Abstract: Evolution of fracture management after the advent of asepsis and anesthesia has changed its trend toward open reduction and internal fixation (ORIF). In maxillofacial skeleton, to re-establish both form and function, semi-rigid fixation has been favored in recent times. Miniplates are commonly made of stainless steel and titanium. The fate of these post-ORIF is still controversial with both schools of thought providing substantial valid arguments. Aim of this study is to assess the incidence, site, type of material and reason for miniplate removal. This retrospective observational study was conducted among patients who reported to the Department of Oral and maxillofacial surgery, Saveetha Dental College, Chennai between June 2019 to March 2020. Inclusion criteria were patients of both gender and any age group undergoing miniplate removal post-ORIF and exclusion criteria were those undergoing hardware removal secondary to other procedures like orthognathic or reconstructive surgery and patients who are suffering from debilitating injuries physically and mentally challenged patients. Among 17 patients evaluated, incidence of miniplate removal was more common in males (76.5%) in the third decade of life. Infection (82.4%) was the most common reason for removal, while stainless steel was the most common type of miniplate removed (82.4%). 88.2% of miniplates removed had an adjacent dentate structure. No association was found between reason for removal and type of miniplate, proximity to dentate structure and reason for removal. Prospective studies and systematic analysis required to arrive at consensus.

Keywords: angle fracture, line of fracture, preservation, removal, third molar
The advent of x-rays brought the closed methods of fixation under scrutiny and was gradually withdrawn and shifted towards methods of open reduction and internal fixation (Hernigou and Pariat, 2017). These are different schools of thought in open reduction and internal fixation (ORIF) from rigid fixation to semi-rigid fixations (Uhthoff, Poitras and Backman, 2006; Hernigou and Pariat, 2017). In treating fractures associated with maxillofacial skeleton, due to the complexity of the structures and the dual importance of function and esthetics, concept of semi-rigid fixation has gained more popularity according to modern literature (Clark and Hayes, 1963). The physiological reduction produced by semi-rigid fixation permitting micro-movement of the segments is found to be a novel concept and is accepted worldwide. It provides surgical ease in terms of technique, time consumption and reproducibility (Santhosh Kumar and M., no date; Akadiri and Omitiola, 2012; Jesudasan, Wahab and Sekhar, 2015; Mp, 2017a, 2017b; Packiri, Gurunathan and Selvarasu, 2017; Rahman and Santhoshkumar, 2017; Rao and Santhosh Kumar, 2018).

Currently, the most commonly used miniplates are made up of stainless steel or titanium. Titanium miniplates due to its biocompatibility have gained increased acceptance, though the increased cost is also a major concern in developing or under-developed countries. The research pertaining to infection rates in stainless steel and titanium plates is still contradictory in nature and for the most part is also influenced by local and systemic factors (Torgersen and Gjerdet, 1994; Matthew et al., 1996; Patturaja and Pradeep, 2016; Patil et al., 2017; Sweta, Abhinav and Ramesh, 2019). Our team has rich experience in research and we have collaborated with numerous authors over various topics in the past decade (Deogade, Gupta and Ariga, 2018; Ezhilarasu, 2018; Ezhilarasan, Sokal and Najimi, 2018; Jeevanandand and Govindarak, 2018; J et al., 2018; Menon et al., 2018; Prabakar et al., 2018; Rajeshkumar et al., 2018, 2019; Vishnu Prasad et al., 2018; Wahab et al., 2018; Dua et al., 2019; Duraisamy et al., 2019; Ezhilarasan, Apoorva and Ashok Vardhan, 2019; Gheena and Ezhilarasan, 2019; Malli Suresshababu et al., 2019; Mehta et al., 2019; Panchal, Jeevanandand and Subramanian, 2019; Rajendran et al., 2019; Ramakrishnan, Dhanalakshmi and Subramanian, 2019; Sharma et al., 2019; Varghese, Ramesh and Veeaiyan, 2019; Gomathi et al., 2020; Samuel, Acharya and Rao, 2020).

In this study we aim to understand the incidence of hardware (miniplate) removal along with the reasons for its removal, composition of miniplate used and its proximity to dentate structures.

**METHODOLOGY**

The retrospective observational study was conducted among patients reporting to the Department of Oral and maxillofacial surgery at Saveetha Dental College and hospital, Chennai during the time period June 2019 to March 2020.

Ethical Consideration: The approval for the study was given by the “Institutional Ethical committee, SIMATS Review Board”.

**Inclusion Criteria**

- Patients of any age and gender undergoing hardware (miniplate) removal post-ORIF (open reduction internal fixation).

**Exclusion Criteria**

- Patients undergoing hardware removal post-orthognathic surgery or reconstructive procedures
- Patients with debilitating systemic diseases
- Patients who are mentally or physically challenged.

**Data collection**

The patients demographic details and data pertaining to study parameters were retrieved from reviewing patient records provided by the institution.

A total of 24 patients had reported to the department of oral and maxillofacial surgery at Saveetha Dental college, Chennai for hardware removal between the study duration. Of the 24 patients, only 17 fulfilled the inclusion criteria and were included in the study. The sample size of the population studied is 17.

**Study parameters**

The following data were extracted for the purpose of the study:

- Demographic details (age, gender)
- Site of fracture from where hardware was to removed
- Proximity of the fracture site from where the hardware was removed, to dentate structure.
- Material of hardware used (miniplates, in this case)
- Reason for removal (infection/asymptomatic)

**Statistical analysis**

The data obtained were subsequently tabulated in excel spreadsheet and was exported to IBM SPSS version 20 for statistical analysis. The data being were analysed descriptively measuring mean, standard deviation,
percentage and frequency. The association between different study parameters were analysed using Fisher Exact test at confidence interval 95%. The output was generated in graphical and tabular representations.

RESULTS AND DISCUSSION

Analysis of demographic data of the study population revealed their mean age to be 28.5 years with the majority of them in their 3rd decade of life (Figure 1) (Table 1). 76.5% of them were males and only 23.5% were females (Figure 2). Regarding the site of fracture area, plate removal was performed - 74.2% in mandible and 35.8% in midface among which, parasymphyisis was the most common site. Within the mandible: parasymphyisis accounted for 36.7%, symphysis 18.8%, angle 18.8% and within midface: Zygomaticomaxillary complex(ZMC) fracture accounted for 27.3; Lefort I: 4.6% (Figure 3). 88.2% of the removed hardware had an adjacent tooth near the site (Figure 4). The reason for hardware removal was found to be asymptomatic in 17.6% of the population while in 82.4% of them, infection was the cause (Figure 6). Analysis of material of hardware removed revealed stainless steel to be the most common (82.4%) while titanium hardware was removed only in 17.7% of population (Figure 5). Association of age with reason for removal of miniplate and gender with reason for removal of miniplate did not yield statistically significant results with p value: 0.8 (>0.05) at CI 95% (Fig 7 and Fig 8). Association between type of miniplate used and reason for its removal was not statistically significant with p value: 0.5 (>0.05) at CI 95% (Fig 9) (Table 2).

Fig.1: Simple bar showing distribution of age in study population where X axis represents age in decades and Y axis represents percentage.

Fig.2: Pie chart showing distribution of gender among study population where males (76.47%) were more than females (23.53%)
Fig. 3: Pie chart showing distribution of site of fracture among study population; Parasympysis (green) (36.36%) was the most common site of fracture followed by ZMC (yellow) (22.73%) while Le Fort type fractures (red) (4.55%) were least common.

Fig. 4: Pie chart showing distribution of tooth related to fracture among study population; In 88.24% patients, tooth was related to the fracture site from which miniplate was removed while in 11.76% patients it was not so.

Fig. 5: Pie chart showing type of miniplates removed among the study population; Stainless steel (82.35%) miniplates were more commonly removed than Titanium miniplates (17.65%)
Fig. 6: Pie chart showing reason for miniplate removal among study population; Infection (82.35%) was the most common reason for miniplate removal followed by asymptomatic removal (17.65%) of miniplate.

Fig. 7: Bar graph showing association between age and the reason for removal of miniplate; X axis represents the age in decades and Y axis represents the reason for removal in percentage; Miniplate removal was common in 3rd decade of life with infection (blue) being the most common cause (35.29%); the association was not statistically significant as Fisher’s Exact Test yielded p value: 0.8 (>0.05) at CI 95%.
Fig. 8: Bar graph showing association between gender and the reason for removal of miniplate; X axis represents the gender and Y axis represents the reason for removal in percentage; Infection (blue) was most common cause for removal in males (58.82%) and all the females in study population underwent miniplate removal only due to infection (23.53%); the association was not statistically significant as Fisher’s Exact Test yielded p value: 0.8 (>0.05) at CI 95%

Fig. 9: Bar graph showing association between type of miniplate used and the reason for removal of miniplate; X axis represents the type of miniplate and Y axis represents the reason for removal in percentage; Stainless steel plates were removed more than Titanium plates with infection (blue) being the most common cause (64.71%); the association was not statistically significant as Fisher’s Exact Test yielded p value: 0.5 (>0.05) at CI 95%
Table 1: Shows descriptive statistics of age where mean age of study population was 28.5 years

<table>
<thead>
<tr>
<th>Age</th>
<th>(N : Valid:17</th>
<th>Missing 0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>28.5294</td>
<td></td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>11.59266</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Association between type of miniplate used (SS/ Ti) and the reason for its removal (infection/ asymptomatic) was not statistically significant as Fisher's Exact Test yielded p value: 0.5 (>0.05) at CI 95%

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
<th>df</th>
<th>Asymptotic Significance (2-sided)</th>
<th>Exact Sig. (2-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pearson Chi-Square</td>
<td>.781a</td>
<td>1</td>
<td>.377</td>
<td>1.000</td>
</tr>
<tr>
<td>Fisher's Exact Test</td>
<td></td>
<td></td>
<td></td>
<td>.535</td>
</tr>
</tbody>
</table>

a. 3 cells (75.0%) have expected count less than 5. The minimum expected count is .53.

b. Computed only for a 2x2 table

Removal of miniplates has been a controversial topic since its introduction and hasn’t ceased to be so. The authors who favor miniplate retention argue the potential risk caused by a second surgery under general anesthesia and profess asymptomatic removal of miniplates as uncalled for and pose more harm than favor(Khandelwal et al., 2019). This argument has been strengthened by the use of biocompatible and osseo-integrative mini plates made up of titanium(Park et al., 2016). The advocates of miniplate removal state that the object however biocompatible is still a foreign body and is subject to potential complications. Also, in pediatric patients growth restrictions were noted when miniplates were retained(Brown et al., 1989). Champy and Cawood advocated routine removal of stainless steel miniplates after 3 months(Michelet, Deymes and Dessus, 1973). The introduction of vitallium and subsequently titanium miniplates questioned the trend(Frost, El-Attar and Moos, 1983; Matthew and Frame, 1999). Mathew IR et al stated that miniplates should not be removed in asymptomatic cases(Islamoglu et al., 2002). The works of Frostetal, Meningaud et al, Champy et al, Brown et al, Iizuka and Lindquist, Morberg et al and Roserberg et al have all produced controversial results with no consensus reached(Matthew and Frame, 1999).

Among the asymptomatic cases of miniplate removal, patient demand was observed to be an important factor which is neglected. In our study, the most common reason for removal was infection (87.4%). This is in consistency with other literatures. However, Park et al reported patient demand as the most common reason for plate removal(Park et al., 2016). Infection of the sub mucosally located miniplates exposed to the heavily loaded microbial flora of oral cavity is not uncommon(Islamoglu et al., 2002). The thin submucosa may also be prone to chronic irritation due to local/ environmental factors that result in loosening of screws, inflammation at tissue around the plate, increased possibility of infection and exposure. Poor surgical and suturing technique, etiology of injury and contaminated wound can contribute to infection of hardware in the future(Brown et al., 1989).(Michelet, Deymes and Dessus, 1973)

The most common type of miniplate removed in this study was stainless steel (82.4%). Though this seems proportional to the reason of hardware removal, no association was found between the two factors at CI-95%.
All the titanium miniplates which were removed were due to infection and no asymptomatic titanium plates were removed. This is consistent with recommendations yielded by previous researches, where asymptomatic titanium plate removal is not recommended.

Another interesting finding in this study was the proximity of the site of hardware removed to the dentate segments. 88.2% of removal hardware had an adjacent tooth near the site. This could explain the possible source of infection and further research is necessary to determine or find the strength of association between the two factors. In this study, no association was found between the 2 factors at CI-95%. This could be due to the narrow size of the study population.

No research is exempt from limitation and ours falls short in that the study population had narrow sample size and the duration between ORIF and plate removal was not considered. Prospective research is necessary to arrive at a consensus regarding the fate of miniplates used in ORIF. Our institution is passionate about high quality evidence based research and has excelled in various fields (Pc, Marimuthu and Devadoss, 2018; Ramesh et al., 2018; Ezhilarasan, Apoorva and Ashok Vardhan, 2019; Ramadurai et al., 2019; Sridharan et al., 2019; Vijayashree Priyadharsini, 2019; Mathew et al., 2020)

CONCLUSION
Within the limits of our study, we found that incidence of miniplate removal was more common in males in the third decade of life. The most common reason for its removal being infection and most common type being stainless steel miniplates. We found no significant association between type of miniplates and reason for removal. Further prospective research and systematic analysis required to arrive at consensus.

REFERENCE
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