Surface Analysis of Indigenous Stainless Steel Miniplates Used in Facial Fractures

Arun Dugal · Gagan Thakur

Received: 6 September 2009 / Accepted: 11 October 2010 / Published online: 14 December 2010
© Association of Oral and Maxillofacial Surgeons of India 2010

Abstract

Aims and Objective The stainless steel (SS) implants are economical and easily available. Tissue reaction due corrosion of metallic plates and release of metal particles in surrounding soft tissues is the main reason put forward by advocates of removal of SS miniplates after period of fracture healing. The objectives of this study were to examine the surfaces changes and corrosion in relation to indigenously manufactured SS mini-plates, both due to intraoperative instrumentation and tissue reaction. The composition of these mini-plates and any metal release in surrounding soft tissues was also studied.

Materials and Methods Total ten plates retrieved from fracture sites, after a period of 4–12 months (mean 8 months), were studied with the help of scanning electron microscope for roughness and corrosive changes. EDX study was done to know the composition of plates and metal release from the plates.

Results Our study found the above parameters were comparable to previously reported studies in the international journals

Conclusion Though no major corrosion and tissue reaction was observed in this study a long term study will be

required for absolute recommendation regarding necessity of removal of indigenous SS plates on regular basis.

Keywords Stainless steel miniplates · Surface analysis · Corrosion · Composition

Introduction

Rigid internal fixation plays an important role in the management of facial trauma, in orthognathic surgery, reconstructive surgery and in access osteotomies. Various metallic implants in the form of screws, bone plates have been used for this purpose.

The ideal plating system should be fabricated from material that is biocompatible, providing no toxins and causing no forms of immune responses or malignant transformation. It should resist corrosion.

Stainless steel (SS) was one of the first metals used in maxillofacial surgery for semirigid fixation. The SS implants are economical and easily available. Tissue reaction due to corrosion of metallic plates and release of metal particles in the surrounding soft tissues is the main reason put forward that advocates removal of SS miniplates after fracture healing. However in routine practice, SS bone plates have not been removed for years after their placement except when the implants become symptomatic.

French HG et al. [1] found that SS miniplates are minimally toxic to human tissue in most circumstances and that the toxic products are well tolerated and do not recommend routine implant removal.

So far not many studies were reported in literature regarding surface changes, corrosion and its use in

A. Dugal (✉)
Department of Oral and Maxillofacial Surgery,
Bharati Vidyapeeth University Dental College and Hospital,
Katraj, Pune 411043, Maharashtra, India
e-mail: dugalag@yahoo.co.in

G. Thakur
Department of Oral and Maxillofacial Surgery, People's College
of Dental Sciences and Research, Bhopal, MP, India

Fig. 1 Scanning electron microscope study. Control plate: showing no surface irregularity and smooth borders

indigenous setting which will serve as a guide for clinicians to recommend the removal of SS miniplates.

This study was undertaken to examine the surface changes in relation to indigenously manufactured SS miniplates both due to intraoperative instrumentation or tissue reaction after retrieving them from the patients, and study of surface corrosion if present with the help of scanning electron microscope. EDX study was also done to know the metallic composition of miniplates. Release of metal particles in surrounding soft tissue were observed,

which can cause inflammatory reaction and necessitate plate removal.

Method

The study was conducted in the Department of Oral and Maxillofacial surgery, Bharati Vidyapeeth Dental College and Hospital Pune, from February 2006 till February 2007 after approval from the University's ethical committee.

Medically fit adult patients who reported with local tissue reactions related to plate or asymptomatic patients keen on removal of plate were considered. Minimum period of plate removal was atleast 3 months after fixation, the study was carried out as an open clinical trial. The study was undertaken with the patient's consent. The details about the surgical procedure, medications and the possible complication associated with the same were also explained.

During the study 15 patients treated with ORIF for various maxillofacial injuries who fulfilled the criteria of the study were selected irrespective of age, sex. The patients were examined thoroughly systemically as well as locally and findings were noted. Pre-operative clinical and intra-operative macroscopic findings were noted. Routine investigations for surgery were advised before implant removal.

Fig. 2 Scanning electron microscope study. Retrieved plates: surface roughness can be appreciated with sharp edges, **b** presence of metal tongue and **c** splinters

Surgical Technique

All patients were operated for the removal of plate under local anesthesia on OPD basis. Patients were prepared for surgical procedure in routine manner. Plates were removed intraorally after reflection of mucoperiosteal flap. Surrounding soft tissues were inspected for pigmentation and/or inflammatory changes. Wound was irrigated to remove any foreign body particles. Incision site was closed primarily using 3-0 vicryl or 3-0 black silk.

Postoperatively, all the patients were maintained on oral antibiotics and NSAIDs for 5 days and followed up for 10 days when sutures were removed if necessary.

Out of 15 patients, in five cases we experienced difficulty while removal of miniplates and were not included in because over instrumentation can itself lead to surface defects.

Plates retrieved were cleaned with soft tooth brush and saline, dried and examined under naked eye for any obvious surface changes.

It was then stored in black bottles and taken to National Chemical Laboratory, Pune for SEM study.

Patients were divided into two groups according to the cause of implant removal.

(1) Symptomatic patients Group I: (5 cases) and (2) Asymptomatic patients Group II: (5 cases).

Results

- (A) Duration between placement and retrieval of the implants in Group I i.e. symptomatic patients was 4–12 months (mean 7.2 month) and Group II: asymptomatic patients was 6–12 months (mean 7.8 month).
- (B) Clinical observation at the time of implant retrieval showed mucosal inflammation, infection and fistula in all symptomatic patients, but not in other group (Table 1).
- (C) Surgical observation at the time of implant retrieval: (Table 2).
Pigmentation, and Inflammation of soft tissues in contact with miniplates was seen in both groups to similar extent. Up to 20–60%.

Table 1 Clinical observation at the time of implant retrieval

No.	Clinical findings	Group I (symptomatic)		Group II (asymptomatic)	
		No	%	No	%
1	Mucosal inflammation	5	100	0	0.0
2	Infection	5	100	0	0.0
3	Fistula	3	60	0	0.0

Table 2 Surgical observations at the time of implant retrieval

No.	Clinical findings	Group I		Group II	
		No	%	No	%
1	Pigmentation	1	20	1	20
2	Inflammation	3	60	2	40

Table 3 Scanning electron microscopic findings

No.	SEM Finding	Group I		Group II	
		No	%	No	%
1	Surface roughness	5	100	5	100
2	Corrosion	0	0	1	20

Table 4 EDX SEM study of stainless miniplates

Elements	Asymptomatic group		Symptomatic group	
	wt% (1)	at.% (mean) (2)	wt% (3)	at.% (mean) (4)
O	2.21	7.28	2.69	8.75
Si	0.75	1.41	0.92	1.70
Mo	2.47	1.36	2.36	1.28
Cr	17.60	17.84	17.53	17.52
Fe	65.16	65.51	65.01	60.55
Ni	11.81	10.60	11.50	10.19
CrC	0.0	0.0	1.0	2.40

- (D) Scanning electron microscopic findings: (Table 3).
Control plate show no surface irregularity and have smooth borders (Fig. 1), while the retrieved plates were found to be rougher than the control plates. Corrosion defects were also found on the chamfer of the underside of SS screw heads restricted to the countersink area. Surface roughness of retrieved plates can be appreciated due to sharp edges, presence metal tongues and splinters (Fig. 2).
- (E) EDX SEM study of stainless miniplates (asymptomatic and symptomatic group): Table 4.

Discussion

- (1) All the examined plates had rough surface and showed evidence of defects of mechanical nature. Metal tongues and splinters were also seen associated with screw threads and in the periphery of plate screw holes.
Jorgensen and Gjerdet [2] in their study of SS and titanium miniplates and screws concluded that Defects of mechanical nature were found in all SS

and titanium devices which could be traced back to handling procedures. Metal tongues and splinters were occasionally found associated with screw threads and in the periphery of plate screw holes. Similar results were reported by Rosenberg et al. [3], Haug [5], and Mathew and Frame [6].

- (2) Corrosion defects were observed, which were restricted to the counterside area and on the chamfer of the underside of SS screw heads in one case only. Coincidentally the same patient was found to have infection and local inflammatory reaction related to the plate.

These findings are similar to the findings observed by Brown and Simpson [4] Torgenson and Gjerdet [2] and Haug [5] in their respective studies of stainless miniplates.

- (3) All the values obtained through EDX SEM study regarding composition of indigenous SS plates was identical to and comparable with the composition of SS miniplates given by Tucker and Ochs [7].

Atomic percentage of iron in symptomatic patients in comparison to asymptomatic patients is less indicating possible leaching of Fe in the surrounding tissues causing inflammatory reaction. Presence of CrC denotes presence of corrosion in relation to miniplates in one case.

Similar results were reported by Rosenberg et al. [3], Mathew and Frame [6] and Brown et al. [8].

Conclusion

According to our study all the removed plates showed mechanical defects like surface roughness which could be traced back to handling procedures. Corrosion was not seen as a common finding and it was found in one patient who had an infection related to plate.

Composition of indigenously manufactured SS plates was comparable to earlier reports in western literature.

The sample size was small to make final remarks on the quality of the indigenously manufactured miniplates on the basis of its composition. None of our patients had any local reaction which required any plate removal. This shows that these economical and easily available plates can be safely used in place of costlier imported plates in routine cases.

Additional study of indigenously manufactured SS miniplates with larger sample size and longer duration is necessary. This study will enable to certain protocol to reduce the handling defects in miniplates during its use in maxillofacial surgery causing local reactions.

References

1. French HG, Cook SD, Haddad RJ Jr (1984) Correlation of tissue reaction to corrosion in osteosynthesis devices. *J Biomed Mater Res* 18(7):817–828
2. Torgersen S, Gjerdet NR (1994) Retrieval study of stainless steel and titanium miniplates and screws used in maxillofacial surgery. *J Mater Sci Mater Med* 5(5):256–262
3. Rosenberg A, Gratz KW, Sailer HF (1993) Should titanium miniplates be removed after bone healing is complete? *Int J Oral Maxillofac Surg* 22:185–188
4. Brown SA, Simpson JP (1981) Crevice and fretting corrosion of stainless-steel plates and screws. *J Biomed Mater Res* 15:867
5. Haug RH (1996) Retention of asymptomatic bone plates used for orthognathic surgery and facial fractures. *JOMS* 54:611–617
6. Mathew IR, Frame JW (1998) Ultra structural analysis of metal particles released from stainless steel and titanium miniplates component in an animal model. *JOMS* 56(1):45–50
7. Tucker MR, Ochs MW (1991) Rigid fixation for maxillofacial surgery. Lippincott, Philadelphia, PA, p 51
8. Brown SA., Huges PJ, Merritt K (2005) In vitro studies of fretting corrosion of orthopedic materials. *J Orthop Res* 6(4):572–579