ORIGINAL ARTICLE

Efficacy of Serratiopeptidase after Surgical Removal of Mesioangular Mandibular Third Molar- A Randomized Controlled Trial

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Abstract

Background: Surgical extraction of mesioangular lower third molars commonly results in restricted mouth opening after surgery, which can significantly affect recovery.

Objectives: To determine the effectiveness of serratiopeptidase in minimizing postoperative trismus after surgical extraction of mesioangular mandibular third molar.

Materials and Methods: A randomized controlled trial was carried out in our Department of Oral and Maxillofacial Surgery, Sharif Medical City Hospital, Lahore from 6 June 2025 to 2 September 2025. A combined total of 110 patients (aged 18–50 years) were allocated randomly to two treatment groups using a single-blind lottery-based assignment: Group A received serratiopeptidase 10 mg twice daily for five days along with standard therapy, which consisted of oral paracetamol (500 mg every 8 hours) and Enziclor mouthwash (chlorhexidine). Group B received only the standard therapy. Exclusion criteria included concurrent oral surgical procedures, impactions close to the inferior alveolar nerve, anticoagulant use, smoking, pregnancy or lactation, peptic ulcer disease, or recent NSAID use within the past week. Measurement of mouth opening was recorded preoperatively and on postoperative days 1, 3, and 5 using the maximum interincisal distance in millimeters.

Result: At baseline, both groups had comparable mouth opening (42.8 ± 4.3 mm vs. 43.1 ± 4.1 mm, $p = 0.71$). On 1st postoperative day, Group A had significantly higher mouth opening than Group B (28.6 ± 5.2 mm vs. 24.9 ± 4.8 mm, $p < 0.001$). This difference remained significant on day 3 (32.9 ± 5.0 mm vs. 28.7 ± 4.9 mm, $p < 0.001$) and day 5 (37.1 ± 5.6 mm vs. 30.5 ± 5.3 mm, $p < 0.001$). More patients in the serratiopeptidase group achieved clinically acceptable mouth opening (>35 mm) by day 5 as compared to controls (69.1% vs. 25.5%, $p < 0.001$).

Conclusion: The use of serratiopeptidase significantly reduces postoperative trismus and accelerates recovery following the surgical removal of mesioangular mandibular third molars. The consistent effectiveness and good safety record of the drug support its value as an adjunctive therapy in postoperative management. Further multicenter trials are recommended to confirm these findings.

Keywords: *Serratiopeptidase, Trismus, Mesioangular impaction, Mandibular third molar, Oral surgery*

Introduction

Extraction of mesioangular impacted third molar especially surgical extraction is probably the most common type of procedure done by an oral surgeon.[1] Although the procedure is regarded as routine, postoperative complications such as pain, facial swelling, and restricted mouth opening are frequently experienced. These symptoms result from tissue trauma, flap elevation, and bone removal during surgery, leading to inflammation and edema in the masticatory muscles. [2]

The subsequent limitation in mouth opening not only affects patient comfort and nutrition but also delays healing and routine oral hygiene maintenance. In a study it was found out that 73% of impacted third molar in mandible and 53% of them are mesioangular angulations. [3] Although removing the third molar surgically is a minor intervention but due to the area of the human body i.e. face and oral cavity makes it very sensitive which can lead to physical and psychological setbacks. Pain, swelling, and trismus are main drawbacks.[4]

In recent years many drugs used to suppress inflammation (i.e. NSAIDs, corticosteroids) but long-term use of them results in many adverse effects such as (abdominal discomfort, bleeding problems, renal problems, breathing discomfort). [5] Talking about Serratiopeptidase, it is a proteolytic enzyme that is de-

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rived from Serratia marcescens and serves as the active salt rather than a brand-name drug. Inflammatory mediators such as bradykinin and histamine are hydrolyzed and fibrin deposits are dissolved, resulting in reduced edema and inflammation.[6]

Clinically, it is used to relieve postoperative swelling, pain, and trismus in oral and maxillofacial surgeries. In the previous study, mouth opening on day 5 was 36.55 ± 7.8 mm in the Serratiopeptidase group and 29.02 ± 7.5 mm in the control group. Swelling measurements were 104.73 ± 13.5 mm in the Serratiopeptidase group and 106.19 ± 9.7 mm in the control group. [6]

During the 1950s in the United States, some enzymes such as bromelain, trypsin, and chymotrypsin were used parenterally for post-surgical inflammation. Serratiopeptidase was first introduced in Japan and was then used parenterally later on enteric coated formulation was also available. Research in Japan and Europe in 80s and 90s found out Serratiopeptidase to be most effective anti-inflammatory enzyme available.[7] Serratiopeptidase is a proteolytic enzyme which has extracellular metalloprotease and helps combating inflammation, edema and is fibrinolytic.[5]

It is produced by the enterobacterium Serratia sp., which is not pathogenic. The microbe was originally discovered in the silkworm gut, where it enables the degradation of the cocoon. It then has been in use for a long time to lessen pain and inflammation. [8]The usual recommended dose of serratiopeptidase for healthy individual is 10 mg B.I.D for 5 days.[6,9]

To address this knowledge gap, the efficacy of serratiopeptidase in reducing postoperative trismus following the surgical removal of mesioangular mandibular third molars was evaluated in this study. By comparing outcomes between patients receiving serratiopeptidase with standard therapy and those receiving standard therapy alone, the aim of this study is to determine whether the addition of serratiopeptidase leads to a measurable improvement in mouth opening and recovery.

To evaluate differences in mean mouth opening in those receiving Serratiopeptidase at a dose of 10 mg twice daily for a duration of five days along with standard treatment. In contrast to which, only standard therapy consisting of paracetamol and Enziclor mouthwash was administered to the control group for the reduction of trismus following the surgical removal of a mesioangular mandibular third molar. Mouth opening (trismus) was measured as the maximum interincisal distance (in millimeters) preoperatively and on postoperative days 1, 3, and 5.

Material and Methods

The Maxillofacial Surgery Department at Sharif Medical City Hospital, Jati Umrah, Lahore, served as the site for this randomized controlled clinical trial **(NCT02493179)** , which was conducted from 6 June 2025 to 2 September 2025. OpenEpi software was used to determine the sample size. At 80% power and a 95% confidence interval, a combined total of 110 patients (55 per group) were required. A previous study, in which the mean mouth opening on postoperative day 5 measured 36.55 ± 7.8 mm in the serratiopeptidase group and 29.02 ± 7.5 mm in the control group, was used as the basis for the sample size calculation.[6] Initially, a total of 160 participants were consecutively screened for the study. Out of these 110 participants meeting inclusion criteria and provided informed consent were selected. Then they were randomly assigned into two equal groups of 55 patients each using the lottery method to ensure random sequence generation. Allocation concealment was kept using sealed, opaque and sequentially numbered envelop to avoid influence over group selection details are given in figure 1.

The study employed a single-blind approach in which the evaluator was unaware of treatment allocation. The inclusion criteria are Patients aged 18–50 years, irrespective of gender, Presence of a mandibular third molar with mesioangular angulation. The exclusion criteria are Patients undergoing any additional oral surgical procedure simultaneously, Participants having roots of impacted 3rd molar near inferior alveolar canal, Patients on anticoagulant therapy, Pregnant or lactating women, Smokers, Participants with a previous history of peptic ulcer disease, Patients who had taken NSAIDs within the last week.

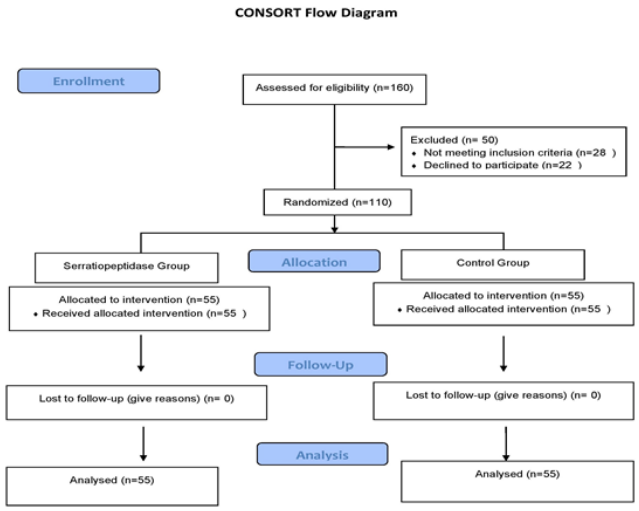

Figure 1: Consort Flow Diagram.

Prior to the commencement of data collection, ethical approval for the study **(SMDC/SMRC/245-22)** was obtained from the Institutional Review Board. Participants who satisfied the eligibility requirements were enrolled from the outpatient clinic. Each participant was provided with a clear explanation of the study objectives and procedures, after which written informed consent was obtained.

An orthopantomogram was performed to confirm mesioangular impaction and rule out cases with proximity to the inferior alveolar nerve. Demographic details (name, age, gender, contact information) and baseline mouth opening were recorded preoperatively on a structured pro forma along with the indication for extraction. Participants were randomly allocated into two equal groups using the lottery method.

Group A (case group) received serratiopeptidase, while Group B (control group) did not.

All the extractions were done using the standardized surgical procedure for removing the mesioangular impacted third molar. All the procedures were performed maintaining strict aseptic measures. Sterile gloves masks and drapes were used for every case and instruments were autoclave-Sterilized before every procedure. The surgical approach was initiated using a Ward's incision, followed by elevation of a full-thickness mucoperiosteal flap. Then Bone removal was performed around the mesial, buccal and distal surfaces of the third molar using slow speed handpiece along with round surgical bur and with copious normal saline irrigation and with high volume suction extending approximately 2 mm below the cementoenamel junction as to achieve maximum crown exposure. Where required, coronectomy of the crown was performed to provide a favorable extraction pathway.

After extraction, the bony margins were smoothed and the tooth socket was irrigated with 0.9% normal saline. Finally closure of the flap was done using 4-0 silk sutures. Patients were discharged the same day and were recalled for follow-up on 1st, 3rd and 5th postoperative day. The same oral surgeon performed all the surgical procedures with more than five years of postgraduate clinical experience to ensure procedural uniformity and reduce operator bias. Each patient received one gram of intravenous amoxicillin one hour before extraction. Postoperatively:

Group A (case): Serratiopeptidase (Danzin DS 10 mg BID for 5 days) + Paracetamol + Enziclor mouthwash.
Group B (control): Paracetamol + Enziclor mouthwash.
Mouth opening was evaluated by recording the maximum interincisal distance (in millimeters) before surgery and on postoperative days 1, 3, and 5 using a calibrated vernier caliper. The readings were recorded on a pro forma by a second-year postgraduate resident.

Statistical analysis was performed using SPSS software version 22.0, and descriptive statistics were computed for all study variables. Repeated measures ANOVA was applied to compare changes in mouth opening over time (preoperative, day 1, day 3, and day 5) between the two groups, assessing both main effects of treatment and time, as well as their interaction. Mauchly's test of sphericity was performed, and the Greenhouse–Geisser correction was applied when necessary. Post hoc Bonferroni tests were used for pairwise comparisons. This study followed the intention-to-treat principle, and as there were no missing data, complete-case analysis was performed. Mean differences and effect sizes for mouth opening are reported with 95% confidence intervals.A p-value of ≤ 0.05 was considered statistically significant.

Results

A total of 110 patients participated in this study where 55 patients were allocated to each group and no patient loss to follow-up (Table 1). The mean age was 29.6 ± 6.8 years in the serratiopeptidase group and 30.1 ± 7.2 years in the control group. The gender distribution was similar, with male patients comprising 58.2% of the sample.In the serratiopeptidase group and 56.4% in the control group. Baseline mouth opening was comparable between groups (42.8 ± 4.3 mm vs. 43.1 ± 4.1 mm; p = 0.71).

The prevalence of comorbidities, such as diabetes mellitus (7.3% vs. 9.1%), hypertension (5.5% vs. 3.6%), and smoking (9.1% vs. 10.9%), was evenly distributed between the groups. There was no statistically significant difference in baseline characteristics between the two study groups (p > 0.05).The primary indication for extraction was pericoronitis (50.9% vs. 49.1%), followed by caries of the adjacent second molar (25.5% vs. 23.6%) and other causes such as pain or prophylactic removal (23.6% vs. 27.3%).

Table-1 Demographic and Baseline Characteristics of Patients (n = 110)

Variable	Group A: Serratiopeptidase (n=55)	Group B: Control (n=55)
Age (years), mean ± SD	29.6 ± 6.8	30.1 ± 7.2
Gender, n (%) – Male	32 (58.2%)	31 (56.4%)
Gender, n (%) – Female	23 (41.8%)	24 (43.6%)
Baseline mouth opening (mm), mean ± SD	42.8 ± 4.3	43.1 ± 4.1
Diabetes mellitus, n (%)	4 (7.3%)	5 (9.1%)
Hypertension, n (%)	3 (5.5%)	2 (3.6%)
Smoking history, n (%)	5 (9.1%)	6 (10.9%)
Previous dental extraction, n (%)	18 (32.7%)	20 (36.4%)
Indication for extraction – Pericoronitis, n (%)	28 (50.9%)	27 (49.1%)
Indication for extraction – Caries of 2nd molar, n (%)	14 (25.5%)	13 (23.6%)
Indication for extraction – Other (pain, prophylaxis), n (%)	13 (23.6%)	15 (27.3%)

Baseline measurements of mouth opening were similar in both groups i.e, (42.8 ± 4.3 mm vs. 43.1 ± 4.1 mm; p = 0.71). On postoperative day 1, patients receiving serratiopeptidase had significantly higher mean mouth opening (28.6 ± 5.2 mm) compared to controls (24.9 ± 4.8 mm), with a mean difference of +3.7 mm (p < 0.001; Cohen's d = 0.74). This improvement persisted on day 3 (32.9 ± 5.0 mm vs. 28.7 ± 4.9 mm; mean difference +4.2 mm, p < 0.001; d = 0.85) and day 5 (37.1 ± 5.6 mm vs. 30.5 ± 5.3 mm; mean difference +6.6 mm, p < 0.001; d = 1.20) as shown in table 2 and figure 2.

Among males, the mean mouth opening was 37.5 ± 5.4 mm in the serratiopeptidase group compared to

Table-2. Comparison of Mouth Opening Between Groups

Time Point	Group A: Serratiopeptidase Mean ± SD	Group B: Control Mean ± SD	Mean Difference	Effect Size (d)	p-value
Preoperative (Day 0)	42.8 ± 4.3	43.1 ± 4.1	-0.3	0.07	0.71
Postoperative Day 1	28.6 ± 5.2	24.9 ± 4.8	+3.7	0.74	<0.001*
Postoperative Day 3	32.9 ± 5.0	28.7 ± 4.9	+4.2	0.85	<0.001*
Postoperative Day 5	37.1 ± 5.6	30.5 ± 5.3	+6.6	1.20	<0.001*

***p ≤ 0.05 considered statistically significant (Independent samples t-test).**

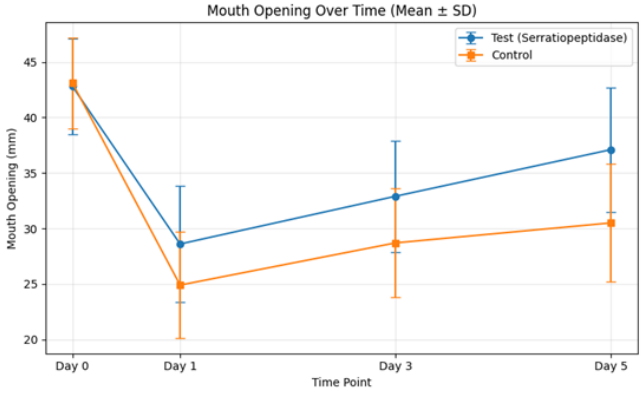

Figure 2: Postoperative mouth opening over time.

30.8 ± 5.2 mm in controls ($p < 0.001$, $d = 1.25$). Similarly, females in the serratiopeptidase group demonstrated greater recovery (36.6 ± 5.8 mm vs. 30.2 ± 5.5 mm; $p < 0.001$, $d = 1.15$). When stratified by age, patients aged 18–30 years and those aged 31–50 years both exhibited significantly better outcomes with serratiopeptidase ($p < 0.001$ for both comparisons), again with large effect sizes (>1.0) as shown in Table 3.

Table-3. Mouth Opening On 5th Post-Operative Day- A Stratified Analysis

Subgroup	Group A: Serratiopeptidase Mean ± SD	Group B: Control Mean ± SD	Effect Size (d)	p-value
Gender				
Male (n=63)	37.5 ± 5.4	30.8 ± 5.2	1.25	<0.001*
Female (n=47)	36.6 ± 5.8	30.2 ± 5.5	1.15	<0.001*
Age Group				
18–30 years (n=60)	37.8 ± 5.7	31.0 ± 5.3	1.20	<0.001*
31–50 years (n=50)	36.4 ± 5.5	30.0 ± 5.4	1.18	<0.001*

***p ≤ 0.05 considered statistically significant (Independent samples t-test).**

In both groups, the mouth opening decreased sharply from baseline soon after the extraction, but in the serratiopeptidase group, mouth opening decreased from baseline (42.8 ± 4.3 mm) to day1 (28.6 ± 5.2 mm) and then gradually improved by day 5 (37.1 ± 5.6 mm). While in the control group patients showed slower recovery, with mouth opening rising from 24.9 ± 4.8 mm on day 1 to only 30.5 ± 5.3 mm on 5th postoperative day as shown in figure 3.

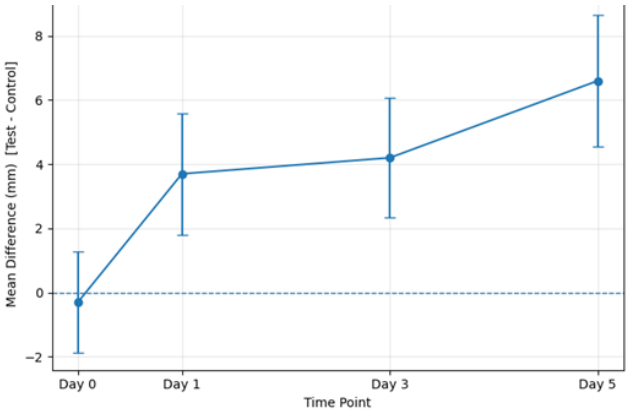

Figure 3: Mean difference in mouth opening with 95% CI

Table-4. Intragroup Comparison of Mouth Opening Over Time

Group	Pre-op (Day 0) Mean ± SD	Day 1 Mean ± SD	Day 3 Mean ± SD	Day 5 Mean ± SD	p-value (ANOVA, repeated measures)
Serratiopeptidase (n=55)	42.8 ± 4.3	28.6 ± 5.2	32.9 ± 5.0	37.1 ± 5.6	<0.001*
Control (n=55)	43.1 ± 4.1	24.9 ± 4.8	28.7 ± 4.9	30.5 ± 5.3	<0.001*

***Statistically significant reduction and recovery trend observed across time points.**

Discussion

This study demonstrates that serratiopeptidase substantially reduces postoperative trismus after surgical removal of mesioangular mandibular third molars. The results demonstrate that mouth opening greatly improves on post-operative days 1, 3, and 5 in patients taking serratiopeptidase as compared to the control group. The outcome is most significant on day 5, where the difference is 7 mm higher in the serratiopeptidase group than in the control group, with large effect sizes d (>0.8) which indicate not only statistically but also a clinically meaningful

benefit.

A difference of 6-7 mm by day 5 suggests improved post-operative functions such as oral hygiene and early return to normal activities which are relevant for the patient comfort. It also shows that it has anti-inflammatory and fibrinolytic properties as shown by a previous study.[10]Several studies have shown that serratiopeptidase exhibits a significant effect in controlling postoperative facial swelling and trismus in oral surgery.

In contrast to corticosteroids such as dexamethasone which also has significant anti-inflammatory benefits but its use may be limited in patients with systemic comorbidities due to their potential adverse effects. Therefore, serratiopeptidase may represent a clinically relevant non-steroidal alternative, particularly when corticosteroid therapy is contraindicated. [11,12] There are several studies which explain the mechanism of action of serratiopeptidase.

In addition to other postoperative approaches, in contrast to NSAIDs, which inhibit cyclooxygenase pathways, serratiopeptidase works by enzymatically degrading inflammatory mediators, i.e., bradykinin and serotonin, as well as histamine. [13] This, in turn, increases vascular permeability, thereby reducing pain and edema which are the main contributors to trismus.

Additionally, it also has fibrinolytic activity, which helps in the drainage of protein-based inflammatory debris and aids in tissue repair at the surgical site. This is why jaw mobility, mouth opening, and recovery improve. In our trial, it was noted that the results were consistent across all age groups and genders and were not specific to any demographic profile, which strengthens and generalizes the findings as also seen in other postoperative interventions.[14]

Moreover, in our study, the serratiopeptidase group showed clinically acceptable mouth opening, that is, more than 35 mm by the 5th postoperative day, which highlights its clinical relevance beyond statistical significance similar to other methods used to reduce postoperative sequelae. [15-18]

In spite of this, there are certain limitations to this study. The first is that the study is limited to measuring the results of trismus upto 5th postoperative day. Long-term follow-up could provide more information about its effect on recovery and any late complications. The second is that it is limited only to mesioangular mandibular wisdom tooth extractions, and other types of impacted teeth or surgical interventions are not included, which indicates that the results are not generalizable. The third limitation is that this study does not compare serratiopeptidase with corticosteroids, which are considered the gold standard in reducing inflammation. Therefore, a three-armed study would better define the role of serratiopeptidase.

A limitation of this study is the absence of a structured record of adverse events therefore, safety conclusions should be interpreted with caution. Finally, this study does not include the pain scores, which limits a broader understanding of its impact on patient experience.

Conclusion

In our study, it was concluded that serratiopeptidase is effective in reducing trismus postoperatively after surgical removal of mesioangular mandibular third molars. However longer follow-up and multicenter trials are necessary to confirm these findings.

CONFLICT OF INTEREST: None

FUNDING SOURCES: None

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Author Contributions

1. **Sheheryar Khan**: Conceptualization of the study, study design, and overall supervision.
2. **Uzair Bin Akhtar**: Surgical procedures, patient management, and methodology development.
3. **Farhan Riaz**: Data collection and postoperative follow-up.
4. **Nadia Saleem**: Literature review and assistance in manuscript drafting.
5. **Maryam Fayyaz Malik**: Statistical analysis and interpretation of results.
6. **Misbah Ijaz**: Critical revision of the manuscript and final approval of the version to be published.