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## Original Article

# Comparison of two incisions for open reduction and internal fixation of mandibular body fractures: A randomised controlled clinical trial evaluating the surgical outcome

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## ABSTRACT

**Purpose:** The purpose of the study is to compare the surgical access and post-operative outcome of two intra-oral incisions used for approaching a mandibular body fracture.

**Methods:** This clinical trial involved 60 patients with mandibular body fractures who were randomly allocated to control and study groups. The fractures were approached using the routine vestibular incision in the control group and crevicular incision with vertical release in the study group. The effects of incision design on the post-surgical outcome variables like swelling, trismus, paresthesia, wound healing and gingival recession were statistically analysed with non-parametric tests by using SPSS 22.0 software. Comparison of continuous variables between the groups and time points was done using Mann Whitney test and Friedman test respectively. Chi-square test was used to compare proportions between groups. Dunn's test with Bonferroni correction was used for pair wise comparisons.

**Results:** The study group demonstrated favourable surgical outcome in the immediate postoperative phase as compared to the control group. The difference in mouth opening, swelling and neurosensory impairment between the two groups was found to be statistically significant ( $p < 0.05$ ).

**Conclusion:** Crevicular incision was found to be an ideal alternative to vestibular incision in achieving surgical access and fixation of mandibular body fractures with reduction in postoperative patient discomfort and better surgical outcome.

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## Introduction

The fractures of the mandibular body constitute one of the frequently encountered fractures of the mandible.<sup>1–3</sup> This is attributed to the presence of mental foramen which weakens the mandibular corpus by (a) concentration of stress and (b) reduction of cross sectional area around the foramen.<sup>4</sup> The anatomic zone constituting the mandibular body extends from the canine line to a line coinciding with the anterior border of the masseter muscle and is divided into 3 parts: anterior, mid and posterior body which demonstrate distinct variations in the biomechanical forces acting on them. The ideal management of body fractures includes open

reduction and internal fixation (ORIF) either by intra oral or extra oral approach as dictated by the type of fracture and fixation method.

The most preferred approach is intra-oral using a vestibular incision<sup>5</sup> followed by fixation with mini-plates or lag screws. However such procedures are frequently associated with post-operative complications like pain, swelling, trismus,<sup>6</sup> wound infection,<sup>6,7</sup> implant failure<sup>8</sup> and most importantly, injury to vital structures. The anatomic structure of concern in the body region is the mental nerve which provides sensory innervation to the lip, chin and gingival mucosa of anterior teeth. When the nerve is exposed to direct or indirect surgical trauma, it presents as bothersome paresthesia which extends over a variable period of time based on the severity of nerve injury.<sup>9–11</sup> Song et al.<sup>12</sup> established that there was a 7 fold increase in risk of postoperative mental nerve paresthesia with surgeons who had less than 3 years of

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surgical experience. The major factors which precipitate the aforementioned postoperative complications are excessive manipulation of the tissues during ORIF and poor surgical approach. A properly designed incision would greatly improve the surgical outcome and reduce postoperative patient discomfort or morbidity.

The aim of this study was therefore to evaluate an alternative incision- the crevicular incision with release to approach the mandibular body fracture and compare its clinical suitability and surgical outcome with the conventionally used vestibular incision for ORIF of body fractures of mandible.

**Methods**

The study was done in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement (Fig. 1) after obtaining the necessary approval from the Institutional Review Board. The Helsinki declaration guidelines have been followed.

*Study design*

A single blind, randomised controlled clinical trial was designed to assess the research objectives. The study sample included patients presenting to the institution for management of fractures of mandibular body. An informed consent was obtained from all the patients after explaining about the procedure.

*Sample selection, inclusion & exclusion criteria*

60 patients (55 males and 5 females), aged 20–50 years who reported to the department of oral & maxillofacial surgery with mandibular body fractures were recruited for the study. The inclusion criteria comprised of patients with undisplaced or minimally displaced mandibular body fractures and patients with American Society of Anesthesiologists (ASA) status I. Patients with mental nerve paresthesia following trauma, compromised systemic status and comminuted fractures were excluded from the study. Displacement of the fracture segments greater than 5 mm were also excluded from the study.



Fig. 1. Study chart according to consort guidelines.

Group allocation

The samples were randomly assigned to control and study groups by lottery method. The incisions used to expose the fracture site varied, that is, vestibular incision was used in control group and crevicular incision with vertical release in study group.

The fractures were taken up for ORIF under general anaesthesia within 2 days of the traumatic episode. A single experienced surgeon (>5 years of experience) performed all the procedures by a standardised technique. All patients were administered preoperative intravenous antibiotics, Taxim 1 g and Metrogyl 500 mg, 12th hourly.<sup>13</sup> Using 7.5% Povidine iodine solution, the surgical site was disinfected. An inferior alveolar nerve block and local infiltration was given with 2% lignocaine with adrenaline at the site of surgical procedure. Fracture exposure in the control group was done using a routine vestibular incision, 5–7 mm inferior to the mucogingival junction<sup>14</sup> extending from the vestibule of the canine to the first molar region (Fig. 2). For the study group, a crevicular incision with release was used which consisted of asulcular incision extending from distal aspect of first molar tooth involving the interdental papillae up to the mesial aspect of the canine tooth. A vertical relieving incision was then given at the anterior aspect, without splitting the interdental papilla (Figs. 3 and 4).

Anatomic reduction of the fracture segments was done and occlusion achieved with intermaxillary fixation. Internal fixation was carried out using a single 2 mm titanium miniplate with 4 holes and screws of 2 mm × 6 mm dimension. The wound closure for the control group was achieved with 4-0 vicryl, using continuous locking sutures. For the study group, 4-0 vicryl interdental sutures were placed to re-approximate the interdental papillae. Vertical release incision was not closed.

Assessment parameters & methods

The following outcome parameters were assessed by a single investigator for both the study and control groups.

- Pre- and post-operative mouth opening
- Pre- and post-operative gingival position
- Postoperative swelling
- Postoperative neurosensory assessment
- Postoperative wound healing

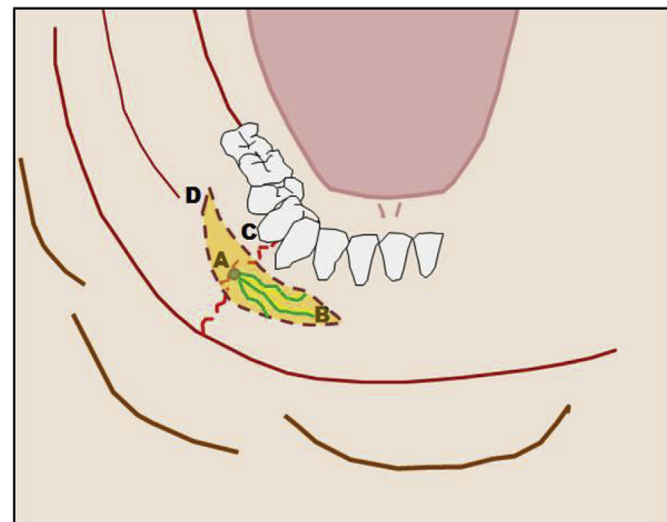


Fig. 2. Diagram showing vestibular incision. (A) Mental foramen, (B) Mental nerve, (C) Fracture line, (D) Incision line.

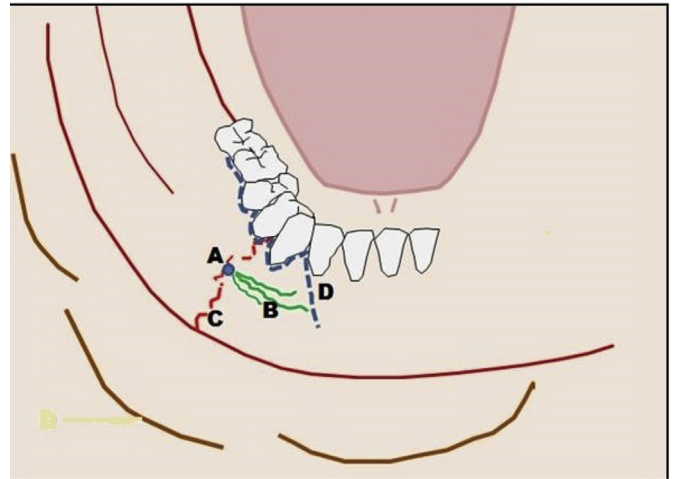


Fig. 3. Diagram showing crevicular incision with vertical release. (A) Mental foramen, (B) Mental nerve, (C) Fracture line, (D) Incision line.

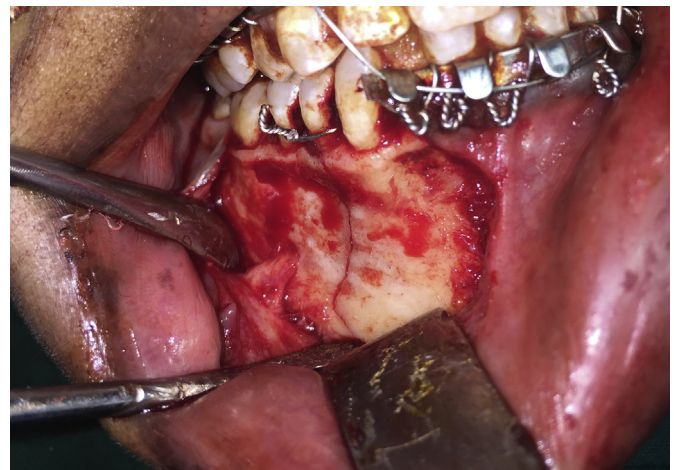


Fig. 4. Intra-operative photograph showing fracture exposure with crevicular incision.

The mouth opening, swelling and gingival position were assessed postoperatively on the 1st, 3rd, 7th and 14th day following surgery. Neurosensory assessment was assessed on 1st, 3rd, 7th, 14th & 42nd postoperative days.

The inter-incisal mouth opening was measured in millimetres using a divider and scale.<sup>15</sup> Post-operative swelling was measured using a flexible measuring tape in millimetres. The reference planes used to record the swelling were AC, AD and BE as described by Gokulanathan et al.<sup>16</sup> (Fig. 5). The degree of swelling was calculated as the difference between the averages of the pre-operative and postoperative values.

Postoperative wound healing was assessed using the modified Landry's criteria where a score of 1 indicated very poor healing; 2, poor healing; 3, good healing; 4, very good; and 5, excellent healing.<sup>17</sup> Pre- and post-operative position of gingival margin was assessed using Miller's grading.<sup>18</sup>

Neurosensory impairment was checked at Level A (direction sense) and Level C (pin prick pain) as described by Tay<sup>9</sup> by an independent surgeon who was blinded to the groups. Patients were made to close their eyes during the assessment and the sensory stimulus was applied on both sides. For Level A, a soft brush was used to stroke the test area 15 times and the patient was asked to report the direction of the touch. Less than 90% correct responses were considered to be abnormal. Level C sensations were checked

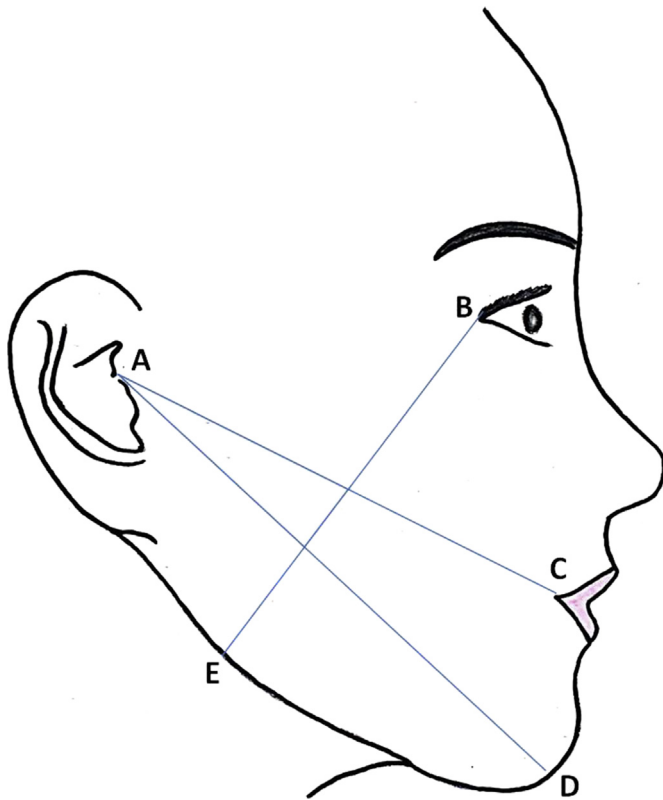


Fig. 5. Diagram showing reference planes used to record the swelling.

using a sharp probe at 3 different anatomic zones, namely, the vermillion, labio-mental fold and chin. The responses were recorded using a sensory analog scale 0–10 where 0 indicated paresthesia and 10 indicated no paresthesia.<sup>9</sup>

#### Statistical tests

The normality tests Kolmogorov-Smirnov and Shapiro-Wilk tests results revealed that all the variables except mouth opening do not follow normal distribution. Therefore to analyse the data, non-parametric methods were applied. To compare the continuous variables between the groups and time points Mann Whitney test and Friedman test were applied respectively. Proportions between the groups were compared using Chi-square test. To compare the proportions between time points McNemar Chi-square test was applied. The mean mouth opening between the groups was compared using independent samples *t*-test. To compare the mean mouth opening between time points repeated measures ANOVA was applied. Dunn's test with Bonferroni correction was used for pair wise comparisons. SPSS version 22.0 was used to analyse the data.

#### Results

Of the total of 60 patients included in this clinical trial, 55 were males and 5 were females. The results of the statistical analysis showed that the postoperative mouth opening was more in the study group than the control group and was found to be statistically significant on all days. ( $p < 0.05$ , Table 1). The postoperative swelling was found to be significantly lower in the study group on all days ( $p < 0.05$ , Table 1).

Postoperative healing of the surgical wound was found to be better in the study group than the control group and the difference was statistically significant on day 1, 3 and 7 ( $p < 0.05$ , Table 2).

No changes in the gingival position were seen in the study group on day 1, 3, 7 and 14 when compared to the preoperative status of the gingival position (Table 3).

The neurosensory assessment for direction sense and pin prick pain showed less impairment in the study group as compared to the control group. This difference in neurosensory disturbance to direction sense was found to be statistically significant ( $p < 0.05$ ) between the control and study groups on day 1 and day 3 post-operatively (Tables 4 and 5). On postoperative days 7, 14 & 42 the difference was not significant between the two groups.

#### Discussion

The successful outcome of ORIF of any fracture is greatly influenced by the flap design and approach to the fracture site. An ideal incision enables direct and immediate access to the line of osteosynthesis and facilitates instrumentation while protecting the adjacent vital structures. Vestibular incision is the conventionally used intra-oral incision to achieve ORIF of mandibular body fracture. However it does not obviate postsurgical sequel like swelling, trismus, wound infection and especially mental nerve paresthesia. This clinical trial was therefore designed to study the reliability of an alternative incision (crevicular with release) in reducing these postsurgical complications as well as simplifying the surgical access in comparison with vestibular incision. The randomised controlled trial (RCT) revealed that the crevicular incision simplified the surgical access and demonstrated more favourable surgical outcome.

#### Exposure of the fracture site

Unlike the vestibular incision, the location of the crevicular incision with vertical release is away from the mental nerve. Blind tissue dissection is not required to identify and relieve the nerve of traction. The anterior vertical release incision facilitates tension-free retraction of the flap and offers excellent visualization of the body region, the superior as well as the inferior border as shown in Fig. 4. This exposure helps in achieving the ideal fixation requirements of body region, which vary according to the biomechanical forces acting on the 3 anatomic subdivisions of the body region; 2 miniplates in the anterior and posterior body while a single miniplate for the mid body. Further, the crevicular incision helps in visualising basal triangle fractures as well as oblique fractures where the superior and inferior limits of fracture are far away. The incision may also be extended further if required. The exposure also facilitates osteotomies which are essential in the management of mal-united fractures. Finally, the flap reflection from the crevicular end is much easier as there are no vital structures between the site of incision and fixation. In contrast the vestibular incision requires reflection from below, traversing across the mental foramen to reach the line of osteosynthesis which is above the mental foramen in mid body region.<sup>19</sup>

As for the exposure of the site of fracture the use of a crevicular incision as opposed to the standard vestibular approach has the following advantages.

1. The incision is a more direct approach to the bone in a subperiosteal plane right from the gingival sulcus whereas the vestibular approach generally requires not only an incision at the mucosal level but also incision and dissection along the submucosal plane and the associated peri-oral musculature. The reattachment of the muscles and restitution of function of the perioral musculature is also facilitated easily in the crevicular approach due to the fact that all the dissection is only in the subperiosteal plane and there is no separation or transection of any of the muscles in this approach.

**Table 1**  
Postsurgical swelling and mouth opening.

Group	Swelling					Mouth opening				
	Preoperative (mean ± SD)	Postoperative (mean ± SD)				Preoperative (mean ± SD)	Postoperative (mean ± SD)			
		D1	D3	D7	D14		D1	D3	D7	D14
Study	2.83 ± 0.99	4.03 ± 0.67	2.83 ± 0.59	0.90 ± 0.66	0	34.63 ± 2.66	42.03 ± 2.75	43.33 ± 2.84	46.43 ± 3.50	48.03 ± 4.19
Control	3.27 ± 1.23	7.17 ± 0.95	4.83 ± 1.02	2.93 ± 0.83	1.17 ± 0.65	32.3 ± 2.88	35.47 ± 2.94	41.77 ± 2.79	44.37 ± 3.59	46.83 ± 3.98
p value	0.180	<0.01	<0.01	<0.01	<0.01	0.002	<0.001	0.035	0.028	0.260

**Table 2**  
Postoperative healing of surgical site.

Group	Distribution of patients according to healing score in percentage														
	D1					D3					D7				
	5 (%)	4 (%)	3 (%)	2 (%)	1 (%)	5 (%)	4 (%)	3 (%)	2 (%)	1 (%)	5 (%)	4 (%)	3 (%)	2 (%)	1 (%)
Study	23.3	46.7	26.7	3.3	0	50.0	40.0	6.7	3.3	0	73.3	16.7	10.0	0	0
Control	6.7	20.0	60.0	13.3	0	6.7	23.3	53.3	16.7	0.0	6.7	30.0	56.7	3.3	3.3
p value	0.008					<0.001					<0.001				

**Table 3**  
Gingival position in the study group.

Sample size (study group)	Gingival position											
	Preoperative				Postoperative							
					D1		D3		D7		D14	
	Class 1 (%)	Class 2 (%)	Class 1 (%)	Class 2 (%)	Class 1 (%)	Class 2 (%)	Class 1 (%)	Class 2 (%)	Class 1 (%)	Class 2 (%)	Class 1 (%)	Class 2 (%)
n = 30	90.0	10.0	90.0	10.0	90.0	10.0	90.0	10.0	90.0	10.0	90.0	10.0

**Table 4**  
Postoperative neurosensory testing - direction sense.

Group	Direction sense					
	Response	Postoperative days				
		D1 (%)	D3 (%)	D7 (%)	D14 (%)	D42 (%)
Study	Normal	86.7	96.7	100.0	100.0	100.0
	Abnormal	13.3	3.3	0	0	0
Control	Normal	36.7	46.7	93.3	100.0	100.0
	Abnormal	63.3	53.3	6.7	0.0	0.0
p value		<0.001	<0.001	0.492	–	–

**Table 5**  
Postoperative neurosensory testing-pin prick pain.

Group	Pin prick pain (mean ± SD)				
	Postoperative days				
	D1	D3	D7	D14	D42
Study	9.73 ± 0.74	9.93 ± 0.25	10.0 ± 0	10.0 ± 0	10.0 ± 0
Control	9.07 ± 1.87	9.97 ± 0.18	10.0 ± 0	10.0 ± 0	10.0 ± 0
p value	0.220	0.557	1.000	1.000	1.000

- The immediate sub-periosteal approach that the crevicular incision offers also cleaves more comfortable plane to the mental neuro-vascular bundle which is much more easy and direct as compared to the vestibular approach where one has to exercise caution while incising close to the mental foramen region and identifying the neuro-vascular bundle.
- The crevicular approach also has a significant advantage when the fractures are severely displaced or telescoped, and need lot of manipulation either manually or with the use of instruments

to set the alignment right. The presence of a band of gingiva attached to the alveolar process in a vestibular incision sometimes restricts the degree of manipulation possible and at times due to its non-elastic nature may produce tears which retard healing. On the other hand the crevicular approach offers complete exposure of the fracture including the alveolar bone where the fracture communicates to the oral cavity and facilitates easier manipulation with no restriction of the alveolar mucosa.

### Postoperative swelling and trismus

Following intra-oral surgical procedures, patient discomfort reaches its peak during the first few postoperative days.<sup>20</sup> This is commonly attributed to a triad of clinical features namely pain, swelling and trismus which greatly affect the quality of normal life. Numerous pharmacological and non-pharmacological methods have been used in the immediate postoperative period to minimise patient discomfort. The use of pharmacological agents like non-steroidal anti-inflammatory drugs and steroids<sup>21</sup> has a long track record and are commonly administered through oral or parenteral route. However they are associated with adverse effects which may be dose dependant or non-dose dependant. Topical application of various drugs has also shown clinical success in improving patient comfort.<sup>22,23</sup> Non-pharmacologically, postoperative swelling is minimized by using compression bandages, kinesiology tapes<sup>5</sup> or drains.<sup>24</sup> But these methods have limitations. Application of innovative methods like lasers<sup>25</sup> and cryosurgery<sup>26</sup> has also been used to reduce the postsurgical discomfort. But most of the above mentioned techniques work towards relief of symptoms only after the inflammatory processes have set in. Addressing the factors which initiate the inflammatory process would be a more definitive measure. This has been established by numerous studies which demonstrate a positive correlation between the postoperative patient discomfort triad and intraoperative tissue manipulation.<sup>21,27</sup> Hence modification in surgical techniques or flap designs have been attempted to minimise tissue dissection or manipulation. This study also demonstrates that the swelling was found to be considerably reduced in the study group, attributable to (1) the lesser tissue dissection needed in comparison to vestibular mucosa, (2) involvement of keratinised mucosa for placing incision that does not favour accumulation of inflammatory oedema underneath, (3) better approximation of the flap which eliminates dead space, and finally (4) the vertical release incision that facilitates drainage of any inflammatory oedema or hematoma.<sup>28</sup>

### Postoperative healing of surgical wound

The post-operative healing was found to be better in the study group, with no incidence of plate exposure due to wound infection or dehiscence since the miniplate was positioned well away from the line of incision, with an adequate mucoperiosteal cover. However, in the control group the miniplates lay immediately under the vestibular incision which favours stasis of food debris and fluids due to the anatomical position. This could lead to increased propensity for infection or delayed healing as observed in this study. Also, the vestibular incision passes through mobile mucosa which predisposes to accumulation of postoperative oedema and precludes flap approximation to bone. Further, wound closure by suturing is through keratinised mucosa in the study group which is more resilient to tissue injury as opposed to the delicate, non-keratinised vestibular mucosa of the control group which may lead to wound dehiscence.

### Neurosensory impairment

Neurosensory impairment is a common finding in patients with trauma to the mandibular body as the inferior alveolar nerve at this region shows a transition from its intra-bony course into forming the extra-bony mental branch. This may either be caused preoperatively due to the trauma itself or in the postoperative phase, secondary to the surgical procedure. Postoperative mental nerve injury can be very annoying to patients, especially when prolonged and has been the basis of lawsuits in very many incidents.<sup>29</sup>

One of the objectives of the study was thus to assess and compare the nerve injury caused by the two surgical approaches. To

specifically evaluate the incidence of iatrogenically induced postoperative neurosensory impairment, patients who presented with pre-operative paresthesia were excluded from the study. The clinical presentation of neurosensory impairment is greatly influenced by the type of injury<sup>30</sup> which may be one of the following: neuropraxia/first degree injury due to compression during fracture reduction, and 3rd/4th degree injury due to tractional forces on nerve during flap elevation/reflection. Rarely neurotmesis/5th degree injury could occur due to nerve transection during incision, dissection or drilling holes for screw fixation. Excessive manipulation of the tissues during ORIF and inexperience of the surgeon have also been cited as the major factors in the incidence of postoperative paresthesia.<sup>31,32</sup>

Following nerve injuries other than neurotmesis, the time taken for neurosensory recovery varies, depending on the type of injury and may extend over 4 months or prolong till about 2 years.<sup>33</sup> The various nerve repair procedures practised to restore neurosensory function include epi- or peri-neural microsurgery, use of nerve grafts and neurotrophic growth factors. However they have limitations<sup>34,35</sup> and most importantly, an observation period of minimum 3 months is required before any interventional procedure is instituted.<sup>36</sup>

Though neurosensory disturbances manifest in various forms, the study assessed level A (Brush stroke direction) and C (pin prick pain) alone, as they are more clinically relevant.<sup>37</sup> The trial demonstrates higher incidence of neurosensory disturbance in the control group, though it recovered over a period of time. The negligible sensory impairment observed in the study group can only be ascribed to the minimal tissue dissection needed to identify and skeletonize the mental nerve and the minimal traction during ORIF. There were no cases of nerve transection in either group and hence permanent damage to nerve was not encountered in any of the cases. However it is worth noting that the use of a crevicular approach almost negates the chances of an incision induced nerve damage as compared to a vestibular approach even in the hands of inexperienced surgeons.

Pal et al.<sup>38</sup> suggested a curvilinear modification of the vestibular incision near the premolar region to circumvent injury to the mental foramen and the exiting mental nerve branches. However it does not negate the disadvantages associated with the conventional vestibular incision.

### Gingival position

A point of concern is often raised regarding the potential compromise of esthetics due to gingival recession and periodontal health of teeth which involve the crevicular incision. Therefore an objective assessment of the gingival position as well as the periodontal status of the teeth involved was done for the study group using Miller's scale.<sup>18</sup> It was found that there was no statistically significant difference between the presurgical and the postsurgical gingival position till the 14th postoperative day.

The study highlights the obvious superiority of the crevicular incision over the vestibular incision in reducing postoperative swelling, pain and trismus along with improved mouth opening & wound healing. In addition, as the incision is away from the mental nerve, it negates the risk of nerve injury. It is an extremely useful approach for beginners who are wary of the mental nerve injury. With the crevicular incision, there is no transection of the mentalis muscle and hence a layered wound closure is not required. On the contrary, vestibular incision is associated with potential complications like loss of vestibular depth due to scarring and inadvertent injury to facial artery.

The only limitation observed with the crevicular incision was the additional time required for suturing to reposition the flap.

Sometimes, the flap reflection after the crevicular incision and wound closure may be cumbersome when archbars are fixed. This inconvenience is negated by use of eyelets or inter-maxillary fixation (IMF) screws for inter-maxillary fixation.

In conclusion, the use of crevicular incision with a vertical release is a very convenient method to approach the fractures of body of mandible. It offers excellent exposure of the superior as well as the inferior border of the mandible that facilitates ORIF while minimizing postoperative complications.

## Funding

Nil.

## Ethical statement

An informed consent has been obtained from all the patients after explaining about the procedure.

## Conflict of interest

None.

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