Original Article

Compositional and surface changes of retrieved stainless-steel hardware and its effects on surrounding soft tissues: A prospective study

ABSTRACT

Purpose: To evaluate the surface, compositional, and histological changes in the overlying soft tissues of retrieved stainless-steel mini-plates and screws used for rigid internal fixation in the maxillofacial skeleton.

Materials and Method: A prospective study was conducted comprising 60 patients who sustained maxillofacial trauma and underwent ORIF in our unit previously and who required hardware retrieval in the post-operative phase. The retrieved hardware was evaluated for surface and compositional changes with the help of a scanning electron microscope for surface roughness and corrosion changes. Energy-dispersive X-ray study was done to know the composition and metal release from the hardware. The data obtained from these results were compared with a control unused and a sterile stainless-steel mini-plate and screw. The effects of the corrosion changes of this hardware on the adjacent soft tissues were evaluated histologically to assess the cellular changes of the soft tissue cover overlying the stainless-steel mini-plates and screws.

Results: A total of 96 stainless-steel mini-plates and 380 stainless-steel screws were retrieved from 60 patients. The control plate was smooth without any surface and corrosion defects, while the retrieved mini-plates irrespective of the reason for removal have shown surface roughness. Fe and Ni ions were found to be significantly reduced in the retrieved mini-plates. The presence of CrC in the retrieved plates indicates corrosion, which was seen only in hardware retrieved from symptomatic patients. The histological study revealed chronic inflammatory cell infiltrate with hyalinized connective tissue in all the samples irrespective of the reason for the removal of the plate.

Conclusion: Stainless-steel mini-plates and screws act as a potent foreign body material and initiate a localized inflammatory reaction due to its corrosive products with longer duration of stay. Hence, the authors advocate the overall shift in the use of stainless-steel hardware to titanium hardware for ORIF.

Keywords: Internal fixation, mini-plates, open reduction, stainless steel

INTRODUCTION

To restore anatomical re-alignment and provide stable internal fixation in order to facilitate early functional rehabilitation, the use of metal plates was initiated.[1] Numerous alloys were tried in the past, but currently, stainless-steel and titanium mini-plates are commonly used. Stainless steel is the most frequently used material for internal fixation due to its mechanical strength and low cost.[2,3] However, the use of stainless-steel hardware in today's contemporary clinical practice is debatable.

The literature reveals that any metal plate that served its purpose in aiding the healing of bone should be considered

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non-functional once its role is complete and later it should be regarded as a foreign body.[4] Considering the biocompatibility of the implant, poor access, and patient choice in addition to the financial and resource implications of a second procedure, these pieces of hardware are generally left *in situ*.[2,3] The removal of such hardware is desirable provided that the procedure does not cause undue risk to the patient.[4]

The frequency of hardware removed in patients after osteosynthesis ranges from 3 to 18%.[5] Among these, removed hardware in the absence of any complications and purely based on the patients' request accounts for 22%.[5] Stainless steel degrades in the biologic environment from an electrochemical dissolution phenomenon, wear, or a synergistic combination of both.[5,6] Corrosion and wear products may give rise to biological changes in the tissues adjacent to implants, ranging from mild fibrosis to infection or necrosis or ultimately leading to bone loss.[5,6] Numerous studies in the past have extensively studied the effects of ORIF on hard tissues, but very few studies laid emphasis on the ions that leach out from the retained hardware and its effects on the adjacent soft tissues.

Hence, this study intended to evaluate the surface and compositional changes as well as histological changes in the overlying soft tissues of retrieved stainless-steel miniplates and screws used for rigid internal fixation in the maxillofacial skeleton to evaluate the need for routine removal of hardware after the period of bone healing.

MATERIALS AND METHOD

A prospective study was conducted during the period of November 2019 to October 2021 in our unit comprising 60 patients who sustained maxillofacial trauma and underwent ORIF in our unit previously and who required stainless-steel mini-plate and screw retrieval because of either plate exposure or infection at the surgical site/palpability/patient's desire in the post-operative phase. Institutional ethical committee clearance is obtained (SSCDS/IRB-E/2019/681) and patients' consents are obtained.

Inclusion criteria

1) Patients who underwent ORIF for trauma/orthognathic surgeries/reconstruction in our unit previously with stainless-steel mini-plates/reconstruction plates and required retrieval of the hardware.
2) Pain and infection at the surgical site necessitating hardware removal.
3) Palpable/exposed hardware necessitating hardware removal.
4) Patients willing to undergo hardware removal after the bone healing even in the absence of any symptoms.

Exclusion criteria

1) Pain/palpability/infection during the first 3 months that necessitated the hardware removal before the complete healing phase is complete.
2) Patients who underwent ORIF in hospitals other than our unit.

The stainless-steel bone plate and screws were retrieved through intra-oral or extra-oral approach. During the process of hardware retrieval, due care was taken to avoid any scratches from the round bur or from the screw driver. Following retrieval of hardware, the plates and screws with minimal distortion, bends, or scratches were selected for evaluation. These plates were cleaned under running water, dried, and stored in a sterilized container. The soft tissue that was just overlying the hardware was excised and sent for histopathological examination for evaluation of cellular changes in the soft tissue cover overlying the hardware. Surface changes like corrosion, surface roughness, and micro-fractures were observed under the scanning electron microscope.

The retrieved stainless mini-plates and screws were examined along with the control plate with aid of a scanning electron microscope (SEM-JSM 840) in order to evaluate for surface roughness and corrosion in the Department of Metallurgy. Before examining the sections under the scanning electron microscope, the specimens were coated with a thin (about 2 nm) gold layer by a sputtering process (EMITECH, K550) for achieving a better topographic contrast. Energy-dispersive X-ray (EDX) study of retrieved stainless mini-plates shows compositional changes as shown in Figure 1. The data obtained from these results were

Figure 1: (a) Scanning electron microscope (SEM-JSM 840) used for evaluating the retrieved stainless-steel hardware for surface roughness and corrosion changes (b) EDX study (EMITECH, K550) done to know the composition and metal release from the retrieved stainless-steel hardware

compared with a control unused and sterile a stainless-steel mini-plate and screw.

RESULTS

This study included 60 patients who underwent ORIF in our unit previously and required hardware removal in the post-operative period due to either palpability of the hardware or pain/infection at the previous surgical site. Among the 60 patients, 42 (70%) were males and 18 (30%) were females with an age range of 18–56 years with a mean age of 31.23 years. The mean time interval between hardware placement and retrieval was 17.17 months with a minimum of 4 months and a maximum of 48 months.

A total of 96 stainless-steel mini-plates and 380 stainless-steel screws were retrieved. The hardware removed from the mandible were 2 mm plates with 2 × 8 mm screws, while the hardware removed from the maxilla and ZMC region were 1.5 mm plates with 1.5 × 6 mm screws. Among these 60 stainless-steel mini-plates and 60 stainless-steel screws, one from each patient which had minimal distortion, bends, or scratch was selected for evaluation. The control plate was smooth without any surface and corrosion defects, while the retrieved mini-plates, irrespective of the reason for removal, have shown surface roughness. The surface roughness can be appreciated due to the sharp edges, presence of metal tongues, and splinters, as shown in Figures 2-4.

The corrosion defects were more common in the plates which were removed due to either infection or pigmentation when compared to the asymptomatic plates.

In 16 patients, hardware was removed from the angle and condyle region (26.7%); in 6 patients, hardware was removed from the mandibular body region (10%); in 28 patients, hardware was retrieved from the symphysis and para-symphysis region (46.7%); and in 10 patients, the hardware was removed from the zygomatico-maxillary complex region (16.7%), as shown in Figure 5. Out of the 60 patients, 32 (53.3%) symptomatic patients underwent hardware retrieval, while 28 (46.6%) asymptomatic patients underwent hardware retrieval due to palpability being the major concern, as shown in Figure 6.

The atomic weight % of the ions in the retrieved plates and screws was slightly less than the atomic weight % of the ions in the control plate. Fe and Ni ions were found to be significantly reduced in the retrieved mini-plates as compared to the other ions. The mean atomic weight % loss for Fe is 44.23 with a standard deviation of 17.10 (the *P* value is 0.95). The mean atomic weight % loss for Fe is 10.43 with a standard deviation of 2.48 (the *P* value is 0.79). EDX SEM study of the retrieved stainless-steel hardware is depicted in Tables 1-3. The presence of CrC in the retrieved plates indicates corrosion, which was seen only in the symptomatic

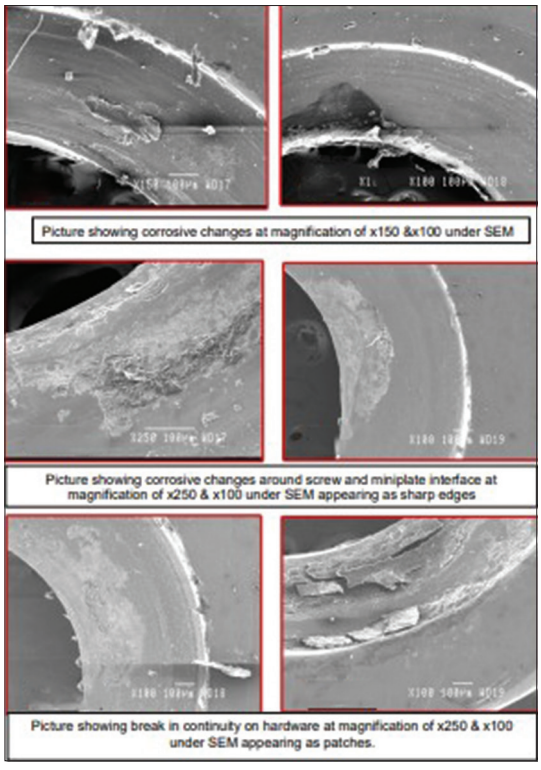

Figure 2: Scanning electron microscopic image showing corrosion on the retrieved stainless- steel hardware

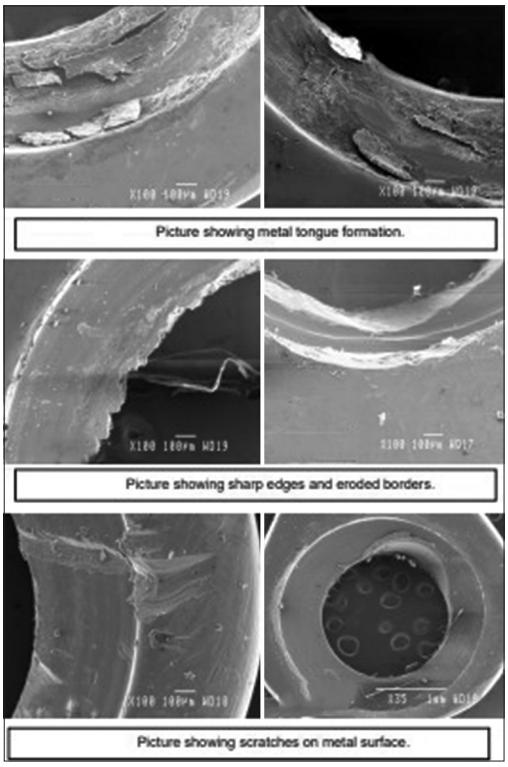

Figure 3: Scanning electron microscopic image showing corrosion in the form of metal tongue formation, sharp edges, and scratches on the retrieved stainless-steel hardware

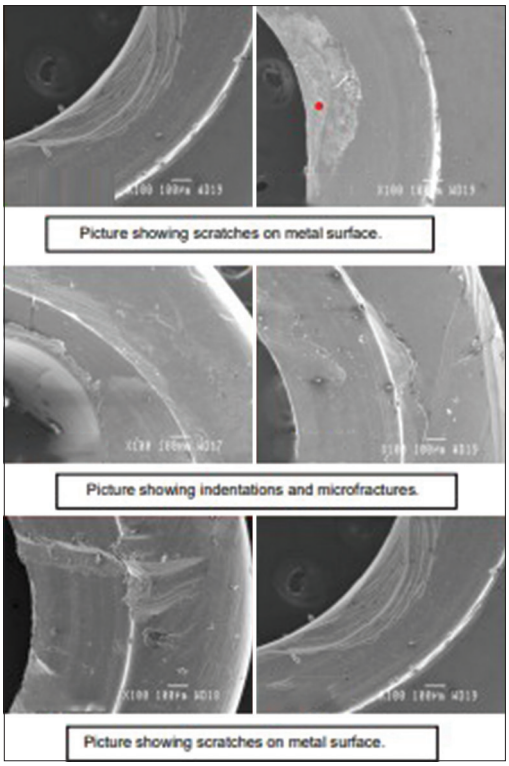

Figure 4: Scanning electron microscopic image showing microfracture on the retrieved stainless-steel hardware

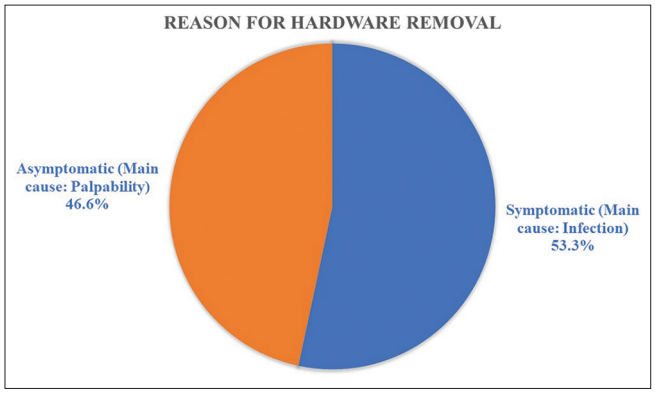

Figure 6: Graph showing the reason for retrieval of stainless-steel hardware

plates. The histological study of soft tissues surrounding the mini-plates showed chronic inflammatory cell infiltrate with hyalinized connective tissue in all the samples irrespective of the reason for the removal of the plate as shown in Figure 7. Statistical analysis was done using SPSS 25.0. Descriptive statistics, Chi-square test, Mann–Whitney test, and Spearman's correlation were performed. The confidence interval was set at 95%. *P* value.

DISCUSSION

The literature from western countries reveals that titanium is the only material of choice for achieving osteosynthesis due to its biocompatibility. However, the Indian literature,

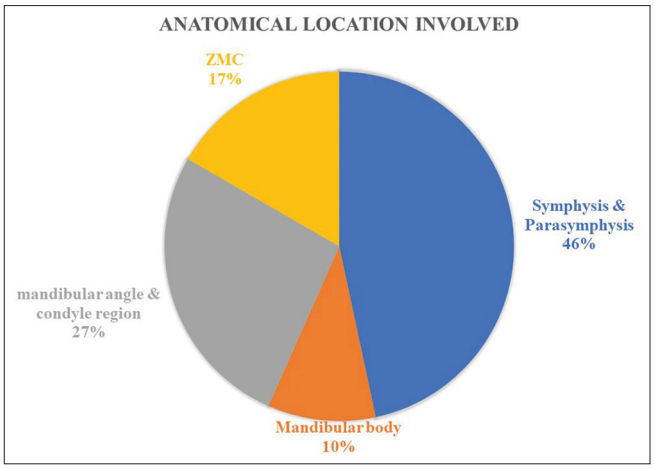

Figure 5: Graph showing the anatomical location involved for retrieval of stainless-steel hardware

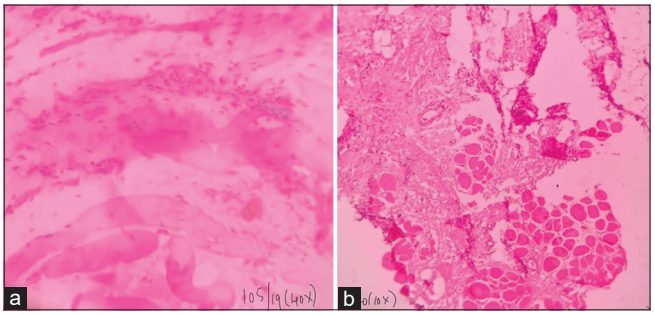

Figure 7: (a) Histopathologic image revealing chronic inflammatory cell infiltrate (b) Histopathologic image revealing hyalinized connective tissue

particularly from rural India, and studies from academic institutions have shown that stainless steel is still being primarily employed for achieving osteosynthesis. This could be attributed to the fact that stainless steel is more cost-effective.[7-9] There is a never-ending debate pertaining to whether the hardware should be retained or removed following a period of time once its purpose is fulfilled. A few authors advocated the routine removal of non-functional hardware, while a few recommended the retention of hardware till their removal is clinically indicated.[10-12]

Previous studies have revealed that incidence of hardware removal was higher in patients undergoing ORIF for maxillofacial trauma than any other procedure.[6,13] It could be attributed to the greater duration of the exposed fracture site to the oral environment, poor oral hygiene maintenance, or patient's age.[14] Following orthognathic surgery, it was noted that the majority of the patients choose to get the hardware removed on their own accord and not due to complications.[15] The results of this study are in accordance with previous studies.

The mean time interval between hardware placement and retrieval in this study was 17.17 months. A few studies

Table 1: EDX SEM study of retrieved stainless-steel hardware

Variable	*n*	Minimum	Maximum	Mean	Std. deviation
C	60	11.77	75.15	33.52	22.92
O	60	2.21	36.18	15.66	11.48
Cr	60	5.55	25.65	19.18	4.47
Fe	60	7.56	78.16	44.23	17.10
Ni	60	0.35	12.61	10.43	2.48

Table 2: Relationship between the reasons for retrieval of stainless steel hardware and compositional changes observed in the retrieved stainless steel hardware

Variable	Infection (*n*=32)		Palpable hardware (*n*=28)		Mann-Whitney *P*
	Mean	Std. deviation	Mean	Std. deviation	
C	32.17	21.35	35.07	25.31	0.76
O	15.72	12.01	15.60	11.29	0.97
Cr	19.53	4.01	18.79	5.08	0.66
Fe	42.13	17.34	46.63	17.14	0.48
Ni	9.94	3.13	10.99	1.32	0.25

Table 3: Relationship between the gender and the compositional changes observed in the retrieved stainless steel hardware

Variable	Male (*n*=42)		Female (*n*=18)		Mann-Whitney *P*
	Mean	Std. deviation	Mean	Std. deviation	
C	33.00	21.28	34.76	27.73	0.85
O	15.51	11.13	16.02	12.95	0.91
Cr	18.58	4.58	20.58	4.12	0.26
Fe	44.36	17.08	43.93	18.18	0.95
Ni	10.51	1.74	10.25	3.82	0.79

reported that the majority of the patients underwent hardware removal during the first year, while a few studies reported that most patients required hardware removal within 6 months following surgery.[13,16,17] It is advocated that the hardware removal is easier within 6 months following surgery and with an increase in time, it would become difficult to remove the hardware, particularly in young patients in whom the hardware is often covered by bone.[16] A previous study revealed that a residual granulation tissue forms around long-standing hardware which becomes necrotic, leading to long-standing inflammation and necrosis.[18] The results of this study reveal that the ideal time for asymptomatic non-functional hardware retrieval is 4 to 6 months following surgery in order to avoid metallurgical changes.

In this study, infection followed by palpability of the hardware is the prime reason for hardware retrieval. A foreign body in the form of hardware could be a region where blood-borne bacterial growth colonizes the hardware, which subsequently escalates the chances for infection. The masticatory forces acting on the hardware may compromise inter-fragmentary stability, and consequently, screws may loosen, resulting in inflammation and thereby contributing to the likelihood of infection. Poor suturing techniques and inadequate bone cooling during drilling for screw placement may also contribute to the hardware failure due to infection. In addition to this, infection rates are influenced by local and systemic factors also. This is in accordance with previous studies.[7,8,19,20]

The results of this study reveal that the majority of the hardware was removed from the parasymphysis region of the mandible. However, previous studies reveal that post-operative infection and hardware exposure were more frequently observed at the mandibular body and angle region, followed by the anterior wall of the antrum.[8,9,21] This could be attributed to the fact that the hardware tends to lie directly under the mucoperiosteum and are more prone to repeated trauma from mastication and dentures, resulting in exposure or infection at the surgical site.

In a biologic environment, stainless steel degrades by a combination of electrochemical corrosion and wear. Metal ions released as a result of this may lead to changes in the surrounding tissues, ranging from fibrosis to infection and necrosis.[2] French HG *et al.* suggested that stainless-steel mini-plates are minimally toxic to human tissue in most circumstances and that the toxic products are well tolerated and do not recommend routine implant removal.[9] Metal alloys like CoCr, Ni-Cr, and Ti, which are frequently leeched out from the hardware, have some degree of cytotoxicity, while elements like Ni and Cr trigger hypersensitivity reactions and may impair healing and/or cause pain.[22]

Compositional analysis of stainless-steel hardware obtained through EDX SEM shows that the atomic % and weight % of metal ions are slightly low when compared to the standard mini-plates, indicating the possible leaching out of the ions into the surrounding tissues. This is in agreement with the study conducted on the Ni-Cr and Co-Cr alloy implants, which stated that all the elements are released from the implant, and therefore, these plates are considered potentially allergic sensitizers, and their permanent retention after healing of the fracture is not advocated. However, it is unsure at what point in time the metals were released. This is in accordance with previous studies.[23,24] Previous studies have shown that stainless-steel plates show a greater extent of deterioration than titanium plates.[25]

In this study, it was observed that around 40% of plates had surface roughness and micro-fractures, especially at margins of the retrieved SS mini-plates. This might be a result of drill injuries, excessive bending, and manipulation of plates during plate fixation. This was observed particularly on the mini-plates retrieved from the mandibular angle region.

However, none of the mini-plates had micro-fracture. Similarly, 26% of plates had corrosive degradation, especially at countersink areas, resulting in patchy areas over the plate. Compositional analysis using EDX SEM revealed carbon, oxygen, chromium, iron, and nickel were the most common metals to be leeched out from hardware. It was observed that the Ni: Cr ratio in the tissues adjacent to metal implants is greater in infected cases when compared to palpable/ non-infected retrieved plates. This is in accordance with previous studies.[26]

In this study, it was observed that metal leaching and corrosive changes on metals were more pronounced in patients where hardware were retrieved after 17 months, concluding that longer the stay, more the surface roughness and more the leaching metal occurs. It was observed that surface roughness on the surface of a majority of the plates could be observed usually as sharp-edged scratches on the free surfaces as well as on the countersink areas of the plates. Micro-fractures were seen in the countersink regions, sometimes leaving metal tongue formation or splinters. The surface roughness and micro-fractures were due to handling and bending of plates during placement and also during drilling injuries in the countersink areas. Corrosion degradation was seen in the countersink areas, often with break in the continuity of the metallic surface appearing as patches often localized to the countersink areas involving one or two countersinks within the same plate. Corrosion did not extend onto the free surface outside the countersink area.

Microscopic evaluation of soft tissue samples adjacent to mini-plates indicated an increased cellular content with mild to moderate inflammatory cell infiltration. Along with that, stroma showed dense mature fibrous collagenous connective tissue with a high degree of hyalinization. Predominantly more lymphocytic infiltration is seen in most of the soft tissue samples who had been within the body for a longer period of time. The above results indicate that stainless-steel hardware becomes a potent foreign body material to initiate localized inflammatory reaction due to its corrosive products with longer duration of stay.

CONCLUSION

Stainless-steel mini-plates and screws act as a potent foreign body material after its purpose is fulfilled and initiate an inflammatory or allergic reaction in the localized area due to its corrosive products with longer duration of stay. Hence, the authors advocate the overall shift in the use of stainless-steel hardware to titanium hardware for ORIF.

Consent

Patient consent taken.

Ethical clearance

Institutional ethical clearance obtained.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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