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Original Article

Durability of botulinum toxin and qualitative analysis for the treatment of gummy smile

Durabilidade da toxina botulínica tipo A e análise qualitativa para o tratamento do sorriso gengival

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Resumo

Objetivo: Avaliar quantitativamente a melhora estética e o rebaixamento do lábio superior após o tratamento do sorriso gengival decorrente de hipercontração muscular com toxina botulínica tipo A. **Método**: O estudo incluiu 16 pacientes que receberam 8 unidades de toxina botulínica tipo A bilateralmente. As avaliações foram realizadas em quatro momentos: T0 (antes da aplicação), T1 (15 dias), T2 (2 meses) e T3 (4 meses). Foram mensuradas duas distâncias: (a) da espinha nasal anterior até a borda inferior do lábio superior e (b) da borda inferior do lábio superior até a borda incisal do incisivo central superior direito. O impacto da toxina botulínica tipo A na qualidade de vida foi adicionalmente avaliado por meio da satisfação dos pacientes, utilizando a Escala Visual Analógica (EVA). **Resultado**: Ao mensurar a distância da espinha nasal anterior até a borda inferior do lábio superior em T3 (14,95 mm), observou-se que a média foi maior que em T0 (14,82 mm), porém menor que em T1 (16,53 mm) e T2 (15,42 mm). Em relação à distância média entre a borda inferior do lábio superior e a borda incisal do incisivo central superior direito, T3 (11,23 mm) foi inferior a T0 (12,11 mm), porém superior a T1 (8,94 mm) e T2 (8,52 mm). Quanto à satisfação dos pacientes, o escore da EVA em T3 (8,4) foi superior aos valores de T0 (4,5), T1 (8,5) e T2 (8,9). **Conclusão**: A toxina botulínica tipo A promoveu melhora qualitativa na qualidade de vida dos pacientes e apresentou durabilidade de pelo menos quatro meses.

Descritores: Toxinas botulínicas tipo A; sorriso; qualidade de vida.

Abstract

Aim: To quantitatively evaluate the improvement in aesthetics and the lowering of the upper lip following gummy smile (GS) treatment for muscle hypercontraction using toxin type A (BTXA). **Method**: The study included 16 patients who received 8 units of BTXA bilaterally. Evaluations were conducted at four time points: T0 (before application), T1 (15 days), T2 (2 months), and T3 (4 months). Two distances were measured: (a) from the anterior nasal spine to the lower border of the upper lip, and (b) from the lower border of the upper lip to the incisal edge of the upper right central incisor. The impact of BTXA on quality of life was further assessed through patient satisfaction, using

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the Visual Analog Scale (VAS). **Result**: When measuring the distance from the anterior nasal spine to the lower edge of the upper lip at T3 (14.95 mm), the average distance was greater than at T0 (14.82 mm) but lower than at T1 (16.53 mm) and T2 (15.42 mm). Regarding the average distance between the lower edge of the upper lip and the incisal edge of the upper right central incisor, T3 (11.23 mm) was lower than T0 (12.11 mm) but higher than T1 (8.94 mm) and T2 (8.52 mm). In terms of patient satisfaction, the VAS score at T3 (8.4) was higher than at T0 (4.5), T1 (8.5), and T2 (8.9). **Conclusion**: BTXA qualitatively improved the patient's quality of life and exhibited a durability of at least four months.

Descriptors: Botulinum toxins, type A; smiling; quality of life.

INTRODUCTION

The beauty standards imposed by society have exerted significant pressure on individuals worldwide. Since ancient times, society has established aesthetic ideals that define what is considered beautiful or attractive. In many cases, such standards are unrealistic and unattainable for most people. Media, advertising, and social networks play a fundamental role in disseminating these norms, leading many individuals to a constant pursuit of perfection and aesthetic balance. In an effort to conform to prevailing beauty standards, many patients seek aesthetic procedures to enhance their appearance[1].

This relentless pursuit of an idealized image can lead to anxiety, low self-esteem, and, more importantly, mental health disorders. In this context, the orofacial harmonization specialist dentist (OHD) plays a crucial role. This professional possesses specific knowledge to work with facial structures. The specialty aims to balance and enhance facial aesthetics through non-invasive procedures, such as fillers, botulinum toxin, and others. The objective is to provide patients with a more harmonious and balanced appearance while respecting their individual characteristics and preserving their identity[1].

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Among the various aesthetic concerns, the gummy smile (GS) is a common issue for many patients, requiring the intervention of an OHD who can address it in the least invasive manner possible. In this context, botulinum toxin type A (BTXA) plays a fundamental role. Its use induces relaxation of the muscles responsible for lifting the upper lip, thereby reducing excessive gum exposure when smiling. A harmonious smile can positively influence social interactions, self-image, and even emotional health. By seeking to balance the GS and improve facial aesthetics, the OHD contributes to enhancing patients' self-confidence and overall quality of life, allowing them to feel more secure and satisfied with their appearance. This aspect of orofacial harmonization reinforces the importance of considering not only aesthetics but also the emotional and psychological well-being of patients[2].

Therefore, the present research is significant in the current social and health landscape, considering the aesthetic needs of patients who seek GS correction in a less invasive and non-surgical manner, avoiding undesirable signs and symptoms while positively impacting their quality of life. Additionally, it is necessary to determine the optimal dosage for achieving the desired effectiveness. The aim is to quantitatively evaluate the improvement in aesthetics and the lowering of the upper lip following GS treatment for muscle hypercontraction using BTXA from the commercial brand Botulift® (Medytox, Bergamo Químico Farmacêutico Ltda., Coreia do Sul) Additionally, a qualitative analysis of the outcome will be performed using the VAS scale. The null hypothesis of this study is that the application of BTXA at the specified points and units does not result in sufficient aesthetic improvement to justify its indication and recommendation.

MATERIAL AND METHOD

This study is supported by the Ethics Committee of the Plataforma Brasil, registered under CAAE 26291119.0.0000.0081. The research was conducted in a private clinic located at Rodovia Raposo Tavares, KM 22.5 – Bloco F, Sala 315, Cotia, Granja Viana/SP, CEP 06.709-015.

This protocol involved targeting the muscles responsible for gingival exposure (one centimeter lateral to the nasal ala and the Yonsei point) in 21 patients (n=21) at four time points: T0

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(pre-application), T1 (15 days), T2 (60 days), and T3 (120 days). Two international units of BTXA were injected at each of two points per side (the lip elevator point and the Yonsei point), resulting in a total of 4 units per side (8 units in total, bilaterally).

The Yonsei point was identified according to the anatomical landmarks, corresponding to the center of the triangle formed by the lateral border of the *levator labii superioris alaeque nasi* muscle, the *levator labii superioris muscle*, and the *zygomaticus minor muscle*; injections at this point primarily targeted the levator *labii superioris alaeque nasi* and *levator labii superioris* muscle complex, whereas the point located 1 cm lateral to the nasal ala targeted the levator *labii superioris alaeque nasi* muscle, following the parameters established by Hexsel et al.[3], 2021.

It is noteworthy that, although the study initially included 21 patients, only 16 (n=16) completed the research, as five patients were lost to follow-up. The diagnosis of GS was established by ruling out other potential causes, with exclusion criteria including (a) altered passive eruption, (b) excessive vertical maxillary growth, (c) alveolar extrusion, and (d) previous BTXA treatment for GS. Muscle palpation during function confirmed the involvement of specific muscles, ensuring that all patients presented GS with more than 3 mm of gingival exposure and keratinized tissue exposure in the anterior and posterior regions of the dental arch. All participants signed an informed consent form before treatment.

Botulift® (BTXA, 100 U; Medytox/Bergamo, Brazil) was reconstituted with 2.0 mL of sterile 0.9% sodium chloride solution, resulting in a final concentration of 5 U/0.1 mL. The injections were performed using a 1-mL syringe fitted with a 30G, 8-mm needle.

Inclusion and Exclusion Criteria

To define the study population, the inclusion and exclusion criteria were established as inclusion criteria: (a) patients over 18 years old; (b) patients diagnosed with GS due to muscle hypercontraction, as discussed by Hong (2023) in their methodology; (c) patients with no absolute contraindications to BTXA application; (d) patients with no known allergies to the formula

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components and (e) patients with adequate gingival health; and exclusion criteria: (a) patients under 18 years old; (b) patients diagnosed with GS of non-contractile origin; (c) patients with absolute contraindications to BTXA application; (d) patients with known allergies to the formula components; (e) patients with inadequate gingival health and (f) patients previously treated with BTXA for GS.

Photographic Protocol

Participants were photographed at four different time points: T0, T1, T2, and T3. All photographs were taken by the same researcher at the clinic where the procedure was performed. A digital camera was mounted on a tripod with a 100 mm lens at an approximate distance of 215 cm from the subject's face. To standardize the protocol, a black guideline was marked on the floor. The camera lens was adjusted to be parallel to the vertical plane of the subject. A natural smile was maintained for all participants. This protocol was based on the studies of Cengiz et al. [4] (2020).

A ring light with a tripod was used for photography, and all images were taken in a clinical setting using a Canon T5i® digital camera equipped with a 100 mm MACRO lens. The camera settings were adjusted to manual mode with the following specifications for facial photographs: f=11; ISO=100; Shutter Speed=1/125.

Outcome Assessment

Outcome assessment was performed by comparing pre-treatment (T0) and post-treatment measurements at T1 (15 days), T2 (60 days), and T3 (120 days). Pain levels were evaluated using the Visual Analog Scale (VAS) at all study time points. The quality of the results was also assessed qualitatively using the VAS. Durability and effectiveness were measured by assessing (a) the distance from the nasal spine to the inferior border of the upper lip and (b) the distance from the inferior border of the upper lip to the incisal edge of the upper right central incisor (tooth 11).

The VAS is a widely used tool for assessing subjective intensity perceptions in clinical, psychological, and pharmacological research. It consists of a straight line of fixed length, where one

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end represents the complete absence of the evaluated attribute and the other end denotes the maximum possible intensity. Participants are instructed to mark a point on the line that corresponds to their perception of the attribute's intensity[5].

Statistical Analysis

For data analysis and result evaluation, Word® (Microsoft Office 365, San Diego, CA, USA) and Excel® (Microsoft Office 365, San Diego, CA, USA) were used. Descriptive statistics were performed, including absolute and percentage distribution calculations for each response obtained.

Statistical analyses were performed using IBM SPSS Statistics, version 29.0 (IBM Corp., Armonk, NY, USA). The normality of the continuous variables (Measure A and Measure B) was assessed using the Shapiro–Wilk test. For normally distributed data, one-way analysis of variance (ANOVA) followed by Tukey's post-hoc test was used to compare measurements across the evaluation time points (T0, T1, T2, and T3).

For VAS satisfaction scores, the Games–Howell post-hoc test was used following ANOVA. When the assumptions for parametric analysis were not met, non-parametric tests, including the Friedman test followed by the Wilcoxon signed-rank test for paired comparisons, were considered. Fisher's exact test was used for contingency analysis of VAS categories.

Correlations between Measures A and B were assessed using Spearman's rank correlation coefficient. A significance level of $\alpha = 0.05$ was adopted, with $p < 0.05$ considered statistically significant.

RESULT

The results indicated that for the measurement of the distance from the anterior nasal spine to the inferior border of the upper lip at T3 (14.95 mm), the mean distance was greater compared to T0 (14.82 mm) but lower than at T1 (16.53 mm) and T2 (15.42 mm). Regarding the mean distance from the inferior border of the upper lip to the incisal edge of the upper right central incisor, T3 (11.23 mm) was lower than T0 (12.11 mm) but higher than T1 (08.94 mm) and T2 (08.52 mm). For the mean

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patient satisfaction score, the VAS scale at T3 (8.4) was higher than at T0 (4.5), T1 (8.5), and T2 (8.9) (Table 1).

The research findings revealed statistically significant differences, particularly concerning the VAS scale values. At the initial time point (T0), patients had lower scores, whereas in the three subsequent time points (T1, T2, and T3), the scores were statistically similar but significantly higher than at T0, as shown in Table 2. At T1, for both Measure A and Measure B, there was a strong correlation between them (Spearman's Rho, -0.632, $p<0.01$), indicating a high degree of association. The ANOVA/Games-Howell test was used for the VAS scale, while ANOVA/Tukey was applied to Measures A and B. These quantitative findings are supported by the representative clinical photographs presented in Figure 1, which demonstrate the progressive reduction in gingival display and the improvement in smile aesthetics following BTXA treatment across the evaluation periods (T0, T1, T2, and T3).



Figure 1. Representative clinical outcomes of BTXA treatment for GS at T0, T1, T2, and T3. Written informed consent was obtained from all patients for the publication of identifiable full-face photographs.

Beyond the previously described statistical findings, the contingency analysis of the VAS scale indicated statistical significance and suggested that patients tend to assign higher scores at T3, as demonstrated in Table 3. Fisher's exact test showed a tendency for individuals to give higher VAS scores at T3 ($p=0.015$). Unlike the VAS scale analyses, Measure A, which varies considerably among individuals, showed no statistical differences across time points. Regarding Measure B, the results indicated higher scores at T0 compared to T1 and T2 (which were statistically similar), followed by a return to statistically equivalent values at T3. An additional hypothesis is that Measures A and B

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may be correlated at T1, possibly influenced by muscle response due to the recent administration of the dose, and may diverge later over time.

DISCUSSION

This study on GS treatment with BTXA is highly relevant to the field of facial aesthetics, as demonstrated by Cengiz et al. [4] (2020). The smile is a key component of an individual's appearance, and the visual imbalance caused by excessive gingival exposure while smiling can negatively impact patients' self-esteem. This condition, known as GS, has a multifactorial origin, and precise diagnosis is essential for an individualized treatment plan. The application of BTXA to the muscles responsible for hypercontraction is an effective therapeutic approach, as it reduces muscle contractions and decreases gingival exposure[5-6]. The methodology described in this study includes identifying the involved muscles and precisely administering the toxin to the correct anatomical points. The research provides important insights into the efficacy and effects of botulinum toxin, highlighting its safety and reversibility as a controllable treatment for GS.

BTXA has been extensively studied in the literature[7-10] and has demonstrated safety and efficacy in treating gingival exposure, with variations in effects depending on the application site and dosage. Proper BTXA use requires a deep understanding of facial anatomy, muscle relationships, and anatomical planes, as well as correct drug dilution[11,12]. It is important to note that BTXA reaches peak efficacy between 7 and 14 days post-application, with effects lasting up to 6 months before gradually and reversibly diminishing[13]. This therapeutic approach is fully controllable and reversible.

At the beginning of the study, an initial group of 21 patients (n=21) was recruited. However, during follow-up, five patients (n=5) discontinued participation for various reasons, resulting in a final sample of 16 patients (n=16). This reduction in sample size may be attributed to personal reasons, logistical difficulties, or other factors impacting continued participation.

Despite this, the study plays a fundamental role in the fields of dentistry and facial aesthetics. Excessive gingival exposure while smiling can have negative aesthetic consequences and impact patients' self-confidence[14-16]. Based on the study’s methodology, involving muscle identification and

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precise BTXA application, an individualized and effective treatment can be offered to each patient. BTXA functions by blocking muscle contractions responsible for GS, thereby reducing gingival exposure. This research provides valuable information on optimal dosage, injection sites, and the duration of BTXA effects, contributing to the refinement of this therapeutic approach. The application of BTXA for GS treatment is a controllable and reversible option, significantly improving facial aesthetics and self-esteem, as corroborated by previous studies[4,6].

Hexsel et al. [3] (2021) conducted a double-blind randomized clinical trial to evaluate the effects of different BTXA doses for anterior GS treatment. Results showed that a 5 U dose significantly reduced gingival exposure compared to 2.5 U. All GS severity groups exhibited statistically significant reductions in gingival exposure at 4 and 12 weeks post-injection. Furthermore, at 12 weeks, over 80% of patients reported being satisfied or very satisfied, aligning with this study's findings, in which the mean satisfaction score on the VAS improved from 4.5 at baseline (T0) to 8.4 at T3. These findings underscore the effectiveness of BTXA as a minimally invasive, safe, and reversible approach for GS treatment. BTXA qualitatively increased the patient's satisfaction with their smile and demonstrated a durability of at least 4 months.

CONCLUSION

BTXA treatment reduced gingival display and improved patient satisfaction in patients with GS. Satisfaction increased from baseline and remained elevated throughout the 4-month follow-up.

AUTHORS' CONTRIBUTIONS

Daniella Pilon Muknicka: Conceptualization; Methodology; Investigation; Writing – original draft; Writing – review & editing; Supervision.

Angélica Castro Pimentel: Conceptualization; Methodology; Writing – review & editing; Supervision. All authors have read and approved the final version of the manuscript.

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CONFLICTS OF INTERESTS

The authors declare that there is no conflict of interest related to this study.

DATA AVAILABILITY

The contents underlying the research text are included in the manuscript.

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Tables

Table 1 - Results found in the research. Legend: VAS - Visual Analog Scale. MED A - Measure A given by the distance from the nasal spine to the lower border of the upper lip. MED B - Measure B given by the distance from the lower border of the upper lip to the incisal of the right upper central incisor. T0 – Time 0 pre-treatment. T1 – Time 1, 15 days post-treatment. T2 – Time 2, 60 days post-treatment. T3 – Time 3, 120 days post-treatment

Patient	**VAS**				**MED A**				**MED B**			
	T0	T1	T2	T3	T0	T1	T2	T3	T0	T1	T2	T3
Medium	4.5	8.5	9.0	10	14.82	16.53	15.4	14.92	12.1	08.9	08.5	11.2

Table 2 - Mean (SD) of VAS, MED A, and MED B values. Comparisons made within the same column. Values followed by the same letter represent statistical similarity ($p>0.05$). Legend: T0 – Time 0; T1 – Time 1; T2 – Time 2; T3 – Time 3; VAS – Visual Analog Scale; MED A – Measure A; MED B – Measure B; SD – Standard Deviation

Time	**VAS**	**MED A**	**MED B**
T0	4.5 (3.0) B	14.3 (2.2) A	12.2 (1.8) AB
T1	8.2 (2.1) A	16.2 (4.0) A	8.9 (4.4) B
T2	8.9 (1.5) A	15.2 (2.0) A	8.5 (2.2) B
T3	8.4 (2.7) A	12.2 (1.9) A	10.8 (2.0) AB

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Table 3 - Contingency table related to VAS/Time scale. Legend: T0 – Time 0; T1 – Time 1; T2 – Time 2; T3 – Time 3; VAS – Visual Analog Scale

VAS	V-T0	V-T1	V-T2	V-T3	TOTAL
0	1	0	0	1	2
1	1	1	0	0	2
2	1	2	3	0	6
3	0	0	0	3	3
4	1	1	0	0	2
5	3	2	1	1	7
6	1	1	1	0	3
7	2	1	1	2	6
8	0	3	0	2	5
9	0	1	6	1	8
10	2	7	7	9	25

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