Evaluation of metal release and local tissue response to indigenous stainless steel miniplates used in facial fractures

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Arun Dugal¹ ✉ · Dadhe DP²

¹ Professor
Dept. of Oral and Maxillofacial Surgery,
Bharati Vidyapeeth University Dental
College and Hospital, Pune
² Lecturer
Dept. of Oral and Maxillofacial Surgery,
Singhagad Dental College and Hospital,
Pune

Abstract The issue of metal release from stainless steel bone plates has gained considerable momentum advocating the removal of stainless steel miniplates after healing of fracture. So far no study has been published in the literature regarding metal release with the indigenously manufactured stainless steel miniplates.

Objective Aim of the study was to find any pathological changes at cellular and ultracellular levels and metal particles in the soft tissue surrounding the stainless steel miniplates.

Method Retrieval of indigenous stainless steel implants, used in treatment of jaw fractures, samples of surrounding soft tissue were histopathologically assessed for tissue response as well as metal release, using light microscope and Transmitted Electron Microscope (TEM).

Result Light microscopic examination revealed chronic inflammation in symptomatic cases, but TEM did not show any significant pathological alteration and metal deposits even in cases with clinically observed pigmentation. Short-term (upto 1 year) retention of stainless steel mini plates will not cause any significant local complications

Keywords Indigenous stainless steel miniplates · Metal release · Soft tissue response

Address for correspondence:

Arun Dugal
Professor
Dept. of Oral and Maxillofacial Surgery
Bharati Vidyapeeth University Dental College
and Hospital, Katraj, Pune – 411043,
Maharashtra, India
Ph: 09822058244/02024373266
E-mail: arun.dugal@bharativedyapeeth.edu

Introduction

Rigid internal fixation plays an important role in the management of facial trauma, in orthognathic surgery, reconstructive surgery and in access osteotomies. Miniplate osteosynthesis currently provides the most effective means of stable bone fixation in maxillofacial surgery. Besides biomechanical properties, the ideal plating system should be fabricated from material that is biocompatible, or bio-inert with the body tissues providing no toxins and causing no forms of immune responses or malignant transformation. Although more biocompatible materials such as titanium and bio-resorbable miniplates are available, most of the times stainless steel is the material of choice in India due to cost factor.

In the recent years, the issue of metal release from stainless steel bone plates has gained considerable momentum. Moberg [1] analyzed the mucous membrane and

bone tissue surrounding Champy's stainless steel bone plates. Chromium, nickel and molybdenum were found in the surrounding soft tissue. Hence Moberg advocated removal of stainless steel miniplates.

On the other hand, French HG et al. [2] found the stainless steel miniplates minimally toxic to human tissue in most circumstances and that the toxic products are well tolerated and do not recommend routine implant removal.

In India, removal of asymptomatic stainless steel/titanium miniplates is not routinely carried out probably because of the financial constraints or difficulty to follow up of the cases. Another reason might be dilemma in surgeon's mind regarding unnecessary removal of asymptomatic bone plates.

So far no study has been published in the literature regarding metal release with the indigenously manufactured stainless steel miniplates. The purpose of this study

was to find any pathological changes at cellular and ultracellular levels in the soft tissue surrounding the indigenous stainless steel miniplates within the span of one year after fixation that may necessitate implant removal as well as to find whether there are any metal particles in these tissues.

Method

The study was conducted in the Department of Oral and Maxillofacial Surgery, from February 2005 to June 2005.

Medically fit adult patients who reported with local tissue reactions related to plate or asymptomatic patients keen on removal of plate were considered. All the patients were follow up cases treated in the department for the fractures. Minimum period for plate removal was atleast 4 months after fixation.

The study was carried out as an open clinical trial. All potential participants were

Fig. 1 Light microscopy: chronic inflammatory cells

explained the need and design of the study. The details about the surgical procedure, medications and the possible complication associated with the same were also informed.

During the study 10 patients (5 symptomatic and 5 asymptomatic) 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. Routine investigations for surgery were advised before implant removal.

An informed, written consent was accordingly obtained from the patients before the study was started.

Preoperative clinical and intraoperative macroscopic findings were noted.

Surgical technique

All patients were operated for removal of the 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 was inspected for pigmentation and/or inflammatory changes. Incisional biopsy sample of soft tissue in the vicinity of the implant was obtained.

Wound was irrigated to remove any foreign body particles and 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.

With the help of Pathology department sample were prepared for study.

Fig. 2 Transmission electron microscopy: increased fibroblasts surrounded by broad fascicles of collagen

Preparation of sample for LM

The samples were cleared of the debris by immersing them in saline. Fixation was done using Formaldehyde (10%) for 24 hours. Trimming was done to give representative sections. Tissue was processed to form paraffin block. Slides were prepared and staining was done using Hematoxyline & Eosin.

Preparation of sample for TEM

The samples were cleared of the debris by immersing them in saline. Fixation was done using Gluteraldehyde (2.5%) pH 7.4 for a period of 2 days. The samples were then put in Cacodylate buffer (0.1 mmol/L) for 2 hours, dehydrated and embedded in an epoxy resin. Ultra thin sections were made with (LKB) microtome and stained with Uranyl Acetate and Lead Citrate for observation with TEM.

Histopathological examination

- 1) Light Microscopic study (LM) was carried out with the help of pathology department
- 2) Samples were taken to Jaslok Hospital, Mumbai for Transmitted Electron Microscopic study (TEM)

Results

Total of 10 cases of implant removal were included in study out of these 5 had symptoms related with implants (Group I) and remaining 5 were asymptomatic (Group II). Mean duration in symptomatic group is 5.60 months while in asymptomatic group is 11.00 months.

A. Clinical observation at the time of implant removal (Table 1)

Mucosal inflammation, infection and fistula were observed in most of the symptomatic group patients. Satisfactory fracture stability (100%) was found in both groups.

B. Surgical observations at the time of implant removal (Table 2)

Only one case (20%) showed pigmentation. In each group fibrosis was seen in nearly all the cases.

C. Light microscopic findings: (Table 3)

Under the light microscope, most of the symptomatic group patient specimens showed chronic inflammatory changes such as granulation tissue and few displayed F.B. giant cells; whereas none in asymptomatic group (Fig. 1).

D. Transmission electron microscopic findings: (Table 4)

Transmission Electron Microscopy demonstrated no evidence of metal particles in any of the cases. Increased fibroblasts were found, but no degenerative changes were observed (Fig. 2).

Discussion

A. Clinical observation at the time of implant removal

In the symptomatic group, all 5 patients (100%) had mucosal inflammation, whereas in the asymptomatic group, 2 patients (40%) had mucosal inflammation.

Infection and fistula were present in all 5 patients (100%) of symptomatic group, which were absent in the asymptomatic group. Total 50% of all cases had infection which is more as compared with Orringer et al. [6] who observed infection in 23.6% cases of implant removal whereas in Nakamura et al. [4] studies only 1% cases showed infection.

But the higher percentage is due the types of sample of the study. Satisfactory fracture stability (100%) was found in both groups.

B. Surgical observations at the time of implant removal

After the implants were surgically exposed, only one case (20%) showed pigmentation in each group. Total 10% of all cases had pigmentation. This differs to the findings of Rosenberg et al. [3] who observed pigmentation in 68% cases. Metal deposits or haemosiderin/melanin may cause pigmentation.

Fibrosis was found in 4 cases (80%) in the symptomatic group and 5 cases (100%) in asymptomatic group. This finding is comparable with Torgersen S et al. [5] who observed fibrosis and mild inflammation around the stainless steel miniplates.

One case (20%) of the symptomatic group showed inflammation whereas in the asymptomatic group, 2 cases (40%) had inflammation at the site of surgery.

None of the cases (0%) showed infection at the site of implant in both groups.

C. Light microscopic findings

Most of the symptomatic group patient showed chronic inflammation. This is in consensus with the findings of Torgerson S et al. [5]. One case (20%) from symptomatic group displayed F.B. giant cells; no case (0%) from asymptomatic group displayed any such cell.

4 cases (80%) of symptomatic group showed granulation tissue whereas one case (20%) showed granulation tissue in asymptomatic group. This is similar to the findings of Nakamura et al. [4] who found granulation tissue around the implants in most of cases where infection was present. The encapsulating fibrous capsule may become necrotic probably because of corrosion, toxicity or hypersensitivity and replaced by granulation tissue.

No pathological change was evident in 1 case (20%) of symptomatic group on the other hand 4 cases (80%) did not show any pathological change.

According to Philipps JH and Rahn B [7], subsequent to the initial placement of metallic implants, a normal local inflammatory response is noted. This includes the accumulation of lymphocytes, neutrophils, plasma cells and macrophages. As further stated by Disegi J [8], this inflammatory response subsides over time. Generally, these materials then become encapsulated in a very sparsely cellular fibrous tissue capsule, isolating them from the rest of the body. The thinner

Table 1 Clinical findings

S.No.	Clinical findings	Group 1		Group II	
		No.	%	No.	%
1.	Mucosal inflammation	5	100.0	2	40.0
2.	Infection	5	100.0	0	0.0
3.	Fracture stability	5	100.0	5	100.0
4.	Fistula	5	100.0	0	0.0

Table 2 Surgical findings

S.No.	Surgical findings	Group 1		Group II	
		No.	%	No.	%
1.	Pigmentation	1	20.0	1	20.0
2.	Fibrosis	4	80.0	5	100.0
3.	Inflammation	1	20.0	2	40.0
4.	Infection	0	0.0	0	0.0

Table 3 Light microscopic findings

S.No.	Light microscopic findings	Group 1		Group II	
		No.	%	No.	%
1.	Chronic inflammation	4	80.0	0	00.0
2.	Foreign body giant cells	1	20.0	0	00.0
3.	Granulation tissue	4	80.0	1	20.0
4.	No pathological changes	1	20.0	4	80.0

Table 4 TEM findings

S.No.	TEM findings	Group 1		Group II	
		No.	%	No.	%
1.	Metal particles	0	0.0	0	0.0
2.	Increased Fibroblasts	1	20.0	1	20.0
3.	Degenerative changes	0	0.0	0	0.0

the fibrous capsule, the more biocompatible the material is considered to be.

Although pigmentation was evident in 2 cases clinically, TEM did not reveal metal deposits. Clinical pigmentation might be the result of haemosiderin or melanin pigments, which is a physiological process. This is dissimilar to the findings of Rosenberg et al. [3] and Moberg et al. [1] who observed metal deposits in the vicinity of the stainless steel miniplates.

D. Transmission electron microscopic findings

Transmission Electron Microscopy demonstrated no evidence of metal particles in any of the cases (0%) either in symptomatic or asymptomatic groups.

Increased fibroblasts were found in one case (20%) each from both the groups. This is comparable with Torgersen S et al. [5] who observed increased fibroblasts in the peri-implant tissue. No degenerative changes were observed in any of the cases in either group.

Conclusion

Although statistically significant chronic inflammation was observed at light microscopy, TEM did not reveal any significant pathological alteration in the tissue. The results of the study do not disclose any evidence of metal release either under LM or TEM.

There is no evidence in this study to suggest that the short-term (upto 1 year) retention of stainless steel miniplates will cause any significant local complications.

However, additional study with larger sample size and longer duration will be necessary which can advocate certain protocol regarding the permanent retention of such implants.

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