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ORIGINAL CONTRIBUTION

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Italian consensus report on the aesthetic use of onabotulinum toxin A

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Summary

Background: The aesthetic treatment of facial and neck wrinkles with botulinum toxin is constantly increasing, thus making it necessary to collect procedures guidelines for the use of botulinum toxin in the treatment of wrinkles and/or cosmetic defects.

Methods: A group of nine Italian doctors, plastic and maxillo-facial surgeons, dermatologists and aesthetic physicians, experts in face and neck aesthetic treatments with onabotulinum toxin A, discussed on procedures used in their clinical practice. From the data collected and discussed by the board, some recommendations on aesthetic treatment with onabotulinum toxin A were developed.

Results: Recommendations have been made on pretreatment, reconstitution of onabotulinum toxin A, as well as on treatment procedures, in terms of injection sites and total dose of onabotulinum toxin A for the following indications: glabellar lines, crown's feet lines, forehead lines, eyebrow shaping, lower orbicularis oculi hypertrophy, bunny lines, sagging nasal tip, gummy smile, masseter hypertrophy, perioral lines, marionette lines, hypertonic mentalis, and platysma bands.

Conclusions: The use of onabotulinum toxin A in the aesthetic field requires careful initial assessment of the patient in its complexity and individuality. Moreover, this treatment needs the use of standardized procedures to achieve the effectiveness and safety of onabotulinum toxin A in clinical practice.

KEYWORDS
aesthetic treatments, botulinum toxin, consensus

1 | INTRODUCTION

According to the most important and influential world statistics, the treatment with botulinum toxin is the most performed in aesthetic medicine, followed by hyaluronic acid.[1] In 2016, in the United States, nonsurgical cosmetic treatments increased by 7%. Out of 11.7 million procedures performed, more than 4.5 million used botulinum toxin. In 2015, in Italy, the treatment with botulinum toxin increased by 12.5% over the previous year.[2]

Three different formulations of botulinum toxin with distinct molecular, biochemical, and physiological features have been approved for aesthetic use in Italy. The formulations have different profiles of efficacy and safety, and potency units of each formulation are not interchangeable with other preparations of botulinum toxin.[3–5]

Onabotulinum toxin A was the first formulation of botulinum toxin available worldwide and is now approved by FDA in adult patients for the temporary improvement in the appearance of:

- Moderate-to-severe glabellar lines associated with corrugator and/or procerus muscle activity
- Moderate-to-severe lateral canthal lines associated with orbicularis oculi activity
- Moderate-to-severe forehead lines associated with frontalis muscle activity

In Italy, it is currently indicated licensed for the temporary improvement of glabellar lines and lateral canthal lines in adult patients, when there is a significant psychological impact.[5]

The efficacy and safety of approved botulinum toxins have been widely investigated over the years and recently discussed in a systematic review of over 10 years of publications of clinical data on the use of the three formulations in nonsurgical cosmetic treatments.[6] The precision of the treatment, in terms of patient assessment, identification and number of injection sites, doses, injected volumes, and recommendations to the patient, is essential to achieve good aesthetic results and replicate the success.

Several consensus recommendations and guidelines have been published in the last years. H. Sundaram et al recently published two papers including botulinum toxin treatment and complication management and combined treatment with botulinum toxin and fillers, highlighting how to optimize the treatment in different patient populations.[7,8] The consensus recommendations published by J. Carruthers et al are also focused on combined treatments and involve not only botulinum toxin and fillers, but also energy devices.[9]

International guidelines or recommendations could be sometimes difficult to apply in real life due to different standards of beauty, patient needs, and culture. This phenomenon led, over the years, to the publication of different consensus recommendations in several countries.[10–12]

In this study, the Italian consensus recommendations on the cosmetic use of onabotulinum toxin A are reported. For this purpose, a group of Italian doctors decided to collect their experiences in the clinical practice pertaining to the use of onabotulinum toxin A in facial and neck wrinkles treatment. The data made it possible to compile a set of recommendations and position statements on the use of onabotulinum toxin A.

2 | MATERIALS AND METHODS

A group of nine Italian doctors, plastic and maxillofacial surgeons, dermatologists, and aesthetic physicians drafted and completed a questionnaire on procedures used in their clinical practice for the treatment of facial and neck areas.

The following information was included in the questionnaire: name and address of the professional's workplace, age range of patients for each of the treated areas, diluent and reconstitution of onabotulinum toxin A, dose in Allergan units (U) of onabotulinum toxin A injected in each site, and total number of U injected. For each facial and neck area, they were asked to identify the specific sites, single or multiple, where the injection of onabotulinum toxin A was carried out, reporting, on actual or anatomical images, symbols that identify the insertion depth at the treated site/s (Table 1).

TABLE 1 Every symbol corresponds to a needle depth

Symbols	Needle depth
*	Needle tip insertion
X	1/3 needle insertion
.	½ needle insertion
^	Full needle insertion

Potential individual variations, derived from clinical experience, were included in the questionnaire as notes or comments.

Once the questionnaires were collected, the Panel of medical experts met to discuss the results and define face and neck treatment recommendations with onabotulinum toxin A. A recommendation was defined as an indication obtaining a consensus of at least 80% (7/9). In case of a consensus of 60% (5/9), the group accepted and included the indication as a *position statement*. Other topics that were defined include assessment of general and specific criteria for patients and the role of photography.

3 | RESULTS

3.1 | Patient assessment

In the evaluation of a patient who is about to receive an aesthetic treatment with onabotulinum toxin A, the following parameters, both general and subjective, must be considered:

- General parameters: age, ethnicity, skin type, previous surgical, or nonsurgical procedures (with semipermanent or permanent fillers), scars, tattoos (on lips or eyebrows).
- Specific parameters: horizontal or vertical facial asymmetries, face proportion and shape (forehead height and distance between the eyebrows), tics or spastic abnormalities related to facial muscles, skin discolorations, eyelid conditions (upper eyelid ptosis, lower eyelid skin laxity, and chronic edema), brow ptosis and potential hypercompensation of the frontalis muscle, contraction of the orbicularis muscle (for crow's feet), smile dynamics (muscle hyperactivity, dental exposure, and degree of occlusion), mentalis muscle hyperactivity (pebbly or golf ball chin), masseter hypertrophy and/or bruxism, and platysma bands.

The evaluation of specific parameters must be carried out when the patient is seated, both at rest and in facial dynamic movements. A change of position of the subject, such as flexion or extension of the head, can cause major changes in the whole image and can lead to an incorrect assessment and an unwanted result.[13]

If the patient is a male, it is necessary to consider that the size and shape differences of the skull[14] are 20% larger than in the female one. Moreover, the supraorbital ridges are more prominent; the eyebrows are lower and with a flatter profile; the glabellar region is wider and prominent; the orbits are more squared and the

forehead is wider and higher; and the chin portion of the jaw is more prominent with more defined angles.[15]

Male facial muscles present some crucial differences, too. Men have a facial muscle mass significantly larger and thicker, characterized by a higher functional activity that anticipates the appearance of wrinkles and makes them deeper. The lower third of the male face, on the other hand, shows fewer signs of aging than its female counterpart, due to the presence of more pilosebaceous annexes, and a more developed vascularization of the same area.[16]

3.1.1 | The importance of photographic documentation

It is generally accepted that all aesthetic procedures must be photographically documented. In agreement with recent French, US, and Canadian Consensus papers,[11,12,15,17] it is suggested to acquire a photographic record before and after the treatment, and at any follow-up visit, obtaining the consent for the processing of personal data, privacy, and patient waiver.[18]

The essential features of photographic documentation in aesthetic medicine and surgery require a standardized lighting, a constant distance between camera and subject, and proper patient and camera positioning (vertical or horizontal views).[19] Images should be acquired in a systematic way, with static and dynamic poses, and patients should not be wearing makeup or jewelry. Photographs should be taken both with natural light and with flash and using a suitable and opaque background (green, blue, or black).

Images should include the whole head including the hair and down to the sternal notch. The framing must be aligned at eye level, on the upper portion of the nose, in accordance with the Frankfort plane which ensures proper head positioning (0° of flexion-extension), reproducibility of the shots, their comparability, and excellent evaluation of the lower third of face and neck.

3.1.2 | Reconstitution of botulinum toxin

A 50 unit vial of onabotulinum toxin A is reconstituted, just before use, with sterile, preservative-free saline (0.9% sodium chloride solution) to a recommended volume of 1.25 mL.

Each 0.1 mL of this solution contains four units (U) of onabotulinum toxin A. The saline has a pH between 4.5 and 7, depending on manufacturer and batch, which may cause a burning sensation during the injection. Alternatively, it is possible to use a bacteriostatic saline solution containing benzyl alcohol (0.9%) which significantly reduces pain during the injection due to its mild local anesthetic effect. The literature, finally, reports reconstitutions of onabotulinum toxin A with different amounts of lidocaine added to the saline solution to reduce the burning sensation, and/or adrenaline to better maintain the injected volume at the injection site. However, there are no clear scientific demonstrations of the actual efficacy of such compositions.[20]

The Panel recommends using 2-mL syringes with their needle, usually a 21G × 1″, for reconstitution. For injection, the recommended needle is a 30G × 1/2″ (TSK Laboratory, Japan), with a standard 1-mL syringe. Special syringes that allow needle change, and that are equipped with a plunger designed to avoid the dead space at the tip, are also now available. To solve the problem of reading more precisely the graduated scale of the 1-mL syringe, it is possible to use 0.3- to 0.5-mL insulin syringes with the disadvantage, however, of a noninterchangeable needle.

According to the summary of product characteristics, the onabotulinum toxin A reconstituted solution should be used immediately; however, it may be kept refrigerated (2-8°C) and used within 24 hours.[5]

However, as previously reported in the scientific literature,[21] the authors of this Consensus never observed a substantial loss of effectiveness of the reconstituted solution when kept refrigerated at a constant temperature of 4°C up to 6 weeks.

The treatment of each facial area in males may require an increase up to 50-100% of the dosages, due to the differences in facial muscle compared to the female anatomy.

3.1.3 | Recommendations for area of treatment

For all the treatments described below, except for the "gummy smile," the Panel has reached a consensus ≥80%. For the "gummy smile" treatment, the consensus was 60%, so the indication was defined as *position statement*.

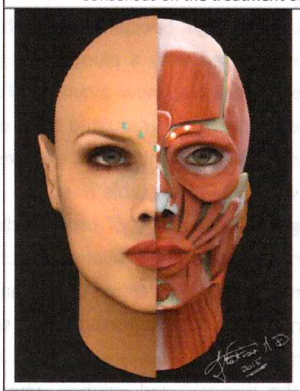
3.2 | Glabellar lines

The target muscles in the treatment of glabellar lines are the two corrugators and the procerus. Five injection sites as shown below are recommended (Figure 1). In this area, the suggested dose for onabotulinum toxin A is 4 U for the procerus muscle and for the medial heads of the corrugator supercilii muscles, and 2-4 U for the lateral part of the corrugator supercilii muscle, a total dose of 16-20 U in women. In case of a powerful muscle mass, the doses may be increased up to 30 U in women and up to 25 U in men. For the procerus injections, a 30G × 1/2″ needle is inserted half-length with a 60-90° angle to the skin surface. The same needle with full penetration, at the same angle, is used for the medial corrugator; to inject the lateral part of the corrugator, needle insertion is only one-third and with a more oblique direction.

The most common complication in this area is eyelid ptosis, caused by diffusion of the toxin to the levator muscle of the eyelid.[6] To minimize this risk, injections in the lateral parts of the corrugator should be performed superficially and the soft tissues should be elevated for 1-2 minutes.

Moreover, it is also recommended to insert the needle with a superolateral direction to stay away from the dangerous areas, when injecting the corrugator supercilii muscles. It is also crucial to inject close to the eyebrow arch, as in Figure 1, to avoid toxin spreading toward the caudal portion of the frontalis muscles with subsequent loss of brow support. Eyelid ptosis is always transient and can be mitigated using eye drops (apraclonidine hydrochloride 0.5%), active on the Müller's muscle. Some experts of the Panel argue that to treat

Consensus on the treatment of glabellar lines



Injection site	3-5 in total
Dosage	
Total	16-20 U in woman, up to 40U in man
Dose per injection site	4 U for the procerus and in each medial corrugator, 2-4 U for the lateral part of the corrugator
Injection technique	
Depth	Deep for the procerus and the medial part of the corrugator, bevel for the lateral corrugator muscles
Angle	60-90° for the procerus; 45-60° for the medial corrugator, more oblique for the lateral corrugator
Direction	Perpendicularly for the procerus, supero lateral for the corrugator muscles

FIGURE 1 Consensus on the treatment of the glabellar lines

the glabellar lines it is possible, in some cases, to limit the treatment to procerus and to the medial part of the corrugator muscles only.

3.3 | Crow's feet lines

The radial lines on the sides of the eyes are called "crow's feet" and are mainly caused by the lateral portion of the orbicularis oculi muscle. However, the zygomatic muscles can also contribute to generate the lower lines. Crow's feet lines are usually managed with three injection sites, lateral to the canthal area.

The insertion of a 30G × 1/2″ needle at 30° should be limited to the tip only, with a medial to lateral direction to keep away from the orbit (Figure 2). The total dose of onabotulinum toxin A recommended is 12-24 U for women and 18-36 U for men.

When the crow's feet lines extend far laterally, or the orbicularis muscle is particularly powerful, it is suggested to inject 1-2 U in two additional bilateral sites, laterally to the previous three, for a total dose of up to 32 U in women and 44 U in men.

Superficial injections are suggested in this area to limit the risk of bruising. Indeed, the subcutaneous tissue at this level is extremely thin and the orbicularis oculi, a highly vascularized muscle, lies almost subdermally. Ideally, the injection should be at the deep dermal level, allowing the toxin to reach the muscle by continuity.

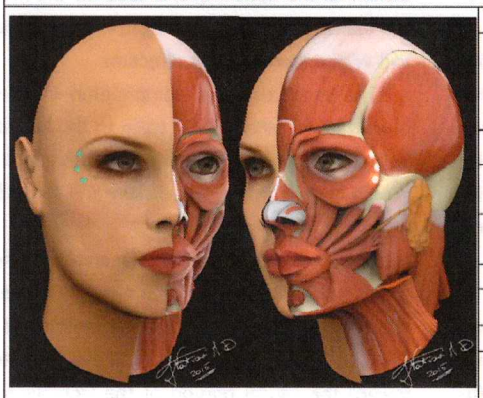
Bruising should be avoided for both aesthetic and safety reasons, namely to prevent diffusion of toxin into the orbit, which may result in a diplopia. Moreover, injections below the point of the greatest prominence of the zygomatic bone should be avoided, to prevent the involvement of the zygomatic muscles, resulting in a modification of normal smile dynamics.

The Panel agrees not to treat patients with a history of swelling of the lower eyelids, as any decrease in muscle tone, induced by the toxin, may accentuate the problem. Likewise, patients with marked laxity of the lower eyelids (highlighted by the snap test), scleral show, or ectropion are not indicated for this treatment.

3.4 | Forehead lines

Forehead lines are caused by the activity of frontalis muscles that raise the eyebrow. Static and dynamic balance of the upper part of the face is determined by the interaction of the frontalis muscles (the only levator muscles) with the procerus, corrugator, and orbicularis muscles which form the group of the depressors.

Consensus on the treatment of crow's feet lines



Injection site	3 injection sites (with additional 2 injections sites in the lateral portion of the orbicularis muscle)
Dosage	
Total	12-24 U (woman), 18-36 U (man)
For each injection site	2-4 U (woman), 3-6 U (man)
Injection technique	
Depth	Deep intradermal
Angle	30°
Direction	Medial to lateral direction to keep away from the orbit

FIGURE 2 Consensus on the treatment of crow's feet lines

Needle penetration should not exceed 1/3 of a 30G × 1/2″ needle at a 45-60° angle. Here again, as in Crow's feet lines treatment, avoiding to reach the muscle is preferable to limit the risk of bleeding. Furthermore, accidental delivery of the toxin deep to the frontalis muscles in the lax preperiosteal plane significantly increases the possibility of gravitational descent of the toxin solution toward the orbit with subsequent involvement of the levator muscle of the eyelid. Therefore, superficial injections are highly suggested.[9]

The total dose for both frontalis muscles is 6-12 U in women and 8-20 U in men (Figure 3). Higher doses can cause ptosis of the eyebrow arch and/or a frozen forehead with loss of expression.

The Panel recommends injecting the toxin into 4-6 sites bilaterally: six sites on two levels for the treatment of a high forehead and four sites on a single level for the treatment of a shallow forehead. In case of frontalis muscles closely united along the midline, an additional point of injection into a central position should be considered.

Ptosis of the eyebrows is the most serious complication in the treatment of forehead lines. With few exceptions, it is possible to reduce this risk by injecting at least 2 cm above the brow level and using appropriate doses.

Brow ptosis is far more common than eyelid ptosis, less severe from a functional and aesthetic standpoint, but nonetheless very significant. The physician should always be aware that toxin injections in the frontalis muscles will always somehow affect the position of the eyebrows, and this should be carefully considered in the treatment plan. In general, low doses are by far preferable although this will imply a shorter duration of the result. If the patient agrees, an excellent option is to treat the forehead mildly and to perform a touch-up more or less at two months, in other words half-way through the usual expected duration of the treatment at full dose. Another unwanted result of the forehead treatment is the "Mephisto" or "Spock" eyebrow, which is generated by injecting the medial part of frontalis muscles only. To prevent this, a mild dose of the drug in the lateral portion of frontalis muscles should always be administered.

Forehead treatment with botulinum toxin may also give rise to mild asymmetries; however, these can be corrected with very low doses of product (0.5-1 U) to be injected where muscle relaxation is required to achieve balance between the two sides.

More importantly, in virgin patients who feature an asymmetry of the eyebrows at rest, it is essential to point out the issue prior to treatment.

Finally, in patients with marked frontalis activity at rest with a high eyebrow position, unilaterally or bilaterally, an underlying visual obstruction, such as eyelid ptosis or dermatochalasis, should be considered and investigated. If present, such conditions would require surgery and not botulinum toxin. Indeed, by reducing frontalis overaction, the treatment could only make things worst.

3.5 | Brow lifting and shaping

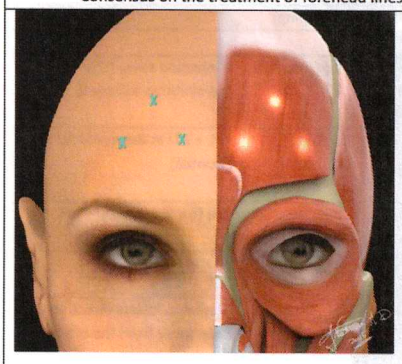
The muscles of the glabellar complex and the upper lateral part of the orbicularis oculi muscles are the main target of onabotulinum toxin A when brow lifting and shaping. These muscles, indeed, depress the eyebrows medially (the glabellar complex) or laterally (the upper lateral portion of the orbicularis oculi). Therefore, targeting the depressor muscles, it is possible to lift the entire eyebrow or just its lateral end. The injection of the upper lateral orbicularis oculi muscle also treats the upper crow's feet lines at the same time.

Brow lifting and shaping is mostly requested by women. Figures 1 and 2 show guidelines on injection site, dose, and technique for glabellar and crow's feet lines treatment. In order to better lift and shape the arch, an injection to the eyebrow tail area should be added using the recommended dose of 2 U (Figure 4). As for the standard treatment of crow's feet lines, the injection should be subcutaneous and superficial. The possible risks are essentially the same as those discussed for glabellar and crow's feet lines.

3.6 | Hypertrophy of lower eyelid orbicularis oculi

This defect appears as a spindle-shaped protrusion along the pretarsal portion of the lower lid, immediately below the ciliary margin. The treatment of hypertrophy of the lower eyelid orbicularis oculi muscle reduces this unwanted bulging. However, in clinical practice,

Consensus on the treatment of forehead lines



Injection site	4-6 injection sites Authors note: the figure shows specifically the injection sites for the treatment of high forehead. For the treatment of lower forehead, only the 4 lower points must be considered.
Dosage	
Total	6-12 U (woman), 8-20 U (man)
For each injection site	1.5-2 U (woman), 2-3 U (man)
Injection technique	
Depth	Subcutaneous
Angle	45-60°
Direction	Perpendicular to the skin

FIGURE 3 Consensus on the treatment of forehead lines

some experts of the Panel also treat this area to expand the eyelid aperture when it is too restricted.

It should be clear that this treatment provides no benefit to the lower eyelid lines.

The recommended total dose per side is 0.5-1 U, for women or men (Figure 5).

The injection is performed intradermally with a 30G × 1/2″ needle at a 30° angle with a lateral to medial direction, parallel to the eyelid margin and approximately at a distance of 2-4 mm from it.

The injection site should be just lateral to the mid pupillary line and should be performed in the point of main muscle hypertrophy. Patients with marked lower eyelid laxity, as confirmed by a positive snap test, scleral show, or ectropion, should not be considered for this treatment.

3.7 | Bunny lines

Bunny lines are generated by the transverse portion of the nasalis muscle in synergy with the levator labii superioris alaeque nasi muscle. The dose per injection site is 2 U per side, both in men and women (Figure 6). The injection is made at a 45° angle to the cutaneous plane with a low to high direction. A single injection is performed on each side of the nose, in the center of the affected area. Needle penetration is limited to the tip only, as the muscle lies immediately under the skin. Care should be taken not to inject too laterally to avoid any interference with the function of the levator labii superioris alaeque nasi muscle. This would produce an undesirable elongation of the upper lip.

Often, when treating the bunny lines, procerus muscle treatment is performed at the same time to manage the horizontal lines at the root of the nose.

3.8 | Sagging nasal tip

The target muscle for the treatment of a sagging nasal tip is the depressor septi nasi. When hypertonic, the depressor septi nasi lowers the tip of the nose. This is usually more visible when the patient smiles. To treat the sagging nasal tip, the Panel recommends a single injection site with a 2-4 U dose in men and women (Figure 7).

The injection should be performed by inserting ½ of a 30G × 1/2″ needle, at the base of the columella, pointing toward the nasal spine. The treatment produces a pleasant upward rotation of the nasal tip and inhibits its downward rotation when the patient speaks or smiles. However, crucial is the clinical assessment for correct patient selection. The treatment of the sagging nasal tip should be avoided in patients with a long upper lip. A long caudal septum is also a contraindication to the toxin treatment as it prevents the desired tip rotation.

3.9 | Gummy smile

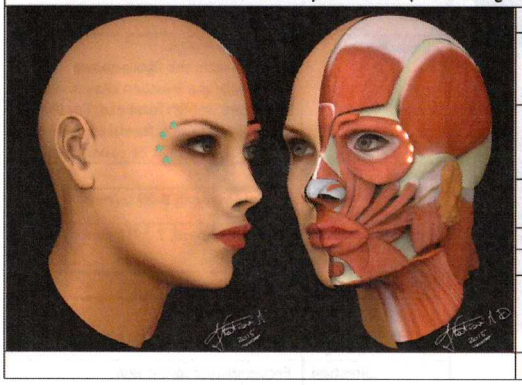
This is a position statement because the consensus agreement was 60% only (5/9).

The levator labii superioris alaeque nasi muscle and the depressor septi nasi are the target muscles. The Panel suggests to treat the gummy smile with three toxin injection sites, one per side for the levator labii superioris alaeque nasi muscle, and a central one for the depressor of the nasal septum (Figure 8). The recommended dose is 2 U per injection site. Regarding the two lateral sites, the needle must be positioned 3-4 mm lateral to the nostril and 1 cm above its base, with half-length penetration. This is to target the upper lip without interfering with the function of the orbicularis oris muscle. For the central site at the base of the columella, please refer to the section on the sagging nasal tip.

It is necessary to see the patient 2 weeks later to evaluate the results. If the gummy smile is undercorrected, two more injections of the toxin in two additional sites are required, each one a centimeter lateral and below the points previously treated. In this case, the target muscle is the levator labii superioris. As previously, half-needle length is used and 2 U of onabotulinum toxin A are injected per side.

The gummy smile treatment should be performed only by an expert in this field. In case of incorrect injection sites or wrong doses injected, unacceptable asymmetries of the smile can occur. This treatment is not indicated in patients with a long upper lip to begin with, because after the treatment it will actually appear to be longer.

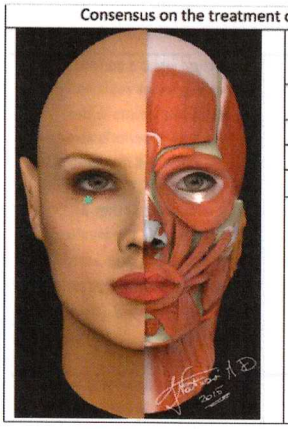
Consensus on the treatment of eyebrows arch (brown lifting and shaping)



Injection site	4 injection sites. (CFL*+ 1 in the eyebrow tail area)
Dosage	CFL + 2 U in the eyebrow tail (woman)
Injection technique (for the eyebrow tail area)	
Depth	Subcutaneous
Angle	30°
Direction	Medial to lateral direction to keep away from the orbit

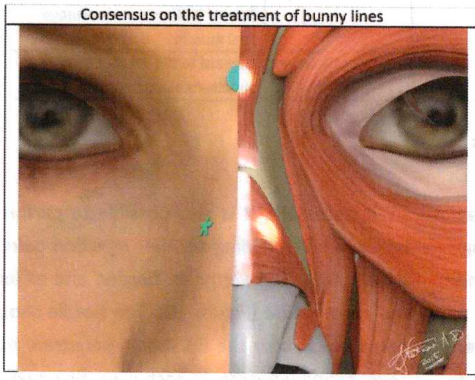
*CFL= Crow's Feet Lines

FIGURE 4 Consensus on the treatment of eyebrows arch (brown lifting and shaping)



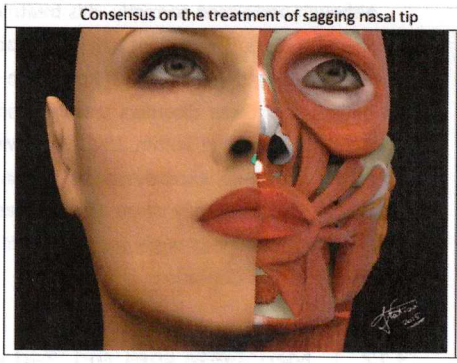
Consensus on the treatment of the lower eyelid hypertrophy	
Injection site	1 injection site in the point of main muscle hypertrophy
Dosage	0.5-1 U per side
Injection technique	
Depth	Intradermally (a small bolus)
Angle	Acute angle almost parallel to the skin (30°)
Direction	Lateral-medial direction, parallel to the eyelid margin

FIGURE 5 Consensus on the treatment of the lower eyelid hypertrophy



Consensus on the treatment of bunny lines	
Injection site	3 injection sites: 1 in the procerus and 2 in the nasalis muscles
Dosage	
Total	8 U
For each injection site	2 U for nasalis muscles (per side) and 4 U for the procerus
Injection technique	
Depth	Subcutaneous
Angle	45° to the coutaneus plan
Direction	From the bottom up

FIGURE 6 Consensus on the treatment of bunny lines



Consensus on the treatment of sagging nasal tip	
Injection site	1 injection site
Dosage	2-4 U (man and woman)
Injection technique	
Depth	Deep subcutaneous (½ needle)
Angle	Along the bisector of the nose-labial angle
Direction	Pointing towards the nasal spine

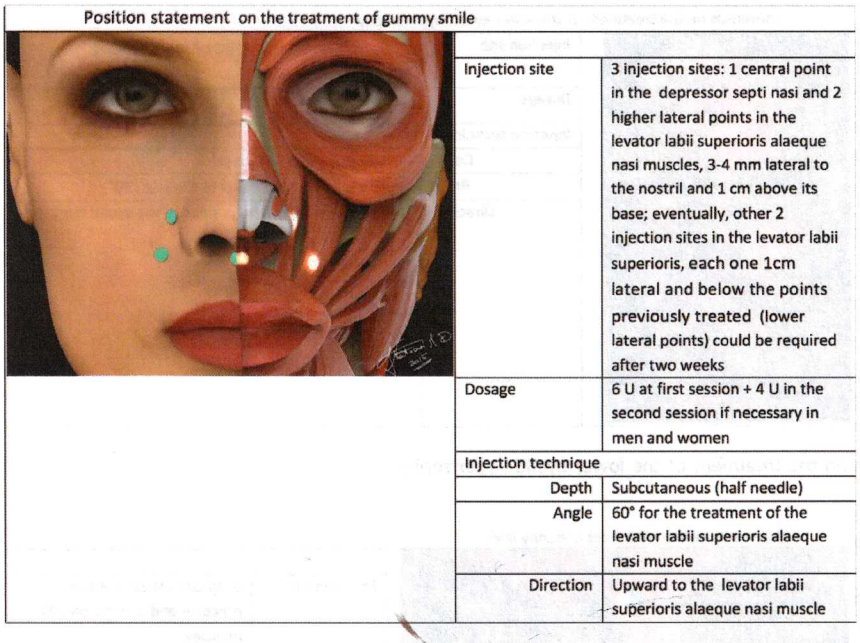
FIGURE 7 Consensus on the treatment of sagging nasal tip

Moreover, patients with a gummy smile of severe degree (when the gum tissue displayed is between 50% and 100% of the length of the teeth) are considered cases of gingival hypertrophy; consequently, the recommended treatment is surgical.[22]

3.10 | Hypertrophy of the masseter muscle

The treatment of this area with onabotulinum toxin A can be performed for aesthetic reasons, that is, to reduce an excessive muscle mass in correspondence of the mandibular angles, or for functional reasons (in case of bruxism), or both. The masseter muscle can be easily identified by asking the patient to clench the teeth, while the physician palpates the area. This will clearly identify the anterior and posterior margins of the muscle, while the upper limit is at the zygomatic arch and the lower one along the inferior margin of the mandible at the angle.

It is recommended to use 3-5 injection sites depending on the size of the area of the masseter muscle. The onabotulinum toxin A dose can vary from 12 to 25 U per side in women and 20 to 50 U in men, according to the muscle mass and strength (Figure 9). The



Position statement on the treatment of gummy smile	
Injection site	3 injection sites: 1 central point in the depressor septi nasi and 2 higher lateral points in the levator labii superioris alaeque nasi muscles, 3-4 mm lateral to the nostril and 1 cm above its base; eventually, other 2 injection sites in the levator labii superioris, each one 1cm lateral and below the points previously treated (lower lateral points) could be required after two weeks
Dosage	6 U at first session + 4 U in the second session if necessary in men and women
Injection technique	
Depth	Subcutaneous (half needle)
Angle	60° for the treatment of the levator labii superioris alaeque nasi muscle
Direction	Upward to the levator labii superioris alaeque nasi muscle

FIGURE 8 Position statement on the treatment of gummy smile

toxin is injected with a 30G × 1″ needle inserted at 90° all the way down to the bone, then just pulled back by 1-2 mm before injecting. The long needle allows to deliver the drug well into the muscle and avoids the possibility of injecting a hypertrophic parotid instead.

In this particular application, the onset of the result is far slower than usual. Whereas correction of wrinkles and modulation of expressions are visible immediately after chemodenervation has taken place, when treating a hypertrophic muscle, the result is due to the relative atrophy that occurs after weeks of reduced activity.

This is why the physician should wait at least 4-6 weeks before the decision that an additional dose is required, the units being decided according to the clinical picture.

Furthermore, in this particular application, the interval between treatments is extremely variable. The physician should reassess the patient periodically and repeat the injections as muscle strength is returning, without waiting for recurrence of the hypertrophy.

3.11 | Perioral lines

To treat or prevent perioral lines, the association between hyaluronic acid and onabotulinum toxin A is recommended.

Hyaluronic acid treatment should follow 7-10 days after the onabotulinum toxin A injections. By judiciously weakening the outer fibers of the orbicularis oris with toxin, the physician can improve the perioral lines and thus reduce the volume of hyaluronic required to complete the correction. A satisfactory result can thus be achieved without a significant impact on lip shape and volume. The treatment of perioral lines with onabotulinum toxin A is generally carried out in two points, one for each hemilip, 1 mm above the vermilion border (or below it when treating the lower lip), and about 5 mm away from the apex of the Cupid's bow.

If necessary, it is also possible to perform the treatment in four injection sites, adding another injection point to each upper hemilip, 1 mm above the vermilion border, and at least 5 mm medial to the oral commissure (Figure 10). The needle should lie almost flat on the skin surface, only the tip should penetrate through the skin with the bevel facing upwards. In each case, however, the recommended dose for each injection should be 0.5-1 U, according to the physician's judgment.

Although performed correctly, this treatment can produce proprioceptive disorders. The patient may report about unusual sensations when articulating the lips, even if lip motion appears normal. Inform the patient that these disorders usually appear after the first treatment only and resolve within 15-20 days without affecting the lip movement. However, excessive doses of the toxin in the treatment of perioral lines truly may cause asymmetries and functional lip disorders, it is therefore strongly suggested not exceed the doses recommended in this Consensus.

3.12 | Marionette lines and "sad mouth"

The marionette lines are mainly caused by ptosis of the soft tissues of the cheek, but within limits also by an overtone of the depressor anguli oris muscle.

This muscle can depress the oral commissures and therefore increase the sad appearance of the patient.

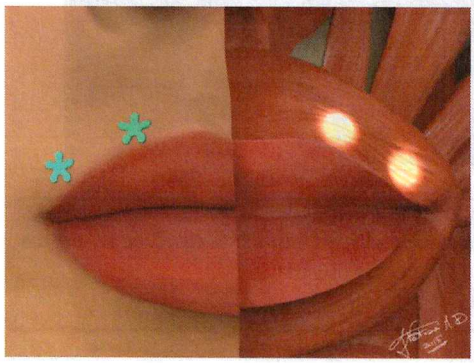
Toxin treatment is performed by inserting 1/3 of a 30G × 1/2″ needle perpendicular to the skin, with a recommended dose of 2-4 U per side both for men and women (Figure 11). The injection site is located 1 cm above the lower margin of the mandible and 1 cm lateral to the labiomental fold. Botulinum toxin injections in this area are at risk of involvement of the depressor labii inferioris muscle,

Consensus on the treatment of masseter muscle hypertrophy

Injection site	3-5 injection sites considering the spread of the toxin and the size of the masseter muscle
Dosage	20-30 U per side (women) 25-40 U per side (men)
Injection technique	
Depth	As close as possible to the bone surface
Angle	None
Direction	Perpendicular to the skin surface

FIGURE 9 Consensus on the treatment of masseter muscle hypertrophy

Consensus on the treatment of perioral lines



Injection site	2 injection sites in the each hemi-lip, 1 mm above the vermilion border. it's also possible to perform the treatment in 4 injection sites, adding another injection point to each upper hemi-lip, 1 mm above the vermilion border and at least 5 mm from the oral commissure.
Dosage	0,5-1 U per site. If necessary, it's possible to retreat after 15 days
Injection technique	
Depth	Superficial intradermal
Angle	≤30°, almost parallel to the skin surface
Direction	Parallel to the vermilion border

FIGURE 10 Consensus on the treatment of perioral lines

which lies immediately below the depressor anguli oris. When this occurs, the smile is very visibly affected and the result unacceptable. An impairment of lip function may also be associated, thereby increasing patient discomfort.[3]

3.13 | Mentalis muscle hypertonia

The mentalis muscles are very strong mimic muscles, with fibers directed vertically from the bony origin expanding in a tree-like fashion toward the skin of the chin. This pattern is quite different to that of the other mimic muscles. The mentalis muscles act as elevators of the lower lip and of the soft tissues of the chin. When hypertonic, they produce a flattening of the chin against the bone and a "golf ball" or "pebbly" or "peau d'orange" appearance of the skin surface, due to the dermal insertions of the contracted muscle fibers. Relaxing the mentalis muscles achieves better soft tissue projection and a smoother skin surface.

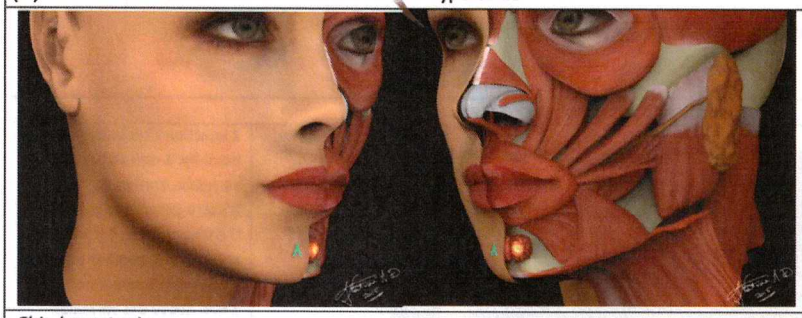
The total dose recommended is 6-8 U in women and 8-10 U in men. Depending on the width of the chin, the treatment can be performed using a single injection site, 1 cm above the lower margin of the chin in the midline, or two injection sites, both 1 cm above the lower margin of the chin and each 0.5 cm away from the midline, on opposite sides. (Figure 11a and b). Half- to full needle lengths are correct for these injections.

When bilateral injections are used, it is important not to exceed the distance of 0.5 mm from the midline to avoid an unwanted

(A) Consensus on the treatment of Marionette lines

Marionette lines	
Injection site	2 injection sites
Dosage	2-4 U per side
Injection technique	
Depth	⅓ of the length of the needle
Angle	90°
Direction	Perpendicularly to the skin

(B) Consensus on the treatment of chin hypertonia



Chin hypertonia	
Injection site	1 injection site, 1 cm above the edge of the jaw in the midline, or 2 injection sites (as in the figure), 1 cm above the edge of the jaw and 0,5 cm from the midline
Dosage	6-8 U (women); 8-12 U (men)
Injection technique	
Depth	It is possible to use the entire needle or a half of its length
Angle	90°
Direction	Perpendicularly to the skin

FIGURE 11 A, Injection points for marionette lines. B, Injection points for chin hypertonia

involvement of the depressor labii inferioris muscle, resulting in lower lip asymmetry. Similarly, single midline or bilateral injections should not be higher than 1 cm from the lower chin margin not to affect the orbicularis oris, with further consequences on lip function.

The Panel recommends the treatment of this difficult area only to highly experienced doctors.

3.14 | Hypertonic platysma bands

The platysma bands can be medial and/or lateral, single or multiple and typically appear after the age of 45-50 years. To achieve the expected results, the treatment of hypertonic platysma bands should be limited to relatively young patients with elastic skin and limited gravitational sagging.

The number of injection sites depends on the position of the bands: medial (most frequent), only lateral (very unusual), or mixed (relatively frequent). The patient should be observed in dynamic: talking, smiling, and clenching.

The injection points of onabotulinum toxin A are located every 2 cm along the bands, in most cases four per band. The recommended dose is 2 U per injection site, a total dose of 6-10 U for each platysma band (Figure 12). Usually, the medial and lateral bands are treated simultaneously in the same session. The needle should penetrate very superficially, almost parallel to the skin, with the tip only.

This is a very critical area: below the thin platysma muscle lie the anterior muscles of the neck, which must never be affected by the drug to avoid severe side effects.

4 | DISCUSSION

Today, the patient faces several many more options than a few years ago. Cosmetic medicine is practiced by various specialists including plastic surgeons, dermatologists, and aesthetic physicians.

From an American online community, which gathers the opinions of thousands of members who underwent a medical aesthetic procedure nearly seven patients out of 10 (68%) would repeat the treatment with botulinum toxin.[23]

This consensus report was designed to develop standardized procedures in the aesthetic treatment of facial and neck wrinkles with onabotulinum toxin A in Italy, also considering the experience of previous reports from other countries.

Indeed, this treatment requires the use of standardized procedures to achieve the effectiveness and safety that onabotulinum toxin A can offer.

4.1 | The importance of patient assessment

Firstly, before any toxin treatment, it is mandatory to carefully assess the patient. In some cases, it is necessary to use a customized injection plan to achieve the desired result. The treatment of the forehead, for example, should be individually tailored, considering the patient's sex, age, forehead size, distribution of frontal wrinkles, and position of the eyebrow.

Moreover, it is recommended to carry out the assessment both statically and dynamically.

Over the last 20 years, men have been requesting more and more aesthetic treatments with onabotulinum toxin A. Thus, it is also essential to consider the anatomical differences between genders. Also, although the target of onabotulinum toxin A is the muscles, the treatment should not be performed without a careful evaluation of the skeletal structure, the skin, the vascularization, and of the other factors that influence aging. A photographic archive is useful in the critical evaluation of the treatment protocols, the results, and any changes needed to identify the best personalized treatment.

The photographs allow the creation of personal records useful as documentation for scientific and clinical purposes.[12]

4.2 | Follow the recommended procedures using onabotulinum toxin A

The cosmetic treatment with botulinum toxin requires precision of execution, as well as evaluation of the initial patient conditions. The choice of injection sites and the amount of toxin required for the treatment of each area are based on years of experience in aesthetic medicine.[3] Onabotulinum toxin A presents the peculiar characteristic of minimal diffusion from the injection site. This allows a very precise localization of the clinical effects and a predictable result.[3] The total dose per treated area should not exceed the recommended dose for each injection site. However, the injecting physician can elect to adjust the dose based on the individual anatomical conditions, the presence of asymmetries, and the patient's expectations.

From 5 to 7 days after the treatment, it is advisable to call the patient inquiring about the outcomes and the possible complications. The patient should be seen within 15 days after treatment to evaluate the result and perform a minor correction if needed.

4.3 | Managing patient expectations

Patients interested in aesthetic treatments with onabotulinum toxin A can find the information on its use, effectiveness, and safety on the web, at any time and independently. This may determine an excess of information, at times even conflicting, which can lead to unrealistic expectations. It is the doctor's obligation, therefore, to lead the patient's approach to cosmetic medicine treatment by delivering full information of the possibilities, results, and risks of the

Consensus on the treatment of hypertonic platysma bands

Injection site	3-5 injection sites per band every 2 cm along the bands (in most cases 4 per band)
Dosage	
Total	6-10 U per bands
For each injection site	2 U
Injection technique	
Depth	Very superficially, with the tip only
Angle	Almost parallel to the cutaneous plane
Direction	Anterior bands: from medial to lateral Posterior bands: from lateral to medial

FIGURE 12 Injection points for the neck

procedure. The patient should be free to choose whether or not to undergo to the aesthetic treatment.

The photographs are also important to communicate the therapeutic plan and to illustrate realistic results.

As in aesthetic plastic surgery, it is mandatory to provide the patient an informed consent form. This form should be developed following seven criteria: (a) expertise from the patient to understand and decide, (b) the presence of a voluntary decision-making, (c) the presence of information material, (d) recommendation of a treatment plan, (e) understanding of terms and conditions, (f) confirmation to perform the treatment, and lastly (g) approval of the treatment plan.[23] There is a device that can provide us precision and reduce pain and is versatile.[24]

5 | CONCLUSION

The paper provides recommendations on the use of onabotulinum toxin A in the aesthetic treatment of facial and neck wrinkles, whose demand is growing steadily worldwide. This treatment requires the use of standardized procedures to achieve the effectiveness and safety of onabotulinum toxin A in the clinical practice.

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