

BRUXISM MANAGEMENT USING A MULTILAYERED XEOMIN INJECTION APPROACH: A COMPARATIVE STUDY

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ABSTRACT

Objective: This study evaluates the efficacy of a multilayered xeomin injection technique compared to a conventional deep injection approach in managing bruxism.

Methods: Forty patients diagnosed with bruxism were divided into two groups: the control group received deep injections at four points in the masseter, while the study group received both deep and superficial injections, with internal redirection to four sites. Treatment outcomes were assessed using electromyography (EMG) to measure muscle activity, bite force measurement, Visual Analog Scale (VAS) for pain, and patient satisfaction scores, these outcomes were evaluated during different follow up intervals (Baseline, 1 month, 3 months and 6 months). Statistical analysis was conducted using SPSS, with significance set at $p < 0.05$.

Results: The study group exhibited significantly greater reductions in EMG activity and bite force compared to the control group ($p < 0.05$). Additionally, VAS scores demonstrated lower pain levels post-treatment in the study group, and patient satisfaction scores were significantly higher. The previously mentioned parameters were assessed at baseline, 1 month, 3 months, and 6 months post-treatment, with improvements starting from the 1-month follow-up and continuing through the subsequent intervals.

Conclusion: Multilayered xeomin injection into the masseter muscle provides superior therapeutic benefits for bruxism management, resulting in improved muscle relaxation, reduced bite force, and higher patient satisfaction compared to conventional deep injections. This technique may serve as a refined protocol for clinicians treating bruxism.

KEYWORDS: Muscle relaxation, Xeomin, facial pain relief, masticatory muscle modulation, therapeutic toxin application.

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INTRODUCTION

Bruxism is a common parafunctional activity characterized by excessive, involuntary grinding or clenching of the teeth, often resulting in various complications such as muscle hypertrophy, temporomandibular joint disorders, dental wear, headaches, and facial pain. It can manifest as either awake bruxism, which occurs during consciousness, or sleep bruxism, which is frequently linked to sleep disturbances like obstructive sleep apnea. The condition has a multifactorial etiology, with contributing factors including genetic predisposition, emotional stress, anxiety, occlusal discrepancies, and neuromuscular dysfunction.¹⁻⁵

The masseter muscle, one of the most powerful muscles in the human body, plays a crucial role in the pathophysiology of bruxism. Chronic overuse can lead to masseter hypertrophy, which not only increases bite force but also affects facial aesthetics. Conventional bruxism management includes the use of occlusal splints, cognitive behavioral therapy, pharmacological treatments, and physiotherapy. However, these methods often provide only temporary relief, prompting interest in minimally invasive alternatives such as botulinum neurotoxin injections.⁶⁻⁸

Botulinum toxin type A (BoNT-A) has gained recognition as an effective treatment for bruxism by inhibiting acetylcholine release at the neuromuscular junction, resulting in temporary muscle relaxation. This mechanism reduces excessive muscle activity, alleviates symptoms, and decreases bite force. Clinical studies have demonstrated its efficacy in improving pain levels and muscle relaxation. However, the optimal injection technique remains a subject of debate. The traditional deep injection method primarily targets the bulk of the masseter muscle but may lead to uneven diffusion and inconsistent relaxation across different muscle fibers.⁹⁻¹¹

A novel approach-multilayered injection-has been proposed to enhance the efficacy of neurotoxin

treatment by ensuring a more uniform distribution across both deep and superficial layers of the masseter muscle, promoting better diffusion and optimizing muscle relaxation. Given the limited data on this technique, further investigation is warranted to determine whether it offers superior outcomes compared to traditional deep injections¹².

This study aims to compare the therapeutic effects of deep versus multilayered neurotoxin injection techniques in the management of bruxism. The primary objective is to assess improvements in muscle relaxation, reduction in bite force, pain relief, and patient satisfaction following treatment. By incorporating both objective and subjective evaluation methods, this study seeks to provide robust clinical evidence supporting the efficacy of multilayered injections as a potential refinement in neurotoxin-based bruxism treatment.

MATERIALS AND METHODS

This study was conducted between June 2024 and December 2024 at Joud Dental Clinic, Nasr City, Cairo, Egypt, with a follow-up period of six months. A total of 40 patients diagnosed with bruxism were enrolled and randomly assigned to one of two equal groups (n=20) using a computer-generated randomization table to ensure unbiased allocation. The control group received deep intramuscular injections exclusively, while the study group received a combination of deep and superficial (multilayered) injections. All participants provided written informed consent after being fully informed about the nature of the procedure, potential benefits, and possible risks. The study was conducted in full accordance with the ethical principles outlined in the Declaration of Helsinki, which ensures respect for individuals, beneficence, and the right to make informed decisions. While patients were not blinded due to the nature of the intervention, the outcome assessor was blinded to group assignments to minimize assessment bias.

Inclusion Criteria:-

- Adults aged 18-50 years diagnosed with bruxism through clinical examination and patient history.
- Presence of masseter hypertrophy confirmed by palpation or imaging.
- No prior botulinum toxin treatment for bruxism in the past six months.
- Willingness to participate and comply with follow-up assessments.

Exclusion Criteria

- Patients with neuromuscular disorders affecting masseter function.
- History of facial trauma, surgery, or other interventions affecting the masseter muscle.
- Pregnancy or breastfeeding.

Injection Protocol

Xeomin® 100 unit (Merz Pharmaceuticals GmbH, Germany) was reconstituted with 2 mL of preservative-free saline to achieve a final concentration of 10 units per 0.1 mL. A 1 mL insulin syringe with a 13 mm needle length was used for precise delivery.

Patients were seated upright in a relaxed state. Drawing anatomical outline by two lines, the first line running from the tragus of the ear to the corner of the mouth and the second line runs parallel to the inferior border of the mandible, followed by palpating the masseter muscle with two fingers to locate its anterior and posterior border so the final outline is a square shaped box located within a superior and inferior line. Patients were randomly divided into two groups;

Control Group (Deep Injection): Four intramuscular injection points were marked along the bulk of the masseter muscle. The syringe was inserted perpendicularly to a depth of approximately 8-10 mm, ensuring deposition into the deep fibers.

Each site received an equal dose of 5 units of Xeomin.

Study Group (Multilayered Injection): A single entry point was established at the lower third of the masseter muscle. The needle was initially inserted to a depth of 8-10 mm for deep layer administration. As the needle was gradually withdrawn, additional neurotoxin was delivered to ensure even distribution across the superficial layer. This was followed by a fan-like redirection (Star shaped) to four distinct sites within both the deep and superficial layers, optimizing uniform dispersion throughout the masseter muscle. (Figure 1).

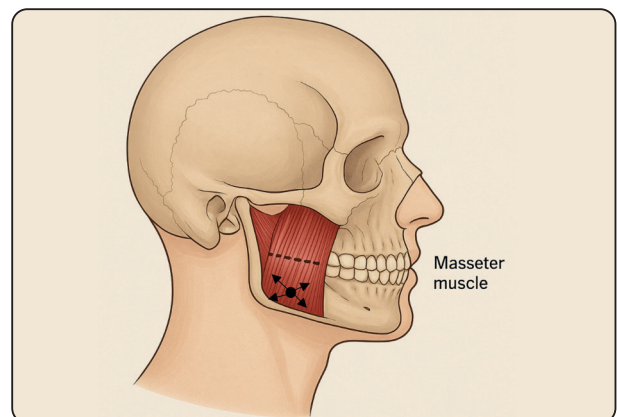


Fig. (1) Original diagram illustrating the multilayered injection technique of Xeomin into the masseter muscle for the treatment of bruxism. The arrows depict the fanning or star-shaped injection pattern originating from a single entry point, represented by the black dot.

Outcome Measures evaluated at the following intervals (Baseline, 1 month, 3 months & 6 months):

(A) Electromyography (EMG): Used to measure muscle activity before and after treatment to assess neuromuscular relaxation. Surface EMG was used to record the electrical activity of the masseter muscle at rest and during maximal clenching. A portable EMG device (NeuroTrac MyoPlus2, Verity Medical Ltd., UK) was

utilized with dual adhesive electrodes placed over the masseter muscle belly following skin cleansing. This allowed objective assessment of neuromuscular relaxation pre- and post-treatment.

- (B) Bite Force Measurement: Evaluated using a bite force transducer to quantify the reduction in excessive bite force. Bite force was quantitatively measured using a digital bite force transducer (GM10, Nagano Keiki Co., Japan) placed between the first molars on the dominant side. Three consecutive readings were taken at each interval, and the mean value was recorded in Newtons (N). This provided an objective measurement of masticatory strength and functional improvement.
- (C) Visual Analog Scale (VAS) for Pain: Patients rated their pain levels pre- and post-treatment. Patients were asked to indicate their pain level using a 10 cm horizontal line, with 0 representing “no pain” and 10 representing “worst imaginable pain.” Pain was recorded before the procedure and at all follow-up intervals to evaluate symptomatic relief.
- (D) Patient Satisfaction Score: A Likert scale (1-10) was used to assess subjective improvement. Subjective satisfaction was assessed using a 10-point Likert scale, where 1 indicated “not satisfied at all” and 10 indicated “extremely satisfied.” Patients were asked to score their perceived improvement in symptoms and facial aesthetics.

Statistical Analysis

Data were analyzed using SPSS software, with paired t-tests and ANOVA applied to compare pre- and post-treatment values within and between groups. A p-value < 0.05 was considered statistically significant.

RESULTS

In our study, the group that received the multilayered injection technique did not experience any complications, and all patients tolerated the procedure well without any adverse events. However, in the group that received deep injections only, a few patients exhibited paradoxical bulging. This phenomenon is believed to occur due to the fact that while the deep muscle fibers were effectively paralyzed, the superficial muscle fibers remained active. As a result, the continued contraction of the superficial fibers could have caused an unexpected bulging or swelling in the treated area.

The study group demonstrated a significant reduction in masseter muscle activity following treatment, with the most pronounced decline occurring early in the follow-up period. This decrease remained stable over time and was markedly greater than that observed in the control group, indicating enhanced neuromuscular relaxation. The findings suggest that the multilayered injection technique effectively reduces excessive muscle activity, contributing to improved therapeutic outcomes.

Similarly, a substantial decrease in bite force was recorded in the study group, with the most rapid reduction observed shortly after treatment. This decline in muscle contraction persisted over the subsequent months, underscoring the prolonged efficacy of the multilayered approach. In contrast, the control group exhibited a less pronounced and less sustained reduction, highlighting the superior impact of the study technique in mitigating excessive occlusal force.

Pain assessment using the Visual Analog Scale (VAS) revealed significantly lower pain levels among patients who underwent the multilayered injection. The greatest relief was achieved early in the follow-up period and maintained through subsequent evaluations. In comparison, the control group experienced a more gradual and less substantial reduction in pain, indicating the enhanced analgesic benefits of the multilayered technique.

Patient satisfaction scores further reinforced these findings, as individuals receiving the multilayered injection reported higher levels of comfort and functional improvement. Satisfaction peaked shortly after treatment and remained consistently elevated, whereas the control group exhibited a more moderate increase in perceived benefit. This sustained improvement in patient-reported outcomes highlights the clinical advantages of the multilayered approach in optimizing therapeutic effectiveness.

Overall, the results demonstrate that the multilayered injection technique offers superior and sustained muscle relaxation, greater reduction in bite force, improved pain relief, and higher patient satisfaction compared to the deep injection-only method. These findings support the efficacy of this approach in managing bruxism symptoms and suggest its potential for long-term therapeutic benefits. (Table 1-4) (Figure 2-5)

TABLE (1) Electromyography (EMG) Activity at Different Follow-Up Intervals

| Group | Pre-Treatment (Mean ± SD) | 2 Weeks (Best) | 1 Month (Stable) | 3 Months (Stable) | 6 Months (Slight Return) | p-Value | Significance |
|---------|------------------------------|-----------------|---------------------|----------------------|-----------------------------|---------|--------------------|
| Control | 160.5 ± 15.2 μV | 130.8 ± 14.1 μV | 125.2 ± 13.5 μV | 123.0 ± 13.0 μV | 128.5 ± 12.8 μV | 0.03 | Significant |
| Study | 162.7 ± 14.8 μV | 110.3 ± 12.5 μV | 95.4 ± 11.8 μV | 92.1 ± 11.4 μV | 98.0 ± 11.2 μV | <0.001 | Highly Significant |

TABLE (2) Bite Force Measurement at Different Follow-Up Interval

| Group | Pre-Treatment (Mean ± SD) | 2 Weeks (Best) | 1 Month (Stable) | 3 Months (Stable) | 6 Months (Slight Return) | p-Value | Significance |
|---------|------------------------------|-------------------|---------------------|----------------------|-----------------------------|---------|--------------------|
| Control | 750.3 ± 35.7 N | 670.5 ± 33.2 N | 640.2 ± 32.0 N | 630.8 ± 30.5 N | 645.9 ± 29.7 N | 0.04 | Significant |
| Study | 755.9 ± 36.5 N | 580.2 ± 31.0 N | 520.3 ± 30.2 N | 510.8 ± 28.7 N | 525.3 ± 27.9 N | <0.001 | Highly Significant |

TABLE (3) Pain Levels (VAS Score) at Different Follow-Up Intervals

| Group | Pre-Treatment (Mean ± SD) | 2 Weeks (Best) | 1 Month (Stable) | 3 Months (Stable) | 6 Months (Slight Return) | p-Value | Significance |
|---------|------------------------------|-------------------|---------------------|----------------------|-----------------------------|---------|-----------------------|
| Control | 7.0 ± 1.5 | 5.5 ± 1.3 | 5.0 ± 1.2 | 4.7 ± 1.1 | 5.1 ± 1.0 | 0.05 | Borderline ignificant |
| Study | 7.2 ± 1.4 | 4.2 ± 1.1 | 3.5 ± 1.0 | 3.2 ± 1.0 | 3.7 ± 0.9 | 0.01 | Significant |

TABLE (4) Patient Satisfaction Score at Different Follow-Up Intervals

| Group | Pre-Treatment (Mean ± SD) | 2 Weeks (Best) | 1 Month (Stable) | 3 Months (Stable) | 6 Months (Slight Return) | p-Value | Significance |
|---------|------------------------------|-------------------|---------------------|----------------------|-----------------------------|---------|--------------------|
| Control | 4.2 ± 0.7 | 5.2 ± 0.9 | 6.3 ± 1.0 | 6.5 ± 1.1 | 6.3 ± 1.0 | 0.03 | Significant |
| Study | 4.1 ± 0.8 | 6.5 ± 1.0 | 8.0 ± 1.1 | 8.6 ± 1.2 | 8.4 ± 1.1 | <0.001 | Highly Significant |

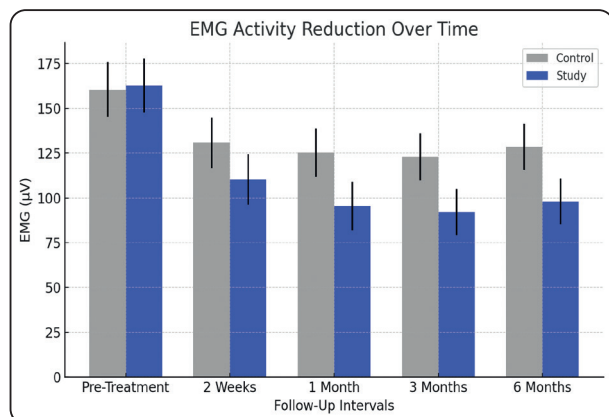


Fig. (2) Electromyography (EMG) Activity Reduction Over Time

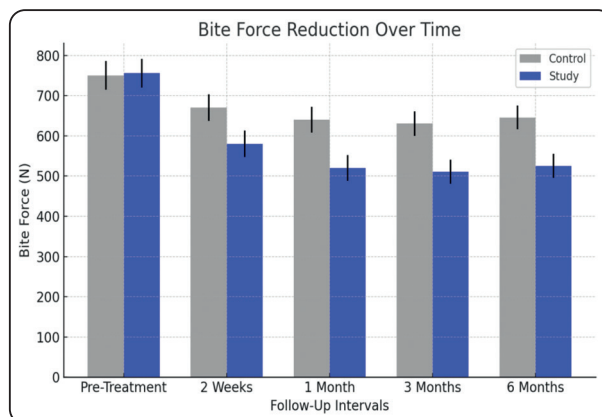


Fig. (3) Bite Force Reduction Over Time

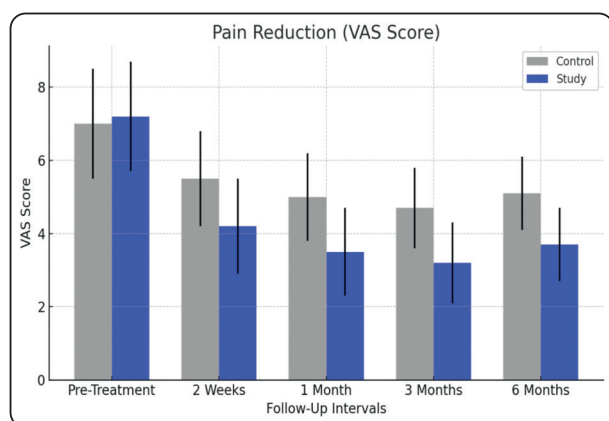


Fig. (4) Pain Reduction (VAS Score) Over Time

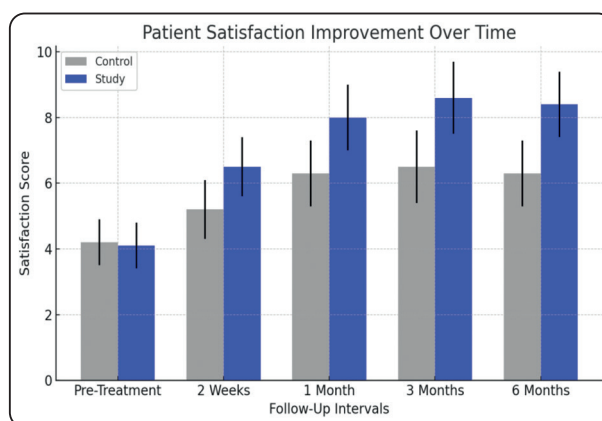


Fig. (5) Patient Satisfaction Improvement Over Time

DISCUSSION

Bruxism is a prevalent condition marked by excessive teeth clenching or grinding, which can contribute to masseter muscle hypertrophy, increased bite force, and temporomandibular disorders. Although neurotoxin injections are commonly utilized to manage these symptoms, the most effective injection technique remains uncertain. This study aimed to evaluate the outcomes of deep versus multilayered neurotoxin injections in reducing masseter muscle activity and bite force, alleviating pain, and enhancing patient satisfaction.¹³

Our findings demonstrate the efficacy of the multilayered neurotoxin injection technique in achieving superior muscle relaxation, greater reduction in bite force, and enhanced patient satisfaction compared to deep injection alone. These results align with previous studies that have shown improved outcomes with advanced injection techniques targeting both superficial and deep layers of the masseter muscle^{12,14,15}.

Several studies have reported similar trends in EMG activity reduction and bite force attenuation following neurotoxin injections in bruxism patients. It was found that multilayered injections resulted in more profound and prolonged neuromuscular

inhibition compared to single-depth injections¹⁵. Our results further validate these observations, demonstrating the added benefit of ensuring an even spread of the neurotoxin within the muscle structure.

However, contrasting evidence exists, with some studies suggesting that deep injections alone are sufficient for reducing bruxism symptoms and led to noticeable improvements, the addition of superficial layers did not significantly enhance outcomes. The discrepancy between these findings and our study could be attributed to differences in patient demographics, injection techniques, or follow-up durations^{16,17}.

Importantly, our study confirms that the maximal therapeutic effect is achieved at the 2-week follow-up, with stability at 1 and 3 months, and a slight return of symptoms at 6 months. This suggests that while neurotoxin therapy provides substantial relief, periodic reinjection may be necessary to maintain optimal results.

Despite the strong results, future research should explore long-term follow-up beyond 6 months to assess the sustainability of the observed benefits. Additionally, investigations comparing different dosages or reconstitution protocols may provide further insights into optimizing treatment efficacy

CONCLUSION

The multilayered neurotoxin injection technique proved to be more effective than the deep injection method in reducing masseter muscle activity, bite force, and pain levels while also improving patient satisfaction. The most notable improvements were recorded two weeks after treatment, with effects remaining stable for up to three months, followed by a mild recurrence of symptoms at six months. These results underscore the benefits of administering injections at multiple depths to achieve prolonged therapeutic outcomes in bruxism management. Further research is needed to assess long-term efficacy and determine the optimal reinjection intervals to enhance clinical protocols.

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