Effect of an Oral Appliance on Lower Facial Contouring After Botulinum Toxin Type A Injection, Assessed Using Three-Dimensional Laser Scanning

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Effect of an Oral Appliance on Lower Facial Contouring After Botulinum Toxin Type A Injection, Assessed Using Three-Dimensional Laser Scanning

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감사의 글

어느덧 2011 년 한 해의 끝을 향해가는 시간 속에서 이렇게 의미 있는 순간을 맞이하게 되어 너무나 기쁘고 행복합니다.

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특히 저의 곁에서 항상 믿고 행복을 주는 아내 명진이와 사랑스러운 우리 딸 도연이와 믿음직스러운 우리 아들 대훈이에게도 이 고마움을 전합니다. 지금까지 저를 훌륭하게 키워주신 어머님과 먼저 하늘에 가신 아버님에게도 이 기쁨을 함께 하고 싶습니다. 그리고 곁에서 든든한 힘이 되어 주는 동생 덕윤이에게도 고맙다고 전하고 싶습니다. 아버님께서 이 순간을 함께 하셨다면 참 많이 좋아하셨을 텐데 아마 하늘나라에서 많이 대견스러워하시며 웃고 계시리라 생각됩니다.

감사합니다.

2011 년 12 월

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ABSTRACT

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This study used three-dimensional (3D) laser scanning to determine the effect of an oral appliance on changes in the external lower facial contour after injecting botulinum toxin type A (BTX-A) into the human masseter muscle. Fifteen volunteers were enrolled in this study. Twenty-five units of BTX-A was injected at two points at the center of the lower one-third of the masseter muscle, bilaterally. The clinical effect of BTX-A was evaluated by 3D laser scanning before the injection and 4, 8, 12, and 24 weeks thereafter.

The subjects wore an anterior bite plane splint (ABS) during the night from 4 to 12 weeks after BTX-A injection. Mean data for the volume and the bulkiest height differed significantly between preinjection and 4, 8, 12, and 24 weeks postinjection both with and without with the

ABS. The use of an ABS during the night from weeks 4 to 12 was ineffective as a supplementary treatment for masseteric hypertrophy after BTX-A Injection. However, the volume of the lower face recovered more slowly in the ABS group than in the non-ABS group over the 24-week postinjection follow-up period. Therefore, future studies should determine the most effective application time for an occlusal splint and to compare the ABS with a full-arch occlusal splint. Furthermore, prospective long-term studies involving larger numbers of subjects of both genders after BTX-A Injection are required.

Keywords : Botulinum toxin type A (BTX-A); masseter muscle; three-dimensional(3D) laser scanning; anterior bite plane (ABS)

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I. INTRODUCTION

Benign masseter muscle hypertrophy is an uncommon clinical phenomenon of uncertain etiology that is characterized by a soft swelling near the angle of the mandible (Al-Muharraqi MA et al. 2009). This condition was first described by Legg in 1880, and while its etiology

remains obscure, Gurney suggested that it is commonly associated with abnormal habits such as bruxism and clenching (Kwon JS 2009). Varying degrees of success have been reported for various treatment options for masseter hypertrophy, which range from simple pharmacotherapy to more invasive surgical reduction (Al-Muharraqi MA et al. 2009). Compared to surgical treatments, botulinum toxin type A (BTX-A) represents a safer and noninvasive drug treatment for patients with masseteric hypertrophy (To E.W et al. 2001). Indeed, an increasing number of patients are now seeking minimally invasive procedures, one of which is BTX-A injection (G. W. C. Jaspers et al. 2011).

BTX-A selectively blocks the release of acetylcholine at the cholinergic nerve terminal, ensuring a temporary reduction in muscular activity in the injected muscles. The process is reversible, the return of synaptic function to the original neuromuscular junction taking approximately 90 days. Clinically useful relaxation usually lasts for 12-16 weeks (Aoki KR et al. 2006). BTX-A is commonly used for the treatment of various neuromuscular disorders such as strabismus, blepharospasm, hemifacial spasm, and several other neurologic disorders characterized by abnormal, excessive muscle activity. For cosmetic purposes, BTX has also been used for facial rhytides in the glabella, forehead, lateral canthal skin, and neck (Kim KS et al. 2009). The use of BTX-A for treating bilateral masseteric hypertrophy was first introduced into dentistry in 1994 by Moore and Wood (Clark GT 1984). Previous studies have used various imaging methods to assess muscle volume reduction. For example, the reported reduction in volume as assessed by ultrasonography was approximately 31%, while Kim and colleagues reported a muscle reduction of 22% on computed tomography (CT). Park and colleagues reported a series of patients who were followed by ultrasonography and CT, and found that CT tended to overestimate the muscle volume, whereas ultrasonography underestimated it. Yu and colleagues used three-dimensional (3D) CT to estimate the reduction of bulkiness, and found it to be approximately 30% for the masseters (Kim KS et al. 2009). In

comparison to ultrasound and CT, 3D laser measurement appears to be a simple, easy, and accurate method, and provides measurements in three dimensions (Ahn KY 2010).

The occlusal splint is the first choice of the most widely accepted methods for the treatment of temporomandibular disorders (TMDs), and particularly those that originate from the masticatory muscles (Savabi O 2007). Occlusal splints may reduce teeth grinding, muscular activities, and myofascial pain (Macedo CR 2007). The occlusal splint decreases muscle activity by altering the occlusal scheme to a more stable condition. In addition, this device increases the vertical dimension, which can also decrease muscle activity (Savabi O 2007). Despite the broad use of occlusal splints in the treatment of TMDs, the efficacy of splints remains controversial.

The purpose of this study was to use 3D laser scanning to determine the effect of an oral appliance on changes in the external lower facial contour after BTX-A injection into the human masseter muscle.

II. MATERIAL AND METHOD

This study was performed in accordance with the 2004 Tokyo revision of the 1975 Declaration of Helsinki. All of the volunteers were dental students and staff at the College of Dentistry, Yonsei University, Seoul, Korea, in 2011 who complained of bulky masseter muscles. Based on screening via digital palpation and taking panoramic and posteroanterior views, volunteers who did not have a bony protuberance of the mandibular angle but had masseteric hypertrophy were enrolled in this study.

Each subject signed a written consent form before admission to the study, after they had received a full explanation of the characteristics and the established use of BTX-A and its potential side effects. The volunteers were free to withdraw from the treatment at any time. After screening for temporomandibular joint (TMJ) and orofacial pain, 15 volunteers aged 25−41 years (mean age, 33 years; 15 females) were enrolled in this study. The exclusion criteria included pregnancy, a history of drug allergy, and any other serious medical illness. All of the subjects were healthy, and none were taking any prescription or nonprescription medication. The control group comprised that included in the study of Shim et al. (2010), which enrolled 15 volunteers aged 22−35 years (mean age, 27.5 years; 4 males and 11 females).

1. BTX-A injection and anterior bite plane

One hundred units of BTX-A (Lanzhou Institute of Biological Products, Lanzhou, China), obtained as a freeze-dried powder, was reconstituted to a concentration of 5 units/0.1ml using 2ml of normal saline. The reconstituted drug was used immediately after preparation.

A total of 25 units of BTX-A was injected into two points at the center of the lower one-third of masseter muscle (separated by 1 cm), bilaterally. The lower one-third of the masseter muscle was selected as the injection site in order to avoid injecting into the parotid gland, parotid duct, and facial artery (Fig. 1).

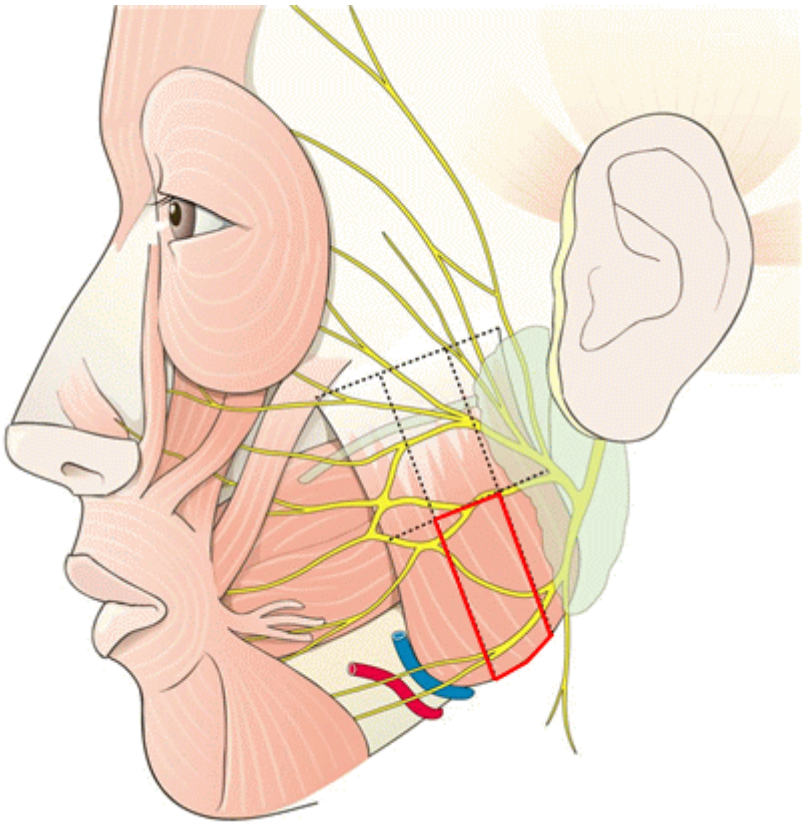

Figure 1. Safety zone (red borderline) of botulinum toxin type A (BTX-A) injection (from Hu KS, Kim ST et al. 2010)

An acrylic occlusal splint covering the maxillary anterior teeth, the so-called anterior bite plane splint (ABS), was fabricated and adjusted for each subject individually (Fig. 2). This splint was applied during the night from weeks 4 to 12 after the BTX-A injections.

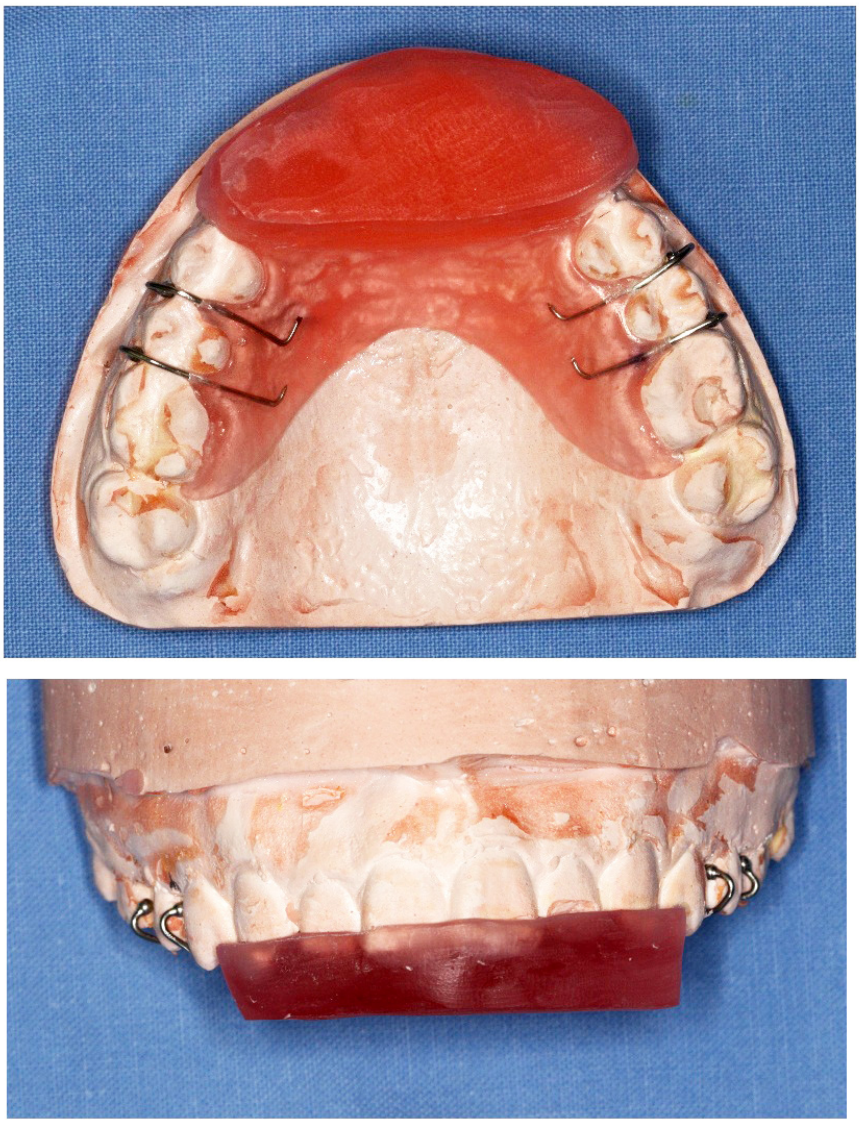

Figure 2. Anterior bite plane splint (ABS)

2. Data collection

The clinical effect of BTX-A was evaluated by 3D laser scanning before the BTX-A injections and at 4, 8, 12, and 24 weeks thereafter. The 3D laser scans were made using a Vivid 9i laser scanner (Minolta, Tokyo, Japan), which emits a harmless class 1 laser beam [rated safe for eyes by the US Food and Drug Administration (FDA); maximum 30 mW at 690 nm]. A technical expert performed all of the scans, and each image was saved onto a personal computer and merged into single 3D facial image analysis software (Rapidform 2004, Inus Technology, Seoul, Korea). The volume of the lower face was measured bilaterally. The border of the lower face was delineated by reference points (Fig. 3). The bulkiest height of the lower face was also measured bilaterally (Figs. 4 and 5). Subjects were interviewed about any adverse reactions. An analysis-of-variance test was used to evaluate the influence of the different side (right and left) on the effect of BTX-A on each of the masseter muscles.

3. Statistical analysis

The data were analyzed using SAS version 8.1software (SAS Institute, Cary, NC, USA).

An evaluation using the paired *t* test revealed that the volume and the bulkiest height of the lower face did not differ significantly between the left and right sides, and hence the number of samples was doubled by pooling the data for the two sides.

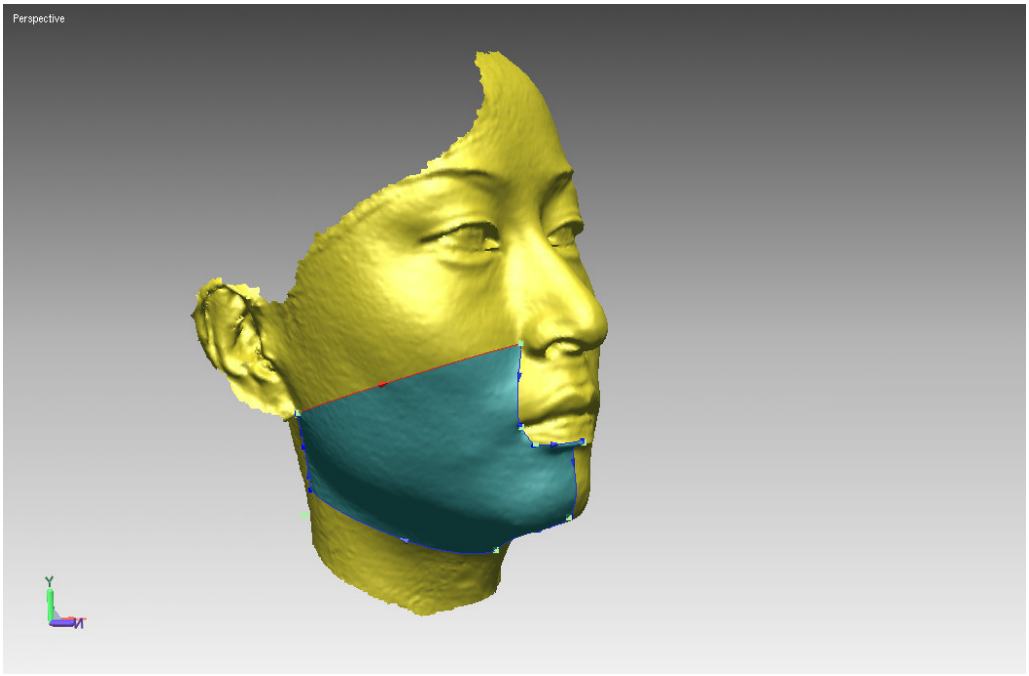

Figure 3. Measuring the volume of the lower face. The border of the lower face was delineated by the following reference points: ala, cheilion, labrale inferius, soft-tissue pogonion, soft-tissue menton, soft-tissue gonion, and tragion.

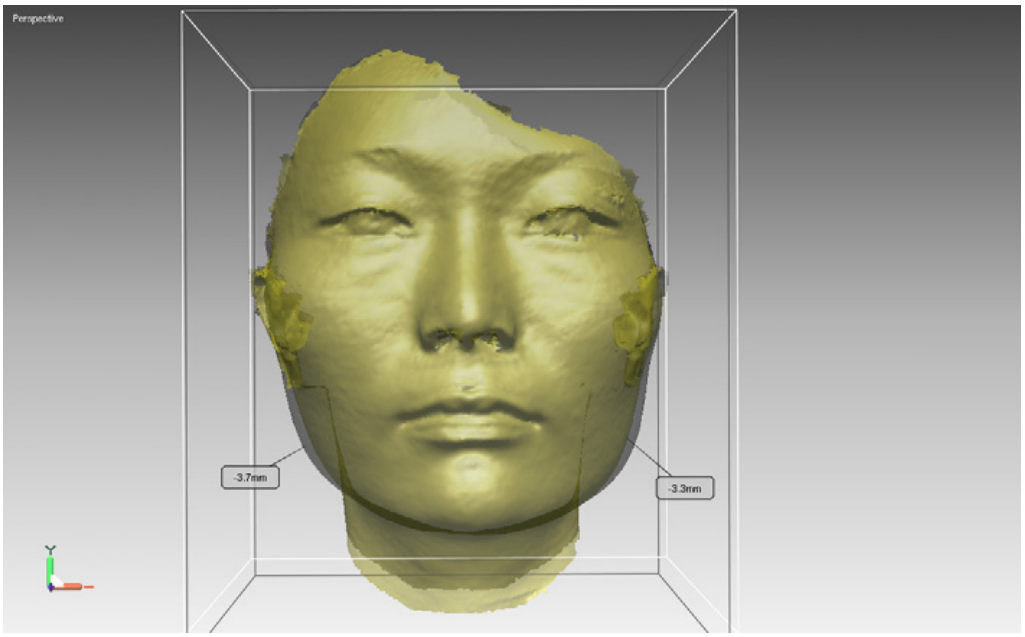

Figure 4. Differences in the height of the lower face (matched by color).

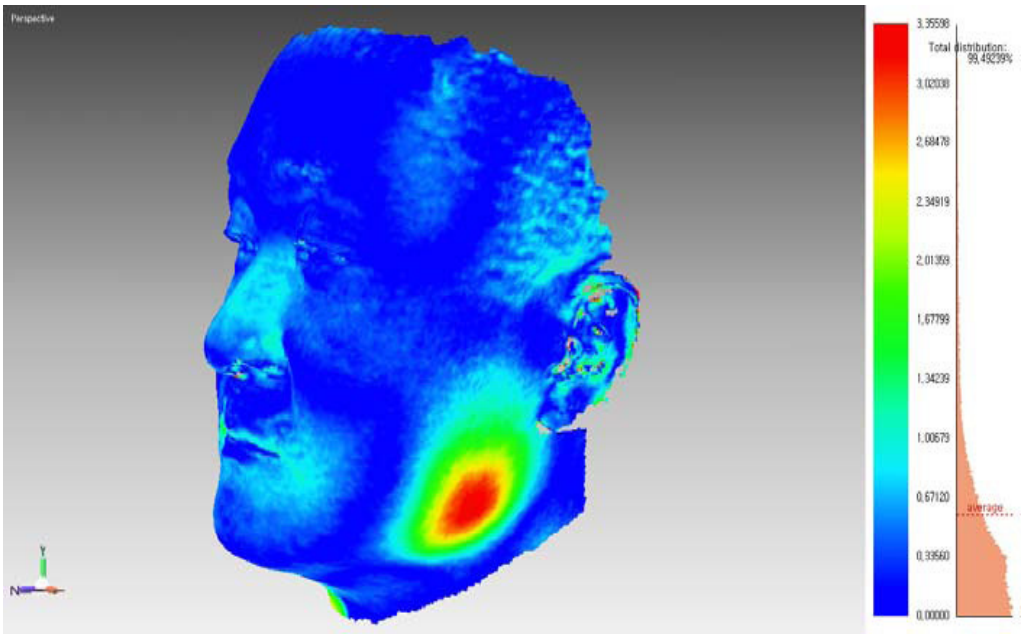

Figure 5. The bulkiest height of the lower face was measured by superimposing three-dimensional (3D) facial images.

III. RESULTS

Mean values of the volume and the bulkiest height at each time point are shown in Figs. 5 and 6. These parameters differed significantly between preinjection and 4, 8, 12, and 24 weeks postinjection both with and without the ABS (Tables 1 and 2). Use of the ABS as a supplementary treatment for masseteric hypertrophy during the night from weeks 4 to 12 postinjection was less effective than not using a splint.

Time point	Volume change,㎣ with ABS	Volume change,㎣ without ABS	***p*-value***
Preinjection	0	0	
4 weeks postinjection	−1303	−1715	0.157
8 weeks postinjection	−1892	−2595	0.034*
12 weeks postinjection	−2308	−2834	0.139
24 weeks postinjection	−2190	−1988	0.557

Table1. Mean volume change of the lower face at each time point (n=30).
ABS, anterior bite plane splint.
* Statistically significant at significant level of 95%

Time point	Height change, mm with ABS	Height change, mm without ABS	*p*-value*
Preinjection	0.00	0.00	
4 weeks postinjection	−1.45	−1.78	0.073
8 weeks postinjection	−2.09	−2.71	0.002*
12 weeks postinjection	−2.37	−2.99	0.002*
24 weeks postinjection	−1.90	−2.17	0.353

Table 2. Mean difference in the bulkiest height of the lower face at each time point (n=30)
* Statistically significant at significant level of 95%

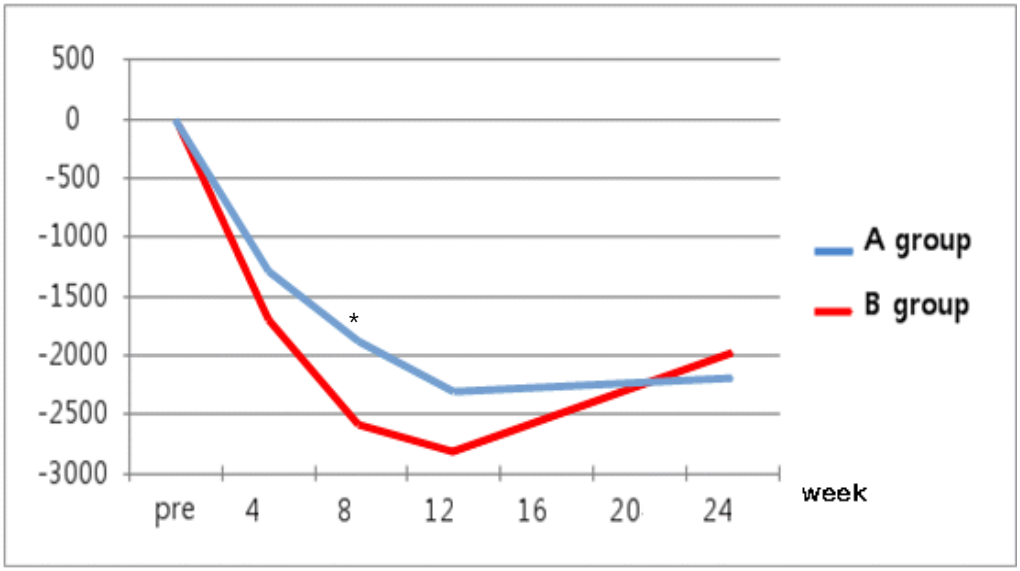

Figure 6. The volume differed significantly between preinjection and 4, 8 and 12 weeks postinjection in the ABS group (A) and the non-ABS group (B); (*:p<0.05).

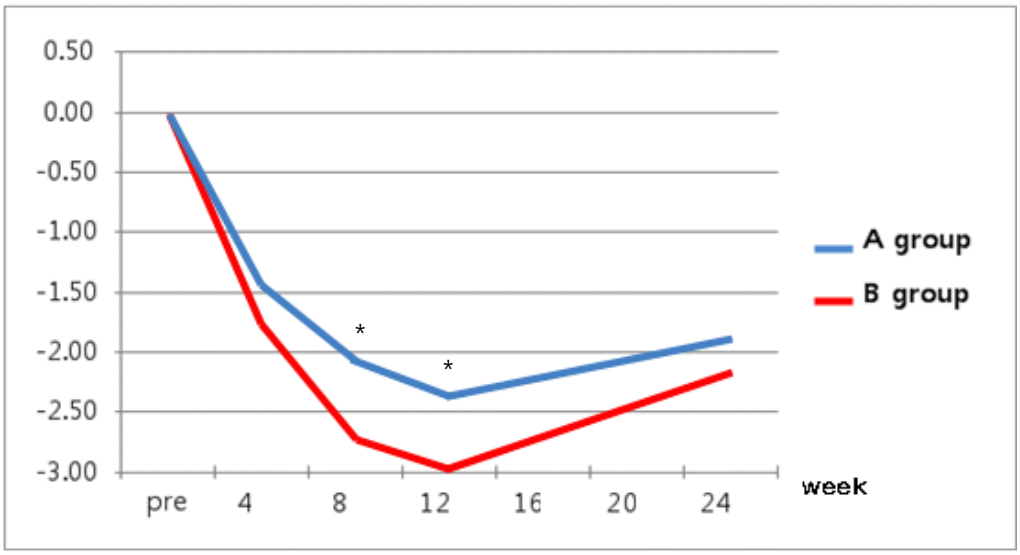

Figure 7. The bulkiest height differed significantly between preinjection and 4, 8, 12, and 24 weeks postinjection in the ABS group (A) and the non-ABS group (B); (*:$p<0.05$).

IV. DISCUSSION

BTX-A is one of the seven different serotypes of BTX (A-G) produced by the anaerobic bacterium *Clostridium botulinum* (Aoki KR et al. 2006).

BTX-A inhibits the discharge of acetylcholine into the synapse by bonding to the nerve at the neuromuscular junction. The toxin is then internalized via receptor-mediated endocytosis, and a toxin-containing vesicle is formed within the nerve ending. These internalized vesicles inhibit the acetylcholine protein (synaptosomal associated protein-25) that is located on the cell membrane. This inhibits muscle contraction, which leads to reversible muscle atrophy (Kwon JS 2009). The first cessation of muscle function occurs after 2–3 days, and the effect is maximal after 2 weeks (G. W. C. Jaspers et al. 2011). However, the maximum clinical effect of BTX-A for masseteric hypertrophy appears to require 3 months because this effect is muscular atrophy secondary to muscular paralysis by BTX-A (Kim HJ et al. 2003). Binding of BTA-X to the nerve is irreversible, and recovery of muscle function occurs by proliferation of axonal nerve buds to the target muscle and regeneration of muscle end plates after roughly 120 days (G. W. C. Jaspers et al. 2011).

BTX-A is used in the treatment of strabismus, blepharospasm, hemifacial spasm, adductor spasmodic dysphonia, bruxism, mandibular dystonia, cervix dystonia, local or segmental dystonia, hypercontractility of the internal anal sphincter, detrusor dyssynergy, spasticity, and stuttering. The demonstrated safety of BTX has led to it also being used in beauty treatments, hyperhidrosis, sialorrhea and neuropathic pain. BTX-A has been used for 20 years to treat diseases associated with accelerated muscle contraction and tension (Sim WS 2011). Besides its FDA-approved uses, BTX-A has a wide variety of clinical

applications. For example, it has been also shown to be useful in reducing pain associated with migraine, tension-type headache, and low-back pain (Kwon JS 2009).

The use of BTX-A in treating bilateral masseteric hypertrophy was first introduced into dentistry in 2004 by Moore and Wood (Kawazoe Y et al. 1980). Masseteric hypertrophy is a benign condition that is characterized by an enlargement of the masseter muscle, and was first described by Legg in 1880. The etiology of this condition is obscure; however, nocturnal bruxism and daytime clenching can explain masseteric hypertrophy (To E.W et al. 2001). It reportedly occurs most frequently among Asians and is associated with ethnic anatomical characteristics (e.g., prominence of the mandibular angle) and dietary habits (Hu KS & Kim ST 2010). The lower one-third of the face is wider in Asians than is Caucasians, and its dimensions are determined by the size and width of the mandibular bone and the thickness of muscles and subcutaneous fat tissues surrounding it (Kim NH et al. 2010). Asian people generally do not like square, wide-looking faces, which has made contouring of the lower face one of most popular esthetic procedures in Asia (Hu KS & Kim ST 2010). Asian women in particular tend to prefer oval or almond-shaped faces (Kim ST 2007).

The treatment of masseter hypertrophy has traditionally involved partial surgical resection, reduction, and modeling ostectomy of the mandibular angle or masseter muscle. However, there are several possible postoperative complications associated with these procedures, such as bleeding, swelling, hematoma, facial-nerve injury, and trismus (Hu KS & Kim ST 2010).

Many conservative treatments that have been advocated in the past-including occlusal adjustment, splint therapy, relaxation therapy, spasmolytics, tranquillizers, and antidepressants- are almost always unsuccessful (Kwon JS 2009).

The use of BTX-A as a treatment for masseteric hypertrophy in the presence of a square face has recently expanded because it is noninvasive and is safer than surgical procedures (Hu KS & Kim ST 2010). Various side effects of a BTX-A injection for masseteric hypertrophy have been reported, including change in bite force, speech disturbance, muscle pain, swelling, bruising, headache, muscle weakness, xerostomia, facial asymmetry, and prominent zygoma. However, But these side effects are all temporary and localized (Kwon JS 2009). To avoid these side effects and obtain effective results, it is necessary to improve our understanding of the location of the anatomic structures near the masseter muscle, such as the parotid gland, marginal mandibular branch of the facial nerve, facial artery, and facial vein, so that they can be avoided when injecting BTX-A in this area (Hu KS & Kim ST 2010).

Previous studies have used various imaging methods to assess muscle volume reduction after a BTX-A injection, including clinical photographs, ultrasound, electromyography, CT, and 3D laser scanning (Kwon JS 2009).

There are several deficiencies in using clinical photograghs to determine the effects of a BTX injection, but atrophy of the hypertrophic muscles has been noted (To E.W et al. 2001).

Many studies have evaluated the effects of BTXA by measuring electromyographic (EMG) activity. To et al. used ultrasound and electromyograph to evaluate the effects on masseteric hypertrophy of BTX-A injection into both masseter muscles. All five patients in their study showed good responses, with a maximal 31% reduction in muscle bulk at 3 months after treatment. CT is more reliable and accurate than ultrasound in evaluating the outcome of BTX-A injection. Kim et al. (2003) used CT to evaluate the effects of BTX-A on masseteric hypertrophy and reported that nine subjects showed a mean reduction of approximately 22% in masseteric muscle volume (Kim HJ et al. 2003). Yu and colleagues

used 3D CT in 15 subjects and found that the reduction of bulkiness was approximately 30% for the masseters (Shim WH et al. 2010). More recently, Shim et al. (2010) introduced the use of 3D laser measurement-which is a simple, easy, and accurate method-to evaluate the effects of BTX-A injection into the masseters in three dimensions (Ahn KY 2010).

The occlusal splint is a noninvasive and reversible biomechanical device used for managing pain and dysfunction of temporomandibular articulation and its associated musculature, as well as being the most commonly used treatment modality for managing the symptoms of TMD (Clark GT 1984). Its advantageous characteristics include it being inexpensive, light, and easy to use. This treatment aims to reduce the parafunctional activity of the muscles by inducing their relaxation and reducing the pressure over the TMJ in order to raise the vertical occlusal dimension, to protect the teeth from attrition and wear, to centralize the position of the condyle, to give diagnostic information, and to induce a placebo effect (Restrepo CC et al. 2011). There is general agreement that an occlusal splint eliminates occlusal interferences with a minimal amount of opening of the 'vertical dimension of occlusion,' and that this causes a change in the degree of tactile afferent impulses from the periodontal mechanoreceptor, and thus muscular relaxation (Kawazoe Y et al. 1980). It has been found that the occlusal splint decreases the EMG activity of the masseter and temporal muscles in the postural position and during maximum muscle activity in patients with functional disorders (Savabi O 2007).

The masseter muscle activity was more significantly reduced in patients with myofascial dysfunction syndrome during maximum clenching with splints than in those without splints. Such a significant difference is not observed in healthy individuals (Kawazoe Y et al. 1980).

Conversely, Okeson (1987) found that muscle activity increased by 20% among hard-splint users (Macedo CR 2007). Wood and Tobias also found an increase in masseter and temporal muscle EMG activity in healthy subjects. The occlusal splint increased the EMG activity of the masseter muscle and decreased the EMG activity of the anterior temporal muscle during maximum clenching in healthy individuals (Savabi O 2007).

Before this study, it was expected that supplementary splint therapy after BTX-A injection would decrease the volume of the lower face by decreasing the EMG activity of the masseter and temporal muscles in patients with functional disorders. However, the opposite results were unexpectedly obtained. This finding regarding the 3D volume and thickness after inserting the occlusal splint is probably attributable to the following mechanism. In subjects with masseteric hypertrophy, BTX-A injection into the masseter muscle decreases the volume and thickness of the muscle for up to 12 weeks. From weeks 4 to 12 after BTX-A injection (the period of splint application in each subject), the subjects are considered to be in a healthy masseteric condition. Use of the splint during this time may increase the muscle activity of the masseter muscle, which would explain the findings of this study. This suggests that the application of occlusion with the aid of supplementary treatment for masseteric hypertrophy after BTX-A injection could actually reduce the effectiveness of the injection over a period of 4-12 weeks.

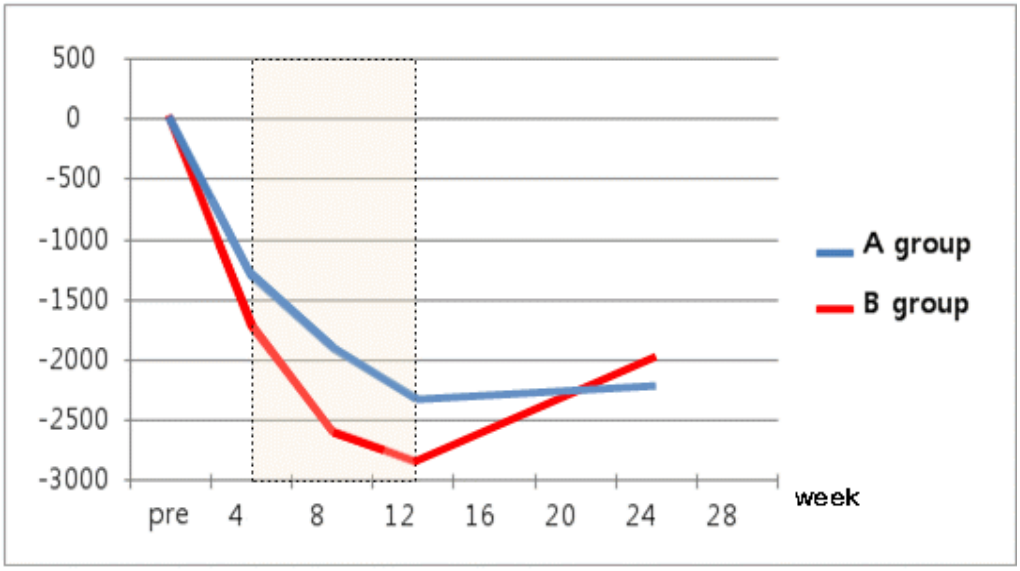

Figure 8. The muscle volume differed significantly between preinjection and 4, 8, and 12 weeks postinjection in both the ABS (A) and non-ABS groups (B) .

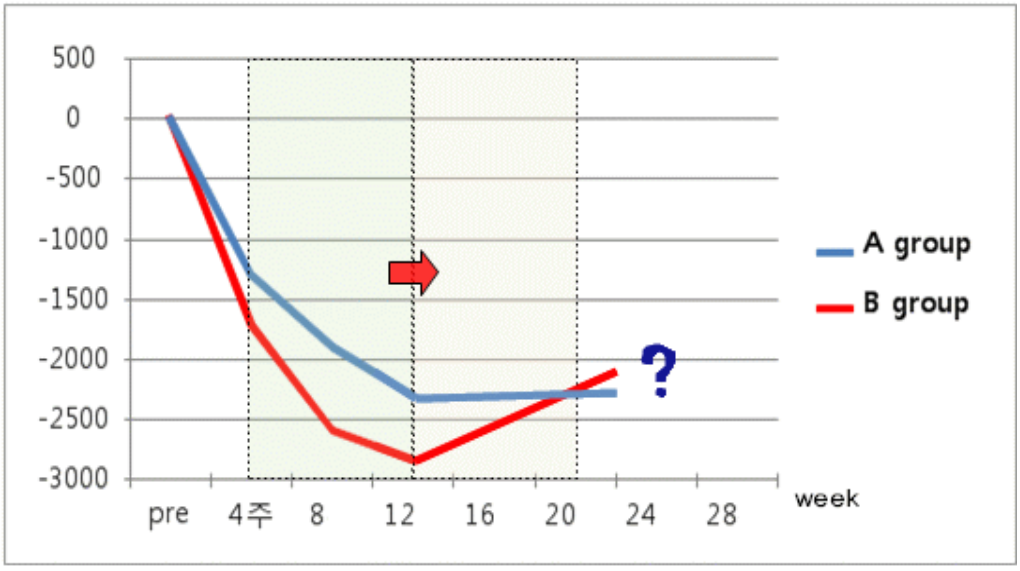

Figure 9. The prognostic graph of muscle volume at preinjection and 4-28 weeks postinjection in the ABS (during weeks 12-20) (A) and non-ABS groups (B).

However, the recovery pattern of muscle volume and thickness after 12 weeks may be more effective in ABS subjects than in non-ABS subjects (Fig. 8).

Future studies should thus change the ABS application period to 12-24 weeks, to determine whether this may better control the speed of the recovery after BTX-A injection (Fig. 9).

Moreover, the effectivenesses of the full-arch occlusal splint and the ABS should be compared.

This study was subject to some limitations. Only 15 patients were included, all of whom were female, it was a short-term study, and only the muscle volumes and heights were measured (Kim ST 2007).

Furthermore, the results of lower-face contouring depend clinically upon the interrelationships between complicated variables such as the amount of subcutaneous fat, body weight, skin laxity, degree of use of the masticatory muscles in everyday use, the amount of masseter muscle hypertrophy, and the individual's anatomy (Ahn KY 2010). Therefore, further prospective, long-term studies with larger numbers of subjects of both genders should be performed, focusing on the application time of the occlusal splint, the use of a full-arch occlusal splint, and measurement of EMG activity and bite force at various time points, following BTX-A injection.

V. CONCLUSION

Application of an ABS during the night from weeks 4-12 following BTX-A injection was less effective as a supplementary treatment for masseteric hypertrophy after BTX-A injection than was the injection alone. However, the recovery pattern following BTX-A injection differed between the control group (non-ABS) and ABS groups. The volume and thickness of the lower face gradually recovered to the same level regardless of the use of the splint, within 24 weeks after BTX-A injection.

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ABSTRACT (in Korean)

3차원 레이저 스캔으로 측정한 보툴리눔 독소 주사 후 구강장치가 하안면윤곽에 미치는 영향

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구 상 균

이 연구는 보툴리눔 A형 독소(이하 BTX-A)를 주사한 경우와 BTX-A 주사와 전방부분 피개장치를 동시에 사용한 경우에서 하안면부 외형 변화를 3차원 레이저 스캔을 이용하여 평가하고자 하였다.

15명의 자원자를 대상으로 BTX-A를 양측 교근에 각각 25 units을 약 1 cm 간격의 두 점에 같은 양으로 나누어 주사하였다. 전방부분피개장치는 BTX-A 주사 후 4주에서 12주간 장착하도록 하였다. BTX-A 의 임상적 효과는 술 전과 술 후 4주, 8주, 12주, 24주에 3차원 레이저 스캔을 채득하여 평가하였다. 대조군은 심 등 2009년 연구의 결과로 하였다.

대조군의 경우 BTX-A 주사 후 전방부분 피개장치 없이 술 전과 술 후 4주, 8주, 12주, 24주에 3차원 레이저 스캔을 채득하여 평가한 것이다.

분석 결과 하안면부의 부피 및 최대 풍융부 높이의 차는 BTX-A 주사 전과 비교하여 4주, 8주, 12주, 24주 후 모두에서 유의한 차이를 보였고 대조군보다 하안면부 변화가 4주, 8주, 12주에서 비교적 덜 효과적이었다. 그러나 24주에서는 그 결과가 역전되어 실험군이 더 효과적이었다.

이상의 결과를 종합하여 보았을 때, BTX-A 투여 후 전방부분 피개장치를 4주에서 12주에 사용한 경우 교합안정장치가 BTX-A의 효과를 감쇠시키는 작용을 하였다고 볼 수 있을 것이다. 24주에는 실험군이 더 효과적인 것을 볼 때 BTX-A 투여 후 교합장치 사용시기에 더 다양한 연구가 필요하리라 사료된다.

핵심 되는 말 : 보툴리눔 A형 독소 주사, 교근 , 3차원 레이저 스캔, 전방부분피개장치