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Comparison between Two Different Techniques of Botulinum Toxin-A Injection for Treatment of Anterior Gummy Smile After Orthodontic Treatment

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ABSTRACT
Thirty-four anterior gummy smile patients underwent orthodontic treatment then divided randomly into two equal groups for botulinum toxin-A (BTX-A) injection. Group A received 1 BTX-A injection per side (Yonsei point). Group B received 3 injections of BTX-A per side. All patients were assessed at 2, 4, 12 and 24 weeks post-injection. They were satisfied by the results,especially after 1 month. Group B showed more improvement at canines regions than group A. It was concluded that BTX-A injection is a safe, satisfying method for anterior gummy smile patients. Multiple injections are more preferred than one injection.

Keywords: Botulinum toxin-A, BTX- A, Botox, gummy smile, anterior gummy smile, orthodontic treatment, Yonsei point.

INTRODUCTION

Attractive smiles become a main concern of dental patients. Gummy smile is one of the common complains in dental clinics. It has been defined as a non-pathological condition causing esthetic disharmony in which more than 3 mm of gingiva is exposed during smiling. It constitutes a prevalent condition that occurs in 10.5%–29% of young adults, with more popularity in women. In terms of incidence, approximately 7% of men and 14% of women have excessive gingival exposure with smiling (15).

The etiology of gummy smile is often multifactorial, associated with genetics and/or developmental factor. From the factors that contribute to GS are: altered passive eruption, lip length, gingival hyperplasia, incisal wear, vertical maxillary excess, and lip hypermobility. The causes of GS must be accurately diagnosed to render appropriate treatment. Various surgical and orthodontic modalities have been described in its treatment. However, these procedures do not help in reducing the hyperactivity of the muscles and therefore, the best orthodontic patients may not be satisfied by the treatment if soft tissue problem is not corrected.

Recently, the injection of botulinum toxin type A (Botox) has been suggested as an effective, conservative, and satisfactory technique for reducing excessive gingival display caused by hyperfunctional upper lip elevator muscles, but this effect is transient (9-11). Botulinum toxin has been widely used for the treatment of various conditions associated with pain and excessive muscle contraction since the 1970s. Clostridium botulinum is an anaerobic bacterium responsible for its production. Among the eight different serotypes of botulinum toxin that exists, Type A (BTX-A) is the most potent and the most commonly used clinically.

From all the previously mentioned, the study of different techniques of botulinum toxin A injection for management of anterior gummy smile in orthodontic patients was found to be a point of worthy investigations. Accordingly, this study was conducted to highlight this aim.

MATERIALS AND METHODS

- **Study design:** Prospective interventional study, randomized parallel arms clinical trial with allocation ratio of 1:1.
- **Ethical regulations:** The research proposal was submitted to Research Ethics Committee (REC) of Faculty of Dentistry, Minia University for its approval, and informed consent of REC was used in this study.

- **Sample size calculation:** G power program version (3.1.9) was used to calculate sample size for this study with priory analysis. T tests were used to detect the difference between 2 independent means regarding the gummy smile improvement as the primary outcome. Based on mean and SD of gummy smile reduction in the previous studies, the calculated effect size was 1.16 (large effect size), alpha error was 0.05 and power of 0.90 was used. The total sample size was 34, divided into two groups, each group 17 patients.
- **Inclusion criteria:** Skeletal Class I non growing patients with average age over 18 years showed more than 3 mm of anterior gingival display during unrestricted (full-blown) smiling with hyperactive upper lip elevator muscles. All patients were treated orthodontically before BTX-A injection. Patients were not suffering from any systemic disease, or taking periodic medication, and exhibiting good oral hygiene.
- **Exclusion criteria:** Contraindication of BTX-A. Previous diseases or treatments affecting the position of the gingiva or upper lips. Pregnant or breastfeeding patients. History of BTX-A injections to the head or neck region. Patients with neuromuscular disorders. Subject's refusal to be treated by orthodontic treatment and/or BTX-A injection.
- **Orthodontic treatment:** All patients included in this study underwent orthodontic treatment before BTX-A injection at the orthodontic clinics, dental hospital, Minia.Clinical examination was done for each patient participating in this study with radiographic x-rays (panoramic and lateral cephalometric) and photographs. After orthodontic treatment termination, patients received orthodontic retainers. Scaling and polishing were done for all cases. Chlorohexidine mouth wash was used prior to BTX-A injection to eliminate any gingival inflammations and emphasis on the existence of good oral hygiene.
- **Pre injection assessment:** Every patient gingival display was assessed by a digital caliper during maximum unrestricted smiling. Dynamic measurements were taken from the gum line at the midline of (right canine, right central incisor, left central incisor, and left canine) to the lowest portion of the upper lip during 4 different spontaneous smiles to ensure maximal smile for each measured area. The digital caliper was held perpendicular to the labial surface, and parallel to the long axis of each mentioned tooth. In addition, facial photos and videos were taken for any included patient at each visit.
- **Patient allocation:** The thirty four patients included in the study were randomly allocated into two equal groups: A & B by double blind sealed envelope method. Each patient in group A had received one injection of BTX-A per side at the Yonsei point. Each patient in group B had received 3 injections of BTX-A per side at levator labii superioris aleque nasi muscle (LLSAN), levator labii superious muscle (LLS) and zygomaticus minor muscle (ZMi) along the nasolabial fold.
- **Anesthesia:** Before injection each patient was topically anesthetized by PRIDOCAINE cream at the sites of injection for pain relief and numbness during injection. It was put using cotton sticks then wait for about 10 minutes before botox injection then removed by pieces of gauze wet with alcohol for disinfection.
- **Vial Reconstitution:** All BTX-A preparation and injection steps followed the guidelines prescribed in the previous studies in the literature. A 100 unit vials botulinum toxin-A (BOTOX 100 ALLERGAN units) were utilized. Each vial was reconstituted with a 2 ml saline free of preservatives. The vial was used within the first 4 hours to ensure maximum effectiveness of the Botox. Any violent shaking or heavy movement of the vial were avoided. Only gentle slight horizontal rotation of each vial to make the BTX powder dissolved in the injected saline without breakage of its molecules was carried out.
- **BTX-A injection:** The dose given to each patient in this study ranged from 4 to 6 units per side injected by insulin syringe. Each patient in group A had received one injection of BTX-A per side at the Yonsei point (1 cm lateral to the ala and 3 cm above the lip line) (fig. 1). Each patient in group B had received the same dose of BTX-A but divided into 3 injections per side to target the three main muscles involved in anterior gummy smile: LLSAN, LLS, and ZMi (an injection 2 mm lateral to the alar-facial groove at the level of the nasal passage, followed by an injection 3 mm lateral and inferior to the first one, with the last injection 3 mm lateral and inferior to the second one) along the nasolabial fold (fig. 2). The depth of all injections in both groups was intramuscular with the needle perpendicular to the skin surface and bevel facing upwards.
- **Instructions after injection:** After receiving Botox injections, all patients were instructed to follow specific post-care instructions to ensure the best results and avoid complications, like: do not rub or massage the treated areas for at least 24 hours. Stay upright and avoid any physical activity, heat exposure such as saunas, hot tubs, or sunbathing, and alcohol for at least 24 hours. Avoid washing their face or putting on make-up, creams, or other skincare products, especially during the first 4 hours after the injection. Cold compress or ice could be applied to the treated area if any mild bruising or swelling had occurred, but gently and avoid pressing too hard.
- **Follow up:** All patients were assessed at 2, 4, 12 and 24 weeks post-injection with same method of assessment described before at the pre-injection assessment section by the digital caliper. The primary outcome measurement was the anterior gingival exposure improvement when the subject got a full, unrestricted, spontaneous smile. In addition, facial photos and videos were taken for any included patient at each visit.

- **Statistical analysis:** All the gathered data was collected, tabulated and statistically analyzed using SPSS.

Fig.1: injection at Yonsei point of group A.

Fig. 2: three points application of group B.

RESULTS

After 2 weeks: Both groups showed a significant decrease in the anterior gummy smile by about half its original amount. The right canine region had the best improvement in gummy smile in group B more than group A (fig.3).

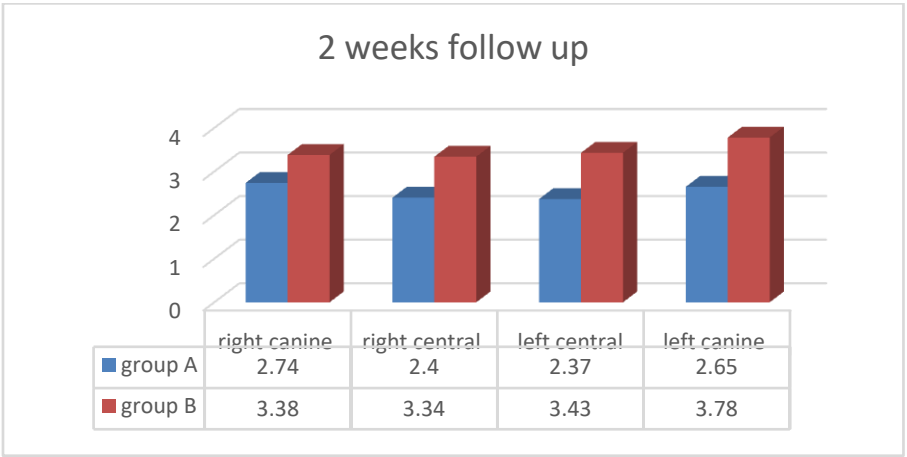

Fig. 3: comparison of both groups after 2 weeks.

After 4 weeks: Both groups showed the best results of anterior gummy smile improvement with the least gingival display at all calculated regions. In group B: canines regions showed the best results of gummy smile

improvement at 1 month follow up more than canines regions in group A. Maximum patients' satisfaction was achieved at 1 month follow up in both groups (fig. 4).

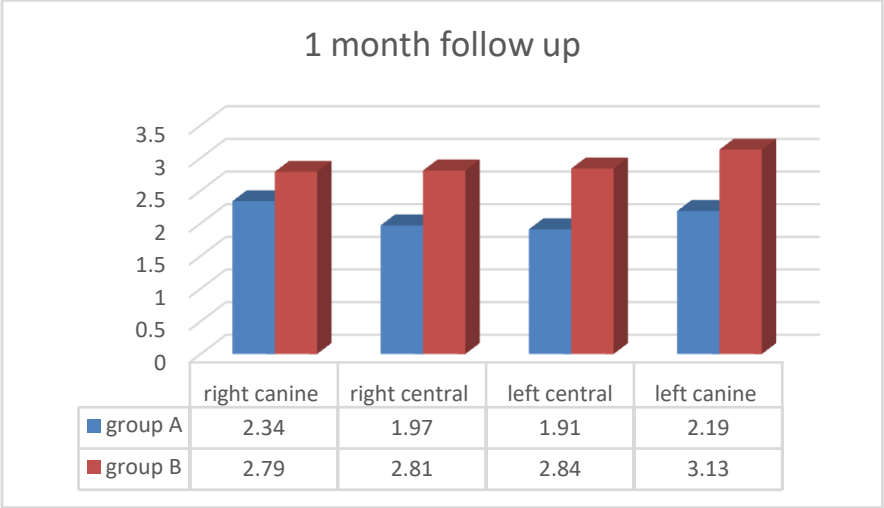

Fig. 4: comparison of both groups after 4 weeks.

After 12 weeks: Both groups showed gummy smile increase but had not reached the former state (fig. 5).

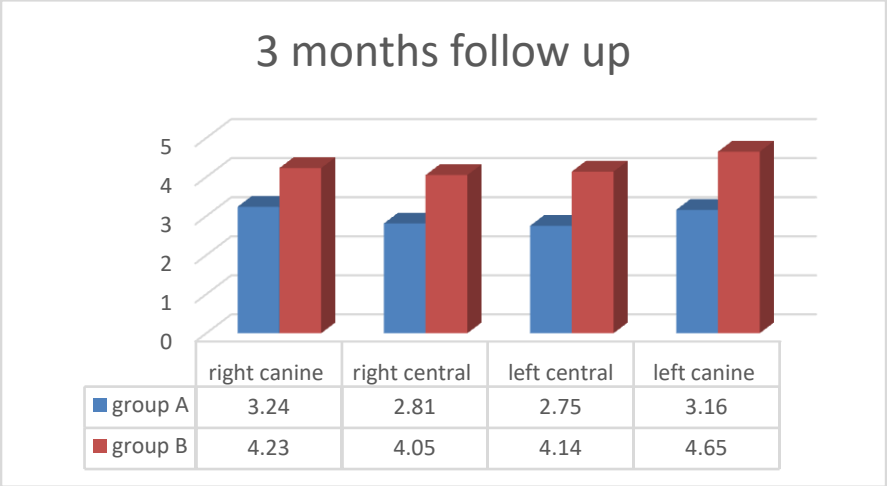

Fig. 5: comparison of both groups after 12 weeks.

After 24 weeks: Both groups showed gummy smile improvement but less than of 3 months follow up. No region in any group had reached the former state of anterior gummy smile. In group A: canines regions showed more relapse than centrals regions. In group B: centrals regions showed more relapse than canines regions (fig. 6).

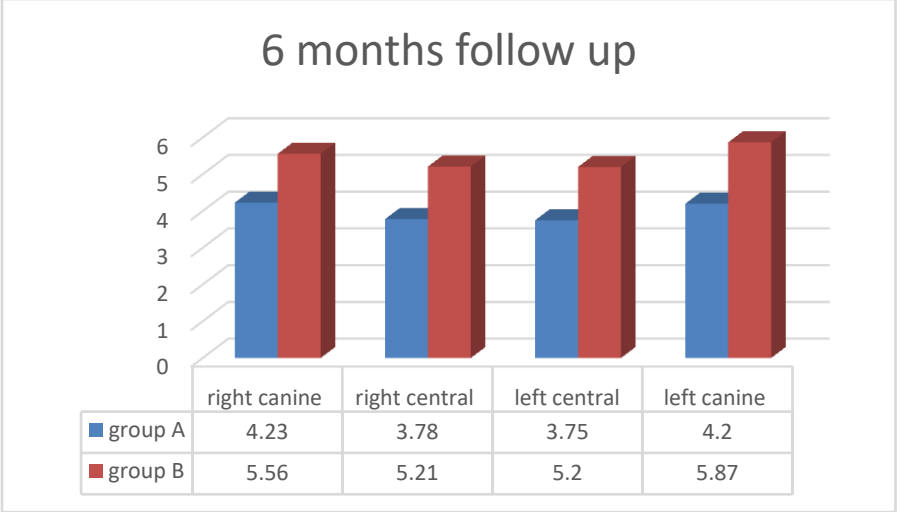

Fig. 6: comparison of both groups after 24 weeks.

Fig. 7: group A patient at day 0, and at 2, 4, 12 and 24 weeks follow ups.

Fig. 8: group B patient at day 0, and at 2, 4, 12, 24 weeks follow ups.

DISCUSSION

- Our research question was: "Which technique of BTX-A injection is preferred for management of anterior gummy smile after orthodontic treatment?" Therefore, the aim of this randomized clinical trial was to compare between two common BTX-A injection techniques for management of anterior gummy smile.
- The first technique we used in this study was the single injection per side technique which was proposed by Hwang WS. et al. (2009)[8] as a safe and reproducible injection point. They found that the insertion of LLS was covered partially or entirely by LLSAN and ZMi, and the three muscles converged on the area lateral to the ala. The three vectors of those muscles passed near a triangular region formed by three surface landmarks. The center of this triangle, named the "Yonsei point", was suggested as an appropriate injection point for BTX-A. Yonsei point is located 1 cm lateral to the ala and 3 cm above the lip line. Following the review of literature, it was determined that "Yonsei point" is a reliable technique for anterior gummy smile management by BTX-A injection, and many researchers prefer this technique more than multiple injections as concluded by Wayli H. (2019)[17], Duruel O. et al. (2019)[5]& Gong X. et al. (2024)[7].
- Other practitioners prefered multiple injections techniques for anterior gummy smile correction by BTX-A as Mazzucu R et al. (2010)[11], Suber JS et al. (2014)[14], Cengez AF et al. (2020)[4]&Aldhaher HA et al. (2022)[2]. Some studies injected 2 points per side[2,3,6,12], the others injected 3 points per side[9,11,13]. In this study we injected 3 points per side along the nasolabial fold. We found that 3 points injections gave best results of anterior gummy smile correction especially at the canines regions.
- Concerning longevity of BTX-A effect we found that it lasted more than 6 months. The measurements on the sixth month did not return to their initial values in all cases. A randomized clinical trial of Costa AB et al. (2022)[4] concluded that increasing the number of BTX-A injection points resulted in a prolonged effect and patient satisfaction but did not increase the intensity of the outcome. Other studies informed that BTX-A lasted less than 6 months. Adel N. (2022)[1]concluded that Botox last for only 2–3 months, with almost complete relapse at 4 months.Fatani B. (2023)[6] reported in her review that the main limitation of botox was the temporary duration range from four to six months, and the reinjection of botulinum toxin was usually needed.
- Regarding the best results of gummy smile correction we found that the bestoutcome was observed at 1 month of injection, but some other studies informed that the maximum effect of botox appeared at 2 weeks, with a tendency for the effect size to decrease from the second week of application onwards as Costa AB et al. (2022)[4]& Rojo-Sanchis et al. (2023)[13].

CONCLUSION

Botulinum toxin-A injection is a safe, satisfying, and conservative modality for management of anterior gummy smile. The three points method gives better outcomes in terms of clinical measurements especially at canines regions over Yonsei point method.

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