



BOTULINUM TOXIN-A INJECTIONS INTO  
FACIAL MUSCLES FOR THE TREATMENT  
OF TEMPOROMANDIBULAR DISORDERS  
AND BRUXISM:  
**A SYSTEMATIC REVIEW**

LIBRARY DISSERTATION

152004006 (2020 – 2023)  
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## STRUCTURED ABSTRACT

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**Background:** Currently it has been shown that botulinum toxin is effective for a wide variety of medical conditions, and can be applied for therapeutic purposes as cosmetic. In recent years, there has been a growing trend in the use of this drug substance to control the muscular overactivity of bruxism. The objective of this study was the use of botulinum toxin type A (BTX-A) than traditional methods, by conducting a systematic review of randomized clinical trials (RCTs) published in the health sciences literature.

**Materials and Methods:** An electronic search was made in the databases of PubMed, Cochrane Library, Google Scholar and LILACS from Jan 2016. Studies that were included were of patients suffering from bruxism and/or TMD, older than 18 years where BTX-A tests were performed on the masseter and / or temporal muscles and the control systems were injections of placebo (saline) or the use of traditional methods for the treatment of bruxism. such as occlusal splints, other medications or cognitive behavioural therapy.

**Results:** Of the 62 articles sourced, 6 fit the inclusion criteria. These studies show that BTX-A injections can reduce the frequency of bruxism episodes, decrease pain levels and maximum occlusal force generated by this pathology, offer superior efficacy in the treatment of bruxism compared to control groups who were treated with placebo or with traditional methods for the treatment of bruxism.

**Conclusion:** Infiltrations with BTX-A are a safe and effective treatment for patients with bruxism, so its use is justified in daily clinical practice, especially in patients diagnosed with severe bruxism.

## INTRODUCTION

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Bruxism is a repetitive activity of the masticatory muscles characterized by tightening or grinding of the teeth and which may have two distinct manifestations: sleep bruxism (SB) or awake bruxism (AB). It is a common condition with an adult prevalence ranging between 8 and 31%, which has acquired considerable clinical relevance due to its association with tooth abrasions and mobility, fracture of dental restorations, hypertrophy of the masseter muscle and myalgia or arthralgia characteristic of temporomandibular disorders (TMD), among other signs and symptoms. Although etiological factors have been proposed, such as emotional stress, neurological disorders, certain drugs and occlusal interferences, the aetiology and pathophysiology of bruxism are still unclear, although it seems to have a multifactorial origin mediated by nervous systems: central and autonomous.

Various modalities of treatment for the management of bruxism have been investigated, such as: occlusal splints, drugs such as benzodiazepine or L-dopa and cognitive-behavioural therapy, but they have not been shown to be completely effective, since their effect does not seem to solve the cause of it and serves mainly for the management of the signs and symptoms of patients, helping to limit the destructive effects of bruxism on anatomical structures. At present, it has been shown that botulinum toxin is effective for a wide variety of medical pathologies, used both for its therapeutic effect and for aesthetic medicine; It is a neurotoxin produced by a Gram-positive aerobic bacterium called *Clostridium botulinum*. There are seven different types of exotoxins, botulinum toxin type A (BTX-A) is a biological variant that temporarily inhibits skeletal muscle by hindering the production of acetylcholine and inactivating calcium channels in nerve endings. In recent years, there has been an increasing trend in the use of this drug to control the activity of bruxism.

The purpose of this systematic review, is the further explore the usage of Botulinum Toxin, for the management and treatment of Temporomandibular Disorders and Bruxism.

## AIM

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The aim of this systematic review was to analyse the existing literature on the use of Botulinum Toxin A injections into Facial Muscles for the treatment of Temporomandibular Disorders and Bruxism

## STRUCTURED QUESTION

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*Does injecting Botulinum Toxin A into the Facial muscles lead to a reduction in Pain in individuals with Temporomandibular Disorders and Bruxism?*

### **PICO Analysis**

**P** – Individuals with Temporomandibular Disorders and/or Bruxism

**I** – Botulinum Toxin A injection into Facial muscles

**C** – Traditional methods

**O** – Pain

## MATERIALS AND METHODS

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### INCLUSION CRITERIA

The planning and preparation of this study has followed the guidelines established by the PRISMA declaration for the preparation of systematic reviews and meta-analysis.

- Randomized controlled clinical trials (RCTs) involving bruxism patients older than 18 years in which the effect of botulinum toxin in the treatment of bruxism compared with traditional therapy is analysed. (Up to 2016)

### Types of studies:

Randomized controlled trials

Clinical trials.

### Types of Participants:

Patients suffering from TMD and/or bruxism

### Types of Intervention:

The use of Botulinum Toxin injection into the facial muscles

### Types of Comparison:

Traditional methods

### Types of Outcome Measures:

Pain

## EXCLUSION CRITERIA

- Randomized controlled clinical trials (RCTs) involving bruxism patients older than 18 years in which the effect of botulinum toxin in the treatment of bruxism compared with traditional therapy is analysed. (Before 2016)
- Studies in which bruxism was caused by psychological or neurological disorders and those who used this therapy aimed at the treatment of other diseases were excluded.
- Descriptive studies
- Observational studies
- Reviews

## SOURCES USED

The Databases of PubMed Central, Cochrane, LILACS, Google Scholar.

Search method for the identification of studies:


To identify the studies to be included for detailed evaluation in systematic review, following search strategy were developed for each database searched:

1. PubMed Central – Randomised Controlled Trial (published till Jan 2016)
2. The Cochrane Central Register of Clinical Trials - Randomised Controlled Trial (published till Jan 2016)
3. LILACS - Randomised Controlled Trial (published till Jan 2016)
4. Google Scholar - Randomised Controlled Trial (published till Jan 2016)

Fig 1. – PubMed Search Terms

Search	Actions	Details	Query	Results	Time
#11	...	>	Search: (#6) AND (#7) Filters: Free full text, Randomized Controlled Trial, in the last 5 years	28	11:42:58
#10	...	>	Search: (#6) AND (#7) Filters: Free full text, Randomized Controlled Trial	65	11:42:46
#9	...	>	Search: (#6) AND (#7) Filters: Randomized Controlled Trial	228	11:42:40
#8	...	>	Search: (#6) AND (#7)	1,725	11:42:29
#7	...	>	Search: (pain) OR (healing)	1,134,140	11:41:17
#6	...	>	Search: (#4) AND (#5)	9,041	10:53:05
#5	...	>	Search: (((((((face) OR (facial)) OR (muscle)) OR (facial muscle)) OR (masticatory muscle)) OR (masseter)) OR (digastric)) OR (pterygoid) OR (myofascial)	1,594,544	10:52:55
#4	...	>	Search: ((((((botox) OR (botulinum)) OR (botulinumtoxin)) OR (botulinumtoxinA)) OR (botulinum toxin)) OR (botulinum toxin A)) OR (BTX-A)	24,755	10:48:57
#3	...	>	Search: (#1) AND (#2)	1,360	10:47:32
#2	...	>	Search: ((((((temporomandible) OR (temporomandibular)) OR (TMJ)) OR (TMD)) OR (temporomandibular disorder)) OR (temporomandibular joint)	38,358	10:47:10
#1	...	>	Search: (((((((brux) OR (bruxism)) OR (grind)) OR (grinding)) OR (tooth grinding)) OR (teeth grinding)) OR (night grinding))	19,661	10:46:16


Fig 2. – PubMed Search Results



**National Library of Medicine**  
National Center for Biotechnology Information

Log in

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X
Search


User Guide

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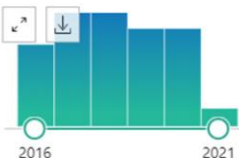
Save    Email    Send to

Sorted by: Best match    Display options

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MY NCBI FILTERS 

RESULTS BY YEAR



TEXT AVAILABILITY

Abstract

Free full text

Full text

ARTICLE ATTRIBUTE

Associated data

ARTICLE TYPE

28 results

Filters applied: Free full text, Randomized Controlled Trial, in the last 5 years. [Clear all](#)

Efficacy of **botulinum toxin** in treating **myofascial pain** and occlusal force characteristics of **masticatory muscles** in bruxism.

Cite: Jadhao VA, Lokhande N, Habbu SG, Sewane S, Dongare S, Goyal N. Indian J Dent Res. 2017 Sep-Oct;28(5):493-497. doi: 10.4103/ijdr.IJDR\_125\_17. Share: PMID: 29072209 [Free article](#). Clinical Trial.

AIM AND OBJECTIVE: The present study was conducted in patients with bruxism to evaluate the effect of **botulinum toxin type A (BTX-A) (Botox)**, Allergan, Inc., Irvine, CA, USA) in the treatment of **myofascial pain** and the occlusal forc ...

Cerebral palsy and bruxism: Effects of **botulinum toxin** injections-A randomized controlled trial.

Cite: Cahlin BJ, Lindberg C, Dahlström L. Clin Exp Dent Res. 2019 Jun 29;5(5):460-468. doi: 10.1002/cre2.207. eCollection 2019 Oct. Share: PMID: 31687178 [Free PMC article](#). Clinical Trial.

Bruxism and temporomandibular disorders are overrepresented. Neuromuscular blocks with **botulinum toxin type A (BTX-A)** may alleviate problems due to muscular hyperactivity. The aim was to evaluate **masticatory muscle BTX-A** injections ...

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Fig 3. – Cochrane Search Terms

The screenshot shows the Cochrane Advanced Search page. At the top, there are navigation links: Cochrane Reviews, Trials, Clinical Answers, About, and Help. Below this is the 'Advanced Search' section with tabs for Search, Search manager, Medical terms (MeSH), and PICO search<sup>BETA</sup>. A 'Save search' button is visible. A message informs the user that they can now select fields from Search manager using the 'S' button. Below the message, there is a search box with the following terms and operators:
 

- Search box: "bruxism"
- Operator: AND
- Field: All Text
- Search box: "temporomandibular"
- Operator: AND
- Field: All Text
- Search box: muscle
- Operator: AND
- Field: All Text
- Search box: "Botox"
- Operator: AND
- Field: All Text
- Search box: pain

 A note at the bottom states: "(Word variations have been searched)".

Fig 4. – Cochrane Search Results

The screenshot shows the Cochrane search results page. At the top, there are navigation links: Cochrane Reviews (1), Cochrane Protocols (0), Trials (5), Editorials (0), Special Collections (0), Clinical Answers (0), and More. A banner for COVID-19 studies is present. The main heading reads: "5 Trials matching 'bruxism' in All Text AND 'temporomandibular' in All Text AND muscle in All Text AND 'Botox' in All Text AND pain in All Text - (Word variations have been searched)". Below this, it says "Cochrane Central Register of Controlled Trials" and "Issue 3 of 12, March 2021". A button prompts the user to "Authenticate to get access to full CENTRAL content" and "Unlock the potential of Cochrane Evidence". The results are ordered by Relevance, with 25 results per page. Three results are shown:
 

- Botox for Treatment of TMJ Disorder With Bruxism**  
NCT02202070  
<https://clinicaltrials.gov/show/NCT02202070>, 2014 | added to CENTRAL: 31 May 2018 | 2018 Issue 5 | CT.gov
- Evaluation of the position of the mandible after application of BOTOX in patients with disorders in the mandibular joint: a randomized study**  
RBR-2b23xm  
<http://www.who.int/trialsearch/Trial2.aspx?TrialID=RBR-2b23xm>, 2020 | added to CENTRAL: 31 October 2020 | 2020 Issue 10 | ICTRP
- Effect of Botox Treatment on the quality of life of patients with teeth grinding and pain in the Temporomandibular Joint**  
RBR-6jhhqzd  
<http://www.who.int/trialsearch/Trial2.aspx?TrialID=RBR-6jhhqzd>, 2018 | added to CENTRAL: 31 March 2019 | 2019 Issue 3 | ICTRP

Fig 5. – LILACS Search Terms

page 1 of 1

YOUR SELECTION PAGE TOP

Refine the search

Database : LILACS Advanced form

	Search	in field	
1	bruxism	Words	index
2	and temporomandibular	Words	index
3	and botox	Words	index

CONFIG CLEAR SEARCH

Search engine: IAH v2.6 powered by WWWISIS

Fig 6. – LILACS Search Results

virtual health library Database search

YOUR SELECTION SEND RESULT NEW SEARCH CONFIG PAGE BOTTOM

Database : LILACS  
 Search on : bruxism [Words] and temporomandibular [Words] and botox [Words]  
 References found : 9 [refine]  
 Displaying: 1 .. 9 in format [Detailed]

page 1 of 1

1 / 9 LILACS

<input type="checkbox"/>	select	<b>Id:</b> biblio-1104154
	to print	<b>Author:</b> Lima, Luísa Sobrino Reis; Guedes, Júlia Laurentino de Souza; Tuñas, Inger Teixeira de Campos.
	Photocopy	<b>Title:</b> Toxina Botulínica em Odontologia: Uma Revisão de Literatura / Botulinum Toxin in Dentistry: A Literature Review
	Full text	<b>Source:</b> <a href="#">Rev. bras. odontol</a> ;77(1):1-8, jan. 2020. Ilus, Tab.
		<b>Language:</b> en.
		<b>Abstract:</b> Objetivo: o objetivo desse trabalho foi, através de uma revisão de literatura, discutir o mecanismo de ação, as características de uso das toxinas botulínicas, suas indicações estéticas e terapêuticas, elaborando um conteúdo prático e ilustrado a fim de que graduandos em Odontologia e cirurgiões-dentistas possam ter um primeiro contato com o tema. Materiais e Métodos: foi realizado um levantamento nas bases de dados Google Scholar, Pubmed e Scielo, com a palavras chave: Toxinas Botulínicas, Odontologia,

Fig 7. – Google Scholar Search Results

The screenshot shows the Google Scholar search interface. The search bar contains the query: "randomised controlled trial AND temporomandibular joint disorder AND bruxis". The results page shows "Articles" with "About 25 results (0.06 sec)".

On the left side, there are filters for "Any time" (Since 2021, Since 2020, Since 2017, Custom range...), a "Search" button, "Sort by relevance" and "Sort by date", and checkboxes for "include patents", "include citations", and "Create alert".

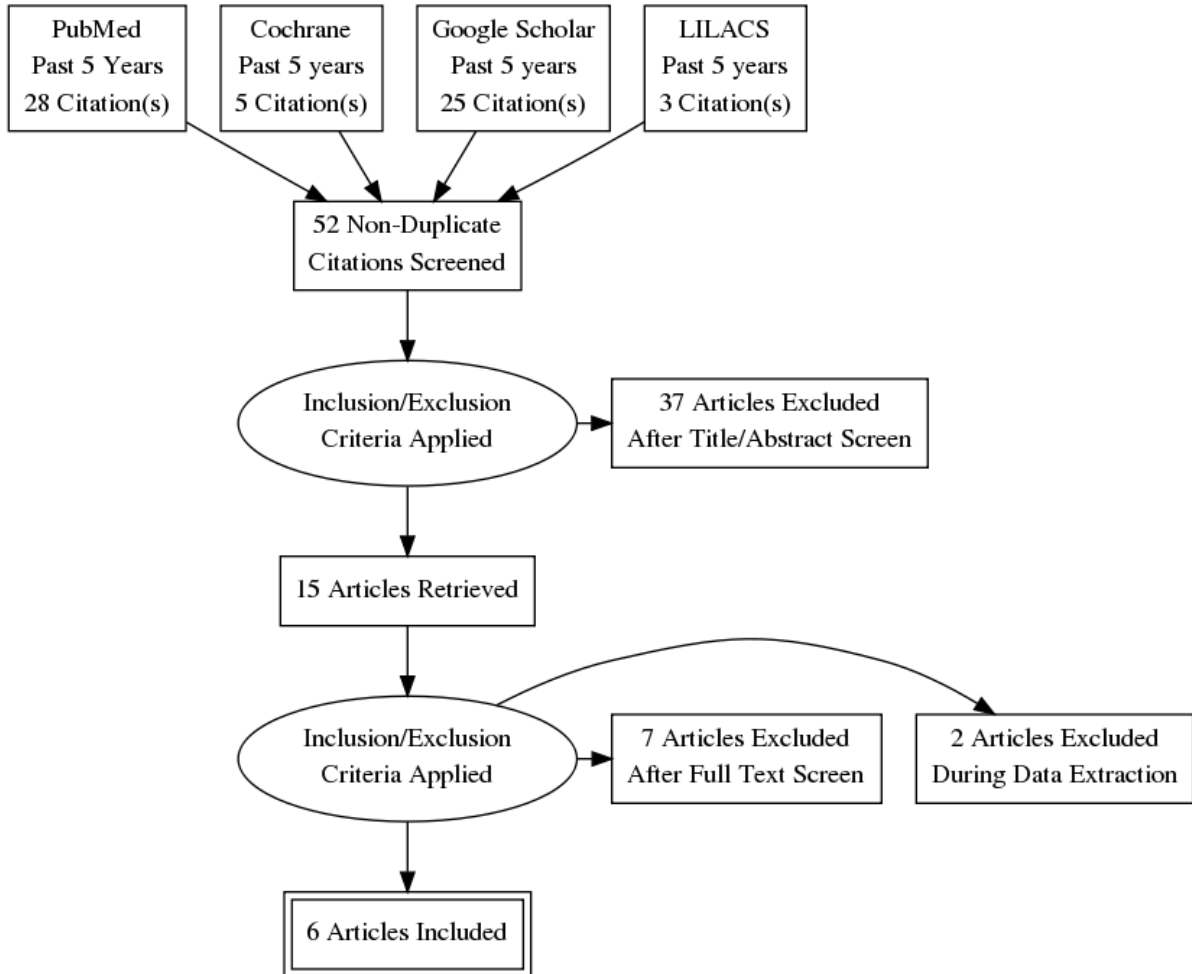
The search results list several articles:

- Improvement in quality of life after botulinum toxin injection for temporomandibular disorder**  
S Villa, G Raoul, F Machuron, J Ferri, R Nicot - Journal of stomatology, oral ..., 2019 - Elsevier  
... Clinical injection of BTX-A in masticatory muscles of patients with TMD can be considered as a useful ... However, additional studies with larger samples are required to extrapolate these results, perhaps a randomised, double-blind, placebo-controlled trial testing a null ...  
☆ ⓘ Cited by 10 Related articles All 5 versions Import into BibTeX
- Photobiomodulation therapy for myofascial pain in temporomandibular joint dysfunction: a double-blinded randomized clinical trial**  
M Nadershah, HM Abdel-Alim, AM Bayoumi... - Journal of maxillofacial ..., 2020 - Springer  
... significant difference in pain reduction between the test and control groups with ... in the treatment of TMDs: a meta-analysis of 14 randomised controlled trials ... laser therapy on experimental orthodontic pain caused by elastomeric separators: a randomized controlled clinical trial ...  
☆ ⓘ Cited by 6 Related articles All 6 versions Import into BibTeX
- [PDF] Impact Age in Treatment Myofascial Pain with Temporomandibular Joint Disorders by Botox Injection**  
ZA Daily, NB Mohammed... - Indian Journal of Forensic ..., 2020 - researchgate.net  
... 14, No. 1 519 drooling in Parkinson's disease: A double-blind, randomized, placebo-controlled study. J. Mov ... 8) Hyun-Suk K., Pil-Young Y., and Young-Kyun K. A clinical evaluation of botulinum toxin-A injections in the temporomandibular disorder treatment ...  
☆ ⓘ Related articles Import into BibTeX ⓘ
- [PDF] The effects of proprioceptive neuromuscular facilitation, myofascial releasing maneuvers and home exercises on pain and jaw function in patients with bruxism**  
E Calisgan, B Talu, O Altun, N Dedeoglu, B Duman - Medicine, 2018 - researchgate.net  
... individuals were listed by number and those to be sampled were selected using a random number table ... Report of a randomised controlled trial ... therapy interventions, relative to dental treatment in individuals with bruxism: Study protocol of a randomized clinical trial, Trials ...  
☆ ⓘ Cited by 1 Related articles All 3 versions Import into BibTeX ⓘ
- Botox: It's Not Just About The Wrinkles**  
N Prado, L Rose, P Korczak - Dental Update, 2018 - magonlinelibrary.com  
... firing of neurons as well as an impairment of the inhibitory mechanisms that control activity in ... parotid surgery (for example, total parotidectomy) and is thought to be due to random regeneration of ... The use of Botulinum toxin in clinical treatments is both well established and safe ...  
☆ ⓘ Related articles Import into BibTeX

Electronic search was carried out using the keywords in the Search engines- PubMed, Cochrane, LILACS and Google Scholar which yielded a total of 52 articles. Based on the specific inclusion and exclusion criteria, the titles of the studies identified from the search were assessed independently by two review authors (Dr. Sabari Nathan Rajamoorthy and Dr. Hemavathy). Conflicts concerning inclusion of the studies were resolved by discussion. 37 articles were identified and excluded by reading titles, abstracts and removing duplicates. Abstracts of selected articles were reviewed independently. 15 articles were retrieved of which 7 were excluded after full text review and a further 2 were excluded during data extraction. Quality Assessment criteria to evaluate the studies were decided by two review authors in accordance with CONSORT and Cochrane Collaboration Guidelines. The risk of bias for each study was independently assessed by the review authors and conflicts concerning risk of bias were sorted by discussion.

**6 Articles** were chosen for analysis in this Systematic Review.

Fig. 8 – PRISMA Flowchart for Included Studies



## DATA EXTRACTION

Data extraction for general characteristics of studies and variables of outcome was done:

For each trial the following data were recorded:

- Author
- Study Design
- Sample Size
- Participants and Group age
- Methodology
- Clinical Parameters Measured
- Recall period
- Statistical Analysis
- Results

*Table 1: Variables of Interest*

S. NO	VARIABLES OF INTEREST
1	Post-operative pain evaluated using Visual Analogue Scale

## QUALITY ASSESSMENT

(Higgins and Green. Cochrane reviewer's hand book 2009)

The quality assessment of included trials was undertaken independently as a part of data extraction process. Four main quality criteria were examined.

1. Method of Randomization, recorded as

- a) YES- Dropouts were explained
- b) NO- Dropouts were not explained
- c) NONE- No Dropouts or withdrawals.

2. Allocation Concealment, recorded as

- a) YES- Dropouts were explained
- b) NO- Dropouts were not explained
- c) NONE- No Dropouts or withdrawals.

3. Outcome assessors Blinded to intervention, recorded as

- a) YES- Dropouts were explained
- b) NO- Dropouts were not explained
- c) NONE- No Dropouts or withdrawals.

4. Completeness of Follow up (was there a clear explanation for withdrawals and dropouts in each treatment group) assessed as

- a) YES- Dropouts were explained
- b) NO- Dropouts were not explained
- c) NONE- No Dropouts or withdrawals.

Other methodological criteria examined included:

- a) Presence or Absence of sample size calculation.
- b) Comparability of Groups at the start.
- c) Clear Inclusion or Exclusion criteria.
- d) Presence or Absence of estimate of measurement error.

Table 2: Description of Included Studies

AUTHOR	SAMPLE SIZE/AGE	EXPERIMENTAL GROUP	CONTROL GROUP	CLINICAL PARAMETERS EVALUATED	RECALL TIME	STATISTICAL ANALYSIS	RESULT	LIMITATION
Wayli et. Al, 2017	50 Aged 20-60	(25 participants)  BTX-A 20 UI Into Masseter bilaterally	(25 participants)  Traditional methods	Average pain scores using 10cm VAS	3 weeks, 2 months, 6 months, 1 year	Student unpaired t-test Wilcoxon sign rank test (P<0.05)	20 UI per side Botulinum toxin injection in the masseter muscles is an effective and safe means of intervention in cases of moderate to severe chronic myofascial and TMJ pain associated with bruxism.	No elaboration on “traditional methods” No blinding done
Guarda-Nardini et. Al, 2014	20  Aged 25-45	(10 participants)  4 Type A botulinum toxin (BTX-A)  (Botox, Irvine, Allergan, Inc., CA).  30 UI – Masseter  3 x 20 UI – Anterior temporalis  100 UI – Total	(10 participants)  Saline placebo injection	<ul style="list-style-type: none"> <li>• Pain at rest and during chewing (VAS)</li> <li>• Mastication efficiency</li> <li>• Maximum non-assisted and assisted mouth opening</li> <li>• Protrusive and lateral movements</li> <li>• Functional limitation during usual jaw movements</li> <li>• Subjective efficacy of the treatment</li> <li>• Tolerance of the treatment</li> </ul>	Baseline, 1 week, 1 month, 6 months	Two-sample permutation test  Anderson- Darling permutation test  Bonferroni- Holm method	Investigation supported the efficacy of BTX-A to reduce myofascial pain symptoms, even though differences with the placebo were not significant in some cases.	Sample size is small Unclear risk



AUTHOR	SAMPLE SIZE/AGE	EXPERIMENTAL GROUP	CONTROL GROUP	CLINICAL PARAMETERS EVALUATED	RECALL TIME	STATISTICAL ANALYSIS	RESULT	LIMITATION
Jadhao et. Al, 2017	24 Aged 20-35	(8 participants) BTX-A 20 UI Into Masseter bilaterally (8 participants) Placebo saline injection	(8 participants) No injection	<ul style="list-style-type: none"> <li>• Pain at rest (VAS)</li> <li>• Pain at chewing (VAS)</li> <li>• Occlusal force analysis (Imotion occlusal force analyser)</li> </ul>	1 week, 3 months, 6 months	Multivariate analysis of variance  Post hoc Bonferroni test  Students t-test (P<0.05)	BTX-A was effective for treatment of bruxism to reduce myofascial pain symptoms in bruxers. We also achieve that the occlusal analysis system precisely imitates the characteristics of occlusal force during treatment of bruxism. BTX-A has obvious advantages for the treatment of bruxism in terms of tumbling the occlusal force.	Small sample size
Baughman et. Al, 2014	32 Aged 18-65	(16 participants) 50 units Botox injection in masseter and temporalis muscles in the first 3 months, then second injection of normal saline at placebo in second 3 months	(16 participants) Injection of normal saline at placebo in first 3 months, then 50 units Botox injection in masseter and temporalis muscles in the second 3 months.	<ul style="list-style-type: none"> <li>• Average pain score using VAS</li> <li>• Maximal opening at incisors</li> <li>• Lateral and anterior excursion</li> <li>• Progression to TMJ arthroscopic and arthroplasty procedures</li> </ul>	Baseline, 3 months, 6 months	-	Primary outcome of the study is 50% reduction in pain.  Secondary outcomes are 50% reduction in surgical therapy, 25% increase in maximal inter-incisal opening (MIO).	No statistical analysis present.

AUTHOR	SAMPLE SIZE/AGE	EXPERIMENTAL GROUP	CONTROL GROUP	CLINICAL PARAMETERS EVALUATED	RECALL TIME	STATISTICAL ANALYSIS	RESULT	LIMITATION
Kaya et. Al, 2021	40 Aged 18-45	(20 participants) BTX-A 24 UI Into Masseter unilaterally	(20 participants) Occlusal splint for atleast 8 hours a day	<ul style="list-style-type: none"> <li>• Pain assessment (VAS)</li> <li>• Maximum bite force</li> </ul>	2 weeks, 6 weeks, 3 months, 6 months	Mann-Whitney U test Freidman test Wilcoxon test Chi-squared test (P<0.05)	BTX-A is a costly procedure that requires repeated dosing and is more invasive than splint applications. According to the results of this clinical study, low doses of BTX-A may be considered as an alternative treatment in patients who cannot use occlusal splints for various reasons.	Methodology vague. Difficult to monitor patients for wearing of occlusal splint for 8 hours.
Ondo et. Al, 2018	23 Aged 18-85	(13 Participants) BoNT-A 200 units (60 into each masseter and 40 into each temporalis)	(10 participants) Injection of normal saline	<ul style="list-style-type: none"> <li>• Clinical global impression</li> <li>• Changes in pain (VAS)</li> </ul>	Baseline, 4 weeks, 8 weeks	-	BoNT-A effectively and safely improved sleep bruxism in this placebo-controlled pilot trial. A large multi-center trial is needed to confirm these encouraging data.	No statistical analysis present. Uneven sample groups

Table 3: Evidence Level of Selected Articles

NO.	STUDY TITLE	AUTHOR	STUDY DESIGN	LEVEL OF EVIDENCE
1	Treatment of chronic pain associated with nocturnal bruxism with botulinum toxin. A prospective and randomized clinical study	Wayli et. Al, 2017	Randomised Controlled Trial	1b
2	Efficacy of Botulinum Toxin in Treating Myofascial Pain in Bruxers: A Controlled Placebo Pilot Study	Guarda-Nardini et. Al, 2014	Randomised Controlled Trial	1b
3	Efficacy of botulinum toxin in treating myofascial pain and occlusal force characteristics of masticatory muscles in bruxism	Jadhao et. Al, 2017	Randomised Controlled Trial	1b
4	Botox for Treatment of TMJ Disorder with Bruxism (TMJ)	Baughman et. Al, 2014	Randomised Controlled Trial	1b
5	Botulinum toxin treatment of temporomandibular joint pain in patients with bruxism: A prospective and randomized clinical study	Kaya et. Al, 2021	Randomised Controlled Trial	1b
6	Onabotulinum toxin-A injections for sleep bruxism: A double-blind, placebo-controlled study	Ondo et. Al, 2018	Randomised Controlled Trial	1b

## RISK OF BIAS IN INCLUDED STUDIES

Risk of bias assessed using Cochrane Collaboration Tool in Revman 5.1

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Baughman et. Al, 2014	⊖	⊖	⊕	⊕			
Guarda-Nardini et. Al, 2014	⊕	⊕	⊕	⊕	⊕		
Jadhao et. Al, 2017	⊕	⊕	⊕		⊖		
Kaya et. Al, 2021		⊖	⊖	⊖			
Ondo et. Al, 2018	⊕	⊕	⊕		⊖		
Wayli et. Al, 2017	⊕	⊖	⊖	⊖	⊕	⊕	

## DISCUSSION

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Botulinum toxins, purified exotoxins of *Clostridium botulinum*, have been used for a long period of time for numerous neuromuscular disorders. These toxins can inhibit neuromuscular transmission, which justifies its clinical application in the treatment of bruxism, since recent scientific evidence has indicated that bruxism has a multifactorial aetiology mediated by the central nervous and autonomic systems, which regulate the motor activity of the chewing muscles. Currently, many authors support the use of BTX-A for the treatment of various conditions of the oral-maxillofacial region based on the positive results obtained in various clinical trials collected in the literature. Rao et al. made a review showing the results of several clinical trials and case reports that supported the use of BTX-A for the treatment of TMD, gingival smile correction, muscle hypertrophy and spasms, headache (migraine), trigeminal neuralgia and even after the placement of dental implants. They noted that although BTX-A could decrease muscle strength and mastication, it is temporary and normal function would return when the effect of the toxin disappeared.

GayEscoda et al. conducted a review of the literature that included clinical trials in which BTX-A was used in the salivary glands for the treatment of sialorrhea derived from different neurological disorders such as infantile cerebral palsy, the disease of Parkinson's and amyotrophic lateral sclerosis. More than half of the authors injected the product into the parotid glands, 9.5% in the submaxillary glands and 38% in both. The total doses of toxin injected varied from 10 to 100 IU of Botox® or 30 to 450 IU of Dysport® according to the different authors. A reduction in saliva production was observed after these injections, and the duration of the therapeutic effect was 1.5-6 months. Six articles (30%) described the presence of adverse effects such as dysphagia, xerostomia and difficulties to chew. The authors concluded that the injection of BTX-A in the salivary glands may be a valid treatment option in patients with sialorrhea, since it is able to improve the quality of life, however, it is important to be aware that the duration of the therapeutic effect is limited in time and usually lasts a few months. In a retrospective study carried out by Alonso-Navarro et al., the evolution of 19 patients with severe bruxism who were treated periodically with infiltrations of BTX-A in both temporal and masseter muscles, using initial doses of 25 IU per muscle, during follow-up periods of 0.5 to 11 was described; the doses were adjusted throughout the follow-up according to the degree of response observed. None of the patients presented side effects. The final dose ranges reached ranged from 25 to 40 IU per muscle and the duration of the effects ranged from 13 to 26 weeks. Based on these results, they concluded that infiltrations with BTX-A are a safe and effective treatment for patients with severe bruxism.

## CONCLUSION

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In conclusion, the infiltrations of BTX-A can reduce the frequency of bruxism episodes, as well as the masticatory force, and decrease the levels of pain derived from it, which translates into an improvement in the quality of life of patients. In addition, in doses <100UI it is a safe treatment with a low probability of adverse effects occurring in healthy patients. Therefore, the use of BTX-A is a safe and effective treatment for patients with bruxism that shows better clinical results than traditional methods such as occlusal splints, drugs or cognitive-behavioural therapy, so its use would be justified in daily clinical practice, especially in patients diagnosed with severe bruxism.

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