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Research Article

Botox A Injection Compared with Modified Lip Repositioning Surgery in the Treatment of Adult Patients with Gummy Smile Due to Hypermobile Upper Lip

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Abstract

Background: Smile esthetics is one of the most important factors affecting facial attractiveness, Gummy smile is recognized by the American Academy of Periodontology (AAP) as a deformity in smile and mucogingival condition that affects the area around the teeth. Which may be related to gingival, skeletal, dental, muscular cause or combinations among the possible causes. The most important esthetic goal in orthodontics is to achieve a balanced smile which can be best described as an appropriate positioning of teeth and gingival scaffold within the dynamic display zone.

Aim: This randomized clinical trial was conducted to assess patient's satisfaction, gingival display, upper lip length, upper vermillion border width and inter-labial gap using BTX-A injection in comparison with modified surgical lip repositioning.

Methodology: Total sample size 20 patients with excessive gingival display more than 3 mm during smiling were selected following eligibility criteria and randomization was performed 1:1 allocation ratio, Group I " the intervention group": patients were treated by Botox injection. Group II " the comparator group": patients were treated by modified lip repositioning surgery. Digital video graphic film was recorded during full smile of all patients, images were then uploaded on OrisCeph Rx3 computer software to obtain pre-operative records of soft tissue measurements (gingival display, upper lip length, vermilion border width and interlabial gap). Also, Visual Analogue Scale (VAS) from 0 to 10 was used to score patient's satisfaction. All patients recalled after 8 and 24 weeks obtain postoperative records.

Results: All data were presented as mean and standard deviation, comparison between both groups was performed by Independent t-test which revealed that patients' satisfaction in group I was significantly higher than group II after 8 weeks ($p < 0.05$), while there was insignificant difference after 24 weeks ($P>0.05$). But in gingival display, upper lip length, vermilion border width and interlabial gap there was insignificant difference between both groups ($P > 0.05$). Inter-observer and intra-observer reliability were performed using Kappa test which revealed strong to almost perfect agreement in gingival display, upper lip length, vermilion border width and interlabial gap. Moreover, correlation between satisfaction of patient and other parameters was performed and revealed strong negative significant correlation between patient satisfaction and gingival display and interlabial gap in both groups.

Conclusion: Although both groups revealed high patient satisfaction and great reduction in gingival display combined with increase in upper lip length, vermillion border length and interlabial gap reduction. However, after 24 weeks follow up complete relapse was seen.

Keywords: BTX-A Injection; Hypermobile; Interlabial Gap

Introduction

Facial and dental attractiveness can significantly impact one's life and interpersonal success. There are numerous constituents of the face that affect appeal, one of them is the smile esthetics which contributed to 25%-31% of facial attractiveness. A most acceptable esthetic gingival display is 1-3 mm upon full smile between the inferior border of the upper lip and the free gingival margin of the maxillary central incisors. In contrast when gingiva-to-lip distance of 4 mm or more is classified as "Gummy smile" [3,4]. The gummy smile is more prevalent and considered more unaesthetic in females than in males, with a reported prevalence between 7% in males and 14% in females [2]. Excessive gingival display (EGD) is also known by a variety of terms including gingival smile, high lip line, full denture smile, horse smile and smile curtain [5-7].

Several etiological factors have been proposed, which can be divided into gingival (gingival enlargement condition in which the enlarged gingival tissues are covering the clinical crowns), dental (Extrusion of the maxillary incisors with their dentogingival complex leads to a more coronal position of the gingival margins and excessive gingival display), skeletal (overgrowth of the maxilla in the vertical dimension), and muscular (the upper lip is shorter than 15 mm or hyperactive of the elevator muscles of the upper lip raising it nearly 20% more than the normal ones during smile) [8-10].

In general, cases of excessive gingival display may have more than one etiology and should therefore be diagnosed carefully, and an interdisciplinary treatment should be considered in cases of multifactorial gummy smile [11-13]. Gingival level classification is considered as the first step of diagnosis taking which affected by several factors such as gender, age, and periodontal health condition. Proper extraoral and intraoral examinations should be performed to detect etiology and allow the clinician to select the best treatment modality that satisfies both patient and operator.

Hypermobile upper lip is the predominant etiology among such patients looking for correction of their gummy smile (GS) being almost 80% of them [8]. Plastic reconstructive surgery was the solution offered in several reports published in the 1970s and 1980s for treatment of such conditions. The first technique reported was the lip adhesion technique described by Rubinstein and Kostianovsky [1]. In this technique, the internal connection of the upper lip is severed and dissected, Then, a lower reconnection is established about 4 mm above the free gingival margin between the upper lip and gingival soft tissues to restrict upper lip elevation during the smile limiting the amount of gingival tissue exposure. Recently, Hyper-functional upper lip cases can be treated using botulinum toxin injections as a new nonsurgical method offered by Polo M in 2005 [7]. It is injected into the area of the upper lip causing chemodenervation of the muscle and decrease its elevating activity. The major drawback of this technique is the short effect of the toxin, which lasts only for 3 to 6 months [14,15].

Botulinum neurotoxin (BTX) is a neurotoxic protein, has been under clinical investigation since the late 1970s. BTX exhibits temporary, nondestructive, dose- dependent, and partial chemical denervation of the muscle, resulting in localized reduction in muscle activity [8,9]. In 2005, it was used on patients with hyper-functional upper lip elevator musculature to correct a gummy smile and to establish the optimal minimal dose of BTX-A needed to obtain cosmetically pleasing results [16-18]. BTA injection is minimally invasive and cosmetically effective procedure as an attempt to camouflage the conditions of gummy smile with hypermobile lip. The improvement achieved is almost immediate but with a temporary nature lasts only for a period of 3-6 months, before slowly fading [19]. This relatively short duration is the major disadvantage of the technique, necessitating constant reapplication [20,21]. Moreover, BTX-A has minimal systemic side effects because it does not travel far from the injection site, so it does not affect other muscles that do not need to be relaxed [22-24]. This study was conducted to evaluate the effect of treatment using Botox A Injection on several aspects and correlate it with patient satisfaction.

Methodology

This randomized clinical trial (NCT03186547) was performed after approval obtained from Ethical Committee of Faculty of Dentistry, Cairo University

Study design

This study was designed as an interventional, randomized, clinical trial with two-arm parallel groups and allocation ratio 1:1.

Participants recruitment

Screening of potential eligible participants were carried out through clinical examination by the researcher at the out-patient orthodontic clinic. Subjects were recruited and confirmed eligible after the confirmation of the supervisors according to the eligibility criteria.

Eligibility criteria

The selected participants were adults with age range from 18 - 35 years, with excessive gingival display more than 3 mm during

smiling, hypermobile upper lip with or without (mild/moderate) vertical maxillary excess, normal morphology of clinical crowns, normal lip separation (ILG) at rest, medically free. On the other hands, patients with systemic diseases or neuromuscular disorders, severely long face (VME) patients, periodontal disease or gingival hyperplasia, medically compromised patients contraindicated for surgery, pregnant or lactating female patients and with inadequate attached gingiva were excluded from this study.

All participants signed an informed consent forms proposed from the Ethical Committee of Faculty of Dentistry, Cairo University, to participate in this study.

Sample size calculation

The sample size was calculated by PS-program and the input data was extracted from similar studies done by Polo M 2008 [24] and Silva., *et al*. 2013 [4] where the difference between the two techniques was 1.31 ± 1.1 mm. Using power 80% and 5% significance level, a sample size of 8 subjects was produced and thus 10 subjects were selected for each group in the study to avoid attrition bias.

Randomization, sequence generation, allocation concealment and implementation

The investigator cropped several small papers and divided them into two equal groups assigning either Botox injection or modified lip repositioning in a random manner. Then the operator ensured the allocation concealment, by making opaque sealed envelopes containing the grouping generated previously. At the day of the trail, the participant chose one paper from the previously mentioned envelopes then it was applied accordingly.

Blinding

Due to the nature of interventions in this trial, it was not possible to blind the participant. Also, the operator couldn't, because of the different application protocols presented. Researcher was blinded only to group allocation at the level of data entry and measurement. However, the outcome assessor was unaware of the treatment the participant had received.

Study setting

The study was carried out at the out-patient clinic, Department of Orthodontics, Faculty of Dentistry, Cairo University, where the patients were selected and the trial was carried on, except the modified lip repositioning surgery which was performed in the Periodontic Surgery department also at Cairo University.

Patients grouping

Twenty adult patients (16 females and 4 males) were enrolled in this study havinggummy smile due to hypermobile upper lip and they were divided into two groups:

- Group I " the intervention group": patients were treated by Botox injection.
- Group II " the comparator group": patients were treated by modified lip repositioning surgery.

For both, gingival display was assessed upon full smile before and after the intervention for a short term follow up at 8, 24 weeks.

Prior to the experiment, subjects were referred to the radiology center for lateral cephalometric radiograph making as a diagnostic aid for measuring the lower facial height which is indicative for vertical maxillary excess. The first stage of the trial was gummy smile registration for each patient by vidiographic imaging while smiling as pretreatment record. Then, each subject had to undergo the intervention, according to the grouping generated previously, after which by two weeks, patients were recalled for Botox retouch in group I and removal of sutures of patients in group II. Then, post-treatment records were taken at 8 and 24 weeks.

Gummy smile registration

Extraoral examination

In the frontal view, Smile line was determined as the position of the upper lip relative to the maxillary incisors and gingiva during a natural full smile, figure 1. A high smile line revealed 100% of the entire teeth crowns with an abundant amount of gingiva (excessive gingival display) [8,21]. This was a common trait in the sample.

Digital caliper was used to determine upper lip length at rest, measured from the subnasale to the lower border of the upper lip [22,23]. Also, the amount of gingival exposure during smile was measured from the lower border of the upper lip during an extensive smile and the level of the midfacial gingival margins of the maxillary anterior teeth [22,23,25]. And the interlabial gap was determined at rest as the distance between the most inferior por-

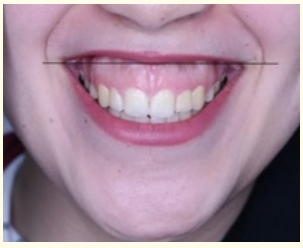

Figure 1: Assessment of smile line.

tion of the upper lip and the deepest midline point on the superior margin of the lower lip, it was considered normal between 2 mm to 4 mm on average. However, if it was 4 mm or more, it was an indication for lip incompetence with vertical maxillary excess otherwise the upper lip being short. upper lip vermilion border width was measured as the vertical distance from the most superior peak of the lip to the most inferior portion of the middle of the upper lip. As a consequence, the margin of the lip shows a transition between the thicker and thinner skin during full smile, caused by the vermilion border rolling in due to the hypertonicity of the upper lip. The

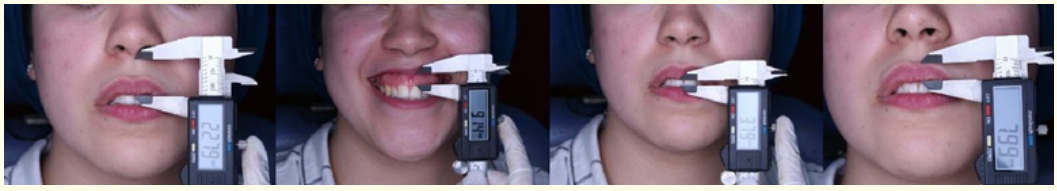

Figure 2: Extraoral soft tissue measurements.

upper lip was considered having agood volume when this distance was 7.5 mm with standard deviation ±1.5 mm, figure 2.

Intraoral examination

Occlusal plane and harmony of the dental arches as indication for dentoalvealar extrusion was determined using a tongue depressor, clinical crown height was measured for maxillary incisors (incisal edge to free gingival margin) to rule out altered passive eruption [22,24], periodontal examination as the width and thickness of the keratinized attached gingiva were measured because the limited amount of tissues creates difficulties in flap design, stabilization and suturing that may lead to relapse. Also probing depth was measured to determine the gingival index for each subject and so the oral hygiene status [4,22,29]. All patients had a history of good oral hygiene, although mild gingivitis was acceptable, figure 3.

Imaging

To record the dynamic smile, Each subject was individually filmed to acquire a standardized digital videography [13,16,17] including a close-up videos with a digital video camera in the photographic area of the department, under quality lighting revealing the facial contours by the same operator using a Canon EOS

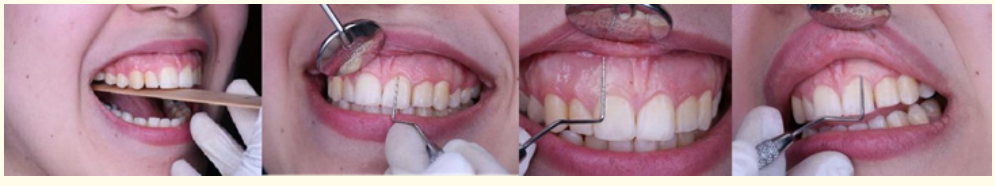

Figure 3: Intraoral soft tissue measurements.

6d DSLR Camera, 20 Megapixels, image sensor 22.3 mm ×14.9 mm, APS-C, CMOS type with maximum output resolution of 5184 × 3456, having 100 mm macro lens with image stabilizer, 0.25 m oblique 8 feet, and light sensitivity of 6400ISO.

The camera was mounted on a tripod (Manfrotto MK190X3-BH 240 cm, 5 kg) set at a standard distance of 150 cm from the individual. Patients maintained a natural head position during smiling using cephalostat which introduced by the orthodontic department.

A measuring scale, ruler, was used for calibration [30]. The ruler placed vertically parallel to the facial midline of the patient while smiling. Spontaneous smiles were elicited by a comical movie on the laptop and then downloaded to the computer and transferred to Quick Time Movie, usually about 10 seconds, in order to analyze the smile dynamics on videoframe level. The raw clip was approximately 12-20 frames, allowing to detect the frame that best represented the patient's unposed smile which was captured with a program called snipping tool and saved as a JPEG file. The smile image was then opened and calibrated by the calibration tool, using OrisCeph Rx3 computer software, by which, soft tissue measurements were done, figure 4.

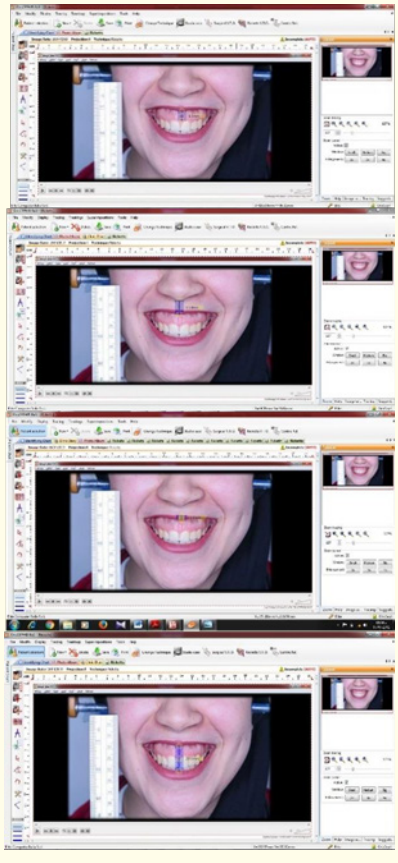

Figure 4: Soft tissue measurements using OrisCeph Computer software.

Botox injection

Preparation, storage and injection technique

The brand of Botox used was Allergan BT Type A, made in Ireland, 100 I.U./vial, in the form of a freeze vacuum-dried powder that clumps at the bottom of the vial. Following the recommended guidelines on reconstitution and storage, immediately before injections, the rubber seal on the vial was wiped with an alcohol swab before using a 3 ml, 23- guage needle syringe to inject 2.0 ml of 0.9% normal saline solution without preservatives for dilution of 100 U of the neurotoxin complex so that each 1 ml contains 50 units of Botox, figure 5. 1/2 cc ultrafine insulin syringe was used for injection as it is less painful to the patients following the manufacturer's dilution technique, the resulted dose was1.0 U/1.0 ml, this syringe was gauging the dose accurately in minute quantities [33,35].

Figure 5: Botox preparation.

A safe and reproducible intramuscular injection point was identified around the converging area of the three elevating muscles (Yonsei point) [16,23], figure 6. Before injection, cotton damped in mild alcohol solution was used to clean the detected areas. Then, topical anesthesia containing lignocaine 5% was applied for ten minutes then swabbed by sterile cotton. During injection skin should be tensed and needle bevel should be facing upwards. Needle was inserted tangentially at each site and passing just subcutaneously. To exert adequate effect, needle should be inserted to the muscle mass. Aspiration before Botox injection was done as a protective measure to avoid inadvertent deposition of toxin into the facial arteries. All the patient received injections in accordance with the conventional technique, a dose of 2.5 U per side was injected as a baseline to start the treatment [18,25].

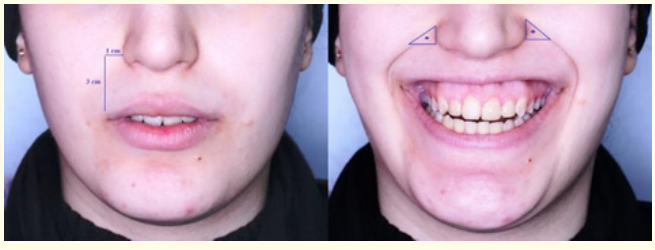

Figure 6: Yonsei point identification.

Modified lip repositioning

The surgical treatment, performed by a sole experienced periodontist N.Y. in the periodontic surgery department, consisted of a modification of the original Rubinstein and Kostianovsky (1973) technique, where the midline maxillary labial frenum was not excised. This modification was introduced to facilitate maintaining the position of the labial midline and symmetry and to reduce the morbidity associated with the procedure [4,25].

The surgical technique was achieved after following complete aseptic precautions (extraoral with 2% chlorhexidine, whereas intraoral with 0.12% chlorhexidine rinse for 1 min.) Paracetamol 500 mg was prescribed one hour prior to the surgery as a preanesthetic medication. The surgical site was anaesthetized by using Artinibsa 4% (One cartridge was used for bilateral infraorbital nerve block and another cartridge for conventional infiltration at the vestibular mucosa between the first maxillary molars for anesthesia and hemostasis in the area). Then the surgical area was outlined using an indelible marking pencil [4,27,29].

The procedure was initiated with a Bard-Parker blade no 15 by giving a partial- thickness incision 1 mm coronal to the mucogingival line following it and extending from the midline until the right first premolar region (14). A second partial thickness incision ran parallel to the first incision in the labial mucosa and apical to the mucogingival junction with a maximum of 10 to 12 mm as the tissue excision amount should be 1.5-2 times of the gingival display amount that needs to be reduced. After that, the horizontal incisions related to two vertical incisions at the central incisor region without involving the maxillary labial frenum and also at the right first premolar region creating a quadrilateral outline. The similar procedure was performed on the other side at (24) and also incisions were joined without touching the maxillary labial frenum in the center [4,27,29]. Then, two strips of the epithelium were carefully dissected within this outline, leaving the underlying connective tissue exposed. The tissue thickness was approximately 1mm. Care was taken to avoid injury of any minor salivary glands in the submucosa [26,27] figure 7.

Concomitant care

For Botox injection group: patients instructed to avoid rubbing or massaging the treated areas, lying down for at least 4-6 hours after the injection procedure. To avoid migration of neurotoxin to another area in the face.

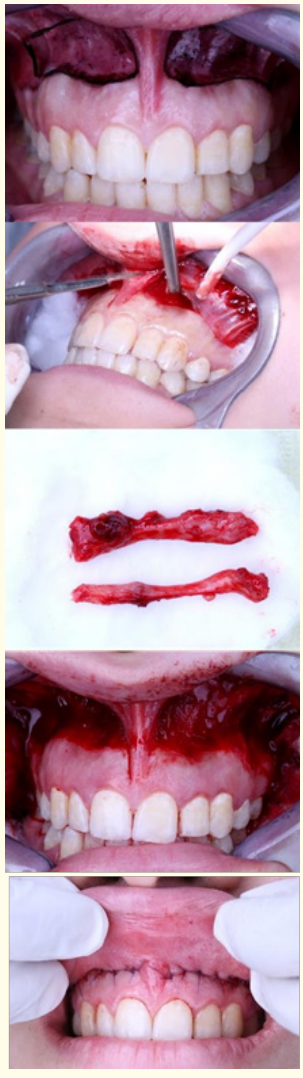

Figure 7: Modified lip repositioning surgery.

For modified lip repositioning surgery group: Post-operative protocol was followed for 5 days [nonsteroidal anti-inflammatory analgesic (ibuprofen 400 tds), oral antibiotic (amoxicillin 500 tds mg) and muscle relaxant (sirdalud 2 mg daily at bedtime) and to use 0.12% chlorhexidine rinse twice daily for two weeks along with cold packs extra orally to decrease postsurgical swelling]. They also instructed to consume only foods with soft consistency during the first week, to avoid mechanical trauma, and to minimize lip movement.

Patient satisfaction assessment

To measure the extent of patient's satisfaction with gumminess correction, each patient was handed a VAS (visual analog scale) [15,16]. This scale was designed to show an ascending degree of quality from right to left, which was anchored by the descriptors as 0 means not satisfied and 10 means the most satisfaction that could be obtained.

Assessment of gingival display and lower face esthetics

To measure the degree of improvement in gingival display, a close-up video was captured with the digital video camera in the photographic area of the department, under the same quality lighting of the pretreatment records by the same operator:

- **Gingival display**: Distance from lower border of the upper lip to midfacial gingival margins of the maxillary anterior teeth in full smile.
- **Upper lip length**: Distance from the subnasale to the lower border of the upper lip.
- **Vermilion border width**: Distance from the most superior peak to the most inferior portion of the middle of the upper lip.
- **Interlabial Gap:** Distance between the upper and lower lip.

Statistical analysis

Statistical analysis was performed using SPSS 20®[1], Graph Pad Prism®[2] and Microsoft Excel 2016[3]. Data was represented as mean and standard deviation and P value was set at < 0.05. Comparison between the two groups was performed by using Independent T-test Also, intra and inter-observer reliability was tested using Kappa - test and correlation was performed using Spearman correlation coefficient test.

Results

Comparison between both groups was performed by using Independent t-test. In patient's satisfaction, group II was significantly lower (P < 0.05) after 8 weeks but after 24 weeks there was insignificant difference between both groups, while in Gingival display, Upper Lip Length, Upper vermillion border width and Inter-labial gap group II was insignificantly lower (P > 0.05) than group I at baseline and after 8 weeks and after 24 weeks as presented in table 1 and figure 8.

		Group I		Group II		P value
		M	SD	M	SD	
Patient satisfaction	Baseline	0.80	0.04	0.5	0.08	0.006
	After 8 weeks	8.71	0.76	7	1.41	0.003*
	After 24 weeks	0.41	0.08	0.38	0.08	0.4
Gingival display	Baseline	6.85	1.15	7.90	1.98	0.13
	After 8 weeks	4.58	0.54	4.40	1.27	0.8
	After 24 weeks	6.85	1.15	7.29	2.19	0.8
Upper lip length	Baseline	15.00	1.56	13.6	0.85	0.06
	After 8 weeks	16.00	0.82	15.4	0.57	0.05
	After 24 weeks	15.00	1.56	13.75	0.35	0.06
Upper vermillion border width	Baseline	3.25	1.79	3.75	0.35	0.37
	After 8 weeks	5.58	1.77	4.9	0.85	0.26
	After 24 weeks	3.20	1.80	3.85	0.21	0.31
Inter -labial gap	Baseline	23.63	2.26	22.2	1.13	0.08
	After 8 weeks	21.18	2.49	19.15	2.62	0.09
	After 24 weeks	23.48	2.08	22	1.41	0.08

Table 1: Mean ± SD of patient satisfaction, gingival display, upper lip length, upper vermillion border width and inter-labial gap in both groups at baseline, after 8 weeks and after 24 weeks.

[1] Statistical Package for Social Science, IBM, USA.

[2] Graph Pad Technologies, USA.

[3] Microsoft Co-operation, USA.

M: mean SD: Standard deviation; *significant difference.

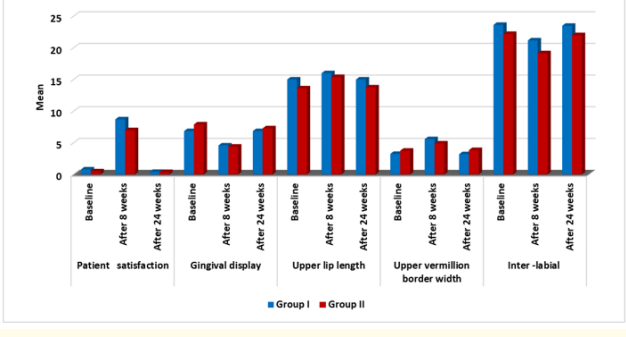

Figure 8: Bar chart represents patient satisfaction, gingival display, upper lip length, upper vermillion border width and inter-labial gap in both groups at baseline, after 8 weeks and after 24 weeks.

Agreement between 1st and 2nd reading of the assessor was evaluated using intra-observer reliability coefficient (Kappa test), also agreement between reading of 1st and 2nd assessor readings was evaluated using inter-observer reliability coefficient (Kappa test), which revealed strong to almost perfect agreement in both groups as presented in table 2.

Correlation between patient`s satisfaction and all other parameters was performed using Spearman correlation coefficient test which revealed strong (>0.5), reverse (-) and significant (P<0.05) correlation between patient satisfaction and gingival display and interlabial gap in both group, while revealed weak (<0.5), positive (+) and non-significant (P>0.05) correlation between patients satisfaction and upper lip length and upper vermillion border width in both groups as presented in table 3.

			Group I	Group II	
		IOC	Reliability	IOC	Reliability
Intra-observer Reliability (agreement between 1st and 2nd read)	Gingival display	0.98	Strong	0.92	Strong
	Upper Lip Length	1.00	Almost Perfect	0.99	Strong
	Upper vermillion border width	0.91	Strong	0.98	Strong
	Inter-labial gap	0.94	Strong	1.00	Almost Perfect
Inter-observer reliability (agreement between 1st and 2nd observer)	Gingival display	1.00	Almost Perfect	0.89	Strong
	Upper Lip Length	0.89	Strong	1.00	Almost Perfect
	Upper vermillion border width	1.00	Almost Perfect	1.00	Almost Perfect
	Inter-labial gap	0.89	Strong	0.89	Strong

Table 2: Intra-observer and Inter-observer reliability in both groups regarding Gingival display, Upper Lip Length, Upper vermillion border width and Inter-labial gab.

	Group 1			Group 2		
Patient satisfaction	r	Indication	P value	r	Indication	P value
Gingival display	-0.82	Strong negative	<0.05 *	-0.8	Strong negative	<0.05 *
Upper Lip Length	0.15	Weak positive	>0.05 ns	0.31	Weak positive	>0.05 ns
Upper vermillion border width	0.19	Weak positive	>0.05 ns	0.32	Weak positive	>0.05 ns
Inter-labial gap	-0.91	Strong negative	<0.05 *	-0.93	Strong negative	<0.05 *

Table 3: Correlation between patient satisfaction and Gingival display/Upper Lip Length/Upper/ vermillion border width/Inter-labial gap.

r: Spearman`s Correlation; P: Probability Level Significant at ≤0.0.

Discussion

The best orthodontically treated patients may not be satisfied with the treatment if soft tissue problem is not corrected, as patient desire to look good not only in a static pose but also during dynamic facial expression. So, along with functionally efficient and balanced occlusion, smile esthetics has become one of the major treatment goals for which people seek orthodontic treatment in the contemporary orthodontic paradigm [6].

EGD due to upper lip hypertonicity may be treated both surgically and nonsurgically[1]. lip repositioning, and Botox injections are the main treatment modalities typically employed for treating the muscular tissue for cases of hypercontraction of elevator muscles

of upper lip. Traditionally, It is used to correct these conditions with lip repositioning surgery aiming to limit smile muscle pull by reducing the depth of the upper vestibule, however, the cost, invasiveness and postoperative morbidity of the procedure cannot always be justified for the outcome achieved. With the introduction of Botox, a more conservative and immediate nonsurgical treatment modality became available. Injecting overactive muscles with measured quantities of botulinum toxin results in a reduction of muscle activity, relaxing the lip muscles and decreasing upward pull on the lip with almost immediate improvement achieved but lasts only for relatively short duration considering it as the major disadvantage of the technique [27,28].

This clinical trial aimed to assess primarily the extent of patient's satisfaction with the degree of improvement in gumminess treated by BTX-A injection in comparison with surgical lip repositioning. Also, to measure the gingival display reduction obtained as a secondary outcome of this study. In addition, to evaluate how much either interventions will affect lower face esthetics parameters upon smiling, including upper lip length, upper vermilion border width and the interlabial gap. Moreover, to monitor the stability of the two techniques which weren't compared clinically to date.

All the recruited patients in this trial strictly followed well defined inclusion and exclusion criteria. Adult patients were selected to ensure having a normal upper lip length and excessive gingival display more than 3 mm during unposed smile. In order to widen the search of the sample in this trial, patients with both mild and moderate vertical maxillary excess were recruited similarly as done by Aly and Hammouda [38]. In the present study, medically compromised patients who contraindicated to surgical intervention and patients having any neuromuscular diseases, where drug interaction may cause adverse events were excluded. To minimize the confounding factors as possible, subjects suffering from gingival hyperplasia, altered passive eruption or sever vertical maxillary excess were also excluded to avoid multidisciplinary treatment which can affect or change results. In addition, nursing or pregnant women were not recruited because it is not known yet whether the drug administered is safe or not to them.

In the current study, randomization was dependent on two interrelated aspects, adequate generation of an unpredictable allocation sequence and concealment of that sequence until the trial occurred. So that the person enrolling participants, who is also the operator in the present study was prevented from knowing in advance which treatment the patient would get. Also, it was important that the decision to enroll a participant was made in ignorance of the treatment to which they were be assigned, as this knowledge might influence the decision on whether to enroll. This process of allocation concealment was necessary to avoid the selection bias.

To prevent the performance and ascertainment bias (different response to treatment, or to measuring effect of treatment due to knowledge of which treatment was received), this study was single blind meaning the assessor. On the other hand, the patients and operator couldn't be blinded to the treatment assignment due to the difference in interventions and its application protocol.

In the clinical examination session and regarding the accuracy of the digital measurements, we used a digital caliper with minimal pressure on application and perpendicular on the soft tissue to avoid changes in the readings due to positional error of the caliper which approve by intra observer reliability results (A well trained second observer from post graduate candidates of Department of Orthodontics, Faculty of Dentistry, Cairo University as 2nd assessor) which revealed strong to almost perfect agreement in both groups. On the contrary Polo [7,24], Somaiah [34] and Singh., *et al.* [44] used a ruler in their studies.

For the Botox injection group, Yonsei point was selected according to the fixed- site approach [16,23,24,43]. BTX-A was injected initially at a low dose 2.5 units per each side of the face as a baseline to start the treatment according to the conventional technique [36,39]. For the other group, we applied modified lip repositioning surgery [4]. This technique didn't include the maxillary labial frenum to prevent the midline being shifted thus guiding for an esthetically pleasing smile and avoids the morbidity associated with the removal of maxillary labial frenum.

During follow up all patients completed a statistically validated questionnaire. This questionnaire should be simple, rapid, valid, and reliable method to rate and score patient's satisfaction, so we used the VAS in our study [15,16,39]. In this questionnaire they reported the beginning of upper lip position changes on smiling, their satisfaction rate, their willingness to undergo this procedure again in the future and whether they would mention it to others with a similar condition.

Beside questionnaire, a video graphic film was captured for all patients during full smile to take post-operative measurements in the same method as pretreatment measurements were taken. All measurements were recorded twice by the assessor where the av-

erage value was taken to detect the intra-observer reliability (agreement between two readings of the assessor). Moreover, the measurements were taken by another assessor to detect inter-observer reliability (agreement between reading of two assessors).

The results patient satisfaction was extremely satisfactory to patients of both groups in this study. Comparison between group I&II was performed by Independent t-test which revealed insignificant difference at baseline and after 24 weeks as $P > 0.05$, while after 8 weeks Group I was statistically higher than group II. This significant attributed pain and tension patients felt during talking and smiling meantime after surgery.

Gingival display in both groups was compared and revealed insignificant difference after 8 and 24 weeks. gingival display was reduced after 8 weeks then increased again after 24 weeks in both groups as complete relapse. In group II relapse and scar contraction are considered critical and frequent issues in surgical procedures.

Increase in the upper lip length on smiling with concomitant reduction in gummy smile was observed in both groups with insignificant difference between them. All patients were pleased with the increased upper vermilion border width observed during dynamic smile, giving a good-looking upper lip.

Most patients in group II complained of mild pain and tension during talking and smiling. Numbness of the left side of the upper lip and edema with a hematoma had formed in one patient, which disappeared within 2 weeks after surgery. On the other hand, three patients in group I reported twitching at the injection site, and one reported slightly more pain after the injection session, even though, they were highly willing to undergo the procedure again.

Despite Botox and modified lip repositioning met the esthetic demands of the patient, they have a transitory effect with no significant difference at different time points, even though, 6 months posttreatment average gingival display still had not returned to baseline values in two subjects in group II. Based on these results, the need for Botox reapplication through the standard technique should be within 6 months as mentioned in previous studies [34,36].

Conclusion

- Even that the gingival display was improved almost equally by both procedures, Modified lip repositioning dididnot offer the degree of patient satisfaction as botox injection due to pain and tension, patients had felt during talking and smiling meantime after surgery.
- Treatment with botox and modified lip repositioning resulted in subsequent increase in the relative the upper lip length and its vermilion borer width with concomitant reduction in interlabial gab, Improving the lower face esthetics during dynamic smile.
- Relapse occurred with both interventions after 6 months, however, Botox, as opposed to the surgical procedure, is minimally invasive and repeatable procedure for the correction of gummy smile caused by the upper lip elevator muscles.

Recommendations

- When using Botox for smile modification, consideration should be given to assess the degree of gummy smile severity, the type of smile and the gender of patient regarding muscle volume as well as the underlying surface anatomy as Individualization of the technique and dose utilized for injection is the key to success.
- In the absence of the modification and severance of labial frenum to apply more invasive techniques like detachment of lip muscles, myectomy or partial removal, lip repositioning surgery may result in significant and apparently stable reduction of gingival display.
- Botox could also be used in conjunction with surgical lip repositioning since its effect is necessary for the muscles to be relaxed before surgery in order to validate more stability of the tissues over time.

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