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# Factors contributing to non-union amongst dentate mandibular fractures treated by load-sharing miniplate osteosynthesis: a case-control study

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#### Abstract

The stability provided by load-sharing miniplate osteosynthesis (LSMO) in dentate mandibular fractures (DMF) is usually adequate for bony healing. Non-union following LSMO is an uncommon complication. We aimed to determine the incidence and identify contributing factors, if any, of non-union amongst DMFs that have undergone LSMO. This retrospective case-control study with an allocation ratio of 1:3 includes cases of non-union DMF following LSMO and controls with healed DMF following LSMO over a five-year period. Relevant sociodemographic data, mandibular fracture characteristics, and treatment variables were collected for both groups. Of the 381 patients who underwent LSMO for DMFs, 12 cases of non-union and teeth in the line of fracture, postoperative infections, and time from injury to LSMO. The odds ratio with chronic alcohol usage was 1.4. Vigilant follow up of patients with chronic alcohol use, those with teeth in the fracture line, and adherence to LSMO principles may help to minimise the non-union complication.

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Keywords: Open reduction and internal fixation; Mandible; Postoperative; Complications; Hardware failure; Non-union

# Introduction

Failure of a mandibular fracture to heal within an adequate timeframe resulting in a non-union is an uncommon complication. There is evidence to support the notion that inadequate fracture reduction and stabilisation resulting in persistent interfragmentary mobility are the main drivers of infection and non-union.<sup>1,2</sup> Champy's principles of load-sharing miniplate osteosynthesis (LSMO) are employed in dentate mandibular fractures (DMF) when good bony apposition post-reduction is possible. The stability of fixation pro-

vided by LSMO is usually adequate for satisfactory bony healing except in fractures with reduced quantity and quality of bone. Though the reported incidence of non-union ranges from 2.8% to 3.9%, most earlier studies include fractures treated conservatively or with less rigid fixation methods, or comminuted fractures with inadequate soft tissue coverage.<sup>3–6</sup> It is possible that the incidence and contributing factors for non-union following LSMO may differ from those following other interventions. The current literature appears inadequate in this regard. This study therefore aimed to determine the incidence and identify contributing factors, if any, of non-union amongst DMFs that have undergone LSMO.

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# Material and methods

This IRB-approved study (JIP/IEC-OS/276/2023) was conducted in the oral and maxillofacial surgery (OMFS) department of a public sector tertiary care medical school. Nonunion was defined as mobility of the fracture segments after six weeks despite adequate fixation.<sup>3,7</sup> The design of the study was a retrospective case-control study with an allocation ratio of 1:3.<sup>8</sup> Hospital medical records over a five-year period (1June 2018 to 1 June 2023) were analysed to identify patients who had developed non-union fracture/s of the dentate portion of the mandible. The criteria for inclusion/exclusion in the non-union group are summarised in Fig. 1. The control group included a random selection of patients who underwent titanium LSMO of DMFs under general anaesthesia and whose medical records showed satisfactory bony healing with no documented evidence of non-union.

Relevant sociodemographic data, mandibular fracture characteristics, and treatment variables were collected for both groups of patients. All patient records and data were anonymised prior to analysis. The results were analysed using R version 4.3.2 (R: a language and environment for statistical computing. R Core Team, https://cran.r-project.org). The chi squared test or Fisher's exact test was applied, odds ratios were calculated, and a p value of < 0.05 was considered statistically significant.

## Results

Twelve cases of non-union following LSMO of DMFs were retrieved from analysis of the medical records of 381 patients (3.1%). As per the predetermined allocation ratio, 36 patients who underwent an uneventful LSMO of DMFs during this period were randomly selected for comparative analysis (control group). Males with DMFs following road traffic accidents were predominant in both groups. An equal distribution of multiple-site DMFs was observed in both groups.

Inclusion	Exclusion
Patients aged 18 years or older.	• DMF treated with Load Bearing
• DMF that had an adequate fixation	Osteosynthesis and bicortical screws
with titanium LSMO (1 mm profile)	(LBO; 2.5/2.7mm plate profile)
and monocortical screws at the time of	• DMF treated with closed reduction or
initial surgery under general	conservatively
anesthesia	Pathological fractures of dentate
Documented diagnosis of non-union	mandible
amongst the DMF treated using	• Non union of fractures of non-dentate
LSMO	regions of mandible
	Patients with incomplete medical
	records

Fig. 1. Inclusion and exclusion criteria for non-union group.

The transoral approach was the preferred route for surgical access in a majority of patients in both groups. The time to ORIF was a statistically significant factor. In the control group the mean (SD) time to ORIF from injury was 5.5 (3.31) days, range 1–10 days, and in those with non-union it was 8 (2.99), range 4–16 days. Demographic and clinical characteristics of both groups are summarised in Table 1.

All non-union cases underwent single-stage revision refixation surgery with rigid internal fixation. The extraction of retained teeth in the fracture line was required in seven patients at the time of the revision surgery. Platelet rich plasma (PRP) grafting was done in two mandibular angle fractures. Postoperative outcomes in all these cases were uneventful, with radiological and clinical evidence of fracture healing at subsequent follow-up visits (Table 2).

A highly statistically significant association was observed between non-union and teeth in the line of fracture (p < 0.001), development of postoperative infection (p < 0.001), and time from injury to initial LSMO (p = 0.02; 95% CI = 3.47 to 7.68). The odds ratio for nonunion with chronic alcohol usage was 1.4 (95% CI = 0.37 to 5.42).

# Discussion

Persistent pain, purulent discharge, and malocclusion seen in patients with non-union of a DMF preclude return to a regular diet and dental rehabilitation. Non-union necessitates a return to theatre for further revision surgery, adding to the cost and morbidity. The potential risk factors for non-union are usually multifactorial and include severity of the fracture, delayed intervention, inadequate immobilisation across the fracture ends, smoking, alcohol, and poor patient compliance.<sup>3</sup> It was unclear, however, if the patient cohort that required repeat fixation of the DMF following stable fixation with LSMO had a similar incidence and risk factors for nonunion as those identified in the literature. The study recorded 12 cases of non-union amongst 381 LSMO of DMFs (3.1%), and found an association between non-union and chronic alcohol use, teeth in the fracture line, surgical site infection, and time from injury to LSMO.

It is commonly believed that delayed surgery of compound mandibular fractures is likely to increase the incidence of postoperative infections which, if inadequately treated, can result in persistent interfragmentary mobility, hardware failure, and non-union.<sup>2</sup> Almost all studies that have examined the relation between time to intervention and surgical site infection (SSI) have been retrospective, with shortcomings such as incomplete data reporting, poorly defined outcomes, and substantial heterogeneity.9 Hurrell et al prospectively evaluated 359 mandibular fractures for which the time from injury to surgery ranged from 0 to 41 days (mean (SD) 4.7 (5.6) days). The outcome results recorded an incidence of 11% and 2% of infection and non-union, respectively. The study concluded that treatment delay did not significantly alter the incidence of postoperative infection.<sup>10</sup> Sundheepkumar et al prospectively analysed 83 cases

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Table 1 Demographic and clinical characteristics.

	Non-union $(n = 12)$	Union $(n = 36)$	p value
Gender:			0.6
Male	11	30	
Female	1	6	
Mean (SD) age (years)	31.4 (8.8)	33.6 (10.5)	0.6
Alcohol abuse	7	17	0.8
Smoking	2	8	1.00
Diabetes/medical comorbidities	0	3	0.5
Mechanism of injury:			0.8
Falls	1	2	
RTA	11	31	
Assault	0	3	
Mandibular fracture site/s at LSMO ORIF:			
Symphysis	0	5	
Parasymphysis	10	26	
Body	4	3	
Angle/ramus	4	20	
Multiple sites	6	18	
Mean (SD) time to LSMO ORIF from injury (days)	8 (2.99)	5.5 (3.15)	0.02
Operator experience:			
Resident	8	27	1
Consultant	4	9	
Surgical access at time of LSMO ORIF:			0.4
Transoral	11	25	
Transcutaneous	1	8	
Transoral + transcutaneous	0	3	
Teeth in the line of fracture:			< 0.001
Retained at time of LSMO ORIF	6	1	
Extracted at time of LSMO ORIF	1	10	
Extracted during follow up after LSMO ORIF	1	1	
Not applicable (missing/avulsed)	4	24	
Surgical site infection	12	2	< 0.001

RTA: road traffic accident; LSMO: load-sharing miniplate osteosynthesis; ORIF: open reduction and internal fixation.

of DMF with delayed LSMO (median (range) 8 (4–19) days). They observed SSIs in eight patients with no statistically significant relation between delayed surgery and infection. Two patients developed non-union and both underwent load-bearing osteosynthesis (LBO) revision surgery with satisfactory healing.<sup>11</sup> Our study, however, found that time to ORIF was a statistically significant factor.

When a fracture SSI is observed, our unit's protocol is to perform local debridement and drainage, remove the odontogenic cause if any, confirm the optimisation of medical conditions, and prescribe antibiotics on a case-to-case basis. In all 12 cases of non-union, a fracture SSI was documented within the first two weeks postoperatively, but the infection could not be controlled with the above measures and eventually resulted in non-union. The four cases of fracture SSI in the control group were satisfactorily managed in outpatients, resulting in uneventful healing.

A surgeon's challenge is to determine why some infections respond to local measures and antibiotics while others progress to a non-union. Teeth in the line of fracture are believed to be an important cause of SSI, with established guidelines on the decision to retain or remove a tooth.<sup>12,13</sup> Often there might be no clear indication for the removal of teeth at the time of surgery, yet some teeth can get infected during follow up and require extraction. SSIs lead to bone "softening" due to the acidic environment induced by the bacteria, resulting in the loosening of fixation devices, sequestration of bone, loss of bone buttressing, and eventually, mobility of the fracture.<sup>14</sup> In our study, only one tooth in the fracture line had been removed at the time of initial LSMO surgery in the non-union group, whereas 10 teeth had been removed at the time of LSMO in the control group. Eight patients with non-union underwent extraction of retained infected teeth in the line of fracture during follow up or at the time of re-fixation revision surgery. Early identification of teeth that are becoming infected and their prompt removal can help to control the infection faster, protect the hardware, and allow the bone to heal completely.<sup>2</sup>

The surgeon often encounters linear mandibular fractures accompanied by one or more comminuted free bone fragments at the inferior border. The surgeon's predicament is to decide whether such fractures should be treated with load-sharing osteosynthesis, as the fragmentation is minimal or considered comminuted and fixed with rigid load-bearing plates. Sukegawa et al recorded four cases of non-union that required reoperation following ORIF of 126 mandibular fractures with either load-sharing or load-bearing osteosynthesis.<sup>15</sup> All four cases of non-union were in comminuted fractures that were treated with a load-sharing miniplate fixation. They observed that with miniplates there was a Table 2

Clinical characteristics of non-union of dentate mandibular fractures treated with LSMO. No patients had medical como	rbidities.
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Gender	Age (years)	Mechanism of injury	Smoking	Alcohol abuse	Fracture location	Time (days) to LSMO ORIF from injury	Operator experience	Surgical access at time of LSMO ORIF	Management of teeth in line of fracture at time of LSMO ORIF	Additional finding/intervention at time of revision surgery with rigid fixation
Male	26	RTA	Ν	Y	PS (R)	1	Consultant	ТО	Retained	Extraction of tooth 45
Male	45	RTA	Ν	Ν	Ang (L) * +PS (R)	4	Trainee	TC	Retained	Extraction of impacted tooth 38; PRP grafting
Male	36	RTA	Ν	Y	PS (L)	3	Trainee	ТО	Retained	Extraction of tooth 33
Male	34	RTA	Ν	Y	PS (L)+Bd (R)*	9	Consultant	ТО	Retained	Screw within the fracture line; extraction of tooth 43
Female	29	RTA	Ν	Ν	Ang (R)*+ Bd (L)	2	Trainee	ТО	Not applicable	PRP grafting
Male	30	RTA	Y	Y	PS (R)+PS (L)*	6	Trainee	ТО	Retained	Sequestra at fracture site; extraction of tooth 34
Male	18	RTA	Ν	Y	PS (R)*+ Rm (L)	8	Trainee	ТО	Retained	Extraction of tooth 44
Male	19	Fall	Ν	Ν	PS (L)	4	Trainee	TO	Extracted	
Male	32	RTA	Ν	Y	PS (L)	8	Trainee	ТО	Not applicable	
Male	38	RTA	Ν	Ν	Bd (R)*+ Rm (L)	10	Trainee	ТО	Extracted	
Male	25	RTA	Y	Y	PS (R)	2	Consultant	ТО	Not applicable	
Male	45	RTA	Ν	Ν	Bd (R)	10	Trainee	ТО	Retained	Extraction of tooth 43,44

\* Non-union fracture site.

LSMO ORIF: load sharing miniplate osteosynthesis open reduction and internal fixation; RTA: road traffic accident; PS: parasymphysis; Ang: angle; Bd: body; Rm: ramus; R:right; L:Left; T: transoral; TC: transcutaneous; PRP: platelet rich plasma.

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significant difference in outcomes based on the number of free bone fragments and the presence of bone fragments requiring removal within 1 cm. They opined that for comminuted mandibular fractures with only one free bone fragment, treatment by miniplates may be possible. However, comminuted fractures that have two or more free bone fragments or that require the removal of fragments should be treated with rigid reconstruction plates.<sup>15</sup> In our study, on re-examining the radiological imaging and operative notes of the initial LSMO of the non-union cases, we observed free bone fragments/bone removal in four cases. Rigid fixation at the initial surgery in these four cases may have avoided non-union. Rigid fixation systems, however, usually require an extraoral approach, a longer operating time, and potential over-treatment of the dentate mandibular fracture.

Another cause often implicated in unsuccessful treatment and non-union is patient compliance.<sup>16,17</sup> Although what constitutes compliance is not unequivocal, it usually includes a soft diet, cessation of tobacco and substance abuse, good oral hygiene, and adherence to follow-up visits. The term compliance suggests that the patient alone is responsible for the failure of the fracture surgery, which is not always the case.<sup>18</sup> A soft, non-chew diet is usually advised for four to six weeks in the postoperative period, though the specific timeline to return to a regular diet is often at the discretion of the surgeon. Manzie et al randomly allocated 146 patients to a two, four, or six-week modified diet schedule and observed no significant difference in the incidence of complications.<sup>19</sup> Although 18 patients required a return to theatre, no details on the severity of the complication or the nature of the reintervention was provided.<sup>19</sup> In our study, the non-union group included nine patients who had assured us of compliance during follow up. We speculate, however, that some may not have been truthful. Other than considering adherence to a follow-up visit schedule as a surrogate marker for compliance, it is impossible for the clinician to be confident that the patient has diligently adhered to the postoperative instructions. Despite patient assurance of compliance with a soft diet, some fractures do not heal, probably because of undetected parafunctional habits such as bruxism.<sup>20</sup> The presence of prominent wear facets on the teeth can identify high-risk patients, and whether these patients would benefit from a more rigid load-bearing fixation at initial surgery needs further research.

A positive correlation has been observed between tobacco and alcohol use and mandibular fracture infections.<sup>7</sup> Radabaugh et al showed that smoking was associated with increased odds of non-compliance, but did not relate it to complications.<sup>21</sup> Our study observed a positive association between chronic alcohol abuse and non-union (odds ratio: 1.4). A recently published study observed a return-totheatre (RTT) rate of 6% for repeat surgery following LSMO of mandibular fractures, and the only patient risk factor with significantly increased odds of developing a complication that required a RTT was excess alcohol intake. As excess alcohol intake could be considered a proxy for generalised compliance with a soft diet, the study recommended consideration of the treatment of such patients with LBO.<sup>22</sup>

Another poorly investigated factor contributing to ORIF failure and non-union is related to the operator. Poor alignment of fracture segments at repair, improper selection of plates and screws, and inadequate fixation will adversely affect the outcome of the treatment. Loosening of the bone screws can lead to fracture mobility and non-union. Loosening of screws is usually due to technical errors like inadequate cooling, improper angulation, or excessive reaming of screw holes and excessive force that causes stripping of the screws.<sup>23</sup> Placing the first screw too close to the fracture line can also contribute to bony resorption near the fracture line and failure of the hardware (case 4, Table 2). Failure to passively adapt the miniplate during screw fixation can also result in loosening of the screws. This potential complication can be avoided by the use of locking miniplate systems wherein precise adaptation of the plate is not required. However, this system requires perpendicular placement of the screw to ensure that it locks into the plate. The consequences of these technical errors are often seen a few weeks after surgery when it becomes almost impossible to determine if the hardware failure and non-union are the result of surgeon factors, patient factors, or a combination of both in varying degrees. Steffen et al performed a retrospective observational study of 630 mandibular fracture patients of whom 17 (2.7%) had undergone revision surgery.<sup>24</sup> Six senior consultants assessed the preoperative and immediate postoperative imaging of all cases of re-fixation to decide if treatment was done in accordance with AO principles. There were eight cases of re-fixation with a combination of AO treatment failure and patient risk factors. Of the six patients with no risk factors, five were judged to have received insufficient treatment according to AO principles. The authors observed that the quality of osteosynthesis was a major factor for long-term success, but admitted that the current guidelines might not be easy to apply in every case.<sup>24</sup>

To the best of our knowledge, our study is one of the few studies to examine the incidence and contributing factors for re-fixation revision surgery due to non-union following LSMO of DMF. The clearly defined inclusion criteria and outcome, standardised LSMO intervention, and casecontrol design are some of its strengths. The retrospective nature of the study, the sample size precluding logistic regression computation, the fact that it was slightly underpowered and included a predominantly younger population with few patients with systemic comorbidities in both groups, are some of the potential weaknesses.

In conclusion, although chronic alcohol use, teeth in the fracture line, and time to LSMO surgery showed statistical significance for non-union, the effect of technical errors by the surgical team cannot be discounted. The results of our study need to be confirmed with larger sample sizes or a higher power. Further research is also needed with regard to the consideration of LBO in uncomplicated DMF in chronic alcoholics and in DMFs with minimal fragmentation.

# **Conflict of interest**

We have no conflicts of interest.

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### Ethics statement/confirmation of patient permission

Ethics approval from Jawaharlal Institute of Postgraduate Medical Education and Research (JPIMER), Pondicherry, India

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