plates and screws must be examined before insertion and comparison must be made between retrieved and unused samples. In this present study out of 20 retrieved titanium plates and screws only 2 plates showed signs of corrosion and metal release into the tissues. Surgical manipulation and manufacturing defects are probably more important sources of particulate metal release into the tissues, when maxillofacial osteosynthesis plates are used. Therefore, from this study, there is no evidence to support the view that titanium miniplates should be removed on routine basis.

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