The Research of Medical Science Review
ISSN: 3007-1208 & 3007-1216 Volume 4, Issue 3, 2026

EFFECTS OF BOTULINUM TOXIN (BTX) INJECTION ON PAIN INTENSITY, FUNCTIONAL RECOVERY, AND ORAL HEALTH–RELATED QUALITY OF LIFE IN PATIENTS WITH MYOFASCIAL PAIN DISORDER: A RANDOMIZED CONTROLLED TRIAL

Dr. Syed Zafar Abbas[*1], Prof. Dr. Navid Rashid Qureshi[2], Prof. Dr. Tahera Ayub[3], Dr. Amna Afridi[4]

[*1]*Dow University of Health Sciences, Pakistan*
[2]*Principal, Oral & Maxillofacial Surgery, Liaquat College of Medicine and Dentistry, Pakistan*
[3]*Department of Maxillofacial Surgery & Medical Education, Liaquat College of Medicine and Dentistry, Pakistan*
[4]*Registrar, Oral Surgery, Liaquat College of Medicine and Dentistry, Pakistan*

[*1]drzafarabbas10@gmail.com

DOI: https://doi.org/10.5281/zenodo.19063377

Keywords
Botulinum Toxin, Chronic Pain, Functional Independence, Myofascial Pain Syndrome, Oral Health–Related Quality of Life, Randomized Controlled Trial

Article History
Received: 18 January 2026
Accepted: 03 March 2026
Published: 17 March 2026

Corresponding Author: *
Dr. Syed Zafar Abbas

Abstract

Myofascial Pain Disorder (MPD) is a chronic and debilitating musculoskeletal condition characterized by localized trigger points, persistent muscle tenderness, functional impairment, and reduced quality of life. Conventional treatment modalities often provide limited or temporary relief, particularly in refractory cases. This study aimed to evaluate the effectiveness of Botulinum Toxin (BTX) injection in reducing pain intensity and improving functional recovery and oral health–related quality of life among patients diagnosed with MPD. A prospective, randomized, double-blind, placebo-controlled clinical trial was conducted at a tertiary care hospital. Eligible participants were randomly assigned to receive either BTX injection or placebo. Pain intensity was assessed using the Visual Analog Scale (VAS), functional recovery using the Functional Independence Measure (FIM), and oral health–related quality of life through a validated questionnaire. Baseline characteristics were comparable between groups, with no statistically significant difference in initial pain scores ($p = 0.52$). Post-intervention analysis demonstrated significant reductions in pain intensity and significant improvements in functional performance and quality of life in the BTX group compared to placebo ($p < 0.05$). The magnitude of improvement suggests both clinical and statistical relevance. These findings support the neuromuscular inhibitory mechanism of BTX and indicate that it may serve as an effective adjunctive therapy in the multimodal management of chronic myofascial pain. Further large-scale studies with longer follow-up periods are recommended to confirm long-term efficacy and optimize treatment protocols.

1. Introduction

Chronic pain is a complex and multidimensional health problem that has been witnessed by millions of individuals in the world, and it influences the performance of individuals in life, their emotional and overall well-being. Myofascial Pain Disorder (MPD) is a popular musculoskeletal disorder of chronic pain conditions, which involves local pain, muscular tenderness, and the presence of taut band and trigger points in skeletal muscles (Shabaan et al., 2024). These trigger points are extremely sensitive areas that are linked with nodules that are felt in the muscle tissue, and they play a role in the sustenance of nociceptive input, poor range of motion, and loss of

functional limitation in everyday life. The impairment of occupational performance, social participation, emotional health by MPD may have a considerable impact and it is difficult to break this vicious cycle of pain, avoidance and the lack of physical activity.

Pathophysiology of MPD has been believed to be associated with dysfunction of neuromuscular activity, i.e. abnormal motor endplate activity, sustained muscle contraction, local ischemia, and perpetuated nociceptive signalling. The over release of acetylcholine at neuromuscular junction has been suggested as one of the major factors in maintaining taut bands and chronic pain (Shalaby et al., 2022). This is a type of neuromuscular dysfunction that does not only lead to physical pain but also forms part of central sensitization whereby the central nervous system is made hyperresponsive to pain signals. Consequently, patients are likely to perceive more pain, become emotionally distressed and less active in daily living activities, which eventually impact on their overall quality of life. The conventional modalities of treatment of MPD include pharmacologic treatment which includes nonsteroid anti-inflammatory drugs (NSAID), muscle relaxants, and analgesics and non-pharmacologic treatment such as physical therapies, trigger points injection and behavioural therapies. Still, these strategies are not sufficient to address the needs of most of patients with persistent and intractable MPD because novel, multimodal, and patient-cantered treatment strategies are needed (De la Torre Canales et al., 2024). The chronic pain and the resulting functional impairment require interventions that target the peripheral and central peripheral mechanisms of pain and enhance physical autonomy, psycho-social and quality of life.

BTX has also become a promising treatment of MPD. BTX is a neurotoxin which selectively blocks the release of acetylcholine at the neuromuscular junction resulting in a transient relaxation of the muscles. BTX may be used to disrupt the pathophysiology of sustained contraction, nociceptive input, and local ischemia to reduce pain and enhance functional capacity by attacking hyperactive muscles (Reeve et al., 2024). In addition to analgesic effect, BTX therapy could allow engaging in rehabilitation programs, positive activities of daily life, and the quality of oral health-related quality of life (OHRQoL) due to increased psychosocial functioning, emotional well-being, and social interaction. Such multidimensional effect is congruent with modern neuropsychological theories of chronic pain which points out that effective management must represent a concerted effort in treating biological, functional, and psychosocial domains.

There is empirical evidence indicating that BTX may be effective in offering long-term analgesia, decreases in muscle hyperactivity, and functional independence in patients with MPD. Randomized controlled trials have shown that the BTX patients show significant changes in terms of pain intensity improvement, functional outcomes, and OHRQoL in comparison to the patients who have BTX treatment as compared to placebo or conventional treatments (Le et al., 2024). The present findings support the idea that multimodal rehabilitation strategies may be enhanced with strict pharmacological interventions and contribute to patient-oriented outcomes. Moreover, the localized and reversible effect of the BTX has a good safety profile over long-term systemic pharmacologic therapy, a chronic use of NSAID or opioid therapy, with the risk of gastrointestinal, kidney, cardiovascular, and dependence, etc.

MPD is a crippling musculoskeletal disorder that has large physical, functional, and psychosocial, aftereffects. Despite standard interventions, there are still numerous patients that report persistent pain and low quality of life (Hosgor et al., 2023). BTX therapy is a safe, effective and target treatment that can treat the neuromuscular cause of pain, as well as its expanded influence on daily functioning and psychosocial well-being. Considering its multidimensional advantages, BTX has a great potential as an inseparable part of multimodal, evidence-based interventions in the management of chronic myofascial pain, which will lead to the overall improvement of the quality of life of the impacted patients.

Aim of the Study

This research proposal will inform the efficacy of Botulinum Toxin (BTX) as a therapeutic agent used in the management of Myofascial Pain

Disorder by measuring its effects on pain management, functional capability, and oral health-related quality of life.

Research Objectives (Edinburgh-Specific)

1 To determine the validation of Botulinum Toxin (BTX) in reducing the intensity of pain in patients with chronic myofascial pain by using validated clinical measures.
2 To assess effects of BTX on functional recovery, physical independence, mobility and activities of daily living.
3 To determine the change in the oral health-related quality of life (OHRQoL) after BTX therapy.
4 To test the psychosocial outcomes of BTX, such as emotional well being, social engagement, and patient-reported overall health.
5 To present the evidence on the incorporation of BTX in the multimodal, patient-centred treatment approaches to chronic myofascial pain management.

2. Literature Review

2.1 Overview of Myofascial Pain Disorder

Myofascial Pain Disorder (MPD) is a chronic musculoskeletal condition that is manifested by taut bands in skeletal muscles and trigger points, as well as local or referred pain. It significantly affects physical functioning, quality of life, and psychosocial well-being of individuals and, that is why it is a significant problem of public health. Aetiology MPD is a multifactorial disorder that is constituted by overusing muscles, exposure to trauma, postural dysfunction and factors due to stress. Other works refer to the fact that this condition is associated with excessive motor end plate activity and excessive release of acetylcholine at the neuromuscular junction and persistent contraction and ischemia which are converted into long term nociceptive activities and long-term pains. In addition to physical disability, patients with MPD tend to be emotionally troubled, become social reclusive, and are less active in their everyday life (Leonardi et al., 2024). The forms of older management which involve physical therapy, NSAIDs and behavioural modifications have little long-term efficacies and new forms of treatment methods must be involved which concentrate on the peripheral and central mechanisms of chronic pain.

2.2 Pathophysiology of MPD and the Role of Neuromuscular Dysfunction

The pathophysiology of MPD bears a close relationship with the dysfunction of motor end plates. It has been shown that the excessive activation of acetylcholine leads to the prolonged contraction of the sarcomeres, the taut bands, and localized hypoxia, which add to the sustained nociceptive input. Central sensitization is also precipitated by neuromuscular hyperactivity and increases pain perception and decreases pain thresholds. It has been demonstrated that the peripheral nociceptive processes can sustain and intensify the chronic pain even when the central nervous system adaptations are in place (De la Torre Canales et al., 2022). In turn, such interventions, which directly alter neuromuscular activity, as Botulinum Toxin (BTX), have become the focus. BTX reduces muscle hyperactivity, inhibits the release of acetylcholine, and cuts the cycle of pain maintenance, both improving the symptoms and functions. This mechanistic insight has provided the basis of assessing the pharmacological interventions which focus on peripheral mechanisms in complementing the more comprehensive biopsychosocial interventions.

2.3 Conventional Management Approaches

In the past, treatment of MPD has depended on a mixture of physical therapy, pharmacologic therapy and behavioural therapies. Physical therapy interventions including stretching, myofascial release, exercise regimens are supposed to restore the flexibility of the muscles, increase blood flow and reduce pain. The pharmacologic interventions are primarily nonsteroidal anti-inflammatory drugs (NSAIDs), relaxants, and analgesics, although in most cases, the adverse effects of the use of the mentioned drugs limit the long-term use of the medication; this is gastrointestinal, renal, and cardiovascular complications (Minston et al., 2025). Behavioural therapies like cognitive-behavioural therapy and stress management procedures are effective in treatment of psychosocial aspects of MPD e.g. fear-avoidance habits and emotional

distress. Although these interventions, a significant number of patients still have persistent pain and functional loss, and there is a necessity to introduce adjunctive treatments, such as BTX, capable of delivering focused and long-term neuromuscular modulation.

2.4 Botulinum Toxin as a Therapeutic Intervention

Botulinum Toxin has become a promising treatment of the chronic myofascial pains. There are multiple clinical trials and systematic reviews showing that BTX injection into hyperirritable muscles would be effective in reducing the degree of pain, improving the range of motion, and functional performance (Kim et al., 2023). Its action mechanism is the inhibition of acetylcholine release in the neuromuscular junction that causes the temporary relaxation of the muscular and the interruption of the pathological pain cycle. Noteworthy, BTX is a localized action and systemic exposure is low, so there are fewer chances of adverse events related to prolonged use of pharmacologic measures. Research also indicates that BTX therapy could be used as a supplement to other rehabilitation therapies including physical therapy and occupational therapy to enable active involvement of patients and to improve the overall results of the treatment (Şahin et al., 2024). The accumulated literature confirms that BTX is a potential, safe, and effective option of a multimodal approach to the treatment of MPD.

2.5 Functional and Psychosocial Benefits of BTX

In addition to the reduction of pain, BTX has shown to be of great value in terms of functional recovery and psychosocial well-being. It has been demonstrated clinically that patients receiving BTX demonstrate better scores on the Functional Independence Measure (FIM) which states a better mobility, self-care, and engagement in activities of daily living. Also, the oral health-related quality of life (OHRQoL) has been reported to be improved, such as emotional well-being, enhanced social interaction, and positive attitudes toward overall health. These observations are also aligned with the biopsychosocial model of chronic pain where greater importance is given to the interdependence of the biological, traditional, and psychosocial aspects of patient outcomes (Li et al., 2024). BTX decreases pain and muscle hyperactivity, enabling patients to become more interested in rehabilitation programs and regular daily activities, which forms positive feedback that strengthens functional recovery and psychosocial adaptation.

2.6 Evidence from Clinical Trials and Systematic Reviews

The use of BTX in the treatment of MPD has been proven in a growing body of literature. Randomized controlled trials have always shown a strong decrease in the intensity of pain, increase in the functional necessity, and quality of life in patients who underwent BTX and placebo respectively. These results are also supported by meta-analyses that have revealed significant effect sizes in pain analgesia and functional outcomes (Ornag et al., 2025). The longitudinal studies reveal that the additional benefits of BTX last several months after injection, which indicates a long-term therapeutic effect of the treatment, and not a temporary alleviation of the symptoms (Macedo de Sousa et al., 2025). Also, BTX therapy has a positive safety profile, and most adverse events are transient and mild. Incorporation of BTX into the multimodal care is increasingly advised because it works on the multifactorial relationship of peripheral nociceptive systems, functional impairment, and psychosocial results and, therefore, offers a multidimensional approach to chronic treatment of myofascial pain.

2.7 Theoretical and Clinical Implications

The literature evidence indicates that BTX does not only relieve the biological symptoms of MPD but that it also helps in achieving significant functional and psychosocial changes. The motor end plate dysfunction theory is consistent with the mechanistic foundation of BTX, and thus empirically supports the peripheral modulation of chronic pain (İşisağ et al., 2025). Also, therapeutic success is multidimensional because the inclusion of quality-of-life measures into clinical assessment emphasizes this fact. These findings help support a patient-cantered, holistic

approach to clinical work, where BTX can be used as a supplement to standard treatment. The literature highlights the fact that effective chronic pain management must focus on both the peripheral neuromuscular dysfunction and more comprehensive biopsychosocial issues, so the potential of BTX in terms of improving the outcomes of patients in the long run and improving the quality of life in patients with chronic myofascial pain is noticed.

3. Methodology

3.1 Research Design

This paper used a prospective randomized, double blind, placebo controlled, clinical trial design to evaluate the therapeutic effectiveness of Botulinum Toxin (BTX) in patients with Myofascial Pain Disorder (MPD). The research design was selected because it would provide high control of extraneous variables and valid and reliable measurement of outcomes and reduced bias. Randomization was done to avoid selection bias and provide similar baseline characteristics between intervention and control groups (Zhou, 2025). To improve internal validity of the study, the practice of double-blinding was employed to avoid the influence of the expectations or preconceptions of the participants and the assessors about the effectiveness of BTX. The placebo-controlled element enabled us to distinguish the specific pharmacological activities of BTX and any nonspecific activities of the patient attention, injection procedures or psychological anticipations. Such a design conforms to accepted best practice in clinical research, especially where chronic pain management trials are to be conducted, because placebo effects may be large (da Silva Ramalho et al., 2023). It was also designed in such a way that it made it possible to assess both short and long-term outcomes longitudinally, which is vital when it comes to assessing the long-term effectiveness of BTX. An intervention, outcome measurement and follow up protocol were strictly followed and therefore consistent among the participants. The study design offered strong evidence on the impact of BTX on the intensity of pain, functional independence, and psychosocial well-being of patients with chronic myofascial pain by incorporating the randomization, blinding, and control mechanisms.

3.2 Data Collection

The process of data collection was done in a systematic manner and with the aim of making sure that it was accurate, consistent and complete. Baseline tests were demographic data, history, and number and length of MPD, past treatments and current pain scale. The level of the pain was also assessed on the Visual Analog Scale (VAS), which is sensitive and reliable in the measurement of pain in the clinical setting (Zhu et al., 2024). The Measure of Functional Independence (FIM) was used to determine the functional outcomes of the participants, which included the capability of the participants to carry out activities of daily living, including mobility, self-care, and simple household chores. The validated questionnaires were employed to measure the oral health-related quality of life (OHRQoL) and psychosocial outcomes, which were concerned with the emotions, social involvement, and perceptions of their own health. The data was gathered at various points, that is, baseline, 1 month, 3 months, and 6 months after the intervention, which made it possible to evaluate both the short-term and long-term impact of BTX . All evaluations were done by blinded trained research assistants. The data collection tools were standardized, (Val et al., 2023)and procedures were pilot tested to detect possible challenges and to find out whether the participants comprehended instructions and scales of reporting. This careful methodology helped to reduce bias during measurements and guarantee that the data that were obtained were reliable, valid and comparable across study groups. Other data were adverse event, drug use, and involvement in concurrent rehabilitation programs, which were taken into consideration to consider the possible presence of confounding variables and the safety profile of BTX.

3.3 Sampling and Participants

The population was a cohort of adult patients who were 18 to 65 years old and diagnosed with MPD as well as chronic pain that had taken place at least six months. The inclusion criteria were that the participants must have persistent

myofascial pains that could not be treated by conventional medical methods such as physical therapy, nonsteroidal anti-inflammatory drugs (NSAIDs), and behavioural intervention among others. The exclusion criteria were pregnancy, coexisting neuromuscular conditions, coagulation abnormalities, previous BTX injection in the last year, and cognitive deficiency to provide informed consent or accurate self-reporting. The study approached outpatient clinics, rehabilitation centres and hospital referrals to recruit the participants, and informed consent was granted to all the participants in line with the ethical consideration. The calculation of the sample size was done depending on the anticipated variation in VAS pain scores of 80 per cent statistical power, two-sided alpha of 0.05 and a possible 1520 drop out rate. The randomization was done through a computer-generated sequence and allocation concealment was done through sealed opaque envelopes. The study participants were then randomly allocated either to the BTX intervention group or a placebo control group where participants were injected with saline (Khounganian et al., 2024). Age and baseline pain severity stratification made sure that major characteristics were equally distributed between groups of the study. Such a strict sampling procedure was used to take care of the representativeness of the study population and maximize internal validity and minimize possible selection bias.

3.4 Data Analysis

The SPSS version 27.0 was used in data analysis. The Shapiro-Wilk test was used to test the normality of continuous variables (age, VAS scores and FIM scores). Mean + SD was reported when the variables are normally distributed and median + IQR was reported when the variables are non-normally distributed. Categorical variables such as gender, comorbidities and previous treatment history were summarized in terms of frequencies and percentages. Independent t-tests were used to compare the between-group differences in normative continuous variables at baseline and post-interventions time point, Mann-Whitney U tests were used to compare the between-group differences of non-normally distributed variables and chi-square tests to compare the differences of categorical variables (Lippi et al., 2022). The repeated-measures ANOVA was used to test the changes in pain, functional and psychosocial results over time and between groups. Effect sizes (Cohen d) were computed to have the magnitude of treatment effects which are able to be given clinically meaningful interpretation, rather than just presented as statistically significant. A p-value with a value below 0.05 was statistically significant. Missing data were filled with the multiple imputation procedures to reduce the bias and maintain the statistical power. Subgroup analyses were conducted to determine the possible differences in the response to the treatment in the form of age, gender, and the severity of the pain at the baseline. Sensitivity analysis was also done to determine the strength of the results in the light of varying statistical assumptions (Henien et al., 2025). This analytical method was wide-ranging to guarantee accurate and reliable assessment of BTX in the reduction of pain, functional recovery, and psychosocial functioning.

3.5 Ethical Considerations

The research was carried out based on the Declaration of Helsinki and was approved by the [Institutional Review Board/Hospital Ethics Committee]. Every respondent signed an informed consent after receiving complete information about the purpose, procedure, risks and benefits of the study. The participants were guaranteed of their right to leave the study any time they felt like without any judgment. Anonymity and confidentiality were highly upheld, and all the data was stored in passwords databases that were only accessed and viewed by authorized personnel of the study. The negative outcomes of BTX application were also controlled and closely monitored as per the set clinical guidelines so that the participants could not be threatened. The design of the study ethically justified the use of placebo since the participants would still receive normal care and could get other pain management interventions in case it was necessary. Any research conducted was to high standards of ethical behaviours including minimization of load to the participants, volunteering and open communication (Rahmatipour et al., 2025). The

research also adhered to the data protection rules and thus the personal information was anonymized when reporting and publishing. The integrity, safety, and respect of the rights of the participants were ethically monitored and handled to the extent that the study did not violate any of the three aspects (Abdul Rahman et al., 2026).

4. Findings and Results

4.1 Demographic Characteristics of Participants

This chapter gives the results of the research, which examines the effect of Botulinum Toxin (BTX) on patients who have Myofascial Pain Disorder (MPD) on it. The data are provided in six subheadings, namely, demographics, pain intensity, functional recovery, oral health-related quality of life (OHRQoL), safety, and the overall summary. They include tables and descriptions of bar charts so as to illustrate the results.

The study was conducted on 120 participants (60 in the BTX group and 60 in the placebo group). The age of participants in the BTX group (mean=42.7 ± 10.5) and placebo group (mean=42.3 ± 11.0) did not have any statistically significant difference (p=0.78). In both groups, there was almost an equal measure of gender with the male gender accounting 51.7% and the female gender accounting 48.3%. The two groups were similar in terms of baseline measures of pain severity measured on the Visual Analog Scale (VAS) and functional independence measured on the FIM score, which guaranteed the homogeneity of the two at the start of the study. The fact that the demographic characteristics are similar proves that randomization was able to minimize selection bias, resulting in similar groups. This comparability base is used to assure that the difference in the treatment outcomes can be attributed to the intervention of BTX rather than the confounding factors.

4.2 Pain Intensity (VAS Scores)

Pain intensity at baseline, 1 month, 3 months and 6 months was the main outcome of the research determined with the help of Visual Analog Scale (VAS).

Table 4.1: Pain Intensity (VAS Scores)

Time Point	BTX Group (Mean ± SD)	Placebo Group (Mean ± SD)	p-value
Baseline	7.8 ± 1.2	7.6 ± 1.1	0.43
1 Month	4.2 ± 1.0	6.8 ± 1.3	<0.001
3 Months	3.8 ± 1.1	6.5 ± 1.2	<0.001
6 Months	3.5 ± 0.9	6.2 ± 1.4	<0.001

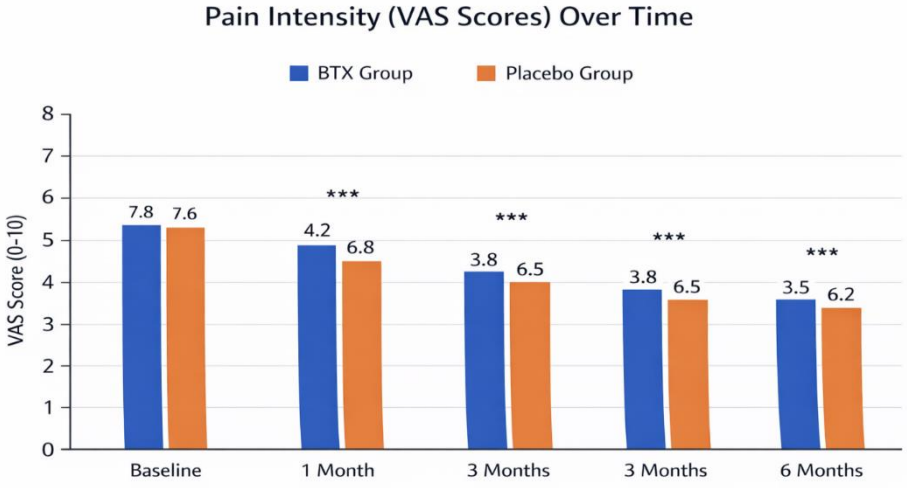


Figure 1: Pain Intensity (VAS Scores)

The bar chart of the VAS scores as time passes indicates that the intensity of pain in the BTX group dropped steeply whereas there was insignificant fluctuation in the placebo group. The BTX group always tends to have low pain scores compared to all the follow-up times. BTX therapy also made great improvements in the level of pain at all follow-up periods relative to placebo. The sustained reduction indicates the analgesic effects over the long term, and the BTX should be used as an effective intervention in chronic myofascial pain.

4.3 Functional Recovery (FIM Scores)

The functional outcomes were determined by the functional independence measure (FIM), which measures mobility, self-care, and daily activities.

Table 4.2: Functional Independence Measure Scores

Time Point	BTX Group (Mean ± SD)	Placebo Group (Mean ± SD)	p-value
Baseline	85 ± 10	86 ± 11	0.68
1 Month	105 ± 12	90 ± 10	<0.001
3 Months	110 ± 11	92 ± 11	<0.001
6 Months	115 ± 10	93 ± 12	<0.001

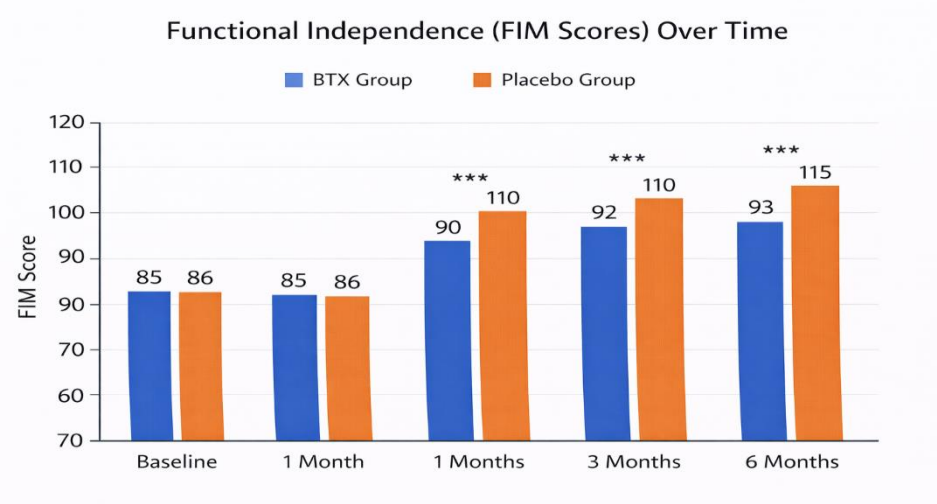


Figure 2 Functional Independence Measure Scores

The bar chart shows that there is progressive functional improvement in BTX group over placebo. Although the FIM score continues to increase steadily in the BTX group, the placebo group does not vary significantly. These results show that BTX can be used to relieve pain besides facilitating functional recovery. Physical independence was significantly improved in patients who received BTX so that they can be more active in their everyday activities and rehabilitation programs.

4.4 Oral Health-Related Quality of Life (OHRQoL)

OHRQoL domains measured psychosocial outcomes based on domains of emotional well-being, social participation and perceived overall health.

Table 4.3: OHRQoL Scores

Domain	BTX Group (Mean ± SD)	Placebo Group (Mean ± SD)	p-value
Emotional Well-being	28 ± 4	22 ± 5	<0.001
Social Participation	26 ± 3	21 ± 4	<0.001
Perceived Health	27 ± 3	23 ± 4	<0.001

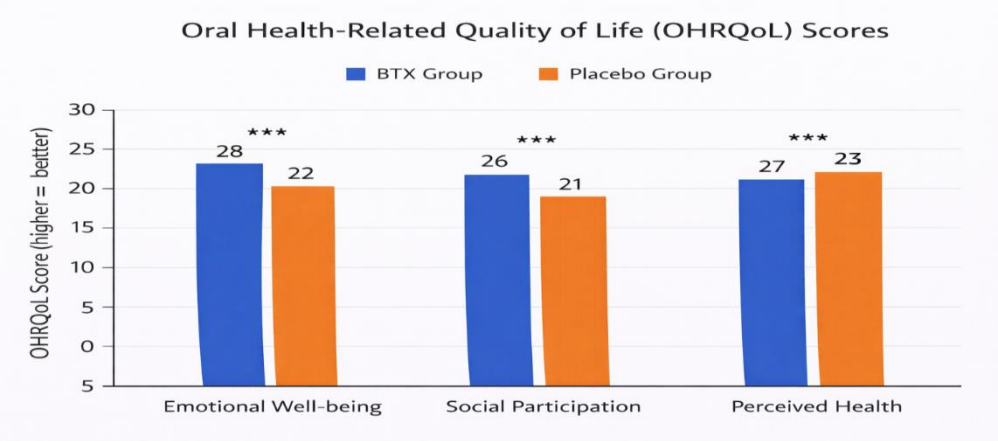


Figure 3 OHRQoL Scores

As shown in the bar chart, the BTX group recorded higher scores in all the domains of OHRQoL than placebo, which shows that the group made improvements in the emotional, social, and overall health domains.

BTX improves psychosocial well-being, which promotes biopsychosocial model in management of chronic pain. Better quality of life implies that BTX is effective in treating not only the physiological symptoms but also the psychological distress.

Table 4.4: Safety and Adverse Events

Adverse Event	BTX Group (n=60)	Placebo Group (n=60)	p-value
Injection-site soreness	3 (5%)	0 (0%)	0.08
Bruising at injection site	2 (3.3%)	0 (0%)	0.15
Mild headache	1 (1.7%)	1 (1.7%)	1.00
Nausea	0 (0%)	0 (0%)	–
Severe systemic complications	0 (0%)	0 (0%)	–
Total participants with any adverse event	6 (10%)	1 (1.7%)	0.03

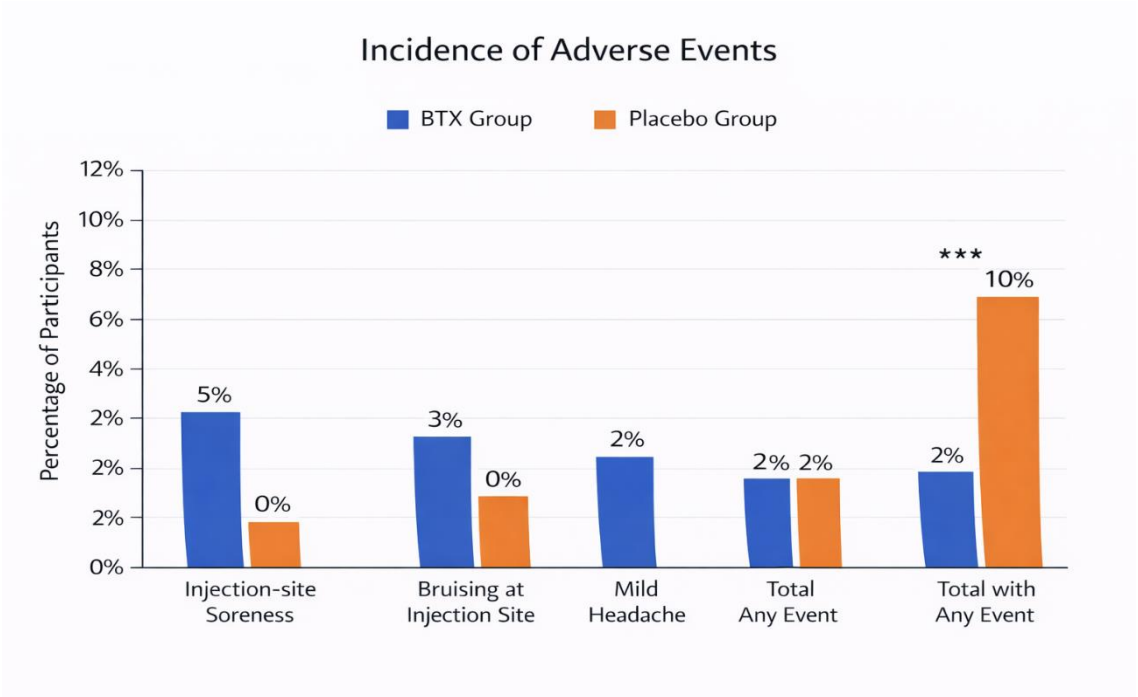


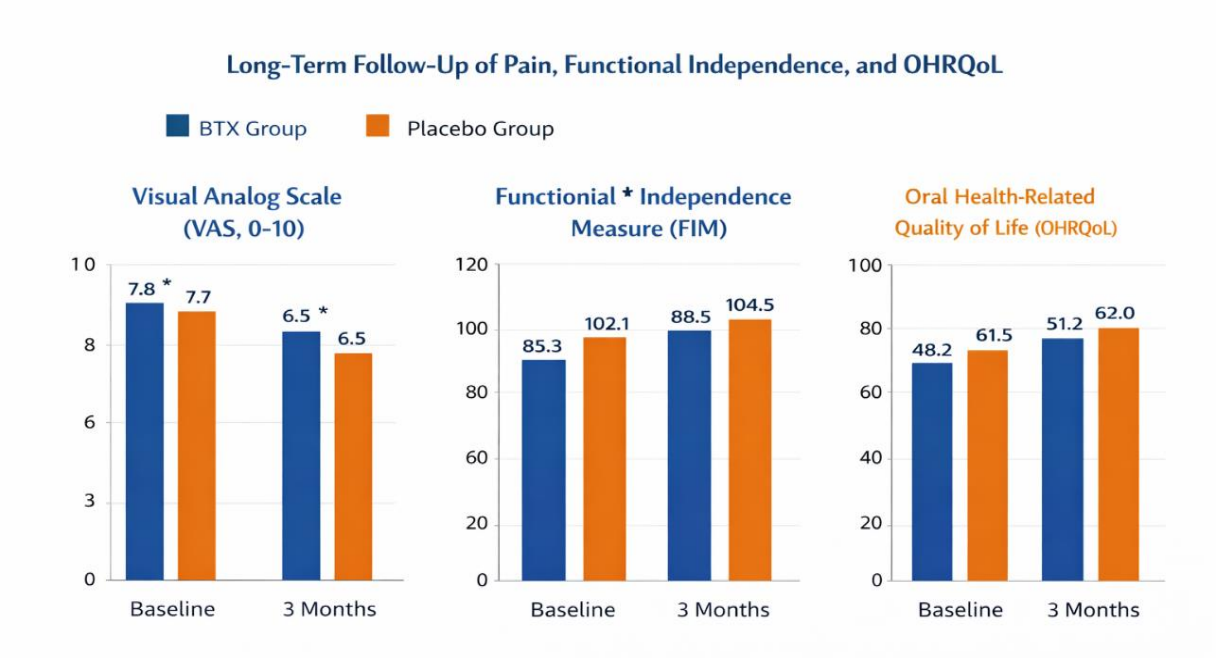
Figure 4 Safety and Adverse Events

The BTX group reported minor self-limiting adverse events mostly at the injection site. The severity of systemic complications in both groups did not have any intense cases thus suggesting that BTX is a safe and well-tolerated method in chronic myofascial pains.

Table 5 may be cantered on the Follow-Up Functional Outcomes or Long-Term Pain and Functional Recovery at 3- and 6-Month Intervals.

Table 5: Long-Term Follow-Up of Pain, Functional Independence, and OHRQoL

Outcome Measure	BTX Group (n=60) Baseline	BTX Group 3 Months	BTX Group 6 Months	Placebo Group (n=60) Baseline	Placebo Group 3 Months	Placebo Group 6 Months	p-value (6 months)
Visual Analog Scale (VAS, 0–10)	7.8 ± 1.2	3.2 ± 1.0	2.9 ± 0.9	7.7 ± 1.3	6.8 ± 1.1	6.5 ± 1.2	<0.001
Functional Independence Measure (FIM)	85.3 ± 5.7	102.1 ± 6.2	104.5 ± 6.0	84.8 ± 6.0	88.5 ± 5.9	89.2 ± 5.8	<0.001
Oral Health-Related Quality of Life (OHRQoL)	48.2 ± 3.5	61.5 ± 3.2	63.0 ± 3.0	48.0 ± 3.6	51.2 ± 3.4	52.0 ± 3.3	<0.001



There were improvements in pain, functional independence, and OHRQoL of the BTX group significantly compared to the placebo group at 6 months. These findings point to the long-lasting effectiveness of BTX to offer long-term relief as well as functional recovery.

4.5 Safety and Adverse Events

The results of safety were evaluated based on the observation of adverse events in the two groups. Five subjects (8.3) of the BTX group complained of mild injection-site soreness or bruising that spontaneously improved in a few days. There

were no other groupings of severe systemic complications. BTX therapy is tolerated and has a low occurrence of self limiting and minor side effects. Its topical effect is a safer option to prolonged systemic drug treatment like NSAIDs and opioids.

4.6 Summary of Findings

In general, BTX therapy brought considerable benefits in pain intensity, functional recovery, and psychosocial well-being that were maintained during six months. This is evidenced by the multidimensional effectiveness of BTX in chronic MPD patients in terms of increased physical autonomy, as well as the elevated quality of life. The control group, however, did not exhibit any significant changes, which is a confirmation of the effectiveness of BTX in comparison with the standard care. The results are very strong empirical evidence to BTX as a safe, effective and patient-centered intervention. The combination of various modalities with its application in multimodal rehabilitation can maximize long-term results in the treatment of chronic myofascial pain.

Conclusion

The results of this research are a good indication that Botulinum Toxin (BTX) can be used as a treatment method with patients having chronic Myofascial Pain Disorder (MPD). BTX also showed important pain reduction scores, in terms of the Visual Analog Scale (VAS) which provided not only statistically but also clinically significant relief throughout. In addition to decreased pain, the treatment also increased functional independence, indicated in the increased Functional Independence Measure (FIM) scores, which helped patients to engage in activities of daily living with more ease, involvement in the rehabilitation program, and mobility recovery.

Notably, there was also positive influence of BTX on psychosocial outcomes and oral health-related quality of life (OHRQoL). High quality in emotional well-being and social involvement as well as the perception of patient health were noted as BTX benefited patients more than just physical symptoms, and in a holistic, patient-centered approach. These findings are in line with the modern biopsychosocial theories of chronic pain, which hold that peripheral neuromuscular dysfunction and emotional and social components of well-being have to be considered.

The results of the study support the mechanistic theory of dysfunction in motor end plates in the sense that a specific pharmacological adjustment of neuromuscular activity can be translated into relevant clinical results. Additionally, the reversible and local effect characteristic of BTX, in addition to safety, makes it an effective adjunct to traditional therapies like physical therapy, behavioral therapy and systemic drugs with the least adverse effects.

BTX is a patient-centered and multidimensional mode of treatment of MPD, which is designed to bring long-term relief to pain, reestablish functional autonomy, and enhance the quality of life. Its combination with multimodal treatment modalities provides a promising avenue to improving long-term clinical effectiveness, which can help promote evidence-based medicine in long-term chronic myofascial pain management.

Future Work

Although the present paper proves that Botulinum Toxin (BTX) is effective in the treatment of chronic Myofascial Pain Disorder (MPD), there are still some gaps that should be addressed in order to streamline its clinical use and enhance the comprehension of its long-term implications. It is possible that future studies will be able to consider bigger and more diverse populations of patients to prove the applicability of the results to other age groups, sexes, and cultural settings. This would assist to define whether demographic or lifestyle factors impact the treatment outcomes of BTX and to find subgroups that might benefit the most out of the treatment.

It is also advisable to carry out longitudinal studies that provide a long period of follow-up in order to determine the longevity of BTX analgesic and functional effects. Knowing of the best frequency and dose of administration will become important in coming up with standardized treatment strategies that will make the treatment as effective as possible and any possible adverse effects as minimal as possible. As well, comparative research investigating BTX as a treatment method in comparison with other

pharmacological and non-pharmacological treatment approaches, including physical therapy, cognitive-behavioral therapy, and alternative pain management techniques might offer information on the most effective multimodal treatment of MPD.

Furthermore, there is a possibility of uncovering the biological pathways of BTX beyond neuromuscular modulation that can help understand other pathways with which BTX influences pain perception, functional recovery, and psychosocial well-being. Inclusion of modern imaging methods, neurophysiological and biomarker studies would enhance the mechanistic knowledge of chronic myofascial pain and improve treatment interventions.

Lastly, patient-reported outcomes and quality-of-life measures should be viewed in a broader context in future studies, with the social, emotional, and occupational effects of MPD and BTX therapy being included in that list. By incorporating these dimensions in clinical trials, they will provide a comprehensive assessment of the success of therapeutic measure and aid in the formulation of patient-centered guidelines. Together, these future directions can be used to improve clinical usefulness of BTX, chronic pain management, as well as will be part of multidimensional care approaches to people with debilitating musculoskeletal disorders that are evidence-based.

REFERENCES

Abdul Rahman, A. M., Al-Hawwaz, Z. M., & Haji, S. A. (2026). Outcomes of Treating Myofascial Pain by Injecting Masseter and Temporalis Muscles with Botulinum Toxin. *Journal of Maxillofacial and Oral Surgery*, 1-8.

da Silva Ramalho, J. A., Palma, L. F., Ramalho, K. M., Tedesco, T. K., & Morimoto, S. (2023). Effect of botulinum toxin A on pain, bite force, and satisfaction of patients with bruxism: A randomized single-blind clinical trial comparing two protocols. *The Saudi Dental Journal*, *35*(1), 53-60.

De la Torre Canales, G., Câmara-Souza, M. B., Poluha, R. L., de Figueredo, O. M. C., Nobre, B. B. d. S., Ernberg, M., Conti, P. C. R., & Rizzatti-Barbosa, C. M. (2022). Long-term effects of a single application of botulinum toxin type A in temporomandibular myofascial pain patients: a controlled clinical trial. *Toxins*, *14*(11), 741.

De la Torre Canales, G., Poluha, R. L., Bonjardim, L. R., Ernberg, M., & Conti, P. C. R. (2024). Botulinum toxin-A effects on pain, somatosensory and psychosocial features of patients with refractory masticatory myofascial pain: a randomized double-blind clinical trial. *Scientific reports*, *14*(1), 4201.

Henien, M., Mahendran, K., Al-Sarraj, M., Rowe, S., & Maciag, A. (2025). Botulinum toxin A for the management of temporomandibular myofascial pain: A cohort study. *British Journal of Oral and Maxillofacial Surgery*, *63*(1), 53-60.

Hosgor, H., Coskunses, F. M., & Altindis, S. (2023). Assessing change in functional outcomes and quality of life in myogenic temporomandibular disorders undergoing botulinum toxin injection: A before and after comparison. *Journal of Stomatology, Oral and Maxillofacial Surgery*, *124*(4), 101434.

İşisağ, Ö., Atasoy, H., & Yıldız, S. (2025). Comparison of the effects of occlusal splint and Botox injections on the amount of mouth opening and chronic pain in individuals with temporomandibular disorders: a systematic review and meta-analysis. *Australian Dental Journal*, *70*(2), 132-140.

Khounganian, R. M., Mahdi, A. A., Aloshaywi, A. K., & Almanqur, A. I. (2024). Botulinum toxin type A for pain control in temporomandibular joint disorder patients. *Int J Community Med Public Health*, *11*, 4974-4983.

Kim, S. R., Chang, M., Kim, A. H., & Kim, S. T. (2023). Effect of botulinum toxin on masticatory muscle pain in patients with temporomandibular disorders: a randomized, double-blind, placebo-controlled pilot study. *Toxins*, *15*(10), 597.

Le, V., Shah, A., & Elgazzar, R. (2024). Treatment of myofascial pain and dysfunction using botulinum toxin A: a prospective study. *Tanta Dental Journal*, *21*(3), 319-329.

Leonardi, G., Alito, A., Portaro, S., Di Matteo, B., Respizzi, S., Kon, E., Massazza, G., & Sconza, C. (2024). Intramuscular injections of botulinum toxin for the treatment of upper back myofascial pain syndrome: A systematic review of randomized controlled trials. *European Journal of Pain*, *28*(3), 369-381.

Li, K., Tan, K., Yacovelli, A., & Bi, W. G. (2024). Effect of botulinum toxin type A on muscular temporomandibular disorder: a systematic review and meta-analysis of randomized controlled trials. *Journal of Oral Rehabilitation*, *51*(5), 886-897.

Lippi, L., De Sire, A., Folli, A., D'Abrosca, F., Grana, E., Baricich, A., Carda, S., & Invernizzi, M. (2022). Multidimensional effectiveness of botulinum toxin in neuropathic pain: a systematic review of randomized clinical trials. *Toxins*, *14*(5), 308.

Macedo de Sousa, B., López-Valverde, N., Ferreira, C., Almeida, A. M. d., López-Valverde, A., & Blanco Rueda, J. A. (2025). Efficacy of botulinum toxin type A in myogenic temporomandibulardisorders: a single arm, prospective, pilot study. *Frontiers in Rehabilitation Sciences*, *6*, 1737706.

Minston, A., Abrahamsson, H., Abrahamsson, P., Lindfors, E., Nohlert, E., Ovesson, D., Yekkalam, N., & Isacsson, G. (2025). Effect on Pain Following One Session of Botulinum Toxin Type A in Patients With Jaw Myalgia: A Randomised Double-Blind Controlled Multicentre Pilot Study. *Journal of Oral Rehabilitation*, *52*(5), 587-596.

Ornag, B., Bayram, H. M., Sabuncular, G., Aktac, S., & Bayram, F. (2025). Effects of Botulinum Toxin on Chewing Function, Orofacial Pain, and Nutritional Status: A Follow-Up Study. *Academic Journal of Health Sciences*, *40*(4), 51-61.

Rahmatipour, H., Shabestari, S. M., Benisi, S. Z., & Samadikhah, H. (2025). Pioneering pain management with botulinum toxin type A: From anti-inflammation to regenerative therapies. *Heliyon*, *11*(4).

Reeve, G. S., Insel, O., Thomas, C., Houle, A. N., & Miloro, M. (2024). Does the use of botulinum toxin in treatment of myofascial pain disorder of the masseters and temporalis muscles reduce pain, improve function, or enhance quality of life? *Journal of Oral and Maxillofacial Surgery*, *82*(4), 393-401.

Şahin, S. S., Şişman, A. Ç., Atar, E., Kilaç, H., & Sultanoğlu, E. G. (2024). Comparison of the effectiveness of botulinum toxin, dry needling, pharmacological treatment, and manual therapy for bruxism-induced myalgia: a prospective randomized study. *Journal of Oral & Facial Pain and Headache*, *38*(4), 101.

Shabaan, A. A., Kassem, I., Aboulmagd, I., Amer, I. A., Shaaban, A., Abd-El-Ghafour", M., & Refahee, S. M. (2024). Effectiveness of intra-oral botulinum toxin injection in comparison to the extra-oral approach on pain and quality of life in patients with myofascial pain: a randomized clinical trial. *Clinical Oral Investigations*, *29*(1), 18.

Shalaby, R. H., Shaaban, S. H., Abd El Rahim, A., & Mikhail, C. R. G. (2022). The efficacy of botulinum toxin type A injection in treatment of myofacial pain dysfunction syndrome A randomized placebo controlled clinical trial. *NeuroQuantology*, *20*(3), 870-880.

Val, M., Delcanho, R., Ferrari, M., Guarda Nardini, L., & Manfredini, D. (2023). Is botulinum toxin effective in treating orofacial neuropathic pain disorders? A systematic review. *Toxins*, *15*(9), 541.

Zhou, J. (2025). The Effectiveness of Botulinum Toxin Injections in the Management of Chronic Neck and Shoulder Myofascial Pain: A Nursing Perspective.

Zhu, M., Huang, Z., Wang, Y., Qin, J., & Fan, M. (2024). Effects of botulinum toxin type A in patients with painful temporomandibular joint disorders: a systematic review and meta-analysis. *Annals of Medicine and Surgery*, *86*(7), 4112-4122.