A randomized controlled clinical trial assessing the surgical outcomes of two incision methods for open reduction and internal fixation of mandibular body fractures.

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ABSTRACT:

Purpose: This study aims to compare the surgical access and post-operative outcomes of two intra-oral incisions used to approach mandibular body fractures.

Methods: The clinical trial involved 60 patients from the Department of Oral and Maxillofacial Surgery (OMFS) at Rama Dental College hospital and Research Centre Kanpur (U.P.) with mandibular body fractures randomly assigned to either a control or study group. The control group underwent the usual vestibular incision, while the study group received a crevicular incision with vertical release. The impact of incision design on post-surgical outcomes such as swelling, trismus, paraesthesia, wound healing, and gingival recession was analysed using non-parametric tests with SPSS 22.0 software. Continuous variables between groups and at different time points were compared using the Mann-Whitney and Friedman tests, respectively. Proportions between groups were compared with the Chi-square test, and pairwise comparisons were performed using Dunn's test with Bonferroni correction.

Results: The study group showed a more favourable surgical outcome in the immediate post-operative phase compared to the control group. Statistically significant differences in mouth opening, swelling, and neurosensory impairment were observed between the two groups ($p < 0.05$).

Conclusion: The crevicular incision proved to be a better alternative to the vestibular incision for surgical access and fixation of mandibular body fractures, offering reduced post-operative discomfort and improved surgical outcomes.

INTRODUCTION:

Mandibular body fractures are among the most commonly encountered fractures of the mandible. This is due to the presence of the mental foramen, which weakens the mandibular body by (a) concentrating stress and (b) reducing the cross-sectional area around the foramen. The mandibular body extends from the canine line to the anterior border of the masseter muscle and is divided into three parts: anterior, middle, and posterior. These sections experience different biomechanical forces. The preferred treatment for these fractures involves open reduction and internal fixation (ORIF), either via an intra-oral or extra-oral approach, depending on the fracture type and fixation method.

The intra-oral approach, using a vestibular incision followed by fixation with mini-plates or lag screws, is the most common. However, these procedures are often associated with postoperative complications such as pain, swelling, trismus, wound infection, implant failure, and, most critically, injury to vital structures. One key structure at risk in the body region is the mental nerve, which supplies sensory innervation to the lip, chin, and gingival mucosa of the anterior teeth. Surgical trauma to the nerve, either direct or indirect, can lead to bothersome paraesthesia that can last for varying durations depending on the severity of the injury. Research by Song et al. showed a sevenfold increase in the risk of postoperative mental nerve paraesthesia in surgeons with less than three years of experience.

Excessive tissue manipulation during ORIF and an inadequate surgical approach are major contributors to these complications. A well-designed incision can significantly improve surgical outcomes and reduce postoperative discomfort or morbidity. This study aims to assess an alternative incision— the crevicular incision with release— for approaching mandibular body fractures and compare its clinical suitability and surgical outcomes with the commonly used vestibular incision in ORIF of mandibular body fractures.

Methods

The study was conducted following the Consolidated Standards of Reporting Trials (CONSORT) guidelines and received approval from the Institutional Review Board. All procedures adhered to the ethical standards outlined in the Helsinki Declaration.

Study Design

A single-blind, randomized controlled clinical trial was designed to evaluate the research objectives. The study involved patients presenting to the institution for mandibular body fracture management. Informed consent was obtained from all participants after thoroughly explaining the procedure.

Sample Selection, Inclusion, and Exclusion Criteria

Sixty patients (55 males and 5 females), aged between 20 and 50 years, with mandibular body fractures, were recruited for the study. Inclusion criteria included patients with undisplaced or minimally displaced mandibular body fractures and those classified as American Society of Anaesthesiologists (ASA) status I. Patients with mental nerve paresthesia resulting from trauma, compromised systemic health, or comminuted fractures were excluded. Additionally, fractures with displacement greater than 5mm were excluded from the study.

Group Allocation

Participants were randomly assigned to either the control or study group using a lottery method. The incision types for exposing the fracture site varied: the control group underwent a vestibular incision, while the study group received a crevicular incision with vertical release. Open reduction and internal fixation (ORIF) were performed under general anesthesia within two days of the trauma. All procedures were carried out by a single experienced surgeon (with over 5 years of experience) using a standardized technique. Preoperative intravenous antibiotics (Taxim 1g and Metrogyl 500mg, administered 12 hours apart) were given to all patients. The surgical site was disinfected with 7.5% povidone-iodine solution. An inferior alveolar nerve block and local infiltration of 2% lignocaine with adrenaline were administered at the surgical site.

For the control group, a routine vestibular incision was made 5-7 mm inferior to the mucogingival junction, extending from the canine to the first molar region. For the study group, a crevicular incision was made from the distal aspect of the first molar, involving the interdental papillae, up to the mesial aspect of the canine. A vertical relieving incision was added at the anterior aspect, without splitting the interdental papilla. After fracture reduction and occlusion achieved with intermaxillary fixation, internal fixation was performed using a 2mm titanium mini-plate with 4 holes and 2mm x 6mm screws.

In the control group, wound closure was done with continuous locking sutures using 4-0 vicryl. For the study group, 4-0 vicryl sutures were placed to re-approximate the interdental papillae, and the vertical release incision was left open.

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

Postoperative assessments of mouth opening, swelling, and gingival position were conducted on the 1st, 3rd, 7th, and 14th days following surgery. Neurosensory evaluations were carried out on the 1st, 3rd, 7th, 14th, and 42nd postoperative days.

Mouth opening was measured in millimeters using a divider and scale. Swelling was measured in millimeters with a flexible measuring tape. Reference points (AC, AD, and BE) for swelling were based on the method outlined by Gokulanathan et al. The degree of swelling was determined by comparing the average preoperative and postoperative measurements.

Postoperative wound healing was evaluated using a modified version of Landry's criteria, where a score of 1 indicated very poor healing, 2 poor healing, 3 good healing, 4 very good healing, and 5 excellent healing. The gingival margin position before and after surgery was assessed using Miller's grading.

Neurosensory function was examined at Level A (directional sense) and Level C (pin-prick pain) following Tay's method, conducted by an independent surgeon who was blinded to group assignments. During testing, patients closed their eyes, and sensory stimuli were applied to both sides. For Level A, a soft brush was used to stroke the test area 15 times, and patients were asked to identify the direction of the touch. Less than 90% correct responses were considered abnormal. For Level C, sensations were tested with a sharp probe at three anatomical zones: the vermilion, labio-mental fold, and chin. Responses were recorded on a sensory analog scale from 0 to 10, where 0 indicated paresthesia and 10 indicated no paresthesia.

Statistical Analysis

Normality tests (Kolmogorov-Smirnov and Shapiro-Wilk) showed that all variables, except mouth opening, did not follow a normal distribution. As a result, non-parametric methods were used for data analysis. To compare continuous variables between the groups and at different time points, the Mann-Whitney test and Friedman test were applied, respectively. Proportions between groups were compared using the Chi-square test. The McNemar Chi-square test was used to compare proportions across different time points. The mean mouth opening between the groups was compared using an independent samples t-test, while repeated measures ANOVA was used to compare mean mouth opening at different time points. For pairwise comparisons, Dunn's test with Bonferroni correction was applied. Data were analyzed using SPSS version 22.0.

Results

Out of the 60 patients included in this clinical trial, 55 were male and 5 were female. Statistical analysis revealed that the postoperative mouth opening was greater in the study group compared to the control group, with this difference being statistically significant on all days ($p < 0.05$, Table 1). Additionally, postoperative swelling was significantly lower in the study group on all days ($p < 0.05$, Table 1). Postoperative wound healing was also better in the study group than in the control group, with statistically significant differences observed on days 1, 3, and 7 ($p < 0.05$, Table 2).

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

The neurosensory assessment for direction sense and pin-prick pain showed less impairment in the study group compared to the control group. The difference in neurosensory disturbance related to direction sense was statistically significant ($p < 0.05$) between the two groups on days 1 and 3 postoperatively (Tables 4 and 5). However, on postoperative days 7, 14, and 42, no significant difference was found between the two groups.

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 (%)
n = 30	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

Discussion

The success of open reduction and internal fixation (ORIF) of fractures is significantly influenced by the design of the surgical flap and the approach to the fracture site. An ideal incision provides direct and immediate access to the fracture, allowing for effective instrumentation while safeguarding adjacent vital structures. The vestibular incision is the traditional intra-oral approach for ORIF of mandibular body fractures. However, it does not eliminate common postoperative complications such as swelling, trismus, wound infection, and, notably, mental nerve paresthesia.

This clinical trial was designed to assess the effectiveness of an alternative incision (crevicular with release) in reducing these complications and simplifying surgical access compared to the vestibular incision. The randomized controlled trial (RCT) found that the crevicular incision improved surgical access and yielded more favorable outcomes.

Exposure of the Fracture Site

Unlike the vestibular incision, the crevicular incision with vertical release is positioned away from the mental nerve, eliminating the need for blind tissue dissection to avoid nerve traction. The anterior vertical release incision allows for tension-free retraction of the flap, offering excellent visibility of both the superior and inferior borders of the mandibular body (as shown in Fig. 4). This enhanced exposure supports the ideal fixation requirements of the body region, which differ according to the biomechanical forces acting on the three anatomical sections of the body: two miniplates for the anterior and posterior body and one for the mid-body. The crevicular incision also facilitates the visualization of basal triangle and oblique fractures, where the fracture's superior and inferior limits are distant. Furthermore, the incision can be extended if needed and helps in performing osteotomies for managing malunited fractures.

Another advantage of the crevicular incision is that it allows easier flap reflection, as there are no vital structures between the incision site and the fixation area. In contrast, the vestibular incision requires dissection from below, crossing the mental foramen to reach the osteosynthesis line, which is located above the mental foramen in the mid-body region.

Regarding exposure of the fracture site, the crevicular incision offers the following advantages over the traditional vestibular approach:

1. The crevicular incision provides a more direct approach to the bone in a subperiosteal plane, beginning at the gingival sulcus. In contrast, the vestibular approach requires an incision at the mucosal level, followed by dissection through the submucosal plane and the peri-oral musculature. The crevicular approach also facilitates easier reattachment of the muscles and restoration of perioral function, as all dissection is confined to the subperiosteal plane, avoiding separation or transection of any muscles.
2. The immediate sub-periosteal approach provided by the crevicular incision offers a more comfortable plane for accessing the mental neurovascular bundle. This approach is more straightforward and less risky compared to the vestibular approach, where extra caution is needed when making incisions near the mental foramen and identifying the neurovascular bundle.
3. The crevicular approach also offers a significant advantage when dealing with severely displaced or telescoped fractures that require extensive manipulation, either manually or with instruments, to restore proper alignment. In a vestibular incision, the band of attached gingiva to the alveolar process can limit the extent of manipulation and may sometimes tear due to its lack of elasticity, slowing down healing. In contrast, the crevicular approach provides full exposure of the fracture, including the alveolar bone where the fracture communicates with the oral cavity, allowing for easier manipulation without the restriction caused by the alveolar mucosa.

Postoperative Swelling and Trismus

Following intra-oral surgeries, patient discomfort peaks in the first few postoperative days, typically characterized by pain, swelling, and trismus, which significantly affect quality of life. Various pharmacological methods, such as nonsteroidal anti-inflammatory drugs (NSAIDs) and steroids, have been used to manage discomfort, though they can have dose-dependent or non-dose-dependent side effects. Topical treatments have also shown success in improving patient comfort. Non-pharmacological methods like compression bandages, kinesiology tapes, and drains can help minimize swelling, although they have limitations. More innovative approaches, such as lasers and cryosurgery, have been explored, but most techniques only alleviate symptoms after the inflammatory process has started. Research suggests a strong correlation between postoperative discomfort and intraoperative tissue manipulation, leading to attempts at minimizing tissue dissection or manipulation through surgical modifications. In this study, swelling was significantly reduced in the study group, which can be attributed to several factors:

1. Less tissue dissection compared to the vestibular approach.
2. The use of keratinized mucosa for the incision, which is less prone to inflammatory edema.
3. Better flap approximation, which eliminates dead space.
4. The vertical release incision, which facilitates drainage of any edema or hematoma.

Postoperative Healing of Surgical Wound

Wound healing was notably better in the study group, with no instances of plate exposure due to infection or dehiscence, as the miniplate was positioned away from the incision line and adequately covered by mucoperiosteum. In contrast, the miniplates in the control group were placed directly under the vestibular incision, where food debris and fluids may accumulate, increasing the risk of infection and delayed healing. The vestibular incision, passing through mobile mucosa, predisposes to edema accumulation and inhibits proper flap approximation to the bone. Additionally, the study group benefited from wound closure using keratinized mucosa, which is more resilient to injury compared to the delicate, non-keratinized mucosa of the vestibular approach, reducing the likelihood of wound dehiscence.

Neurosensory Impairment

Neurosensory impairment is a common issue in patients with mandibular body trauma, as the inferior alveolar nerve transitions to form the extra-bony mental branch in this region. Such injuries can occur either from the trauma itself or as a result of the surgical procedure. Postoperative mental nerve injury can be troublesome for patients, particularly when prolonged, and has led to legal action in many cases. One goal of this study was to evaluate and compare the incidence of postoperative neurosensory impairment between the two surgical approaches. Patients with preoperative paresthesia were excluded from the study to specifically assess iatrogenic injury. Neurosensory impairment can vary in severity, ranging from neuropraxia (compression during fracture reduction) to more severe injuries (tractional forces during flap elevation or nerve transection). Excessive tissue manipulation and a surgeon's inexperience are major contributing factors to postoperative paresthesia. In this study, there were no cases of neurotmesis (nerve transection), and no permanent nerve damage was observed in either group. The study group showed negligible sensory impairment, likely due to minimal tissue dissection and gentle handling of the mental nerve. The crevicular incision reduced the risk of nerve damage compared to the vestibular approach, even for less experienced surgeons.

Pal et al. suggested a curvilinear modification of the vestibular incision near the premolar region to reduce mental nerve injury, but this does not eliminate the disadvantages of the conventional vestibular approach.

Gingival Position

A concern with the crevicular incision is the potential impact on aesthetics, specifically gingival recession and periodontal health. To assess this, the gingival position and periodontal health of the teeth involved were evaluated using Miller's scale. No statistically significant differences were found between pre- and post-surgical gingival positions up to the 14th postoperative day.

Conclusion

This study highlights the clear advantages of the crevicular incision over the vestibular incision in reducing postoperative swelling, pain, and trismus, along with improved mouth opening and wound healing. Additionally, the crevicular incision, being positioned away from the mental nerve, eliminates the risk of nerve injury, making it a valuable technique for inexperienced surgeons. The crevicular approach avoids the need to transect the mentalis muscle, simplifying wound closure, whereas the vestibular approach carries risks such as loss of vestibular depth and potential injury to the facial artery. The only drawback of the crevicular incision is the additional time required for suturing to reposition the flap.

The flap reflection and wound closure after a crevicular incision may be difficult when archbars are applied, but this inconvenience can be resolved by using eyelets or inter-maxillary fixation (IMF) screws for the fixation.

In conclusion, the crevicular incision with vertical release is a highly effective approach for treating fractures of the mandibular body. It provides excellent exposure of both the superior and inferior borders of the mandible, facilitating open reduction and internal fixation (ORIF) while minimizing postoperative complications.

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