

Infralingular Versus Supralingular Medial Osteotomy in Sagittal Split Osteotomy of the Mandible: A Randomized Control Study

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Purpose: A recently proposed modification of the sagittal split osteotomy (SSO) of the mandible places the horizontal medial cut ‘low and short’ of the lingula. The purpose of the study was to answer the following clinical question: Among patients undergoing mandibular setback procedures (≤ 8 mm) via SSO, does the placement of the medial horizontal osteotomy below the lingula (infralingular), when compared to placement above the lingula (supralingular), results in different neurosensory, bite force, and range of motion outcomes?

Materials and Methods: This was a single-center, double-blind, parallel-group study among patients undergoing mandibular setback by SSO (≤ 8 mm), between January 2021 and September 2022. Patients were randomly allocated in a ratio of 1:1 to the supralingular (control) and the infralingular (study) group. Primary outcome variables included neurosensory disturbance of the inferior alveolar nerve based on clinical neurosensory testing and severity graded using Zuniga and Essick’s protocol, bite force, and maximum mouth opening evaluated postoperatively during the first week (T1), first month (T2), and third month (T3) of follow-up. Secondary outcome measures included the incidence of a bad split and distal segment interferences intraoperatively. Association between the variables was assessed using Pearson chi-squared test or Fisher’s exact test based on the expected observations. A *P* value of $\leq .05$ was considered statistically significant.

Results: A total of 29 patients (58 osteotomies) were included in the study. Group 1 consisted of 15 patients (9 females and 6 males) with a mean age of 26.4 years. Group 2 consisted of 14 patients (8 females and 6 males) with a mean age of 25.9 years. Patients with severe neurosensory disturbance of the inferior alveolar nerve were more common in group 2 ($n = 15$, 53.6%) than group 1 ($n = 4$, 13.3%) at T1 (*P* value = .0001) and insignificant between the two groups at T2 (*P* value = .63) and T3 (*P* value = .99). Comparison of maximum mouth opening between the two groups at T1 (*P* value = .535), T2 (*P* value = .934), and T3 (*P* value = .703) and bite force at T1 (*P* = .324), T2 (*P* = .113), and T3 (*P* = .811) was not significant.

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Conclusion: Both SSO techniques have similar clinical outcomes among patients having mandibular setbacks (≤ 8 mm) for the variables studied.

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The sagittal split osteotomy (SSO) of the mandible remains the workhorse orthognathic procedure for three-dimensional repositioning of the mandible. Ever since introduced by Obwegeser and Trauner,¹ the surgical procedure has undergone considerable modifications for reducing bad splits and injury to the inferior alveolar nerve (IAN). The modification by Dalpont aimed to increase the surface area of bony contact and hence the vertical (lateral) osteotomy was placed further anteriorly at the molars.² Later, Hunsuck proposed the idea to limit the posterior extension of the medial (horizontal) osteotomy just past the lingula.³ Therefore, the osteotomy terminated at the fossa behind the lingula rather than extending until the posterior border of the ramus of the mandible. Additional osteotomy of the inferior border for complete fracture was proposed by Wolford and Davis.⁴

The medial osteotomy technique conventionally followed is where the osteotomies are placed 2-3 mms above and extending 4-5 mms beyond the lingula (supralingular technique).^{5,6} Posnick et al., proposed a modification of the medial osteotomy, placed below and ended just short of the lingula (infralingular technique), to avoid bad splits and posterior interferences, especially during a mandibular setback.⁷ This overcomes the disadvantage of the Hunsuck modification where the fracture may inadvertently propagate toward the condylar process and ensures broad bony contact as well.⁷ The same technique of osteotomy was performed by Susarla et al., in patients with atypical ramus morphology and was found to be reliable.⁸ Concerns about the IAN remaining in the proximal segment when using this infralingular technique and the neurosensory disturbances (NSDs) that follow the procedure exist. Overzealous attempts to distalise the IAN are unnecessary and there has been no sensory disturbance in patients who underwent SSO with the nerve maintained in the proximal segment.^{7,9} However, clinical trials that compare the two techniques of medial osteotomy and evaluate the postoperative sequelae do not exist in the literature.

The purpose of the study was to answer the following clinical question: Among patients undergoing mandibular setback procedures (≤ 8 mm) via an SSO, does the placement of the medial horizontal osteotomy below the lingula (infralingular), when compared to placement above the lingula (supralingular), results in different neurosensory, bite force, and range of motion outcomes? We hypothesised that, 1)

the modified medial osteotomy technique (infralingular) can be used safely without permanent NSD to the IAN in all patients requiring mandibular setback (≤ 8 mm) and 2) posterior/distal segment interferences during setback of the mandible are less with the infralingular technique. The specific aim of the present study was to compare the clinical outcomes such as NSD of the IAN, maximum mouth opening, and bite force between the two horizontal medial osteotomy techniques postoperatively.

Materials and Methods

STUDY DESIGN

This randomized study was conducted at the Department of Oral and Maxillofacial Surgery of our institution between January 2021 and September 2022. The study was registered and approved by the Institutional Review Board of Government Dental College, Kottayam (IEC/M/24/16/DCK). The study was carried out following the principles in the Declaration of Helsinki. A written informed consent from each participant was obtained for the study.

The study sample consisted of patients who reported with dentofacial deformities, requiring SSO setback with or without other orthognathic procedures. To avoid possible bias, only those patients with dentofacial deformities requiring SSO mandibular setback (symmetric/asymmetric setback with or without concomitant maxillary orthognathic procedures) were included in the study. The exclusion criteria were as follows: 1) patients aged less than 18 years, 2) patients in whom the required setback was > 8 mms, 3) patients requiring chin correction with genioplasty concurrently, 4) patients with temporomandibular joint disorders, 5) patients with atypical ramal morphology in cone-beam computed tomography (CBCT), 6) patients under medication for any psychiatric illness, 7) patients with unrealistic expectations, and 8) patients who did not consent to be a part of the study.

SAMPLE SIZE CALCULATION

The two groups of patients who received the intervention were group 1: the control group or the supralingular medial osteotomy group, and group 2: the study group or the infralingular medial osteotomy group. Using nMaster 2.0, based on a previous study¹⁰ showing NSD after conventional SSO to be 60%,

assuming 5% change by infralingular method, 80% power, and 95% confidence interval (CI), the sample size was calculated as 18 patients (36 osteotomies) in each group. Due to feasibility, the study included all patients who fulfilled the inclusion criteria during the study period.

STUDY VARIABLES

The primary objectives were to compare the NSD of the IAN, maximum mouth opening, and bite force postoperatively and secondary objectives were to compare the incidence of a bad split, and distal segment interferences intraoperatively. The other variables such as age, sex, amount of mandibular setback required, status of the IAN after splitting the mandible, concomitant procedures, and complications if any were also recorded.

STUDY PROCEDURE

Simple randomization based on the lot system with an allocation ratio of 1:1 was followed in the study. The randomization sequence was generated using Random Allocation (Windows software version 2.0) and the allocation was concealed in opaque sealed envelopes. The study was double-blinded: the outcome assessor who evaluated the patient during follow-up was blinded to the osteotomy performed for that particular patient and the patients were blinded to the osteotomy technique executed.

All patients who participated in the study were operated upon by two senior consultant surgeons of the institution. Mandibular third molars were extracted at least 6 months before the planned surgery to avoid any bias in the incidence of bad splits between the two groups. The conventional SSO technique with supralingular osteotomy (medial cuts placed above the lingula) and the modified technique (medial cuts placed below and ended short of the retrolingular fossa) with or without concomitant orthognathic procedures were performed bilaterally under general anesthesia. In the present study, the deepest concavity along the transition of the ascending ramus from the retromolar region was taken as the reference point and the medial osteotomy was placed just above this reference point (Fig 1) for the infralingular technique. This corresponds to a point just above the mandibular plane of occlusion. The optimal anteroposterior length of the osteotomy was custom-determined based on the preoperative CBCT, to terminate a minimum of 5 mms ahead of the lingula and marked accordingly on the surgical bur. The IAN was distalized gently with an elevator whenever the nerve was found in the proximal segment to avoid possible kinking during posterior repositioning of the mandible. Intermaxillary fixation was done after mobilizing the segments

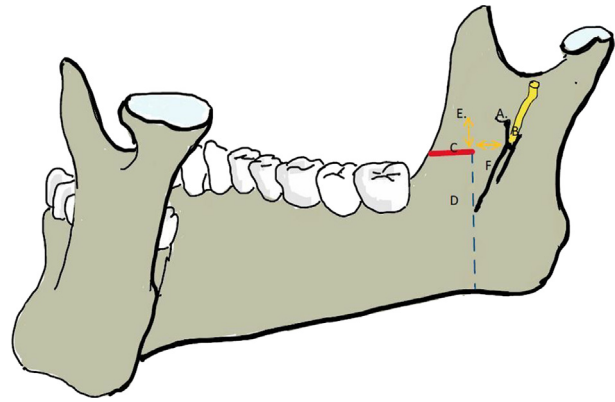


FIGURE 1. Pictorial representation of the technique showing: lingula (A), mandibular foramen (B), infralingular osteotomy (C), fracture line (D), vertical position of the infralingular cut from the lingula (E), and anteroposterior extent of the cut terminating at least 5 mms anterior to the line along the lingula (F).

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with an interocclusal splint, followed by fixation with titanium miniplates and monocortical screws. Postoperatively, all patients were given guiding elastics from the third day and discharged on the fifth day.

DATA COLLECTION

Clinical neurosensory testing (CNT) to identify the NSD of the IAN included various tests as follows: contact detection, thermal discrimination, two-point discrimination, and brush-stroke directional identification. Based on CNT, the severity of NSD of the IAN was graded using Zuniga and Essick's protocol¹¹ bilaterally as no impairment, mild/moderate/severe impairment, and complete anesthesia, by an independent assessor throughout the study. The interincisal distance was measured with a measuring scale for maximal mouth opening without pain in both the groups at baseline (before surgery), T1, T2, and T3. Bite force was evaluated using a jaw bite force measurement device (GM10 device, Japan) at molars on both sides and the average of both sides (Newton [N]) was taken for a patient at baseline (before surgery), T1, T2, and T3. Intraoperatively, the position of the IAN, the incidence of a bad split, and distal segment interference were noted. Radiographs (panoramic radiographs or CBCT) were taken at T1 to evaluate the postoperative status and ascertain the position of the medial osteotomy cuts (Figs 2 and 3).

DATA ANALYSIS

Data were entered in Microsoft Excel and analysed using Statistical Product and Service Solution software (IBM SPSS Statistics for Windows, Version 22.0. Armonk, New York: IBM Corp). Categorical variables

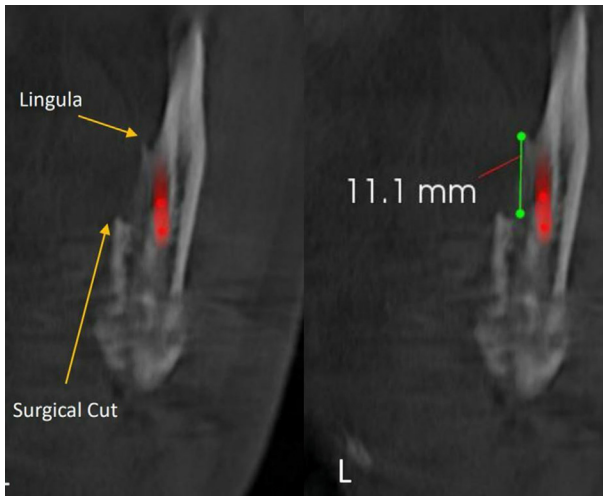


FIGURE 2. The vertical position of the infralingular medial osteotomy in relation to the lingula as seen in the coronal section of the CBCT.

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were expressed in frequency (percentage) and numeric variables were expressed using mean with standard deviation or median with interquartile range based on the distribution. Association of the nerve status during surgery, NSD, mouth opening, and bite force with the type of technique was assessed using Pearson chi-squared test or Fisher's exact test based on the expected observations. A P value of $\leq .05$ was considered statistically significant. Per-protocol analysis was carried out in this study.

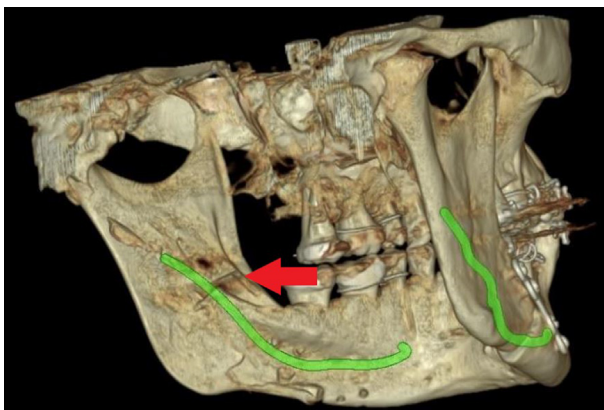


FIGURE 3. Three-dimensional view of the medial side of the mandible postoperatively showing the position of the lingula and the osteotomy (red arrow).

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Results

The recruitment of participants for the study and allocation to each intervention is shown in the Consolidated Standards of Reporting Trials flow diagram (Fig 4). A total of 29 patients (58 osteotomies) were included in the study. The baseline characteristics of the patients are given in Table 1.

The mean mandibular setback in group 1 and 2 was 5.60 and 5.71 mm, respectively. The status of the IAN during surgery is given in Table 2. The incidence of the IAN in the proximal segment was higher with the infralingular osteotomy at 57.1% ($n = 16$) than with the supralingular osteotomy at 13.3% ($n = 4$). The association of the type of medial osteotomy with the position of the IAN during surgery was found to be statistically significant (P value = .002). CNT after surgery revealed that patients with severe NSD of the IAN were more common in group 2 ($n = 15$, 53.6%) than in group 1 ($n = 4$, 13.3%) at T1 (P value = .0001). Comparison between the two groups for NSD of the IAN at T2 (P value = .63) and T3 (P value = .99) did not reveal any statistical significance (Figs 5 and 6).

Descriptive data regarding mouth opening and bite force are given in Table 3. A comparison of maximum mouth opening between the two groups at T1 (P value = .535), T2 (P value = .934), and T3 (P value = .703) and bite force at T1 ($P = .324$), T2 ($P = .113$), and T3 ($P = .811$) did not reveal any statistical significance. The concomitant maxillary orthognathic procedures performed in group 1 (Lefort 1 osteotomy, $n = 2$) and group 2 (anterior maxillary osteotomy, $n = 1$, and U-shaped osteotomy, $n = 1$) were not comparable.

The incidence of a bad split in our study was 3.3% ($n = 1$) (fracture extending to the condylar process) in group 1 and none in group 2. Two patients in group 1 and 1 patient in group 2 required a mandibular setback of 8 mm. Both the cases in group 1 had distal segment interferences during SSO rotation of the mandible, requiring an additional osteotomy through the distal segment. However, a comparison between the two groups concerning the incidence of a bad split and distal segment interferences during the setback of the mandible was not statistically significant.

Discussion

The purpose of the study was to answer the following clinical question: Among patients undergoing mandibular setback procedures (≤ 8 mm) via an SSO, does the placement of the medial horizontal osteotomy below the lingula (infralingular), when compared to placement above the lingula (supralingular), results in different neurosensory, bite force, and range of motion outcomes? We hypothesized that 1)

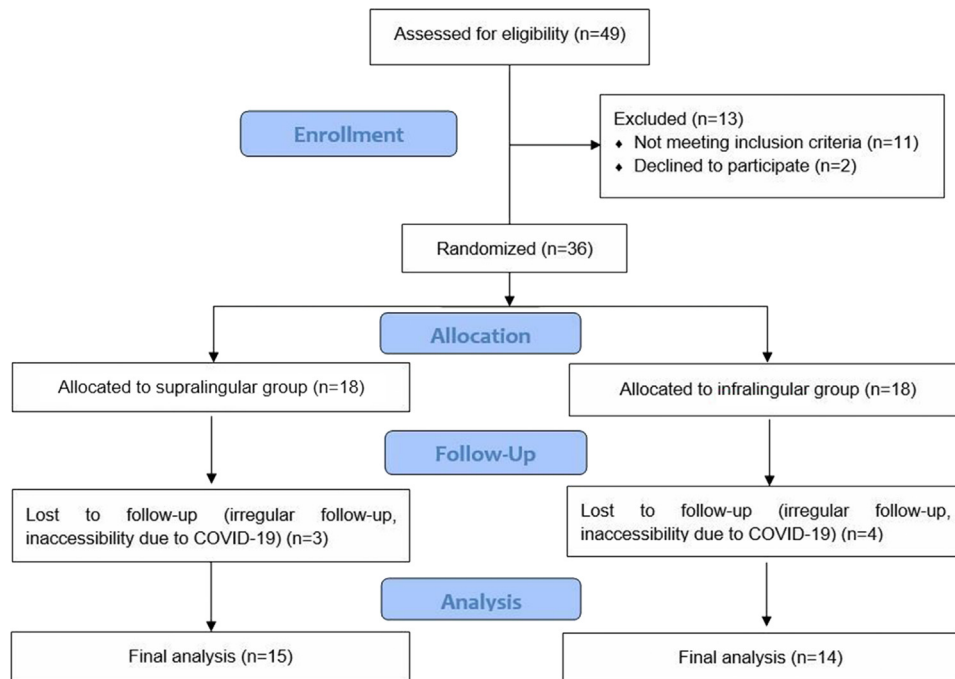


FIGURE 4. CONSORT flow chart.

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the modified medial osteotomy technique (infralingular) can be used safely without permanent NSD to the IAN in all patients requiring mandibular setback (≤ 8 mm) and 2) posterior/distal segment interferences during setback of the mandible are less with the infralingular technique. The specific aim of the present study was to compare the clinical outcomes such as NSD of the IAN, maximum mouth opening, and bite force between the two horizontal medial osteotomy techniques postoperatively.

The SSO of the mandible has been used for decades in the surgical management of mandibular dentofacial deformities. Placement of the horizontal medial osteot-

omy above the lingula propagates a bad split, thus affecting the healing and the long-term outcomes.⁷ Furthermore, posterior interferences during mandibular setback by SSO, especially in cases that require correction of roll and yaw may lead to malalignment of the proximal and distal segments.^{7,12} This mandates the need to perform a third osteotomy through the distal segment, just posterior to the last molar.¹³ Therefore, Posnick modified the medial osteotomy to a rather unconventional position, below the lingula. This osteotomy was placed below and terminated just short of the lingula anteroposteriorly.^{7,12} This was later studied by Susarla et al, in patients with atyp-

Table 1. DEMOGRAPHIC DATA OF THE STUDY

Parameter	Supralingular Group	Infralingular Group
Age (Mean Years)	26.4 ± 5.21	25.9 ± 5.43
Gender		
i) Males (n)	6	9
ii) Females (n)	6	8
Osteotomies performed	30	28
Setback (mean mms)	5.60 ± 1.52	5.71 ± 1.24

Note: Data presented as mean ± standard deviation. Abbreviation: n, size of the sample.

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Table 2. ASSOCIATION BETWEEN THE OSTEOTOMY TECHNIQUES AND NERVE STATUS DURING SURGERY

Group	Nerve Not Seen (n, [%])	Nerve in the Proximal Segment (n, [%])	Nerve in the Distal Segment (n, [%])	Total
Supralingular	8 (26.7)	4 (13.3)	18 (60.0)	30 (100)
Infralingular	5 (17.9)	16 (57.1)	7 (25.0)	28 (100)

Abbreviations: n, size of the sample; %, percentage.

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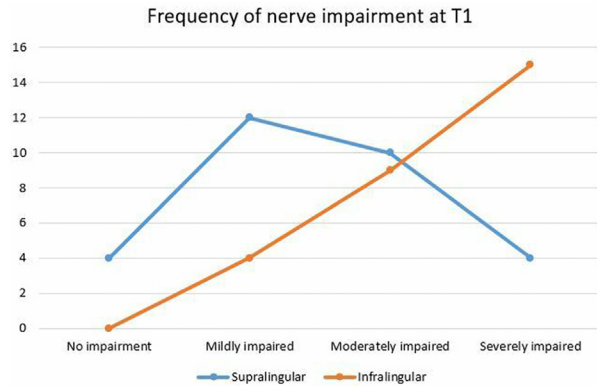


FIGURE 5. Neurosensory disturbance at T1.

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ical ramus morphology and concluded that the infralingular technique of SSO may be employed dependably in patients with thin ramal width.⁸ It was also found that the newer technique carries less risk of bad split and excludes the need for additional osteotomy. The safe anteroposterior extent of the osteotomy was further defined by Ettinger et al, as ideally < 15 mms based on the proximity of the IAN to the medial cortex.¹⁴ The infralingular technique has the additional advantage of eliminating the posterior interferences, promoting even approximation across the osteotomy sites. This also ensures the smooth positioning of the condyle within the glenoid fossa.^{7,12}

However, the perturbing aspect of the infralingular technique is the unorthodox position of the IAN during the separation of the proximal and distal segments. In the present study, the IAN was more likely to be contained within the proximal segment in the infralingular group than in the supralingular group (P value = .002). Contrary to the consensus and contem-

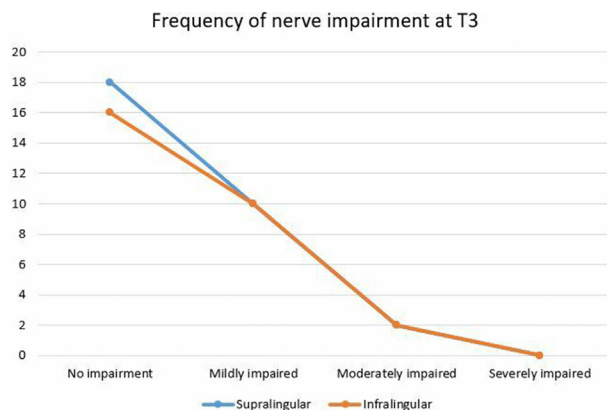


FIGURE 6. Neurosensory disturbance at T3.

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porary practice to free the tangled nerve from the proximal segments, Susarla et al⁹ confirmed the futility of surgical manipulation to distalize the IAN from the proximal segment. The neurosensory function was not affected in those patients where the IAN was maintained in the proximal segment.⁹ However, maintaining the nerve within the proximal segment during the setback of the distal segment may contribute to IAN injury due to kinking of the nerve.⁹ This was the rationale behind distalizing the IAN in the present study. Therefore, the difference in NSD of the IAN between the two groups at T1 could be related to the act of manipulating the nerve rather than the split itself. Perhaps our attempts to distalize the proximally positioned IAN among patients in group 2 ($n = 13$) have caused neuropraxic injury to the IAN, thereby leading to an increased NSD in the first week of follow-up. This is confirmed by the absence of any significant difference in NSD between the two groups at T2 and T3. Furthermore, none of the patients had persistent/severe NSD of the IAN after 3 months of follow-up. In the present study, patients with NSD were kept under observation and no active intervention was required. Early improvement in functional outcomes such as mouth opening and bite force was anticipated due to minimal muscle stripping with the modified technique. However, a comparison between the two groups did not yield statistical differences in the present study.

A bad split in mandibular orthognathic surgery is a rare but unfortunate event that imperils the healing and jeopardizes the outcome of surgery.⁷ In our study, there was 1 case (group 1) of fracture propagation to the condyle which was managed by closed treatment with intermaxillary fixation for 4 weeks. Two cases in group 1 that required 8 mms of mandibular setback had distal segment interferences endorsing an additional osteotomy to circumvent the interferences during rotation of the distal segment. A similar case in group 2 had no interference during mandibular repositioning. Although the incidence of bad split and distal segment interferences was high in group 1, they were not statistically significant on comparing the two groups. This finding was consistent with the results of Zamiri et al¹⁵ who concluded that the occurrence of bad splits would probably depend on the thickness of the ramus rather than the extension of the medial osteotomy cuts placed. The feasibility of bicortical fixation with the infralingular technique has been a concern due to the limited availability of the lingual portion of the distal segment.⁷ There was no such difficulty during the present study as monocortical screws were used for all the patients.

Limitations of the study include a smaller number of patients enrolled, selection bias, and inherent bias in the study due to the incidence of bad splits being

Table 3. BITE FORCE AND MOUTH OPENING AT T1, T2, AND T3

Parameter	Time	Supralingular (Mean N)	Infralingular (Mean N)
Bite force	Before surgery	328.62 ± 22.74	323.91 ± 41
	T1	191.99 ± 14.89	183.91 ± 20.05
	T2	232.71 ± 17.39	221.97 ± 22.88
	T3	312.69 ± 24.57	299.95 ± 24.48
Mouth opening	Before surgery	52.27 ± 4.26	53.21 ± 5.10
	T1	36.73 ± 4.93	37 ± 4.27
	T2	46.27 ± 5.35	47.57 ± 5.63
	T3	51.93 ± 4.59	53 ± 4.96

Note: Data presented as mean ± standard deviation.

Abbreviations: N, Force in Newton; T1, one week after surgery; T2, one month after surgery; T3, three months after surgery.

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rare. The short-term follow-up is not a substantial limitation, as the study intended to analyse the NSD rather than the functional sensory recovery of the IAN, which would ideally require a longer follow-up.

A split-mouth trial would allow each patient to serve as their own control, mitigate the effects of age and gender, and allow for a symmetric sample. However, assorting clinical outcomes such as mouth opening and bite force to each technique will not be feasible as these parameters are influenced bilaterally. Therefore, the same osteotomy was performed within each patient rather than performing the supralingular approach on one side and the infralingular approach on the other. Zuniga and Essick's algorithm¹¹ was used in the present study for evaluating NSD as the protocol is optimal and provides staging which is easier for evaluating trigeminal nerve injuries. Studies that use subjective tests such as visual analog scale and advanced testing such as electrical stimulation analysis and electromyography to evaluate the NSD of the IAN are recommended. Further trials involving a larger sample size are required, with emphasis on the selection of patients (larger mandibular setbacks/advancements), variables such as bone healing, stability, and neurosensory evaluation with long-term follow-up taken into consideration.

In conclusion, with reference to NSD of the IAN in conjunction with SSO mandibular setback, by 3 months after surgery, both infralingular and supralingular techniques of medial osteotomy have similar outcomes. There was no significant difference in maximum mouth opening and bite force between the two groups at any period. The incidence of a bad split and distal segment interference was high with the supralingular technique, although not significant when comparing the two groups. Therefore, both SSO techniques have similar clinical outcomes among patients having mandibular setbacks (≤ 8 mm) for the variables studied.

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