

Effects of Botulinum Toxin Type A on Contouring of the Lower Face

SEONG WOOK CHOE, MD,* WAN IK CHO, MD,* CHANG KYUN LEE, MD,† SEONG JUN SEO, MD*

*Department of Dermatology, College of Medicine, Chung-Ang University, Seoul, South Korea; †Gwooonsesang Clinic, Seoul, South Korea

BACKGROUND. Masseteric muscle hypertrophy is an uncommon condition represented as a swelling of the masseter muscle. Recent reports have demonstrated the successful use of botulinum in the treatment of masseteric hypertrophy.

OBJECTIVE. This study was a prospective trial to evaluate the effectiveness of botulinum toxin type A (Botox) in the treatment of masseteric muscle hypertrophy according to doses of 10, 20, and 30 U.

MATERIALS AND METHODS. Twenty-two patients were referred to the dermatologic clinic for the management of masseteric muscle hypertrophy. Ultrasonographic measurements of the thickness of the masseter muscle were performed, and clinical photographs

were taken before treatment and 1, 2, 3, 4, 6, and 9 months after the treatment.

RESULTS. The median values of percentage reduction of muscle mass were 10.3%, 16.5%, 23.7%, 24.7%, 21.6%, 16.5% in the 10 U group; 11.9%, 18.8%, 24.8%, 27.7%, 26.7%, and 21.8% in the 20 U group; and 12.0%, 19.4%, 25.0%, 27.8%, 37.8%, and 24.1% in the 30 U group.

CONCLUSION. The adequate dose of botulinum toxin type A for treatment of masseteric muscle hypertrophy should be above 20 U. The effect of botulinum toxin type A is maintained for at least 9 months as the treatment of masseteric muscle hypertrophy.

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MASSETERIC MUSCLE hypertrophy is an uncommon condition that can be presented as swelling of the masseter muscle.¹ It may be unilateral or bilateral.¹ It is most common between the ages of 20 and 40 years and is not gender specific.² Mandibular retrognathia and masticatory muscle hyperactivity have been described as possible causes.³ The origin of this condition is unclear because masticatory muscle hyperactivity or parafunction and dysfunction in the stomatognathic system cannot be verified in all instances of hypertrophy.² Compensatory and stress hypertrophy has been assumed in most cases.⁴ Changes in the proprioceptors have also been discussed.^{5,6} Cases of muscular hypertrophy in connection with neuroleptically induced facial dystonia suggest that the hypertrophy may be attributed to a disturbance of the neurotransmitter balance between dopamine and acetylcholine.⁷

To date, treatment of masseteric muscle hypertrophy has involved using conservative therapy and surgery. In the conservative therapeutic approach, an attempt has been made toward reducing the muscular hyperactivity by

using occlusal splints or administering muscle relaxants.⁸ Surgical therapies usually involve partial surgical resection of the masseter muscle and modeling osteotomy in the region of the masseteric tuberosity.⁸

In all surgical interventions, attention was focused not only on the general risks associated with operations but also on the risk of damaging the facial nerve.⁸

In this regard, as a breakthrough to the conventional approaches of conservative therapy and surgery, recent articles have demonstrated the successful use of botulinum in the treatment of masseteric hypertrophy. Most dermatologists give the patients 20 to 30 U of botulinum toxin type A (Botox). However, there is no quantitative basis that justifies doctors' prescribing doses of 20 to 30 U of botulinum toxin. To evaluate the optimal dose in the treatment of masseteric muscle hypertrophy, we conducted a prospective trial of serial ultrasonographic and photographic evaluation according to 10, 20, and 30 U doses of botulinum toxin. We also investigated the duration of the effect on masseteric muscle hypertrophy according to the dose of botulinum toxin.

Patients and Methods

Twenty-two patients were referred to the dermatologic clinic for management of masseteric muscle hypertrophy.

Address correspondence and reprint requests to: Seong Jun Seo, MD, Department of Dermatology, Yong san Hospital, Chung-Ang University, 65-207, 3ka, Hangang-Ro, Yongsan-Ku, Seoul, 140-757, South Korea, or e-mail: drseo@hanafos.com.

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Exclusion criteria for this study included pregnancy, active nursing, preexisting neuromuscular conditions, a history of drug allergy or any other serious medical disorder, and medications such as aminoglycosides, penicillamine, quinine, calcium channel blocker, and anticoagulant drugs.⁹ All 22 patients who entered the study were medically fit, and their ages ranged from 21 to 35 years (mean 26.2 years). All patients were female.

Botulinum toxin was supplied in 100 U of freeze-dried powder and was reconstituted with 1 mL of physiologic saline solution. A 1 mL syringe and a 25-gauge needle were used on the lower posterior portion of masseter muscle and 0.1 mL of diluted botulinum toxin was injected into the hypertrophic muscle. Because of prevention of paralysis of the risorius and zygomaticus muscles and injury to the parotid duct, we injected the diluted botulinum toxin into the lower posterior portion of the masseter muscle. Injections were given in 44 muscles of 22 patients with masseteric muscle hypertrophy. Single doses of 10, 20, and 30 U of botulinum toxin were applied to the patients on both sides of the masseter muscle (Table 1). Ten units of botulinum toxin was injected into 15 masseter muscles, 20 U was injected into 14 masseter muscles, and 30 U was injected into 15 masseter muscles. At 9 months after treatment, only 20 masseter muscles of 10 patients were used in this study. We originally planned on 6 months of follow-up for this study; therefore, the patients were asked to agree to only 6 months of participation. However, during the process of lengthening the duration of the study to 9 months, we were not able to obtain the consent of 12 patients. Therefore, it was impossible to state the statistical validation for the ninth month of the study. Randomized selected patients were injected at a different dose of botulinum toxin.

Ultrasonographic measurements of the thickness of the masseter muscle were performed and clinical photographs were taken before treatment and 1, 2, 3, 4, 6, and 9 months after treatment (Figures 1 and 2). At 9 months after treatment, ultrasonographic measurements were made with 10 patients and clinical photographs were also taken. The patients were treated according to the clinical follow-ups, accompanied by serial ultrasonography.

All of the ultrasonographic examinations throughout the study were carried out by a single sonographer. During each examination, measurements of masseter muscle were made at three constant sites: at the level of the ear lobe, which was the upper portion; the angle of the mandible, which was the lower portion; and midway between the upper and lower portions. All measurements were made on transverse scans of the masseter muscle, and the mean value was drawn from these. The ultrasonographic data were analyzed by paired Student's *t*-test.

The photographic evaluation scores have been made as four scales (0 = poor or no change; 1 = good; 2 = very

good; and 3 = excellent). Three dermatologists evaluated the photographic changes over time.

Table 1. Patients Referred to the Dermatologic Clinic for Management of Masseteric Muscle Hypertrophy

Patient	Site	Dose, U
1*	Rt	30
	Lt	30
2	Rt	10
	Lt	20
3	Rt	30
	Lt	10
4	Rt	10
	Lt	10
5	Rt	10
	Lt	10
6*	Rt	10
	Lt	10
7*	Rt	30
	Lt	30
8	Rt	20
	Lt	20
9	Rt	10
	Lt	20
10*	Rt	30
	Lt	30
11*	Rt	20
	Lt	20
12*	Rt	20
	Lt	20
13	Rt	10
	Lt	30
14	Rt	10
	Lt	10
15*	Rt	30
	Lt	10
16	Rt	30
	Lt	10
17	Rt	20
	Lt	20
18*	Rt	20
	Lt	10
19	Rt	30
	Lt	30
20	Rt	30
	Lt	20
21*	Rt	30
	Lt	30
22*	Rt	20
	Lt	20

Single doses of 10, 20, and 30 U of botulinum toxin were applied to the patients on both sides of the masseter muscle. Ten units was injected into 15 masseter muscles, 20 U was injected into 14 masseter muscles, and 30 U was injected into 15 masseter muscles.

*At 9 months of treatment, the number of participants decreased, and therefore the total number of participants was 10.

The patients were asked the degree of their satisfaction, on a scale from 0 to 3 (0 = poor or no change; 1 = good; 2 = very good; and 3 = excellent), as a tool of the effectual change they feel on the muscle bulk.

Results

The mean masseteric muscle thickness before injection was 9.9, 9.3, and 10.6 mm, respectively, in the 10, 20, and 30 U groups. The 10 U group showed the mean values of percentage reduction of muscle mass after injection, respectively, as 10.3%, 16.5%, 23.7%, 24.7%, 21.6%, and 16.5% measured as time elapsed by 1, 2, 3, 4, 6, and 9 months since injection. Those of the 20 U group were equivalent to 11.9%, 18.8%, 24.8%, 27.7%, 26.7%, and 21.8%, and in the 30 U group, they were 12.0%, 19.4%, 25.0%, 27.8%, 27.8%, and 24.1%. Muscle atrophy reached its maximum at 4 months after injection and has been reduced since then (Table 2 and Figure 3).

Botulinum toxin was injected into the lower portion of the masseter muscle, so we also observed the atrophic effect of botulinum toxin on the injected site of the masseter muscle. The percentage reduction was also brought

out on this part, respectively, at the time of 1, 2, 3, 4, 6, and 9 months after injection: 14.1%, 23.5%, 36.5%, 35.3%, 35.3%, and 35.3% in the 10 U group; 16.7%, 28.9%, 35.6%, 41.1%, 38.9%, and 36.7% in the 20 U group; and 13.4%, 26.8%, 39.2%, 40.2%, 43.3%, and 41.2% in the 30 U group (Table 3 and Figure 4).

The mean values of photographic evaluation were 0.6, 1.2, 1.7, 2.1, 2.2, and 2.5 in the 10 U group as time elapsed by 1, 2, 3, 4, 6, and 9 months since injection. With the 20 U group, the mean values of photographic evaluation were 0.6, 1.2, 1.7, 2.2, 2.4, and 2.5. With the 30 U group, the mean values of photographic evaluation were 1.3, 1.8, 2.1, 2.3, 2.4, and 2.5 (Table 4 and Figure 5).

The mean values of patients' satisfaction levels in the 10 U group were 0.4, 0.9, 1.1, 0.5, 0.2, and 0, respectively, at 1, 2, 3, 4, 6, and 9 months. The values of the 20 U group were 0.8, 1.1, 1.3, 0.9, 0.5, and 0. In the 30 U group, the values were 0.8, 1.2, 1.7, 1.4, 0.6, and 0.1 (see Table 4 and Figure 6).

There have been no major local or systemic complications associated with the injection of botulinum toxin type A. The most common adverse effects were local pain on the injection site, which was the case for 59.1% (13 individuals) of the patients. Most of the subjects, except one, experienced local pain for 1 to 3 days. The other patient complained of local pain on the injection site lasting for 3 weeks. Two patients (9.1%) experienced mild headaches after being injected. Headache persisted for 2 and 4 days and subsided spontaneously.

Discussion

Botulinum toxin type A binds to the presynaptic cholinergic nerve terminals and inhibits the release of acetylcholine, causing paralysis and subsequent functional denervated muscle atrophy.¹⁰ This process may not be completed for 2 weeks and may effectively destroy the affected neuromuscular junction, causing muscular paralysis. However, the axon terminals begin to proliferate within 2 days of exposure to the toxin and form new extrajunctional acetylcholine receptors¹¹ as new synapses make contact with the adjacent muscle fibers.^{12,13} Such an

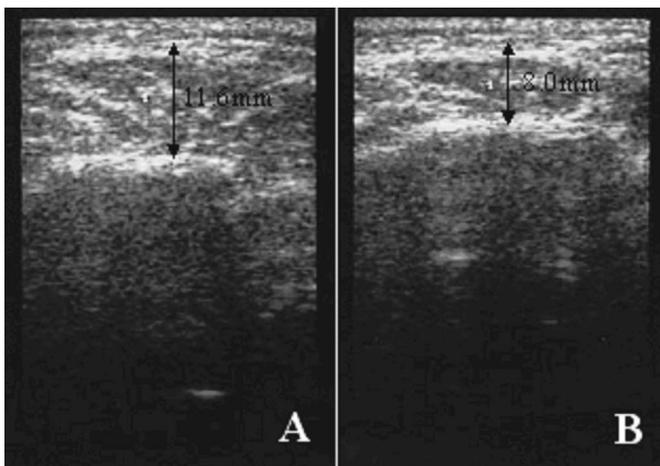


Figure 1. Ultrasonographic findings of measured masseter muscle, which was performed before treatment (A) and 3 months after treatment (B).



Figure 2. Follow-up photographs of patients before treatment and at 1, 2, 3, 4, 6, and 9 months after treatment in the 10 U (A), 20 U (B), and 30 U (C) groups.

ongoing turnover of neuromuscular junctions is enhanced by toxin exposure that muscular function begins to return at approximately 3 months and is usually complete by 6 months.^{9,10}

Masseteric muscle hypertrophy is a clinical entity of unknown etiology. It can be unilateral or bilateral and is commonly associated with abnormal habits, such as bruxism. The hypertrophic muscle is also thought to cause secondary enlargement of the mandibular angle as a result of functional remodeling that occurs at the muscle insertion sites.⁸ The highest incidence is in the second and third decades of life, and there is no sex predilection.¹⁴ One of the therapeutic modalities of masseteric muscle hypertrophy is surgical reduction of the muscle bulk. The disadvantages of surgical reduction include the risks of a general anesthetic, postoperative hemorrhage, edema, hematoma, infection, scarring, and facial nerve damage. Recently, it was suggested that botulinum toxin type A injection is an alternative treatment for masseteric muscle hypertrophy.

This clinical study was a prospective study using ultrasonographic measurements and photographic evaluation

to assess the response of the hypertrophic masseter muscle to botulinum toxin type A injection. We also evaluated the mean values of masseteric muscle mass at the varied doses of botulinum toxin and the duration of effectiveness of botulinum toxin for masseteric muscle hypertrophy.

Mean values of muscular atrophy were increased or plateaued 4 months after the injection, whereas the patients' satisfaction was decreased abruptly. In the 20 and 30 U groups, the plateau was maintained for 6 months after treatment. We considered that atrophic changes of masseter muscle were maintained up to 6 months in the 20 and 30 U groups, although muscular functions were restored by 6 months. In contrast, muscular function began to return at approximately 3 months, and patients' satisfaction was dependent on the restoration of muscular function.

The mean values of the percentage reduction of masseter muscle are at their peak at the time of 4 months after injection, which was common in the three groups. However, for the percentage reduction of the lower portion of masseter muscle, the result was different among the three groups. The 10 U group attained the highest at 3 months,

Table 2. Mean Changes in Muscle Thickness and Mean Values of Percentage Reduction of Muscle Mass after Botulinum Toxin Injection as Time Elapsed by 1, 2, 3, 4, 6, and 9 Months

Time	Thickness: Mean ± SD (% Reduction)		
	10 U	20 U	30 U
Baseline	9.7 ± 1.5	10.1 ± 2.0	10.8 ± 1.5
1 mo	8.7 ± 1.6 (10.3)	8.9 ± 1.9 (11.9)*	9.5 ± 1.4 (12.0)*
2 mo	8.1 ± 1.7 (16.5)	8.2 ± 1.9 (18.8)*	8.7 ± 1.6 (19.4)*
3 mo	7.4 ± 1.9 (23.7)	7.6 ± 1.9 (24.8)*	8.1 ± 1.9 (25.0)*
4 mo	7.3 ± 1.7 (24.7)	7.3 ± 1.9 (27.7)*	7.8 ± 1.7 (27.8)*
6 mo	7.6 ± 1.7 (21.6)	7.4 ± 1.8 (26.7)*	7.8 ± 1.9 (27.8)*
9 mo	8.1 ± 2.1 (16.5)	7.9 ± 1.9 (21.8)*	8.2 ± 2.0 (24.1)*

*Mean values were significantly different from those of the 10 U group ($p < .05$).

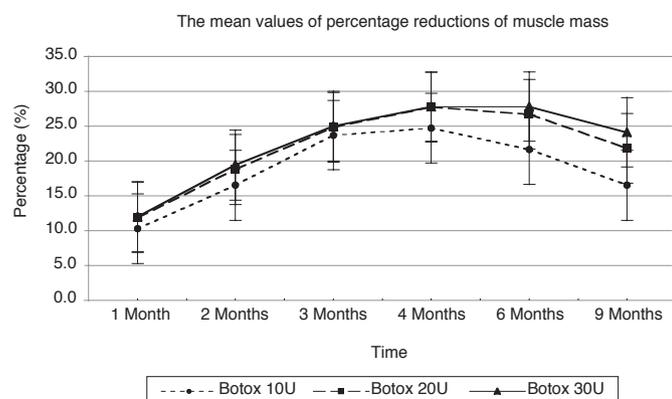


Figure 3. Mean values of percentage reductions of muscle mass after injection as time elapsed by 1, 2, 3, 4, 6, and 9 months. The 20 and 30 U groups showed the greater mean values of the percentage reduction of muscle mass than the 10 U group ($p < .05$). Of the 20 U and 30 U groups with greater mean values, there could be no statistically significant difference in general between values.

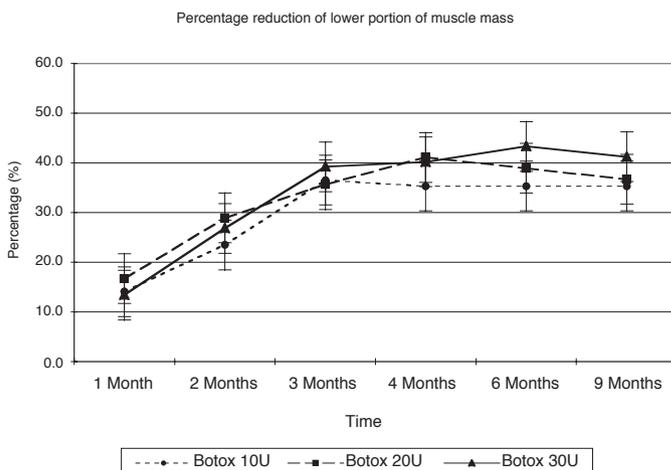


Figure 4. Mean values of the percentage reduction of the lower portion of masseter muscle after injection as time elapsed by 1, 2, 3, 4, 6, and 9 months. The changes in the percentage reduction of the lower portion of masseter muscle showed the nearly plateau form for 3 months after injection.

whereas it was at 4 months and 6 months, respectively, that the 20 U and 30 U groups attained the highest. It is thought that the time of peak percentage reduction of the lower portion of masseter muscle may be related to the dose of botulinum toxin. The 20 and 30 U groups showed the greater mean values of the percentage reduction of muscle mass than the 10 U group ($p < .05$). Of these two groups of greater mean values, there could be no statistically significant difference in general between the values of the two. Owing to the decreased number of subjects at 6 months, the data after this time were not reliable enough to be statistically significant and informative. The change in the percentage of reduction of the lower portion of masseter muscle showed the nearly plateau form for 3 months after injection. The effects of botulinum toxin for masseteric muscle hypertrophy were maintained for 6 months. Although the injected sites were the lower portion of masseter muscle, it is thought that atrophic change caused by botulinum toxin injection led to disuse of masseter muscle.

The scores of photographic evaluation continuously increased over time, in contrast to those of patients' satisfaction levels, which were at their peak at 3 months after injection. Most Asians have prominent cheekbones, which are accentuated by the maximum atrophic changes of the masseter muscles at 3 months. As a result, the whole facial contour looks unnatural. Atrophic masseter muscle is restored to its normal contour and thickness (not to the hypertrophic state before treatment) at 6 months compared with 3 months after injection. That is why the facial

contours seem to become more natural as the time elapses. This is related to the pharmacologic effect of botulinum toxin, in which muscular function begins to recover at approximately 3 months after injection and is usually complete by 6 months. Also, muscular thickness is restored to normal thickness at 6 months. In addition, patients tend to interpret the restoration of muscular function as the diminished effect of botulinum toxin on masseteric muscle.

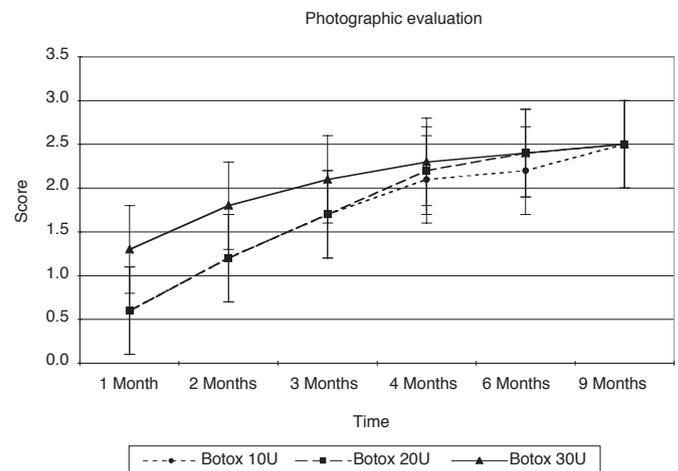


Figure 5. Mean values of photographic evaluation scores after injection as time elapsed by 1, 2, 3, 4, 6, and 9 months in the 10, 20, and 30 U groups. Three dermatologists evaluated the photographic changes. Scores are rated as 0 = poor or no change; 1 = good; 2 = very good; 3 = excellent.

Table 3. Mean Changes in Muscle Thickness of Lower Portion and Mean Values of Percentage Reduction of Lower Portion of Muscle Mass after Botulinum Toxin Injection as Time Elapsed by 1, 2, 3, 4, 6, and 9 Months

Time	Thickness: Mean \pm SD mm (% Reduction)		
	10 U	20 U	30 U
Baseline	8.5 \pm 1.4	9.0 \pm 1.8	9.7 \pm 1.1
1 mo	7.3 \pm 1.0 (14.1)	7.5 \pm 1.4 (16.7)	8.4 \pm 1.0 (13.4)
2 mo	6.5 \pm 0.9 (23.5)	6.4 \pm 0.9 (28.9)	7.1 \pm 0.9 (26.8)
3 mo	5.4 \pm 0.9 (36.5)	5.8 \pm 0.9 (35.6)	5.9 \pm 0.8 (39.2)
4 mo	5.5 \pm 0.9 (35.3)	5.3 \pm 0.6 (41.1)	5.8 \pm 0.8 (40.2)
6 mo	5.5 \pm 0.7 (35.3)	5.5 \pm 0.5 (38.9)	5.5 \pm 0.7 (43.3)
9 mo	5.5 \pm 0.7 (35.3)	5.7 \pm 0.4 (36.7)	5.7 \pm 0.7 (41.2)

Table 4. Mean Values of Photographic Evaluation Scores (A) and Patients' Satisfaction Levels (B) over Time

Time, mo	10 U		20 U		30 U	
	A	B	A	B	A	B
1	0.6 \pm 0.5	0.4 \pm 0.6	0.6 \pm 0.5	0.8 \pm 0.6	1.3 \pm 0.7	0.8 \pm 0.8
2	1.2 \pm 0.6	0.9 \pm 0.6	1.2 \pm 0.6	1.1 \pm 0.7	1.8 \pm 0.7	1.2 \pm 0.8
3	1.7 \pm 0.6	1.1 \pm 1.0	1.7 \pm 0.8	1.3 \pm 1.1	2.1 \pm 0.6	1.7 \pm 0.8
4	2.1 \pm 0.6	0.5 \pm 0.6	2.2 \pm 0.5	0.9 \pm 0.9	2.3 \pm 0.7	1.4 \pm 0.7
6	2.2 \pm 0.6	0.2 \pm 0.6	2.4 \pm 0.5	0.5 \pm 0.9	2.4 \pm 0.7	0.6 \pm 0.8
9	2.5 \pm 0.5	0 \pm 0	2.5 \pm 0.5	0 \pm 0	2.5 \pm 0.7	0.1 \pm 0.3

Three dermatologists evaluated the photographic changes. Scores are rated as 0 = poor or no change; 1 = good; 2 = very good; 3 = excellent. Values are represented as mean \pm standard deviation.

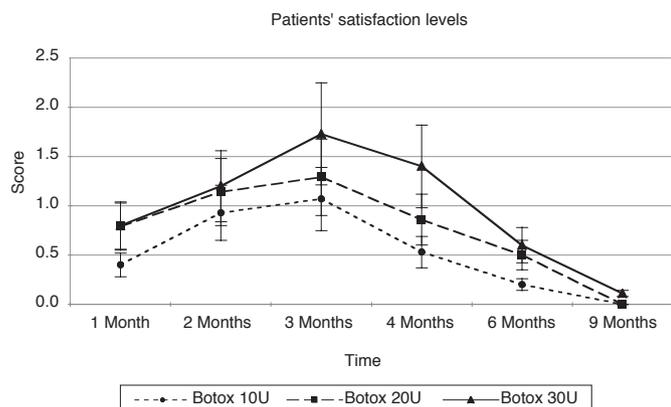


Figure 6. Patients' satisfaction scores as time elapsed by 1, 2, 3, 4, 6, and 9 months in the 10, 20, and 30 U groups. Scores are rated as 0 = poor or no change; 1 = good; 2 = very good; 3 = excellent.

This study suggests that an injection of botulinum toxin resulted in the relatively satisfactory clinical effect on masseteric muscle hypertrophy. Another recent study and our report have shown that the use of botulinum toxin type A for masseteric muscle hypertrophy can be a simple, safe, and predictable alternative method.^{2,8,12} Furthermore, our study suggests that an adequate dose of botulinum toxin for treatment of masseteric muscle hypertrophy should be over 20 U. We also believe that the effect of botulinum toxin is maintained for at least 6 months as the treatment for masseteric muscle hypertrophy.

Commentary

As several studies are currently available worldwide concerning the effect of botulinum toxin type A (Botox) on masseter muscles, Choe and colleagues' article is a valuable addition to the literature. In particular, the long-term follow-up evaluation conducted after injection in a relatively large number of patients, which is often difficult in cosmetic surgery patients, is a merit of this study. We would like to comment on a few points regarding this article compared with the results of our study on a similar topic published in May 2003.¹

Currently, no literature or article is available to provide accurate criteria for the diagnosis of benign masseteric hypertrophy in terms of the thickness or size of the masseter muscle. Benign masseteric hypertrophy is a condition that is mostly defined based on clinical observations. Therefore, differential diagnoses should be made based on the results of several diagnostic evaluations, including the bulkiness of masseter muscle and subcutaneous fat, the asymmetry or protuberance of the mandibular angle evaluated by palpation, cephalogram or panoramic view, and ultrasonogram, and so on. In addition, potential causes of

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benign masseteric hypertrophy, including the chewing of gum, bruxism at night, a history of long-term dental treatment, and temporomandibular joint pain, should be investigated before injection.

Concerning the injection method, the local range of efficacy of botulinum toxin is determined by the dilution and dose of injected botulinum toxin. In this study, changes in the masseter muscle thickness were evaluated following an injection at a single site of the lower posterior portion of the masseter muscle. The results of this study also show that the effect of an injection is different between the injection site and the entire muscle, which consequently results in a considerable difference in the rate of decrease in muscular thickness. In my experience, however, injecting the same total dose of botulinum toxin evenly at multiple sites seems to be much more effective than injecting at a single site for contouring of the lower face. Among the patients referred to me owing to side effects, some patients who have received a single-site injection often complain about muscular bulging at sites other than the injection site during mastication. In such cases, this muscular bulging usually disappears following a reinjection of 5 U of botulinum toxin at the bulging portion.

The thickness of the masseter muscle varies considerably depending on the measuring regions and among individuals, and it takes a considerable amount of effort to measure the thickness of the same region repeatedly over a long period of time. For statistical analysis of the changes in the muscle thickness after the botulinum toxin type A injection, it is appropriate to include only those individuals whose masseter muscles had been repeatedly measured for the same period of time. However, in this study, the treatment groups, which had been followed up for 9 months, consisted of only seven masseter muscles (ie, 3.5 patients) per group. Considering the considerable time and effort put into this work, it is very regrettable to mention that these insufficient data would make it difficult to argue for the statistical significance of the data. In addition, whereas muscular atrophy continued to progress or remained at a plateau level up to 6 months following the treatment according to the ultrasound imaging and photographic measurements, patient satisfaction decreased sharply after 4 months of treatment. The authors of this study attributed the short duration of the patients' satisfaction to the prominent cheekbones of Asian women. It seems necessary to consider alternative explanations for the result. According to our experience, most patients remain satisfied with the treatment for approximately 10 months following one session of

injection, and the total injection dose should be reduced to achieve patient satisfaction, especially for the patient with prominent cheeks.

It is essential that botulinum toxin type A injections for cosmetic purposes should achieve the desired results with the minimum dose without any functional discomfort. Thus, further studies are needed to determine the optimal dosage of botulinum toxin type A. In conclusion, this study provides valuable information on the comparison of injection methods between single- and multiple-site injections. In addition, it may be helpful to understand the difference between the currently recommended dose of 30 U per each side and the lower doses in terms of the efficacy and the duration of the effect for the contouring of the lower face.

MEE YOUNG PARK, MD, PHD
KI YOUNG AHN, MD, PHD
Daegu, Korea

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