Effect of Botulinum Toxin Type A Injection on Treatment of Masseteric Hypertrophy Evaluated by Three-dimensional Laser Scanning

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A Dissertation Thesis

Submitted to the Department of Dental Science,

the Graduate School of Yonsei University

in partial fulfillment of the

requirements for the degree of

Doctor of Philosophy of Dental Science

Woo Hyun Shim

December 2009

This certifies that the doctoral dissertation

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감사의 글

너무나 많은 분들의 도움과 가르침 속에 좋은 결과가 있었습니다. 앞으로 더욱 정진하여 제가 받았던 가르침을 다른 이에게 전할 수 있다는 약속을 드리며 감사의 글을 시작하고자 합니다.

논문의 처음과 끝을 알려주시고, 성심으로 지도해주신 김성택 교수님께 가장 큰 감사를 드립니다. 많이 미숙한 저를 첫 지도학생으로 선택해 주시고 잘 이끌어주신 은혜를 평생 마음속에 간직하며 살아갈 것입니다. 수련생활과 강사생활 동안 그리고 지금 학교를 떠나 사회에 있는 저에게 많은 가르침과 격려를 주시는 최종훈 교수님께도 감사 드립니다. 피와 살이 되는 조언을 해주신 안종모 교수님, 김희진 교수님, 안형준 교수님께도 감사 드립니다. 실무에서 많은 도움을 주신 권정승 교수님과 구강내과학교실원 모두에게도 감사 드립니다. 학위과정을 무리 없이 마칠 수 있게 배려해 주시고 격려해 주신 리빙웰치과병원 이상철, 김현철 병원장님 이하 모든 원장님께도 감사 드립니다.

언제나 저를 믿어주시는 어머니와 동생 내외, 처가집 식구들께도 큰 감사를 드립니다. 인생의 가장 큰 의미인 아내 박선미와 아들 심원준의 배려, 내조와 재롱이 학위를 마치는데 가장 큰 힘이 되었습니다. 다시 한 번 도움을 주신 모든 분들께 머리 숙여 감사 드리며 이제 겸손한 마음으로 이 논문을 여러분 앞에 드립니다.

2009 년 12 월

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Botulinum toxin type A(BTX-A) injection into the masseter muscles have been used to treat masseteric hypertrophy. The aim of this study to evaluate changes in the external facial contour after injecting BTX-A on the human masseter muscle with three-dimensional(3D) laser scanning. 15 volunteers were enrolled in this study. A total of 25 units of BTX-A was injected into each side bilaterally at two points at the center of the lower 1/3 of the masseter muscle. The clinical effect of BTX-A was evaluated by 3D laser scans before the injection and 4, 8, 12, and 24 weeks after the injection. Mean values of the volume and the bulkiest height differed significantly between preinjection and 4, 8, 12, and 24 weeks postinjection. This is the first prospective study using 3D laser scanning to evaluate the effects of BTX-A in lower facial contouring. BTX-A can be safely used as a nonsurgical treatment for lower facial contouring, especially masseteric hypertrophy.

Key words : Botulinum toxin type A (BTX-A); masseter muscle; three-dimensional(3D) laser scanning; lower facial contouring.

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Ⅰ. Introduction

Botulinum toxin produced by *Clostridium botulinum* induces muscle paresis and atrophy through the blockade of acetylcholine secretion in the neuromuscular junctions (Burgen, Dickens, and Zatman 1949 ; Dressler, and Adib Saberi 2005). This results in temporary chemodenervation, which is effective for both striated muscles and eccrine glands (Klein 2003). It is commonly used for treating a variety of neuromuscular disorders such as strabismus, blepharospasm, hemifacial spasm, and torticollis (Ahnert-Hilger, and Bigalke 1995 ; Traba Lopez, and Esteban 2001). In addition, the Canadian Opthalmologist Jean Carruthers used it cosmetically in the treatment of glabellar frown lines and other facial wrinkles (Carruthers, and Carruthers 1998). Botulinum neurotoxin therapy has also been reported to alleviate the pain associated with various conditions. Reports of botulinum toxin type A for the reduction of primary pain include a tension-type headache (Wheeler 1998),

chronic whiplash-associated neck pain (Freund, and Schwartz 2000), myofascial pain (Acquandro, and Borodic 1994 ; Cheshire, Abashian, and Mann 1994), and migraine headache prophylaxis (Silberstein et al. 2000).

The use of botulinum toxin type A (BTX-A) in treating bilateral masseteric hypertrophy was first introduced into the cosmetics field in 1994 (Moore, and Wood 1994). The main causes of a wide lower face (square face) are prominent mandibular angle and masseter muscle hypertrophy. Individuals who have a square face, especially women, want to make their facial contour slimmer for cosmetic reasons, and various treatments have been performed, which include mandibular angle ostectomy, angle splitting ostectomy, and partial resection of the masseter muscle (Lee et al. 2007).

Compared to surgical treatments, BTX-A represents a safer and noninvasive drug treatment for patients with masseteric hypertrophy (To et al. 2001). However, good clinical data for treating masseteric hypertrophy by injecting BTX-A into masseter muscles were obtained only recently. Some authors have reported that BTX-A can reduce the size of the masseter muscle, as documented by photography (von Lindern et al. 2001), ultrasonography (To et al. 2001 ; Kim et al. 2005), and computed tomography (CT) (Kim et al. 2003). However, changes in the external contour as a result of atrophy of the masseter muscles are more important clinically than a decrease in their thickness (Lee et al. 2007). Moreover, a patient and his or her friends and family evaluate the success of treatment mainly based on visual cutaneous changes (Baik, Jeon, and Lee 2007). A timely development is the application of three-dimensional (3D) image capturing tools that are applicable in the cosmetics field. The aim of this study to evaluate changes in the external facial contour after injecting BTX-A on the human masseter muscle with 3D laser scanning.

Ⅱ. Materials and Methods

This study was performed in accordance with the 2004 revision in Tokyo of the 1975 Declaration of Helsinki. The study population consisted of volunteers recruited from dental students and staff at the College of Dentistry, Yonsei University, Seoul, Korea who had complained of a bulky masseter muscle. After screening by 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. Before admission to the study, the nature and the established use of BTX-A as well as its potential side effects were fully explained, and a signed informed consent was obtained from each volunteer. The volunteers were advised that they were free to withdraw from the treatment at any time.

After screening for TMJ and orofacial pain, a total of 15 volunteers aged 22 to 35 years (mean age 27.57 years, 4 males and 11 females) were enrolled in this study. The exclusion criteria for this study included pregnancy and a history of drug allergy or any other serious medical illnesses. All of the subjects were healthy, and none were taking any prescription or nonprescription medication.

1. Botulinum toxin injection

The BTX-A (BTXA®, Lanzhou Institute of Biological Products, Lanzhou, China) supplied as a freeze-dried powder was reconstituted at a dose of 100 units in 2 ml of sterile saline to give a concentration of 5 units/0.1 ml. The reconstituted drug was used immediately. A total of 25 units of BTX-A was injected into each side bilaterally using a 1-ml syringe with a 29-gauge, 1/2-inch-long needle. It was injected into two points at the center of the lower one-third of the masseter muscle that were separated by 1 cm. Preventing to inject into the

parotid gland, parotid duct, and facial artery, the center of the lower one-third of the masseter muscle was selected for the site of injection.

2. Collection of data

The clinical effect of BTX-A was evaluated by 3D laser scans before the injection and 4, 8, 12, and 24 weeks after the injection. The 3D laser scans were made with a Vivid 9i laser scanner (Minolta, Tokyo, Japan), which emits a harmless Class Ⅰ laser beam (rated safe for eyes by the US Food and Drug Administration; maximum 30 mW at 690 nm) (Fig. 1). A technical expert performed all the scans, and each image was saved on a personal computer and merged into single 3D facial image using 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. 2). The bulkiest height of the lower face was also measured bilaterally (Fig. 3, 4). Subjects were interviewed about 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. 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.

3. Statistical analysis

The data were analyzed using SAS version 8.1 (SAS Institute, Inc., Cary, N.C.).

Figure 1. Vivid 9i laser scanner (Minolta, Tokyo, Japan), which emits a harmless Class Ⅰ laser beam (rated safe for eyes by the US Food and Drug Administration; maximum 30 mW at 690 nm).

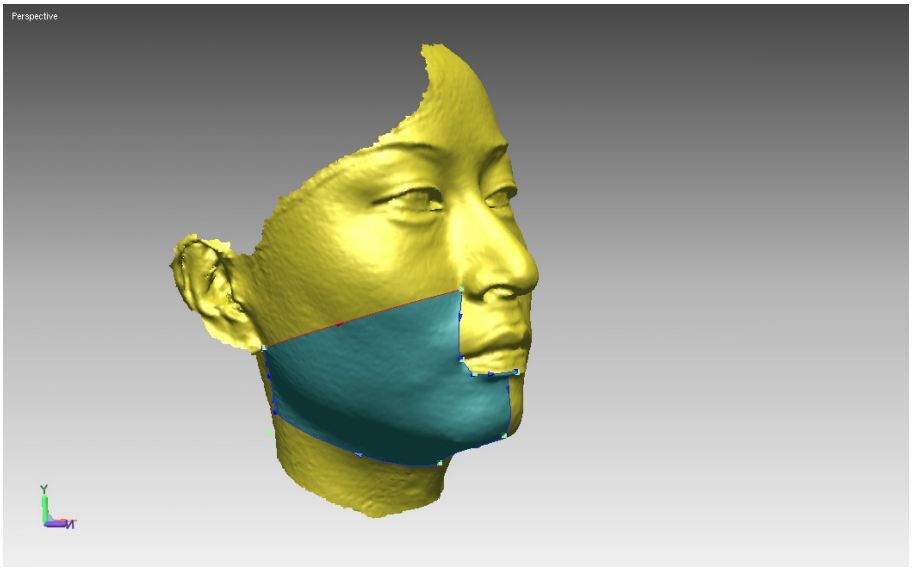

Figure 2. Measuring the volume of the lower face. The border of the lower face was delineated by reference points (ala, cheilion, labrale inferior, soft tissue pogonion, soft tissue menton, soft tissue gonion, and tragion).

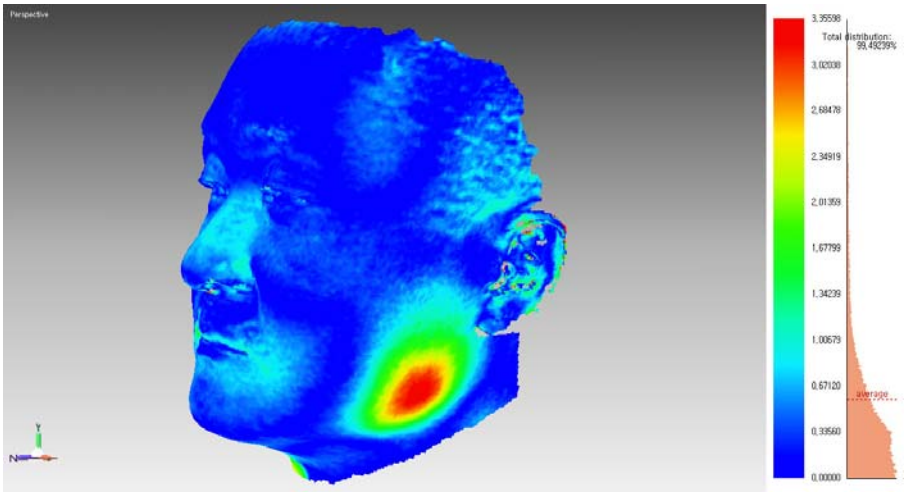

Figure 3. Measuring difference of the height of the lower face (matched by color).

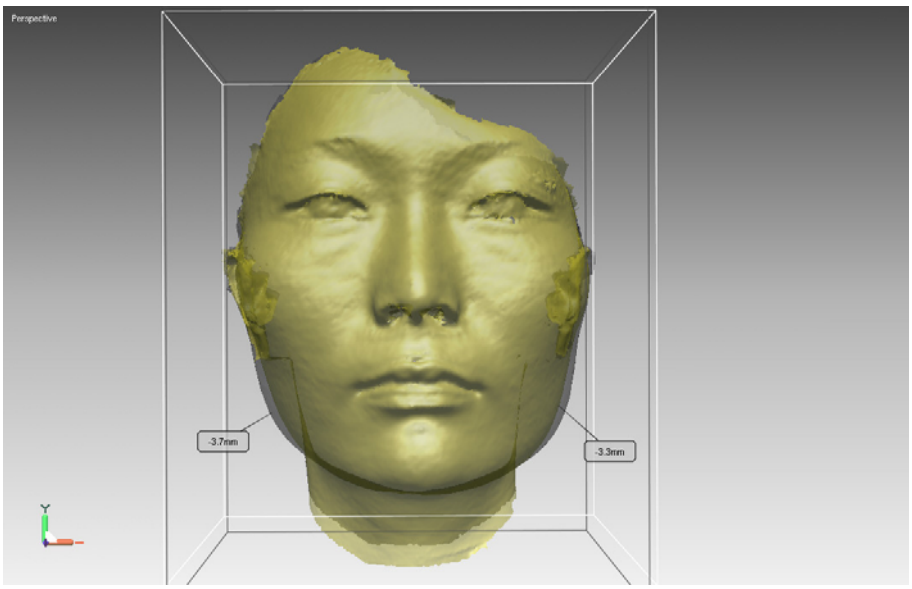

Figure 4. The bulkiest height of the lower face was measured by superimposing 3D facial images.

Ⅲ. Results

Mean values of the volume and the bulkiest height at each time point are shown in Figures 5 and 6. These parameters differed significantly between preinjection and 4, 8, 12, and 24 weeks postinjection (Table 1, 2).

Table 1. Mean volume of the lower face at each time point (n=30).

Time point	Volume, mm^3 (mean±SD)	*p* value
Preinjection	**61985.73±11116.37**	
4 weeks postinjection	**60270.50±10944.48**	**<0.001**
8 weeks postinjection	**59391.20±10682.93**	**<0.001**
12 weeks postinjection	**59151.87±10459.64**	**<0.001**
24 weeks postinjection	**59808.80±10864.79**	**<0.001**

Table 2. Mean difference in the bulkiest height of the lower face at each time point (n=30).

Time point	Height, mm (mean±SD)	*P* value
Preinjection	**0.00±0.00**	
4 weeks postinjection	**-1.78±0.66**	**<0.001**
8 weeks postinjection	**-2.71±0.77**	**<0.001**
12 weeks postinjection	**-2.99±0.73**	**<0.001**
24 weeks postinjection	**-2.39±1.15**	**<0.001**

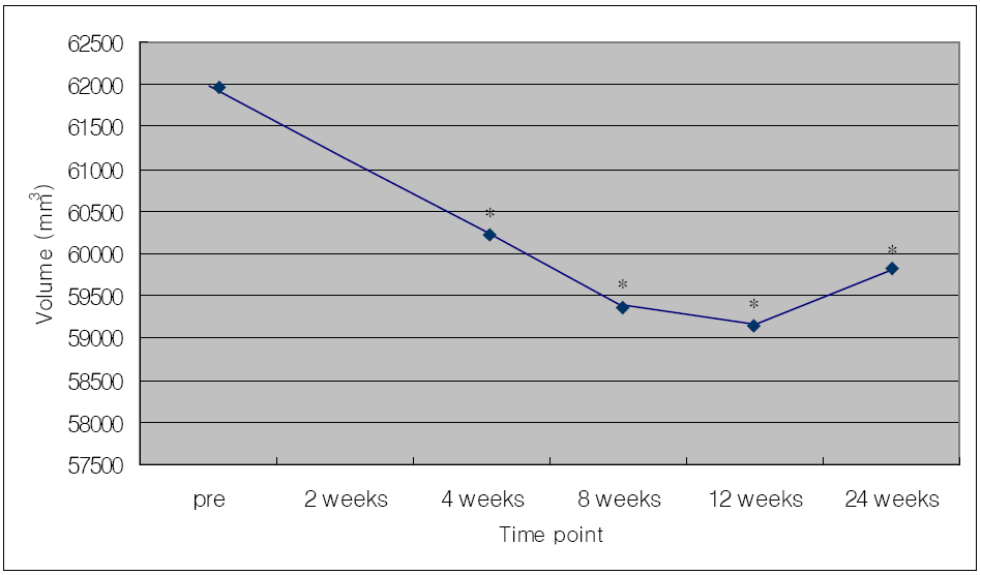

Figure 5. The volume differed significantly between preinjection and 4, 8, 12, and 24 weeks postinjection. (*: $p<0.01$)

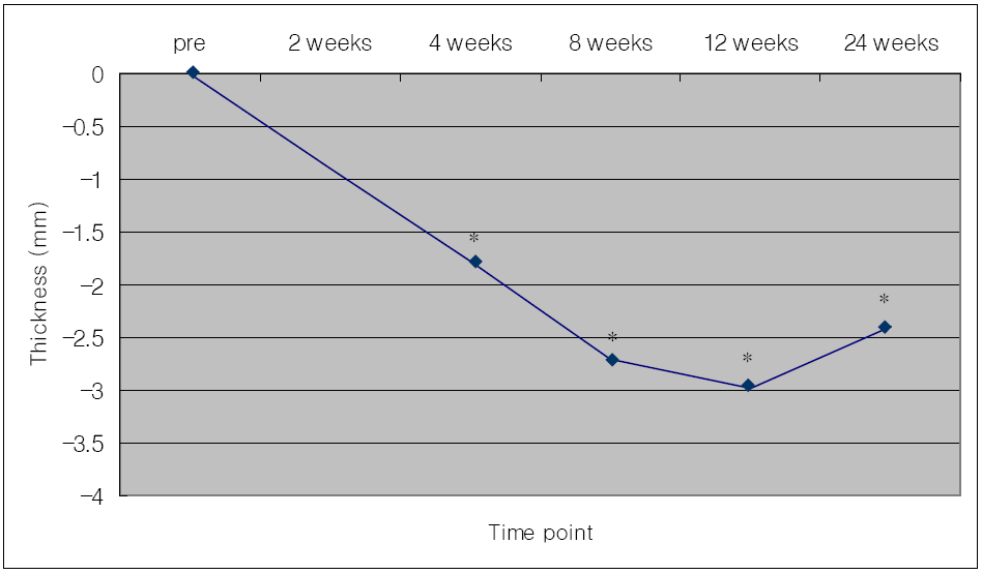

Figure 6. The bulkiest height differed significantly between preinjection and 4, 8, 12, and 24 weeks postinjection. (*: $p<0.01$)

Ⅳ. Discussion

BTX-A is one of the 8 exotoxins produced by the bacterium *Clostridium botulinum*. It is a neurotoxin and causes its effects on the neuromuscular junction by inhibiting the release of acetylcholine, causing weakness or flaccid paralysis (Niamtu 3rd 1999). The storage or synthesis of acetylcholine is not affected by BTX-A, but its action affects the vesicle bound acetylcholine (Blitzer et al. 1993). It binds specifically to cholinergic motor endplates and blocks the release of acetylcholine from the presynaptic vesicles, causing neuromuscular blockade (Moore, and Wood 1994). When highly diluted unit dose of BTX-A is injected into the striated muscles, the toxin produces a reproducible temporary state of regional denervation (Borodic, and Pearce, 1994 ; Smyth 1994).

It is commonly used for treating a variety of neuromuscular disorders such as strabismus, blepharospasm, hemifacial spasm, and torticollis (Ahnert-Hilger, and Bigalke 1995 ; Traba Lopez, and Esteban 2001). Botulinum neurotoxin therapy has also been reported to alleviate the pain associated with various conditions. BTX-A may track centrally and has some effect on the trigeminal vasculature loop, the 5-HT receptors and/or the release of irritative neuropeptides (Chan, McCabe, and MacGregor 2009). BTX-A appears to inhibit exocytosis of neurotransmmiters and other neurally active substances (Hohne-Zell et al. 1997). In dentistry, BTX-A is used for the treatment of masseteric hypertrophy (Kim et al. 2007). It gives rise to semi-permanent, transient decrease of muscle volume (Kim et al. 2008).

The main causes of a round or square-angled face, which is especially prevalent in Asians (Kim et al. 2005), are a prominent mandibular angle and/or masseter muscle hypertrophy (Lee et al. 2007). Masseteric hypertrophy is most common between the age of 20 and 40 years, is not gender specific (von Lindern et al. 2001), and can be treated either conservatively or surgically. In all surgical interventions, it is necessary to pay attention to not

only the general risks associated with operations but also the risk of damaging the facial nerve. Compared to surgical treatments, BTX-A represents a safer and noninvasive drug treatment for patients with masseteric hypertrophy (To et al. 2001).

Some authors have reported that BTX-A can reduce the size of the masseter muscle. In 2001, von Lindern et al. reported that patients with masseter muscle hypertrophy showed marked atrophy in the region of previously hypertrophic muscles after BTX-A injection, as documented by clinical photographs. Kim et al. reported that the volume of the masseter muscles was reduced after injecting 30 units of BTX-A on each side, as documented by CT (Kim et al. 2003). To et al. observed that the masseter muscle mass was reduced after injecting BTX-A, as documented by sonography (To et al. 2001), and several authors reported a reduction in the bite force thereafter (Ahn, and Kim 2007 ; Kim et al. 2009). However, changes in the external contour as a result of atrophy of the masseter muscles are more important clinically than a decrease in their thickness (Lee et al. 2007). Newly developed tools for capturing 3D images that have been applied in the cosmetics field provide more objective and reliable measurements of real external facial contours than is possible by photography, ultrasonography, and CT. The emergence of 3D imaging technologies in the 1970s and 1980s facilitated realistic interactive surgical planning (Brewster et al. 1984 ; Moss et al. 1988). The recent innovations in this field have lead to the development of non-invasive, optically based, 3D digitization techniques (McCance et al. 1992). The most popular 3D data acquisition technique that has been successfully applied to human facial measurement is laser surface scanning (Arridge et al. 1985). This technique involves projecting a stripe of laser light onto the object of interest and viewing its contour from an offset camera. The laser scanner is a valuable tool because of its ease of application and creation of accurate 3D images (Toma et al. 2009).

Our use of 3D laser scanning in this study to measure changes in the external facial contour (volume and the bulkiest height) revealed statistically significant differences in the

volumes and the bulkiest heights of the masseter muscles between preinjection and 4, 8, 12, and 24 weeks postinjection. Whilst previous studies have mainly measured differences in the volume and thickness of the masseter muscle, our measurements of differences in the volume of the lower facial area were based on clearly delineated reference points and the bulkiest height. The reported values directly reflect changes in the lower facial contour.

In previous studies, the changes in the bite force were greatest within 2 weeks (Ahn, and Kim 2007) and the changes of the value in the EMG were greatest at 4 week postinjection, respectively (Kwon et al. 2009). Hong et al. reported that the changes of the mean area of the cross section of the masseter muscle were greatest at 12 weeks (Hong et al. 2005). Those were similar to the results of this study. BTX-A is rapidly (within hours) and irreversibly bound to presynaptic neurons at the neuromuscular junction. It is internalized and then acts on a zinc-dependent endoprotease to disrupt some of the peptides necessary for acetylcholine release (Hambleton 1992). This action, which may take 2 weeks to complete, effectively destroys the affected neuromuscular junction, causing muscular paralysis (Klein 2003). In addition to, during biting, the temporalis muscle and median pterygoid muscle are required, and those may reinforce for the weakness of the masseter muscle. Therefore, we consider that changes in bite force and EMG reflect a stiffness decrease. After muscle paralysis, there is ongoing turnover at the neuromuscular junction; however, this is enhanced by toxin exposure such that muscular function begins to return at approximately 3 months and is usually complete by 6 months (Klein 2003). Muscle atrophy is a temporary event and new neuromuscular synapses can be resynthesized over a period of a few months (To et al. 2001). This could explain the changes the mean area of the cross section of the masseter muscle were greatest at 12 weeks.

Concerning the clinical effects, most of the changes in the volume and the bulkiest height appeared after 12 weeks, at which time it is considered that the peak effect of BTX-A for lower facial contouring can be achieved (Kim et al. 2003). Generally a second (booster) injection is performed between 4 and 6 months after the initial injection (Kim et al. 2005).

However, in the present study there were statistically significant differences in the volume and the bulkiest height of the masseter muscle between preinjection and 24 weeks postinjection. Therefore, we consider that more research is needed to determine the optimal time point for the second injection in lower facial contouring.

Some side effects have been reported after injecting BTX-A into hypertrophic masseter muscles. Kim et al. reported a change in facial smiling as well as the presence of a sunken cheek after a BTX-A injection (Kim et al. 2003). Other studies have occasionally found several mild side effects such as swelling, bruising, or pain in the area of the injection, headache, muscle weakness, discomfort in mastication, and a dry mouth, but these side effects were all both temporary and localized (Ahn, and Kim 2007 ; Kim et al. 2007).

The limitations of this study are the small sample and the study design not being specific to each gender and other factors. Song et al. reported that the sudden increase in the female lateral facial dimension and the female-to-male proportions from the young to middle-aged is correlated with the body weight change either directly or indirectly (Song et al. 2009). Therefore, body weight is the important factor with regard to the facial dimension. Although further studies are therefore needed, this is the first prospective study using 3D laser scanning to evaluate the effects of BTX-A in lower facial contouring. BTX-A can be safely used as a nonsurgical treatment for lower facial contouring, especially masseteric hypertrophy.

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국문요약

3 차원 레이저 스캔을 이용하여 평가된 교근비대 치료에 대한 보툴리눔 A 형 독소 주입의 효과

보툴리눔 A 형 독소(BTX-A)를 사람 교근에 주사하는 방법은 교근 비대의 치료로서 널리 이용되어져 왔다. 본 연구이 목적은 사람 교근에 대한 보툴리눔 A 형 독소 주입이 하안면부 외형에 미치는 영향을 3 차원 레이저 스캔을 이용하여 평가하고자 하였다.

15 명의 자원자를 대상으로 BTX-A 를 양측 교근에 각각 25 units 씩 주사하였다. 주사 부위는 교근 하방 1/3 의 중앙 부위로서 25units 을 약 1cm 간격의 두 점에 같은 양으로 나누어 주사하였다. BTX-A 의 임상적 효과는 술전과 술후 4 주, 8 주, 12 주, 24 주에 3 차원 레이저 스캔을 채득하여 평가하였다.

분석 결과, 하안면부의 부피 및 최대 풍융부 높이의 차는 BTX-A 주사 전과 비교하여 4 주, 8 주, 12 주, 24 주 후 모두에서 유의한 차이를 보였다. 본 연구는 하안면부 윤곽성형술을 위한 BTX-A 의 효과를 평가하는데 있어 3 차원 레이저 스캔을 이용한 첫 번째의 전향적 연구라는데 의의가 있다 하겠다. BTX-A 는 특히 교근비대가 원인일 경우 하안면부 윤곽성형술을 위한 비수술적 치료로서 안전하게 이용될 수 있다 하겠다.

핵심되는 말 : 보툴리눔 A 형 독소, 교근, 3 차원 레이저 스캔, 하안면부 윤곽성형술