Evaluation of the botulinum toxin effects in the correction of gummy smile 32 weeks after application

Carlos Eduardo Alonso Vieira¹, Wilson Rodrigues de Almeida¹, Paula Cotrin², Renata Cristina Gobbi de Oliveira¹, Ricardo Cesar Gobbi de Oliveira¹, Fabrício Pinelli Valarelli¹, Julie Watanabe Zamuner¹, Karina Maria Salvatore de Freitas¹

¹Departamento de Ortodontia, Centro Universitário Inga (UNINGÁ) – Maringá (PR), Brazil
²Departamento de Ortodontia, Faculdade de Odontologia de Bauru, Universidade de São Paulo (USP) – Bauru (SP), Brazil

Corresponding Author: Paula Cotrin - Universidade de São Paulo, Faculdade de Odontologia de Bauru - Alameda Dr. Octavio Pinheiro Brisolla, 9-75 – CEP: 17.012-901 - Bauru (SP), Brazil - E-mail: cotrin@hotmail.com

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ABSTRACT

Introduction: The use of botulinum toxin type A (BTX-A) to correct gummy smile has become popular in recent years. Objective: To evaluate the effects of BTX-A application in the correction of gummy smile 2 and 32 weeks after application. Methods: The sample comprised 35 patients (30 female, 5 male) at a mean age of 25.51 years (±5.59) with gummy smile due to muscular hyperfunction. In each patient, 2U of botulinum toxin was applied in the levator labii superioris alaeque nasi, 2 mm from the nasolabial fold. Photographs of spontaneous smiles were taken at 3 stages: before, 2 and 32 weeks after BTX application. Measurements of the gingival display were performed with the Radioface Studio 2 Software, and the calibration used the actual size of the right maxillary central incisor. Comparison of the three stages evaluated was performed with repeated measures ANOVA and Tukey tests. Results: Gingival display decreased significantly 2 weeks after BTX-A application and increased after 32 weeks but did not return to the initial value. Conclusion: There was a significant improvement in gummy smile 2 weeks after botulinum toxin application, and a significant relapse in the gingival display after 32 weeks, however not returning to baseline values.

Keywords: smiling; gingiva; gingival overgrowth; botulinum toxins, type A.
INTRODUCTION

We are living in a connected world. The internet has become one of the main tools for exchanging information and entertainment. In this internet era, social media have gained enormous popularity, and consequently, people began to have self-promoting behavior, leaning on to post selfies and self-presented photographs. Everyone wants to look beautiful in the photographs.

With the advent of the internet and social media, patients are increasingly attentive to the beauty of their faces. Nowadays, new techniques of smile design are being developed. Esthetic procedures performed by dentists have gained special attention, such as dental whitening, dental contact lenses, gingivoplasty, and lately, facial harmonization, like botulinum toxin and dermal fillers. Patients undergoing single cosmetic procedures report overall improvements in quality of life.

The facial esthetic harmony comprises the equal proportion of the sizes of the three facial segments, the width of the nose (narrow in women and average in men), and the soft tissue profile. In addition to that, it is also directly correlated with the union of three components of the smile: teeth, gum and lips. Some characteristics are considered essential for the attractiveness of the smile, like smile arc, maxillary dental midline coincident with the facial midsagittal plane and gingival display at smiling. The gingival exposure, when in excess, is one of the factors that most displeases patients. Gingival display of more than 2 mm is rated as progressively less attractive.

The etiology of the gummy smile can be: dentogingival, due to an abnormal dental eruption, with a short clinical crown; muscular, caused by hyperactivity of the main muscles involved in gingival exposure, like levator muscle of the upper lip, levator labii superioris alaeque nasi, risorius and the zygomatic muscles (major and minor);

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dentoalveolar (skeletal), due to excessive vertical growth of the maxilla, and due to a combination of more than one of the above-described factors. A good diagnosis could be done, and the right treatment plan could be set up only after a careful analysis based upon the etiopathogenetic factors. The most common therapeutic modalities proposed for the treatment of gingival smile include gingivectomy or gingivoplasty, orthodontic intrusion of the incisors, orthognathic surgery, and recently a less invasive approach, the botulinum toxin.

Botulinum neurotoxin type A (BTX-A) is a neurotoxic protein produced by the Gram-positive strictly anaerobic bacterium Clostridium botulinum. The BTX-A exhibits transient, nondestructive, dose-dependent and localized actions, with minimal side effects. The BTX-A inhibits the release of acetylcholine, which is the neurotransmitter responsible for the activation of muscle contraction. This inhibition process reduces the muscle tone at the site of application. Its cosmetic facial application is safe, predictable and without serious complications when following the recommended guidelines.

There are several studies in the literature evaluating the application of botulinum toxin for the correction of gummy smile with follow-up of its effects from 2 to 24 weeks after injection. However, no published studies evaluate its effects for more than 24 weeks after application. This way, this study aimed to evaluate the effects of BTX-A in the correction of the gummy smile with 32 weeks follow-up.

METHODS

This prospective study was approved by the Ethics Research Committee from UNINGÁ, Maringá (PR), Brazil, under CAAE - 13664719.8.0000.5220, number 3.632.694 and all patients signed informed consent.
The sample size calculation was performed based on an alpha significance level of 5% and a beta of 20% to detect a minimum difference of 1.75 mm with a standard deviation of 2.58 for the measurement of the upper lip stomion to the incisal border of the maxillary central incisor. Thus, the sample size calculation resulted in the need for 36 subjects.

The data were collected according to the following inclusion criteria: the presence of gingival display greater than 2 mm in the maxillary anterior region due to muscle hyperfunction; no vertical maxillary excess, as determined by lateral cephalometric analysis, presence of good periodontal health, no previous esthetic or surgical procedures to correct the gummy smile. Patients with more than 5 mm of gingival display were excluded from the study.

The sample comprised 35 patients (30 female; 5 male) at a mean age of 25.51 years (±5.59) and was conducted at University Center, Maringá (PR), Brazil.

Previously, at the site of injection, topical anesthesia gel (lidocaine 4%, LMX 4®, MI, USA) was used for 15 minutes. An alcohol swab (saturated with 70% isopropyl alcohol) was used to decontaminate the area of injection.

The BTX-A was diluted according to the supplier recommendations (Dysport 300, Ipsen Limited, UK) to yield 2 units (U) per 0.01mL of sodium chloride solution. A 0.1mL syringe with a 31-gauge needle was used to apply the reconstituted solution. A dosage of 2 U per side was applied and all participants received the same dosage.

The solution was injected bilaterally with the needle placed 45º in relation to the facial plane. The site of injection was the levator labii superioris alaeque nasi, 2 mm from the nasolabial fold (Figure 1).
After the injection, all patients were instructed to avoid lying down, exercising or massaging the injection site for at least 4 hours.17

The patients were evaluated at 3 stages: before BTX-A application (T1), 2 weeks (T2) and 32 weeks after BTX-A injection (T3).

The photographs of the frontal smiles were taken of each patient by the same operator with a Canon T3 digital camera (Canon Corporation, Tokyo, Japan), with a Canon 100 mm macro lens and circular macro flash (Shenzhen Yongnuo Photography Equipment, China). The macro lens adjusted to focus on a stable object-to-lens distance obtaining an image of the lower facial height. All photographs were taken at the same distance in all patients.

The photographs were imported to the Radioface Studio 2 Software (Radiomemory, Belo Horizonte, MG, Brazil), and the gingival display was measured.

The gingival display was defined as the linear distance between the lower margin of the upper lip to the incisal edge of the maxillary central incisor minus the size of the crown of the right maxillary central incisor (Figure 2). The severity of the gingival display was characterized as follows:25 mild (gingival display of 2-3 mm), moderate (gingival display of 3-4 mm), severe (gingival display of 4-5 mm) and more severe (gingival display >5 mm).

For calibration and to correct the photograph magnification, the real size of the right maxillary central incisor was obtained and then transferred to each photograph, and a rule of three was applied to calculate the real value of the gingival display.
Error study

One month after the first measurement, 30% of the photographs were randomly selected and re-measured by the same examiner (CEAV). The random errors were calculated according to Dahlberg’s formula and the systematic errors were evaluated with dependent t tests.

Statistical analysis

The normal distribution of the data was evaluated with Kolmogorov-Smirnov tests. Descriptive statistics were performed to evaluate the age of the patients. The comparison of the three evaluated stages was performed with repeated measures ANOVA and Tukey tests. The statistical analysis was performed with Statistica software (Statistica for Windows version 7.0; StatSoft, Tulsa, Okla, USA). The results were considered statistically significant at p<0.05.

RESULTS

The random error was 0.63 and was within the acceptable range (Table 1). There was no significant systematic error.

The gingival display decreased significantly 2 weeks after application and significantly increased after 32 weeks but did not return to the baseline value (Table 2).

DISCUSSION

The excessive gingival display is a disharmonious periodontal condition that brings esthetic and social disadvantages to the patients. Its treatment should be based on a correct diagnosis. According to the current literature, when this excessive gingival
display was due to a muscle hyperfunction, this condition could be treated with surgery. Surgical treatments can often be invasive and painful to the patient. In this present study, the choice of applying botulinum toxin for the treatment of excessive gingival display was due to the simple, safe, comfortable and less invasive technique.

The dosages of BTX-A used for cosmetic purposes are usually less than 100 U. There is no consensus in the literature on the number of units that should be applied in the region for the correction of gingival smile. It is suggested that the dosage and sites of application must be customized according to the severity of each case. In the present study, 2 U per side was applied because the amount of gingival display was moderate. This dosage is in agreement with some previous studies.

Only 5 of the 35 patients in the sample were male. This can be justified since women care more about their beauty and esthetics and also seek more cosmetic treatments than men. Besides that, it is known that the upper lip of the female subjects is in a more superior position at maximum smile than male subjects. Furthermore, men exhibit a longer upper lip than women. Therefore, authors found more female subjects in their study as well.

The levator labii superioris alaeque nasi is the ideal muscle for injection, however, other authors performed injections in different sites, like levator labii superioris. In the present study, the applications were performed only in this area because it offers fewer complications and more predictable results.

In this study, in order to quantify the decrease in the gummy smile, photographs of spontaneous smiles were taken with the same camera, lenses and distance from the patient to the camera. Also, to correct magnification of the image, the real measurement
of the right maxillary central incisor was performed and then a rule of three was applied to the photographic measurements. Al-Fouzan et al.\textsuperscript{20} used a similar methodology, but instead of the maxillary central incisor, they used only software to quantify the improvement. Polo\textsuperscript{27} used just the measurements performed directly on the photographs.

There are some contradictory claims in the literature regarding the effects of the BTX. While some authors rely on the short duration of the BTX-A treatment effects\textsuperscript{35,40}, they also consider the transient nature of the BTX effects as an advantage due to the predictability of relapse. Therefore, further studies are needed regarding the duration of BTX-A effects.

Several studies showed that BTX has a significant effect in reducing gingival smile, progressively decreasing over time. They also showed that some results could be maintained and did not return to pre-injection values after 12 weeks, depending on the muscle thickness and anatomy\textsuperscript{20,26,35,39}. However, there is no known study showing these effects after more than 24 weeks of BTX injection. Even though the reported effects of BTX last about 24 weeks, we decided to evaluate its duration for 8 more weeks, to reduce the number of injections in the patient. In our study, a significant decrease in the gingival display was observed 2 weeks after application. Then, gingival display increased significantly 32 weeks after BTX application, but did not return to baseline values. Polo\textsuperscript{27} found related results, but he evaluated only 24 weeks after BTX injection. A longer follow-up is needed to determine if the relapse of the gingival display returns to the baseline value over time.

**Conclusion**

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BTX-A application caused a significant improvement in gummy smile after 2 weeks, and a significant relapse of the gingival display was observed 32 weeks after the injection, but not returning to the baseline value.

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**Figure 1**: Injection sites (red dots)
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**Figure 2:** Excessive gingival display (red line)
Table 1: Random and systematic errors (Dahlberg’s formula and dependent t test).

<table>
<thead>
<tr>
<th>Variable (mm)</th>
<th>1st Measurement</th>
<th>2nd Measurement</th>
<th>Dahlberg</th>
<th>p</th>
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<td></td>
<td>Mean</td>
<td>s.d.</td>
<td>Mean</td>
<td>s.d.</td>
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<tr>
<td>Stomion-incisal edge</td>
<td>12.54</td>
<td>2.66</td>
<td>12.48</td>
<td>2.68</td>
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</table>

s.d.: standard deviation

Table 2: Intrigroup comparison of gingival display at the 3 stages evaluated (repeated measures ANOVA and Tukey tests).

<table>
<thead>
<tr>
<th>Variable (mm)</th>
<th>Before injection</th>
<th>2 weeks after</th>
<th>32 weeks after</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>s.d.</td>
<td>Mean</td>
<td>s.d.</td>
</tr>
<tr>
<td>Stomion-incisal edge</td>
<td>13.77&lt;sup&gt;A&lt;/sup&gt;</td>
<td>2.33</td>
<td>10.25&lt;sup&gt;B&lt;/sup&gt;</td>
<td>1.93</td>
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<td>Gingival Display</td>
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<td>1.94</td>
<td>-0.04&lt;sup&gt;B&lt;/sup&gt;</td>
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</table>

s.d.: standard deviation.