

To evaluate the effect and longevity of Botulinum toxin type A (Botox®) in the management of gummy smile – A longitudinal study upto 4 years follow-up



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ARTICLE INFO

Keywords:

Gummy smile
Botulinum toxin
Botox® injection
Aesthetics

ABSTRACT

Aim: the current study was aimed (1) To study the effect of Botulinum toxin (BT) A on gummy smile (2) To determine the efficacy, predictability & longevity of the effect of Botox® in the management of gummy smile and lastly (3) To identify the treatment groups for Botox® as a single modality for the non-surgical treatment of gummy smile.

Material and method: only patients who were willing to get the treatment done with Botox® injection were enrolled in the study, irrespective for the need for the surgery. Thus, total of 32 patients were divided into two groups, group I, having a gummy smile with less than 5 mm who were treated with 3 units of Botox® and group II, having gummy smile of more than 5 mm who were treated with 5 units of Botox® and each group underwent 2 cycles of injection 7 months apart given at the Yonsei's point and were followed for a period of 14 months.

Results: the procedure was tolerated well by the patients; none developed any allergic reaction or antibodies related to BT. In the less than 5 mm and more than 5 mm of gingival show group the results remain excellent till 3 months after which gummy smile gradually reaches to the baseline levels. Significant changes start to reappear by the 5th month.

Conclusion: Authors recommend use of BT for the treatment of gummy smile as the technique is safe, economical and easy to use. Though not long lasting, it may motivate patients to go for surgical procedure, mainly who have gummy smile of more than 5 mm because of maxillary vertical excess.

1. Introduction

Aesthetics and cosmetically pleasing teeth have been recognized for more than four millennia.¹ From early Hebrews laws to Egyptian and Japanese civilizations understood the importance and accomplishments restorative and cosmetic dentistry could bring.^{1,2} In today's time, a harmonious and an attractive smile, in spite of a healthy gingiva is what brings many people to the dental office for smile correction.³ According to Graber-Salama⁴ the smile has 3 components, teeth, lips and the gingival scaffold. Any discordant among the three components, disturbs the harmony of a smile. Tjan et al.⁵ in 1984, divided the smile line into 3 types:

1. Exposure of all dental crown/teeth along with contiguous gingival band becomes a high smile.
2. When 70%–100% of teeth are being exposed it is an average smile.
3. Less than 70% of exposed teeth falls under low smile.

More than 2–3 mm of gingival exposure while smiling is considered undesirable and is known as a gummy smile,^{6,7} and is also known as high smile line, horse smile, gingival smile line, high lip line and full denture smile,⁸ also indicating various reasons for a gummy smile.⁹ Treatment of gummy smile can be divided into two types surgical and less or non-invasive non-surgical depending upon the cause. Surgical crown lengthening, gingivectomy, lip-repositioning surgeries and orthognathic surgeries remain few of the surgical modalities which are used to treat

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<https://doi.org/10.1016/j.jobcr.2021.02.006>

Received 9 December 2020; Received in revised form 3 January 2021; Accepted 1 February 2021

Available online 10 February 2021

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gummy smile.³ Amongst non-surgical treatment modalities orthodontic treatment,³ use of lip fillers and use of Botox® (BTX) remain the most common ones. Surgical treatment modalities cause pre-operative anxiety which causes post-operative complications such as pain and delayed wound healing¹⁰ along with other complications related to it, due to which, non-surgical treatment modalities have become common, out of which, injection with Botox® is fast becoming a choice of treatment. Botox® or Botulinum Toxin (BTX) is the most poisonous substance known to mankind, however when used in diluted quantities, acts as a wonder drug which acts by blocking the transmission of acetylcholine.¹¹ It's this property is being utilised as an effective non-surgical treatment alternative for gummy smile. This fast, simple and easy to use technique is applied to upper lip elevator muscles namely which cause excessive gingival display.⁸

2. Material and method

In this longitudinal study, a total of 32 patients who were willing to undergo Botox® injections for the treatment of gummy smile irrespective of the surgery needed were enrolled keeping inclusion and exclusion criteria into consideration (Table 1). Sample size was collected using the Paired *t*-test, as calculated by the G*Power 3.1.9.2 program. The patients were divided in two groups. group 1, having a gummy smile with less than 5 mm who were treated with 3 units of Botox® and group II, having gummy smile of more than 5 mm who were treated with 5 units of Botox® and each group underwent 2 cycles of injection 7 months apart. After appropriate medical and dental history taking, a thorough facial and dental examination was carried out along with the Photographs of the patients who were willing to undergo a non-surgical correction of the gummy smile.

The gingival show (Fig. 1.) was measured using a scale and a Vernier calliper for precise measurements between two marked points. The distance between point A which is the tip of the lower margin of the upper lip and point B which is the midpoint of the gingival margin of the central incisor was measured as the gingival show (Fig. 2).

DILUTION OF THE BOTOX® VIAL: The correction dilution of the Botox® vial is the key to achieving good results. Freeze dried Botulinum Toxin (A) vial 100 units is available in a freeze-dried powder that clumps at the bottom of the vial and is diluted using 2.5 ml of .9% normal saline giving a dilution of 1 unit per 0.1 ml.

PROCEDURE: After complete pre-procedural protocols were followed and checked upon, Intramuscular injection at Yonsei point¹² was given

Table 1

Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Patients between 18 and 40 years of age.	History of neuromuscular disorder (e.g. myasthenia gravis, Eaton-Lambert syndrome).
No history of previous treatment for correction of gummy smile.	Allergic to any of the components of BTX-A or BTX-B (i.e. BTX, human albumin, saline, lactose and sodium succinate).
Patients wanting aesthetic smile correction without surgery.	Patients who have previously undergone any treatment for gummy smile.
Patient compliance for repeated injection.	Pregnant or lactating (BTXs are classified as pregnancy category C drugs).
Smiles based on the Tjan et al. ⁶ classification system were included:	Taking medications that can interfere with neuromuscular impulse transmission and potentiate the effects of BTX (e.g. aminoglycosides, penicillamine, quinine, and calcium blockers).
1. Exposure of all dental crown/teeth along with contiguous gingival band becomes a high smile.	
2. When 70%–100% of teeth are being exposed it is an average smile.	
3. Less than 70% of exposed teeth falls under low smile.	
–	Patients with underlying mental disorder/ Psychologically unstable or who have questionable motives and unrealistic expectations were not included.



Fig. 1. Pre-operative gummy smile.

(Fig. 3). This point has been chosen as the levator labii superioris alaeque nasi (LLSAN), levator labii superioris (LLS) and zygomaticus minor (ZMi) converge toward the lateral area with regard to the ala, and the three muscle vectors pass through a common triangular area forming an imaginary circle producing a landmark lateral to the ala contained. Botulinum toxin-A after dilution is injected at this point. A patient showing gingival display of less than 5 mm is being treated with 3 units of Botox® bilaterally and in cases of more than 5 mm of gingival display, 5 units of Botox® bilaterally was injected.

POST INJECTION MEASUREMENTS: Botox® reaches its peak activity within 10–14 days of the injection. So the measurement of the gummy smile was made after 2 weeks of the injection thereafter the follow-ups were at 3 months and 6 months. At every follow-up visit patients clinical images were taken and the gingival display was measured. Also patient's satisfaction was evaluated.

3. Results

All the patients showed excellent results (Fig. 4) and tolerated the procedure well. There was no allergic reaction seen in any of the treated patients. 3 units of Botox® was used bilaterally in gingival show (GS) of less than 5 mm and 5 units in cases of more than 5 mm which showed significant improvement in gummy smile at the end of 7 months, also known as the cycle 1. A second dose of Botox® was given, 7 months–14 months, named as cycle 2. Figs. 5 and 6 show other patients showing 3 mm and 8 mm of gingival show treated with Botox®. Statistical Comparison was done between cycle 1 and cycle 2 of both the groups analysing decrease in gingival show month-wise and the longevity of the drug used. Robust Linear mixed model was used for the statistical analysis.

In the graph Showing 5 mm or less than 5 mm of gummy smile at the baseline and post treatment at 3, 4, 5, 6 and 7 months, the x-axis shows the months starting from 3 months onwards and the y-axis shows difference in gingival show from the start of the treatment in mm. Here in cycle 1, meaning when the first dose of Botox® is given to the patient, if

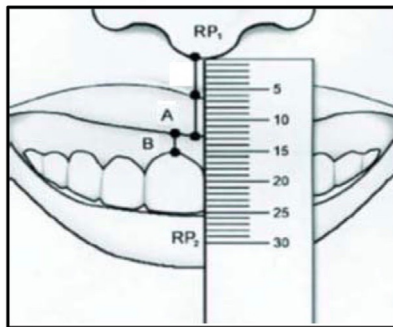


Fig. 2. Measurement of gummy smile.

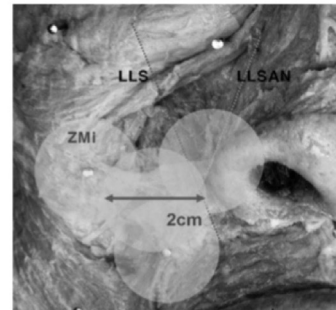
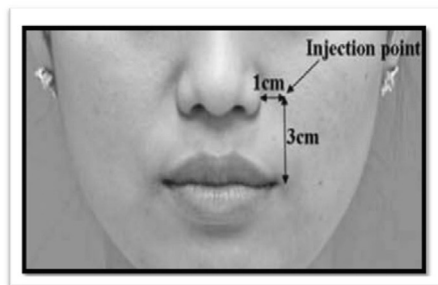


Fig. 3. Location of Yonsei point.



Fig. 4. Post-operative image.

the gingival show is less than or equal to 5 mm, for the first 3 months there is almost complete coverage of the gummy smile, which slowly

starts to deteriorate and by 7 month it becomes 0.5 mm which approaches to the baseline levels. The results of Botox® injection are very well within the acceptable range of gummy smile definition at 3 months (Fig. 7a). In the cycle 2, the second dose of Botox® was given to patients after 7 months of the first one. The results show that till 3 months the gingival coverage gain was 2.5 mm, 0.5 mm less than the first cycle, after which it starts to decrease and at 7 months approaches to the baseline levels. (Fig. 7b). And in the graphs (Fig. 8a and 8.b) where the dosage of Botox® given and gingival show at the baseline and post treatment at 3, 4, 5, 6 and 7 months in concerned, the x-axis shows the months starting from 3 months onwards and the y-axis shows gingival show in mm. It is clear for both the graphs that at 3 months when 3 units of Botox® was injected in patients having gingival display of 5 or less than 5 mm, comes down to 1 mm which gradually increases to the baseline levels. Noticeable change in gingival show starts from 5th month onwards in cycle 1 and 2 both, when gingival display goes beyond acceptable range of gummy smile and becomes 2.5 mm. At the end of first 7 months or in cycle 1 median is 3.5 mm, however, 25% of subjects have gingival display beyond 3.5 and 25% below 3.5 mm. In cycle 2, at the end of 6 months, gingival display is 3 mm, 0.5 mm less than the first cycle which remains stable at the end of 7 months as well.

Coming to the gingival show of more than 5 mm, the baseline and post treatment at 3, 4, 5, 6 and 7 months, in cycle 1 (Fig. 9a and 9.b), figure meaning when the first dose of Botox is given to the patient, if the gingival show is more than or equal to 5 mm, for the first 4 months there is good coverage of the gummy smile, which slowly starts to deteriorate and by 7 month becomes 1 mm which is more or less equal to the baseline

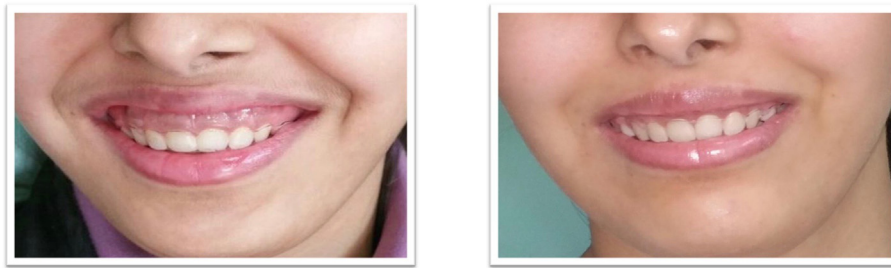


Fig. 5. Pre and Post-injection image of patients with gummy smile of 2 mm: gummy smile correction done using 3 units of Botox®.



Fig. 6. Pre and Post-injection image of patients with gummy smile of 8 mm: gummy smile correction using 5 units of Botox®.

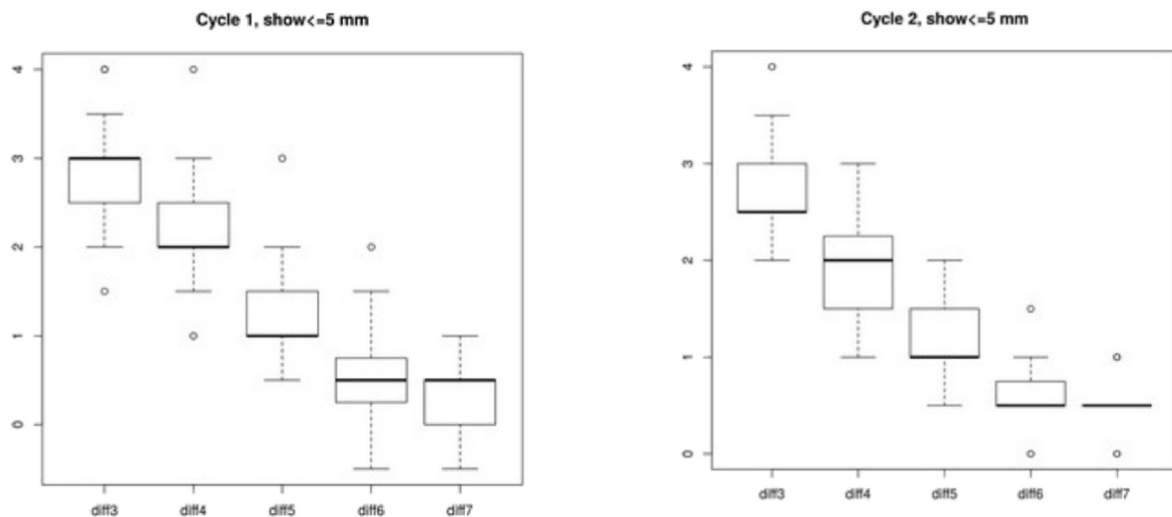


Fig. 7. ab: Showing 5 mm or less than 5 mm of gummy smile in mm at the baseline and post treatment at 3, 4, 5, 6 and 7 months.

levels. Thus the gummy smile reduced by 4 mm on the average. The gingival coverage at 3 months is 4 mm, which is not very well within the acceptable range of gummy smile definition. However for 50% of the patients it was acceptable. And in the second cycle where the gingival show is more than 5 mm, the results of gingival coverage are 0.3 mm less than the first cycle and remain stable till 3 months, after which it starts to decrease and by 7 months becomes same as the baseline. And when the dosage of Botox® is concerned, it is clear from both the graphs that at 3 months gingival display was 2 mm, very well within the acceptable range of gummy smile, which gradually increased close to baseline levels at the end of 7 months when the first dose was given (Fig. 10a). However, when the second dose was given in cycle 2 (Fig. 10b) gingival display at 6 months stabilized itself at 5 mm and showed a mild non-significant increase of 0.2 mm at 7 months.

4. Discussion

There are various studies in literature which have shown that gummy smile is considered unattractive and unpleasant. Hunt et al.⁶ studied 120 subjects who showed a gingival display of more than 2 mm while smiling and stated that it was considered unattractive. Frush and Fisher^{13,14} first described a ‘smiling line’ and pointed out that natural teeth follow an upward curve made naturally by the lips while smiling. In a study by Kaya and Uyar,¹⁵ and authors concluded that amount gingival show and smile attractiveness had statistically significant influences on the perception of smile attractiveness. In another study, Akhare and Daga¹⁶ evaluated and compared the amount of gingival display and how it affects smile and facial attractiveness in both the sexes of different facial forms and the authors stated that a 0–2 mm of gingival display was acceptable to both the lay-man and the orthodontists, and the ratings

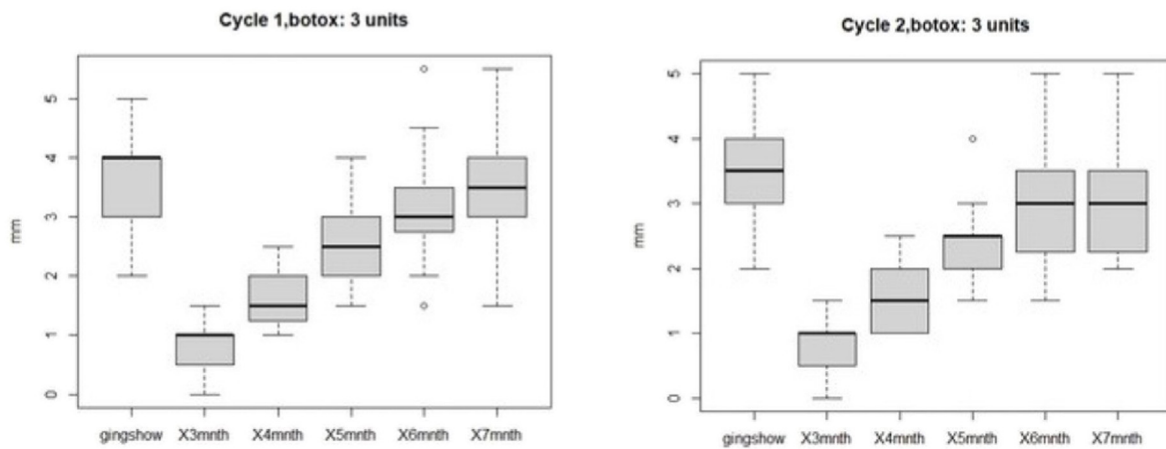


Fig. 8. ab: Showing dosage of Botox® given and gingival show in mm at the baseline and post treatment at 3, 4, 5, 6 and 7 months.

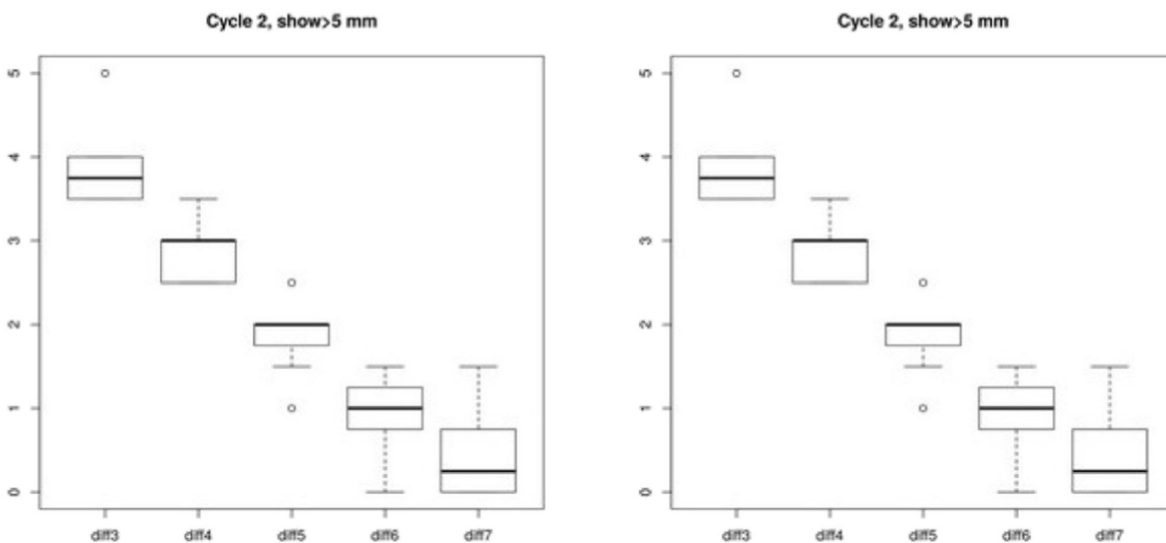


Fig. 9. ab: Showing 5 mm or less than 5 mm of gummy smile in mm at the baseline and post treatment at 3, 4, 5, 6 and 7 months.

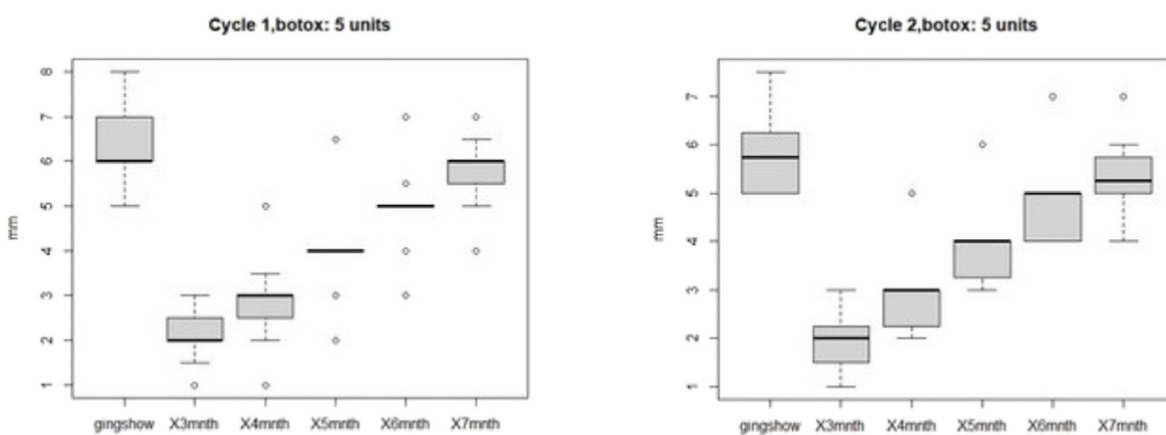


Fig. 10. ab: Showing dosage of Botox® given and gingival show in mm at the baseline and post treatment at 3, 4, 5, 6 and 7 months.

decreased as the gingival display increased.

So what causes a gummy smile? There are many causes of gummy smile which can be broadly divided into divided into 3 categories⁸:

1. Hereditary: Hereditary Gingival Fibromatosis
2. Congenital: skeletal deformity/vertical maxillary excess

3. Acquired: altered passive eruption, hypermobile upper lip, gingival enlargement,

But to be more specific, according to Garber and Salama⁴ a gummy smile can occur due to basic 2 problems:

1. Vertical maxillary excess

2. Altered Passive eruption

And according to the authors only proper diagnosis can result in definitive treatment, nonetheless the cause, treatment with Botox® injections is fast becoming very common as each surgical modality may cause a relapse, or patient simply doesn't want to go in for a surgical procedure due to fear, anxiety or the complications involved, also, many references in literature state that it is not necessary that an orthodontic treatment would be able to produce a corrected occlusion which will be balanced or beautiful in appearance.¹⁷ The only disadvantage of Botox® injection is that its effects are temporary and though procedures like orthognathic surgery are permanent, however, they are costly, time consuming and has its own limitations.¹⁸

Thus, Botox® becomes the easiest treatment any person suffering from a gummy smile or anyone who is conscious about the smile is can get. It is a very quick treatment, which gives 95–100% results, it is affordable and omits fear of surgery. The effect of BT lasts anywhere between 4 and 7 months,¹⁹ thus patient will have to get repeated injections to treat gummy smile. As a result patient compliance is necessary. However, this can also be used as tool to motivate the patient for aesthetic surgery, as can be seen in the cases presented, results are promising and encouraging. In the current study results lasted till 7 months, depending upon the type of BT used and degree of gummy smile corrected. However, as mentioned in the results, the gummy smile starts to reappear by 4 months when gingival show is less than 5 mm and by 3 months when it is more than 5 mm. That is why many patients started to visit the dental office by 4 or 5 months for the correction of gummy smile and by 7 months the gingival show had come to the baseline levels of 0.5 mm in both the groups. Thus, it can be safely stated that changes longevity of Botox® lasts for 3 months, but significant difference can be seen at 5 months. And at 7 months though the gingival show levels are approaching baseline, 25% of the subjects have gingival show at 1.5 mm when gummy smile is less than 5 mm and 3 units of BT has been given and gingival show is very well within the definition of acceptable range of gummy smile. However, the same cannot be said for the group where gummy smile is more than 5 mm.

Another dichotomy, is that there are antibodies which develop against BT. These antibodies may not interfere with the treatment when their titres are low, but if high which can occur with repeated dosage partial or complete therapy failure can occur. BT-B can produce more antibodies as compared to BT-A. However, with repeated injections the neuromuscular adaptation tends to work to help camouflage the gummy smile to some extent,²⁰ also, the incidence of developing antibodies during continuous treatment ranges between 0.5%/year and 1.5%/year.^{21,22} This implies that high values of up to 15% can be expected for the prevalence of antibodies in patients being treated for ≥10 years.²³ In the current study, this was clearly not the state, none of the patients were studied for a very long duration, nor any of the patients were given more than 2 round of injections, 7 months apart, but there was no development of any antibodies.

5. Conclusion

To conclude, author would recommend use of BT for the treatment of gummy smile as the technique is safe, economical and easy to use.

Though not long lasting, it may motivate patients to go for surgical procedure, mainly who have gummy smile of more than 5 mm because of maxillary vertical excess.

Declaration of competing interest

None declared.

Acknowledgement

To Dr. Nilotpal Chowdhury, faculty, AIIMS (Rishikesh) for helping through the statistical analysis.

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