Saudi Dental Journal (2021) 33, 1004–1011

King Saud University

Saudi Dental Journal

www.ksu.edu.sa
www.sciencedirect.com

ORIGINAL ARTICLE

Botulinum toxin and occlusal splints for the management of sleep bruxism in individuals with implant overdentures: A randomized controlled trial

Samer Mostafa Ali [a], **Ahmed Yaseen Alqutaibi** [b,c,*], **Afaf Aboalrejal** [d], **Dina Mohamed Elawady** [a]

[a] *Department of R.Prosthodontics, Faculty of Dentistry, October University for Modern Sciences and Arts, Egypt*
[b] *Substitutive Dental Science Department, College of Dentistry, Taibah University, Al-Madinah, Saudi Arabia*
[c] *Prosthodontics Department, College of Dentistry, Ibb University, Ibb, Yemen*
[d] *Oral Biology Department, College of Dentistry, Ibb University, Yemen*

Received 13 February 2021; revised 6 June 2021; accepted 1 July 2021
Available online 10 July 2021

KEYWORDS

Botox;
Occlusal splint;
Sleep bruxism;
Patient satisfaction;
Sleep quality;
Implant-supported overdenture

Abstract *Background:* The available treatment options fail to provide definitive or curative management for bruxer patients rehabilitated with implant overdentures (OD). The data regarding Botulinum toxin (BTX) injection as a management strategy for bruxism remains unclear. This randomized, single-blinded, control-group, pretest–posttest prospective trial evaluated the occlusal guard and Botox injections (BTX) effectiveness in managing sleep bruxism (SB) in subjects whose one of the edentulous arches had been restored with the implant-supported OD.

Methods: Forty-two patients diagnosed with definite bruxism were selected, all of which had implant-retained ODs opposing natural dentition. The participants were allocated randomly to three equal groups. Participants in group I (control group) were instructed to remove the OD at night; group II was managed with conventional occlusal stents. Those in group III were given BTX injections. New ODs were constructed for all groups, and all ball attachments were replaced with a new nylon cap. A baseline assessment (one month of OD insertion) of patient satisfaction and sleep quality was conducted, and then again at 3, 6, 9, and 12 months of treatment. Subjective sleep quality was evaluated using Pittsburgh Sleep Quality Index (PSQI). Patients' satisfaction was evaluated using Temporomandibular disorders/numeric scales (TMD/NS). Prosthodontic (mechanical) complications were recorded during the follow-up period.

* Corresponding author at: Department of Prosthodontics, Faculty of Dentistry, Taibah University, Madinah, Saudi Arabia.
E-mail address: am010120002@gmail.com (A.Y. Alqutaibi).
Peer review under responsibility of King Saud University.

Production and hosting by Elsevier

https://doi.org/10.1016/j.sdentj.2021.07.001

Results: Group III showed a statistically significant improvement in patient satisfaction and sleep quality compared to the other two groups at 3, 6, 9, and 12 months follow-up period (***P*** = 0 0.001, 0.0001, 0.0013, and 0.0001 respectively). Regarding prosthodontic (mechanical) complications, the highest number of events was revealed in the control group.

Conclusions: BTX and occlusal appliances effectively improve patient satisfaction and sleep quality of Bruxer patients rehabilitated with single arch implant overdentures.

1. Introduction

Bruxism has been shown to affect the dental prosthesis's success rates, including removable dentures (Zarb et al., 1997), and reported as a common cause of denture soreness (Bolender et al., 2004). Bruxism should therefore be identified and managed before commencing any management plan. This is especially true for denture wearers, as bruxism is a risk factor for poor prosthetic rehabilitation through an increased incidence of mechanical and technical complications. (Thomson, 1971; Baker and Ivanhoe, 2003; Lobbezoo et al., 2010; Papanagiotou et al., 2012; Manfredini et al., 2014).

Lobbezoo et al. (2018) reported that "Sleep bruxism is masticatory muscle activities that occur during sleep (characterized as rhythmic or non-rhythmic). In otherwise healthy individuals, bruxism should not be considered as a disorder, but rather as a behavior that can be a risk or protective factor for certain clinical consequences."

Bruxism negatively affects sleep quality and patient satisfaction. Bruxer patients with single arch implant OD may lose OD retention and experience increased wear of artificial teeth and attachments due to contact with the opposing arch when the denture is removed for sleep. The traditional approach of removing ODs during sleep to allow for the tissue to rest (Zissis et al., 2006; Figueiral et al., 2007) may result in unnecessary contact between the attachments and opposing dentition, soft tissue, or prostheses in bruxers, resulting in discomfort and possible wear or breakage of teeth, implants, or attachment components (Bakke et al., 2002; Baker and Ivanhoe, 2003; Papanagiotou et al., 2012).

Various treatment options are available for bruxism, including physical therapy, behavioral management, ultrasound therapy, and trigger point injections. However, these treatment modalities are not consistently effective and have several undesirable side effects.(LeResche, 1997; Freund et al., 2000; Lobbezoo et al., 2008; Paesani, 2010; Rajpurohit et al., 2010). Various occlusal splints are deemed the most convenient and frequently used adjuncts in managing SB's harmful effects. However, they fail to provide definitive or curative management. (Moss and Garrett, 1984; Dahlström, 1992) Poor patient compliance and technical complications in fabrication are some of the reported limitations of occlusal splint therapy (Dunn and Lewis, 2011; Alqutaibi and Aboalrejal, 2015; Alqutaibi et al., 2020).

BTX injection weakens muscle contraction by interrupting acetylcholine neurotransmission to the muscles. In the conclusion of some studies, BTX therapy seems promising and beneficial and may be used as an alternative and effective in treating SB (Lee et al., 2010; Santamato et al., 2010).

The benefits of using BTX over other appliances or approaches are that it does not rely on patient compliance, and it also has an advantageous twenty-four-hour effect. Despite this, fears about injection and possible complications, such as facial dissymmetry and reduced chewing power, have hindered its widespread use as a management strategy (Monroy and da Fonseca, 2006; Song et al., 2007).

Clinical studies on the effects of bruxism on removable prosthesis do not seem to be available in the literature; only case reports are available, which cannot provide a robust conclusion (Baker and Ivanhoe, 2003; Papanagiotou et al., 2012).

Therefore, this randomized controlled trial was designed to answer the following question: "When compared to occlusal stents, is BTX effective in the management of sleep bruxism in patients with implant-retained single OD concerning patient satisfaction, sleep quality, and prosthodontic (mechanical) complications ?"

The study tests the hypothesis that "when compared to the controls (OD removal overnight), either BTX administration or occlusal appliances would present significant differences in the management of bruxism."

2. Material and Methods

2.1. Trial design and registry

This study was conducted as a 3 -arms parallel randomized controlled trial with a 1:1:1 ratio. The trial protocol was registered on the Clinical Trials.gov Protocol Registration and Results System with a registration number (Clinical Trials.gov identifier NCT04366869) on 24/04/2020.

2.2. Participants

2.2.1. Patient selection

Forty-two patients were enrolled in the study from the outpatient clinic of the Faculty of Dentistry, MSA University. The Ethics Committee of MSA University approved the study under No. (ETH 12). Patients were included if they were diagnosed with definite SB, have natural dentition in one arch, either maxilla or mandible with a minimum of six anterior teeth (canine to canine), and the utmost one or two premolar/molar missing in any quadrant. The selected patients had implant-retained single OD loaded one year before the study. Patients were excluded if they had received any bruxism management before the research or had a medical condition that would affect the TMJ, such as radiation, osteoarthritis, or trauma. The enrolled patients provided their informed consent and were instructed about the treatment protocol and objectives.

2.2.2. Diagnosis of bruxism

As advocated by, Lobbezoo et al. (2018), the participants diagnosed with definite bruxism were selected if he/she showed at least one of the SB signs/symptoms defined by the 'American Academy of sleep medicine AASM, (Sateia, 2014). Furthermore, ambulatory electromyography and electrocardiographic device (Bruxoff; Spes Medica) was used to define bruxers by recording the SB events per hour. This device agrees with the findings of the polysomnography (the gold standard of diagnosing the SB) (Manfredini et al., 2014).

The participants were instructed to place the device electrodes on their bodies just before bed (Castroflorio et al., 2014). A specific software program (Bruxmeter; OT Bioelettronica) was used for automatic evaluation. Participants were also questioned about the intervals of time in which they wear their ODs and whether they wear them during sleep or not. Patients' ODs were also examined for signs of artificial teeth wear (Casett et al., 2017).

2.3. Sample size calculation

Sample size calculation was accomplished based on a previous study (Algabri et al., 2017), 42 participants were sufficient to detect an effect size of 0.8 ± 0.9 in patient satisfaction, a power of 80% at $\alpha = 0.05$.

2.4. Randomization

2.4.1. Sequence generation

The 42 patients were assigned randomly to three identical groups, each containing 14 patients, using a research randomizer (https://www.randomizer.org).

2.4.2. Implementation

Only one investigator, who was not involved in the selection or treatment of the patients, was aware of the randomization sequence and had access to the randomization lists stored in a password-protected portable computer. Allocation concealment was performed, and each participant selected an opaque sealed envelope containing the computer-generated random number to determine the group to which he/she belonged. In Group I, the control group, Patients were allocated the traditional management method of removing ODs overnight. Group II would be subjected to occlusal stent management. Group III would be managed using BTX injections.

2.5. Blinding

Neither the subject nor the care provider could be blinded due to the apparent differences between the three management types.

Regarding patient satisfaction and the subjective sleep quality, the care provider was not present when the subjects completed the TMD/ NS questionnaire and PSQI and were counseled to avoid commenting on the treatment options in the presence of patients.

For the prosthodontic (mechanical) complications, only single blinding was feasible (the assessor only). An independent assessor who was not aware of the type of intervention assessed the outcome.

2.6. Prosthetic procedure

New ODs were constructed for all patients to replace old ODs with worn artificial teeth. New medium retention nylon caps were also inserted in their metal housings to assure adequate retention throughout the study. The opposing partially edentulous arches were restored with fixed partial dentures. Patients were allowed to use their new ODs for one month, during which modifications and occlusal corrections were made if necessary.

2.7. Pre-treatment outcomes recordings

Patient satisfaction was evaluated at baseline (one month from new OD insertion) using a TMD/ NS questionnaire, which included: headache, limitations in mouth opening, joint pain, tooth sensitivity, and pain during mastication. The questions were translated into Arabic and validated by Algabri et al. (Algabri, Alqutaibi et al., 2017). The patients filled the complete questionnaire and rated each domain from 0 (highest satisfaction) to 10 (lowest satisfaction) in the waiting room to eliminate bias.

Subjective sleep quality was evaluated using PSQI. This index evaluates and differentiates between "poor" and "good" sleep quality in the past months. Seven sleep components are evaluated using 19 self-report items. Each of the 7 components is scored from 0 to 3. (Solanki et al., 2017).

2.8 Intervention

For the course of the study, Group I patients, referred to as the control group, were instructed to remove their ODs at night when sleeping, whereas group II and III patients were asked to keep wearing their ODs during sleep. For Group II patients, occlusal guards were conventionally fabricated. Patients were instructed to wear these clear heat-cured stents over their dentate arches during sleep for the whole year (Fig. 1).

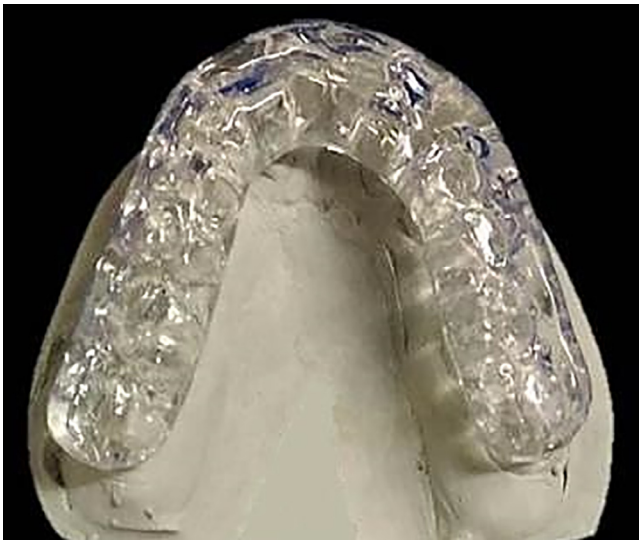

Fig. 1 Occlusal stents onto a duplicate cast.

Group III: BTX injection was performed into the masseter and temporalis muscles.

Neuronox 100-unit vial (clostridium BTX type A) reconstitution by 2.5 mL of 0.9% non-preserved sterile saline (sodium chloride ions) was performed according to the manufacturer's instructions. Dilution protocol was strictly followed, yielding 4 units of BTX in each 0.1 mL. The solution was aspirated in 4 syringes of 1 mL each (Fig. 2).

2.9. Follow up

All patients were recalled every three months for the completion of the TMD/NS questionnaire. Group III patients were recalled every three months before the BTX injection. Data was collected. The total PSQI score was calculated by summing all the component scores (0 to 21), whereas poor sleep quality was indicated if the total scores were higher than 5.

During the follow-up period, prosthodontic (mechanical) complications for the three groups were registered. One of the investigators (A. A) not involved in treatment procedures reported mechanical complications according to the following events: Matrix activation Matrix replacement, Matrix worn, Patrix worn, Patrix replacement, OD fracture, OD reline, OD remake.

2.10. Statistical analysis

The collected data was analyzed using an SPSS statistical package (Version 21, Chicago, IL). After checking for normality with the Kolmogorov-Smirnov tests, Mean values of satisfaction and quality of sleep were compared with one way ANOVA followed by Tukey's Post Hoc test examines the differences between the clinical situations (treatments). The repeated-measures ANOVA was used for different time intervals comparisons for each clinical situation. Sociodemographic characteristics were tested by likelihood ratio chi-square and independent *t*-test.

The whole study procedures were conducted following the CONSORT checklist (Schulz et al., 2010).

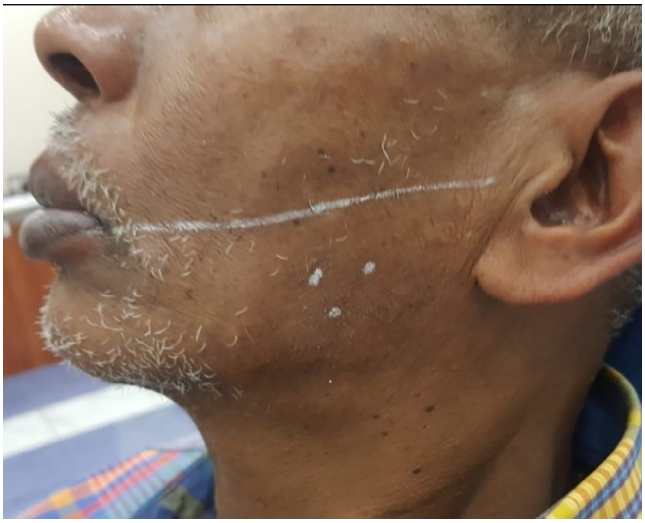

Fig. 2 Masseter muscle injected with 25 units of BTX in three sites.

3. Results

The study design flow diagram is shown in Fig. 3. This study was conducted from July 2019, the patients' recruitment period ended in August 2019, and concurrently the follow-up period of 12 months started. The study was completed in August 2020, and data were collected. A non-significant difference was present in gender distribution, age, education level, and tobacco consumption ($P > .05$) among the three groups (Table 1).

According to the total score of the numerical scale ($P > .05$), non statistically significant differences were recorded for the three groups before treatment (baseline). The control group failed to show substantial improvement in the patient satisfaction numerical scale's total score between the baseline assessment and different follow-up periods. In contrast, a significant difference was recorded in both the occlusal splint and BTX groups in the total score from the baseline assessment time to the different follow-up periods ($\boldsymbol{P} < .01$). There was no significant difference from 9 to 12 months Table 2.

Group II (occlusal splint) revealed a statistically significant improvement in their total score throughout the follow-up periods compared to the control group. However, there was a statistically significant decrease in the total score recorded for Group III (BTX) compared to the other groups at 3, 6, 9, and 12 months ($P < .01$).

Concerning subjective sleep quality at baseline, a non-statistically significant difference in sleep quality was revealed between the groups ($P > .05$). Group II and Group III displayed a significant improvement in sleep quality at different follow-up periods, with a significant difference recorded at the 3 months interval. However, the control group showed no significance in the sleep quality throughout the study. Group II showed a statistically significant improvement in sleep quality compared to Group I for the duration of the follow-up periods. Group III showed a statistically significant improvement in sleep quality compared to the other two groups at 3, 6, 9, and 12 months ($P < .01$) Table 3.

Concerning prosthodontic (mechanical) complications, a statistically significant difference was revealed in Matrix activation ($P < 0.0001$), Matrix replacement ($P = 0.001$), Matrix wearing ($P < 0.0001$) and, Patrix wearing ($P = 0.03$) between groups with the highest number of events in the control group.

A non-statistically significant difference was revealed in Patrix replacement (P value = 0.20), OD fracture (P value = 0.052), OD reline (P value 0.20) , and OD remake (P value = 0.41) between groups.

3.1. Harms

No adverse effects were reported for the study participants; however, two patients in the BTX group complained of temporary mild pain at the injection site. Three patients in Group II complained of discomfort when wearing the occlusal splints.

4. Discussion

The alternative hypothesis was accepted as there were significant differences between controls and BTX/occlusal appliance groups.

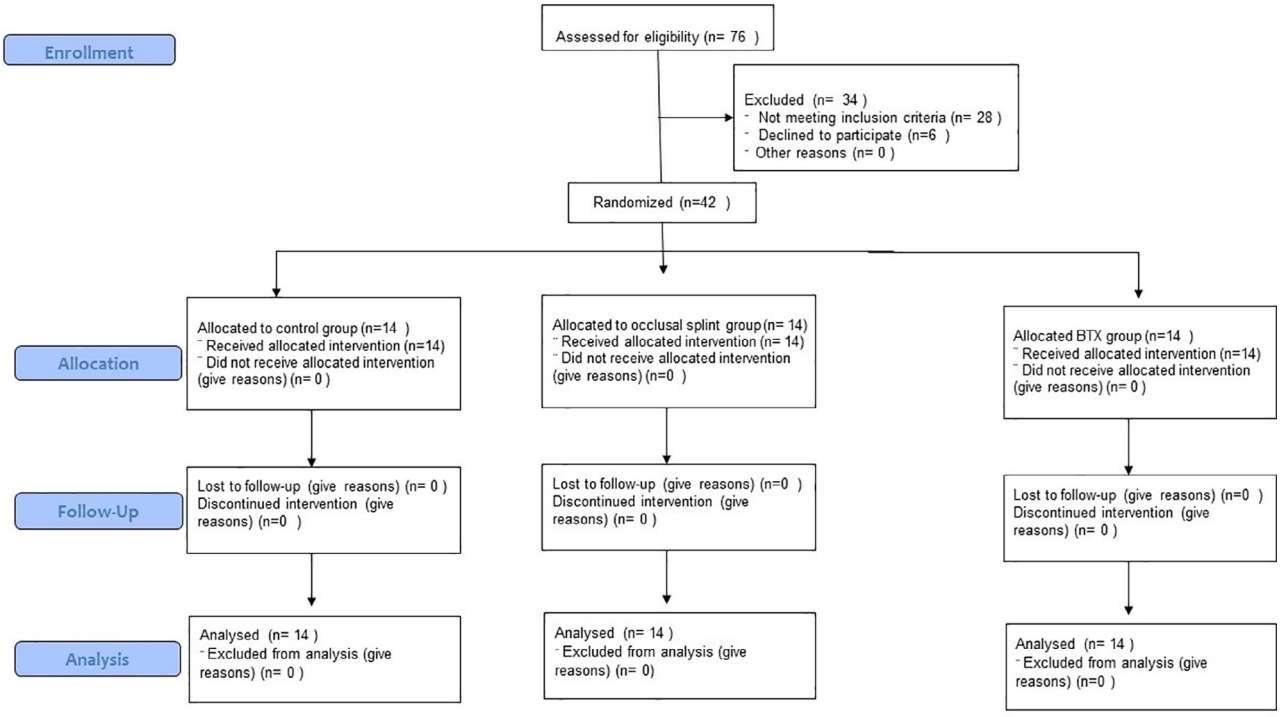

Fig. 3 CONSORT flowchart of the study.

Table 1 Baseline Characteristics (study subjects).

		Control gp N = 14	Occlusal splint gp N = 14	BTX gp N = 14	*P* value
Mean age (year)		58.7 ± 9.2	57.48 ± 8.3	53.7 ± 6.3	0.67
Gender (%)	Male	8(57.15)	5(35.7)	7(50)	0.87
	Female	6(42.85)	9(64.3)	7(50)	
Edentulous period mandible (year) mean ± SD		6.4 ± 3.1	5.3 ± 2.8	4.9 ± 2.2	0.53
Location of implant retained OD	Maxilla	9(64.3)	6(42.85)	8(57.15)	0.77
	Mandible	5(35.7)	8(57.15)	6(42.85)	
Educational level	*Basic education*	8(57.15)	7(50)	9(64.3)	0.71
	High school	5(35.7)	4(28.6)	3(21.4)	
	College	1(7.15)	3(21.4)	2(14.3)	
Tobacco consuming	Yes	5(35.7)	7(50)	8(57.15)	0.68
	No	9(64.3)	7(50)	6(42.85)	

Table 2 Mean scores for patient satisfaction for three groups.

	Control	Occlusal Splint	BTX
	Mean ± SD	Mean ± SD	Mean ± SD
Baseline	8.51 ± 1.1Aa	8.72 ± 1.25 Aa	9.02 ± 1.05 Aa
3 months	7.92 ± 1.84 Aa	6.02 ± 2.97 Bb	5.5 ± 0.88 Bb
6 months	8.71 ± 0.88 Aa	5.1 ± 1.88 Bb	4.3 ± 0.87 Cb
9 months	7.76 ± 1.06 Aa	4.7 ± 0.91 Bb	4.1 ± 1.77 Bb
12 months	7.49 ± 1.87Aa	4.3 ± 1.07 Bb	3.8 ± 1.02 Bb

Distinct uppercase letters indicate differences between groups (***P*** < .05). Distinct *lowercase letters indicate differences among timepoints (**P** < .05)*.

Table 3 Mean scores for PSQI for three groups.

	Control	Occlusal Splint	BTX
	Mean ± SD	Mean ± SD	Mean ± SD
Baseline	8.30 ± 1.78Aa	8.17 ± 1.52 Aa	7.91 ± 2.25 Aa
3 months	7.70 ± 3.42 Aa	6.83 ± 2.91 Bb	6.20 ± 2.34 Bb
6 months	8.22 ± 1.23 Aa	6.63 ± 3.02 Bb	5.92 ± 2.11 Bb
9 months	7.80 ± 1.52 Aa	7.13 ± 2.12 Bb	5.17 ± 1.92 Cb
12 months	8.30 ± 1.78Aa	6.94 ± 1.72 Bb	5.04 ± 2.12 Cb

Distinct uppercase letters indicate differences between groups (***P*** < .05). Distinct lowercase letters indicate differences among time points (***P*** < .05).

This study was conducted as a randomized controlled trial, which provides the highest level of evidence. Randomization, blinding, control, and optimum follow-up were performed. However, because of the apparent differences between the two types of management, only single blinding (the assessor) was feasible.

For the study duration, each examiner had a specific role to play under the same circumstances: selecting the subjects, fabricating the prosthesis, injecting the BTX, and recording the data. New ODs were constructed for all patients to preclude denture cracks and worn artificial acrylic resin teeth. New medium retention nylon caps were inserted in their metal housing to counteract any loss of retention that might have occurred before the study. Patients of groups II and III complied with wearing these new ODs during sleep.

Group, I (the control group) showed no improvement throughout the study after removing the OD overnight. This may explain the consistent relationship between the vertical opening and muscle activity levels, whereby the dentures raise the vertical dimension of occlusion. This coincides with a study that recommended that the OD should not be removed at night while sleeping (Von Gonten and Rugh, 1984).

Group II (occlusal splint) showed a significant difference in sleep quality readings at 3-, 6-, and 9-month intervals. This can be attributed to a reduction in SB and improved jaw muscle relationship resulting from the occlusal splint providing a more balanced and stable occlusion. This method also minimizes occlusal interference (Alqutaibi and Aboalrejal, 2015). The same group displayed no significant difference in sleep quality at 9 to 12 months, which may be due to a reduction in the intra-articular pressure in the TMJ and centric relation positioning of the condyles.

Group III (BTX) revealed a significant difference in sleep quality at 3, 6, and 9 months. This can be explained by the effect of the potent BTX produced by the bacterium clostridium botulinum, which prevents the release of the neurotransmitter acetylcholine and leads to reduced muscle contraction (Schwartz and Freund, 2002; Villa et al., 2019).

The same group showed an insignificant difference at 9 to 12 months compared to the previous intervals, which may be linked to muscle thickness and cross-section reduction (Lee et al., 2017). Furthermore, this group's superior results might be explained by the fact that patient participation was not required. So they did not influence the treatment themselves (Lee et al., 2017).

On comparing the results of the three groups, the findings suggest that BTX may be the superior choice of management. This can be accredited to the direct effect of the acetylcholine inhibitor, in addition to the absence of patient compliance, unlike with occlusal splints (Al-Ani et al., 2005; Lee et al., 2017).

BTX was injected every 3 months(Schwartz and Freund, 2002), as it has a reversible effect; the effects of BTX occur within 1 to 14 days, reach a maximum at 4 weeks, and then begin to decrease after 12 weeks (Dutt et al., 2015).

In accordance with the conclusion of a recent systematic review which reported that BTX could manage the consequences of SB, minimizing symptoms and reducing the intensity of contractions for repetitive masticatory muscle activity rather than SB itself (De la Torre Canales et al., 2017).

The use of repeated injections in the current study is supported by the work of Baker JS and Nolan PJ. The authors reported that repeatedly injecting BTX-A into the bilateral temporalis and masseter muscles may be a safe and effective way of managing chronic masticatory myofascial pain (Baker and Nolan, 2017).

Regarding patient satisfaction, Group I (the control group) failed to significantly improve the total score of the patient satisfaction from the baseline assessment to different follow-up periods. Group II and Group III reported a statistically significant improvement compared to the control group throughout the follow-up periods. This may be because the patients in Group I did not receive direct treatment for definite bruxism.

During the treatment, two patients of group I complained of reduced OD retention, possibly due to the continuous detrimental contact of the opposing natural teeth with the attachment overnight. This corresponds with other studies (Papanagiotou et al., 2012 and Baker and Ivanhoe, 2003). Papanagiotou et al., 2012, constructed a protective acrylic nightguard to place over the ERA attachment aim of protecting the teeth from making contact with attachments during sleep and Baker et al., 2003 fabricated an occlusal device to protect implant abutments and subsequently support ODs from nocturnal parafunctional habits.

Group II (occlusal splint) showed a decrease in the TMD/NS score from baseline to the end of the study. Patients reported an improvement in both the frequency of headaches and the limitation of mouth opening, which may affect the patient is being obliged to wear the stent overnight. However, one patient from this group reported an occlusal splint fracture, which required a new occlusal splint to be made.

Group III (BTX) patients reported a dramatic improvement in patient satisfaction throughout the study.

The highest number of prosthodontic (mechanical) complications revealed in the control group regarding matrix activation /replacement and matrix /patrix wearing can be explained by the continuous detrimental contact of the opposing natural teeth with the attachment overnight.

Although a non-statistically significant difference was revealed in patrix replacement or OD fracture /reline / remake, a clinically meaningful result was disclosed. The highest number of events was related to the control group. Three ODs were remade in the control group and only one OD in the BTX group, broken by an accidental drop while washing it by the patient.

4.1. Study limitations

Noncompliant individuals were included in analyses; three patients in Group II complained of discomfort when wearing the occlusal splints. They did not comply with wearing the stent every night and reported no improvement in tooth sensitivity for the follow-up periods. These actions may have led to detrimental contact between the teeth and attachments, explaining why better results were reported in Group III.

Furthermore, for patients' recruitment, a cutoff level of pain was not set; participants with some degree of myofascial pain were selected. Thus, the study population had a heterogenous pain intensity, which may be considered a limitation of the study. Individuals with SB with no pain may have better subjective sleep quality and patient satisfaction.

Additionally, studies have established that bruxism is a significant risk factor for TMD pain (Johansson et al., 2003;

Raphael et al., 2012); consequently, some included participants may have TMD, which might be considered a confounding factor that might affect treatments outcomes.

Future research addressing pain intensity and investigating differences across pain thresholds are recommended, with a more extended follow-up period and evaluating electromyography objectively (e.g., number of bruxing episodes based on the EMG recordings obtained during PSG).

5. Conclusion

Considering study limitations, BTX and occlusal appliances are effective in improving patient satisfaction and sleep quality of bruxer patients rehabilitated with single arch implant overdentures compared to the standard overdenture removal overnight.

Authors' contribution

A.S.M., E.D., and A.A.Y. participated in the study conception and design as well as coordinated the study including data collection. E.D. was responsible for fabrication of the occlusal guards and implant supported overdentures, their delivery and adjustments. A.S.M. was responsible for administering BTX injections. A.A.Y. performed the statistical analysis and drafted the manuscript. A.A. made substantial contributions to the conception and design of the study and overall supervision of the project.. All authors read and approved the final manuscript.

Ethical Statement

The study was approved by the Institutional Review Board (IRB), College of Dentistry, MSA University under No. (ETH 12). The study is conducted according to the principles of the Declaration of Helsinki (version 17c, 2004).

Informed consent was obtained from each participant.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgement

The authors would like to acknowledge Prof. Eman Ahmed Maher ,Professor in Clinical Neurophysiology unit, Faculty of Medicine, Cairo University for her unlimited help during preparation of this manuscript.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.sdentj.2021.07.001.

References

Al-Ani, Z., Gray, R.J., Davies, S.J., Sloan, P., Glenny, A.M., 2005. Stabilization splint therapy for the treatment of temporomandibular myofascial pain: a systematic review. J. Dent. Educ. 69 (11), 1242–1250.

Algabri, R.S., Alqutaibi, A.Y., Elkadem, A.H.E., Maher, E.A., Kaddah, A.F., 2017. Patient's satisfaction and muscles activity after management of temporomandibular disorders patients using computer-aided design/computer-aided manufacturing versus conventional occlusal splints (randomized clinical trial). Int. Dental Med. J. Adv. Res. 3 (1), 1–8.

Alqutaibi, A., Aboalrejal, A., 2015. Types of occlusal splint in management of temporomandibular disorders (TMD). J. Arthritis 4 (176), 2.

Alqutaibi, A.Y., Algabri, R., Ibrahim, W.I., Borzangy, S., 2020. Does the facebow affect the outcome of CAD/CAM occlusal splint. Randomized clinical trial. Saudi Dental J..

Baker, J.S., Nolan, P.J., 2017. Effectiveness of botulinum toxin type A for the treatment of chronic masticatory myofascial pain: A case series. J. Am. Dental Assoc. 148 (1), 33–39.

Baker, P.S., Ivanhoe, J.R., 2003. Fabrication of occlusal device for protection of implant overdenture abutments with O-ring attachments. J. Prosthet. Dent. 90 (6), 605–607.

Bakke, M., Holm, B., Gotfredsen, K., 2002. Masticatory function and patient satisfaction with implant-supported mandibular overdentures: a prospective 5-year study. Int. J. Prosthodont. 15 (6).

Bolender, Z., Zarb, G., Eckert, S., 2004. Prosthodontic treatment for edentulous patients. Complete denture and implant-supported prostheses. Mosby.

Casett, E., Réus, J., Stuginski-Barbosa, J., Porporatti, A., Carra, M., Peres, M., de Luca Canto, G., Manfredini, D.J., 2017. Validity of different tools to assess sleep bruxism: a meta-analysis. J. Oral. Rehabil. 44 (9), 722–734.

Castroflorio, T., Deregibus, A., Bargellini, A., Debernardi, C., Manfredini, D., 2014. Detection of sleep bruxism: comparison between an electromyographic and electrocardiographic portable holter and polysomnography. J. Oral Rehabil. 41 (3), 163–169.

Dahlström, L., 1992. Conservative treatment methods in craniomandibular disorder. Swed. Dent. J. 16 (6), 217–230.

De la Torre Canales, G., Câmara-Souza, M.B., Do Amaral, C.F., Garcia, R.C.M.R., Manfredini, D., 2017. Is there enough evidence to use botulinum toxin injections for bruxism management? A systematic literature review. Clin. Oral. Investig. 21 (3), 727–734.

Dunn, D.B., Lewis, M.B., 2011. CAD/CAM Occlusal splints: A new paradigm. Australas Dent. Pract. 22, 130–134.

Dutt, C.S., Ramnani, P., Thakur, D., Pandit, M., 2015. Botulinum toxin in the treatment of muscle specific Oro-facial pain: a literature review. J. Maxillofacial Oral Surgery 14 (2), 171–175.

Figueiral, M.H., Azul, A., Pinto, E., Fonseca, P., Branco, F.M., Scully, C., 2007. Denture-related stomatitis: identification of aetiological and predisposing factors–a large cohort. J. Oral Rehabil. 34 (6), 448–455.

Freund, B., Schwartz, M., Symington, J., 2000. Botulinum toxin: new treatment for temporomandibular disorders. Br. J. Oral Maxillofac. Surg. 38 (5), 466–471.

Johansson, A., Unell, L., Carlsson, G.E., Söderfeldt, B., Halling, A., 2003. Gender difference in symptoms related to temporomandibular disorders in a population of 50-year-old subjects. J. Orofac Pain 17 (1).

Lee, H.-J., Kim, S.-J., Lee, K.-J., Yu, H.-S., Baik, H.-S., 2017. Repeated injections of botulinum toxin into the masseter muscle induce bony changes in human adults: A longitudinal study. Korean J. Orthodont. 47 (4), 222–228.

Lee, S.J., McCall Jr., W.D., Kim, Y.K., Chung, S.C., Chung, J.W., 2010. Effect of botulinum toxin injection on nocturnal bruxism: a randomized controlled trial. Am. J. Phys. Med. Rehabil. 89 (1), 16–23.

LeResche, L., 1997. Assessment of physical and behavioral outcomes of treatment. Oral Surgery, Oral Med. Oral Pathol., Oral Radiol. Endodontol. 83 (1), 82–86.

Lobbezoo, F., Ahlberg, J., Raphael, K., Wetselaar, P., Glaros, A., Kato, T., Santiago, V., Winocur, E., De Laat, A., De Leeuw, R., 2018. International consensus on the assessment of bruxism: Report of a work in progress. J. Oral. Rehabil. 45 (11), 837–844.

Lobbezoo, F., Hamburger, H., Naeije, M., 2010. Etiology of bruxism. 53–65.

Lobbezoo, F., Van Der Zaag, J., Van Selms, M., Hamburger, H., Naeije, M., 2008. Principles for the management of bruxism. J. Oral Rehabilitat. 35 (7), 509–523.

Manfredini, D., Ahlberg, J., Castroflorio, T., Poggio, C., Guarda-Nardini, L., Lobbezoo, F., 2014a. Diagnostic accuracy of portable instrumental devices to measure sleep bruxism: a systematic literature review of polysomnographic studies. J. Oral Rehabil. 41 (11), 836–842.

Manfredini, D., Poggio, C.E., Lobbezoo, F., 2014b. Is bruxism a risk factor for dental implants? A systematic review of the literature. Clin. Implant Dentistry Related Res. 16 (3), 460–469.

Monroy, P.G., da Fonseca, M.A., 2006. The use of botulinum toxin-a in the treatment of severe bruxism in a patient with autism: a case report. Spec. Care Dentist. 26 (1), 37–39.

Moss, R.A., Garrett, J.C., 1984. Temporomandibular joint dysfunction syndrome and myofascial pain dysfunction syndrome: a critical review. J. Oral Rehabilit. 11 (1), 3–28.

Paesani, D.A., 2010. Evidence related to the treatment of bruxism. In: Bruxism. Theory and practice. Quintessence, London, pp. 359–382.

Papanagiotou, H., Armaou, M., Kamposiora, P., Papavasiliou, G., Sklavounou, A., 2012. Fabrication of a custom protective guard for an era maxillary overdenture: A case report. Balkan J. Stomatol. 16 (1), 60–64.

Rajpurohit, B., Khatri, S.M., Metgud, D., Bagewadi, A., 2010. Effectiveness of transcutaneous electrical nerve stimulation and microcurrent electrical nerve stimulation in bruxism associated with masticatory muscle pain-a comparative study. Indian J. Dental Res. 21 (1), 104.

Raphael, K.G., Sirois, D.A., Janal, M.N., Wigren, P.E., Dubrovsky, B., Nemelivsky, L.V., Klausner, J.J., Krieger, A.C., Lavigne, G.J., 2012. Sleep bruxism and myofascial temporomandibular disorders: a laboratory-based polysomnographic investigation. J. Am. Dent. Assoc. 143 (11), 1223–1231.

Santamato, A., Panza, F., Di Venere, D., Solfrizzi, V., Frisardi, V., Ranieri, M., Fiore, P., 2010. Effectiveness of botulinum toxin type A treatment of neck pain related to nocturnal bruxism: a case report. J. Chiropr. Med. 9 (3), 132–137.

Sateia, M.J., 2014. International classification of sleep disorders. Chest 146 (5), 1387–1394.

Schulz, K.F., Altman, D.G., Moher, D.J.T., 2010. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ 11 (1), 1–8.

Schwartz, M., Freund, B., 2002. Treatment of temporomandibular disorders with botulinum toxin. Clin. J. Pain 18 (6), S198–S203.

Solanki, N., Singh, B.P., Chand, P., Siddharth, R., Arya, D., Kumar, L., Tripathi, S., Jivanani, H., Dubey, A., 2017. Effect of mandibular advancement device on sleep bruxism score and sleep quality. J. Prosthetic Dent. 117 (1), 67–72.

Song, P., Schwartz, J., Blitzer, A., 2007. The emerging role of botulinum toxin in the treatment of temporomandibular disorders. Oral Dis. 13 (3), 253–260.

Thomson, J., 1971. The load factor in complete denture intolerance. J. Prosthet. Dent. 25 (1), 4–11.

Villa, S., Raoul, G., Machuron, F., Ferri, J., Nicot, R., 2019. Improvement in quality of life after botulinum toxin injection for temporomandibular disorder. J. Stomatol. Oral Maxillofacial Surgery 120 (1), 2–6.

Von Gonten, A., Rugh, J., 1984. Nocturnal muscle activity in the edentulous patient with and without dentures. J. Prosthetic Dentistry 51 (5), 709–713.

Zarb, G.A., Bolender, C.L., Carlsson, G.E., 1997. Boucher's prosthodontic treatment for edentulous patients, Mosby St. Louis.

Zissis, A., Yannikakis, S., Harrison, A., 2006. Comparison of denture stomatitis prevalence in 2 population groups. Int. J. Prosthodont. 19 (6).