CONSENSUS RECOMMENDATIONS FOR THE USE OF JUVÉDERM VOLUMA

Hervé Raspaldo, Klaus Hoffmann and **Sandrine Sebban** present recommendations for the use of Juvéderm VOLUMA following a round-table consensus discussion

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ABSTRACT

Background:
Appreciation that volume deficits influence facial aesthetic appearance has spurred volume restoration and contouring to treat facial ageing, congenital volume deficits, and HIV-associated lipoatrophy. Volumising and contouring have become fundamental to minimally-invasive multimodal approaches to facial aesthetic treatments. Juvéderm® VOLUMA™, a member of the Juvéderm family of hyaluronic acid products, is a robust, viscous, smooth, highly cohesive HA gel formulation intended for injection between the deep dermis and periosteum to restore volume and enhance 3D facial rejuvenation.

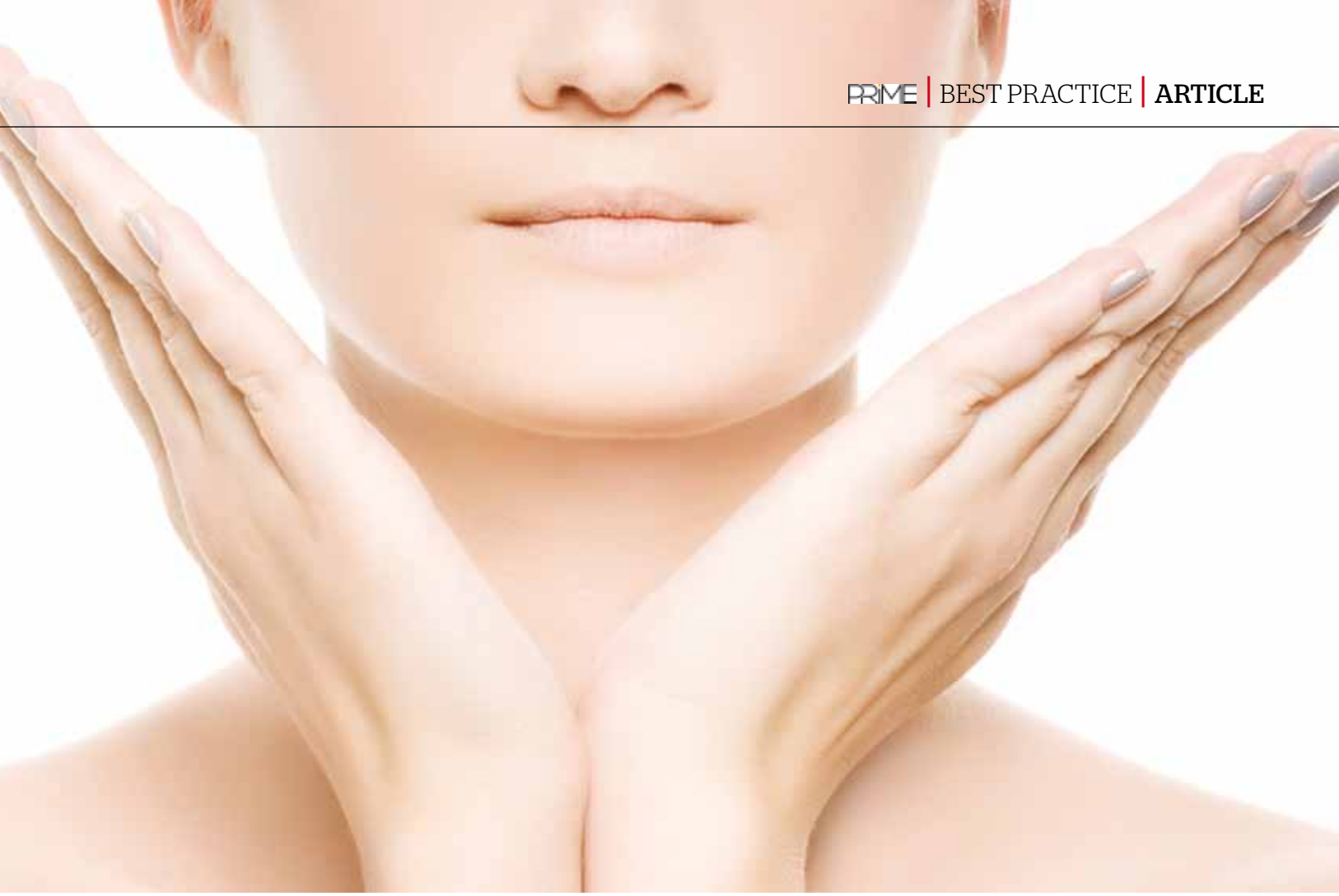
Methods:
Experienced physicians and plastic surgeons reviewed the properties and uses of Juvéderm™ VOLUMA™ based on clinical study results and their collective practical experience. They provided specific guidelines for the use of Juvéderm™ VOLUMA™.

Results:
Pre- and post-treatment recommendations are similar to those for other minimally-invasive aesthetic procedures. Juvéderm™ VOLUMA™ is suitable for patients requiring volume restoration, creation, or contouring. Primary uses include the malar area, chin, jaw, and pre-jowl sulcus. Juvéderm™ VOLUMA™ is supplied with needles or cannulas to accommodate clinician experience and preference. Clinicians should complete specific training with Juvéderm™ VOLUMA™ before undertaking treatments. Inexperienced users should confine their use to malar or chin restoration.

Conclusions:
Juvéderm™ VOLUMA™ retains the reversible and resorbable properties of hyaluronic acids, offers a high level of effectiveness with long-lasting outcomes, stability at the injection site, and an excellent safety profile. It is best administered by clinicians experienced in volumising and who have received specific training in its use. It is also ideal for use in combination with botulinum toxin and hyaluronic acid.

KEYWORDS
Hyaluronic acid, soft tissue augmentation, rejuvenation, consensus, volumisation, dermal filler, facial 3D

JUVÉDERM® VOLUMA™ (ALLERGAN, INC., Pringy, France) is a smooth-consistency, highly cohesive, viscous, fully reversible, volumising gel intended for facial volume restoration; it is CE-marked for this purpose and has been available in a number of European countries for at least 2-3 years (depending on the country). A member of the Juvéderm family of hyaluronic acid products, Juvéderm VOLUMA shares many of the positive attributes of these products, but is a unique formulation that differs substantially in its intended uses and in the skills necessary for optimal clinical use. This article provides clinicians with the information they need to administer Juvéderm VOLUMA effectively and safely based on the consensus recommendations of a group of specialists in facial aesthetics. The participants comprised both aesthetic physicians and plastic surgeons from countries in which Juvéderm VOLUMA has been CE-marked and is available for use. Each participant was very highly experienced in volumising procedures and in using the product for their patients.



Understanding the anatomic basis of facial ageing

The use of botulinum toxin type A in aesthetic medicine has helped spur the growth of minimally-invasive procedures in facial aesthetics. Interest in and knowledge of the specific processes of ageing and their effects on appearance have expanded greatly. Similarly, what has been termed a 'paradigm shift' has taken place in medical approaches to facial rejuvenation, a shift that incorporates the concept of a 3D approach[1-5]. The loss of volume (*Figure 1*) is now increasingly appreciated as a fundamental aspect of ageing that can be treated using minimally-invasive procedures and products, including multimodal approaches intended to provide a more natural, relaxed appearance by addressing muscle activity and contour.

Regardless of cultural ideals and ethnic differences, the ideal in facial aesthetics tends to be characterised by symmetry, smooth convexities (e.g. an ogee curve to the cheek), and a larger facial dimension in the upper face relative to the lower face, providing aesthetically appealing angularity[7]. The inverted triangle, or heart shape[8], typifies the younger face and is, in general, considered more aesthetically pleasing than the reverse[3,4] (*Figure 2*). Inherent in this view is the concept of evaluating the entire face to maintain overall harmony and balance.

Fundamental to successful facial rejuvenation and volume restoration is an in-depth knowledge and understanding of facial musculature and its innervation, soft tissue anatomy (e.g. fat distribution), associated vasculature, and physiology of these structures and systems, as well as knowledge of the dynamic and volumetric changes that occur in ageing. Such knowledge is an absolute prerequisite to the use of products such as Juvéderm VOLUMA and other volumising and dermal filler agents. A comprehensive aesthetic evaluation of the entire face, grounded in anatomy and physiology, allows the development of a facial rejuvenation plan that can help patients obtain a natural, balanced, harmonious, and, therefore, satisfactory outcome[9].

The Juvéderm family of hyaluronic acids

Hyaluronic acid is an attractive, highly suitable option for soft tissue augmentation because it occurs naturally in all species, can bind large volumes of water, and is viscoelastic[10]. The main limitation of native hyaluronic acid—its short half-life in tissue resulting from enzymatic degradation—can be overcome by crosslinking to create a product of longer duration[10,11]. As a result of manufacturing differences, existing hyaluronic acids vary in the amount and type of crosslinking, amount of free or soluble hyaluronic acid, total concentration, and formulation consistency and hardness that they exhibit[11]. Consequently, commercially available hyaluronic acids also differ in their clinical performance properties.

The Juvéderm family of hyaluronic acid is distinguished from other products in a number of ways. Importantly, the Juvéderm products are homogenised during the

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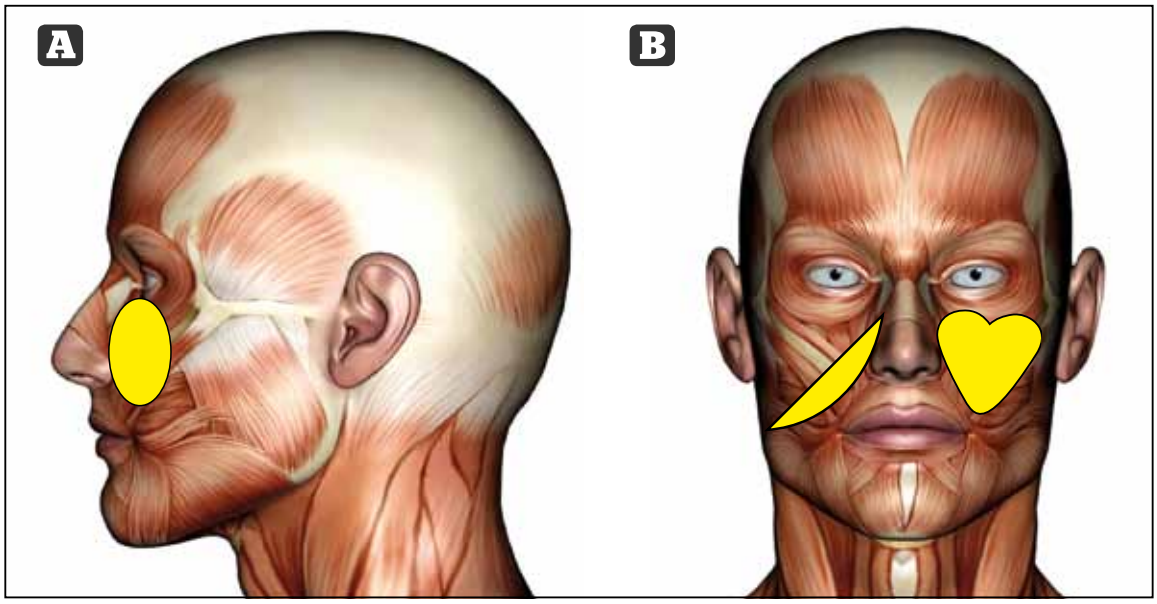

Figure 1 The anatomic foundation of facial ageing[6]. (A) Young face with midface fat; (B) older face with sagging fat

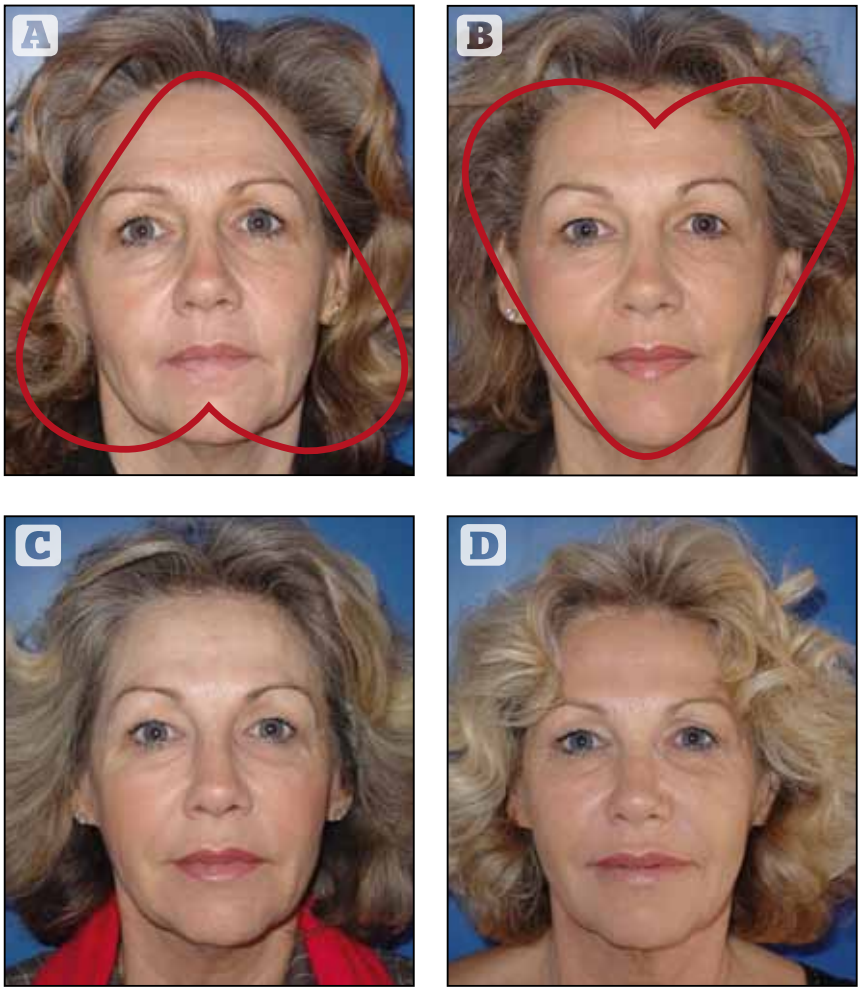

Figure 2 The triangle of beauty: HeArt of Face™[4]. Illustration of a 57-year-old female treated with 20 U BOTOX® Cosmetic in the glabella, Juvéderm™ VOLUMA™ 1 cc in the midface area, and 0.4 cc of Juvéderm® ULTRA 2 in the upper lip contour plus 0.4 cc of Juvéderm® ULTRA 3 in each nasolabial fold. (A) before treatment, (B) 3 months after treatment, (C) after 2 years, and (D) after 5 years

manufacturing process using Hylacross technology, which results in smooth, cohesive gels. In comparison, others such as the Restylane® (Q-Med, Uppsala, Sweden) family of products, are sized into average particle sizes by a sieving process that results in a more granular formulation with a tendency to be slurry-like in consistency[11, 12]. The differences in cohesiveness were apparent in an *in vitro* comparison between Juvéderm VOLUMA and Restylane SubQ, a 1000 gel particle/mL formulation. The flow of liquid from the more slurry-like product is evident and is in contrast to the cohesive nature of Juvéderm VOLUMA. This difference may underlie clinical consequences such as the migration and mobility of implanted material observed with Restylane SubQ, but not with Juvéderm VOLUMA.

Formulations also vary considerably in their rheologic properties[13]. The Juvéderm products extrude evenly and permit clinicians to inject gradually and gently with a steady flow[12]. This is in contrast with Restylane products, which may require a higher injection pressure to initiate the flow followed by modulation of the pressure[12]. Consequently, an irregular flow may create subdermal irregularities when Restylane products are injected.

All of the products in the Juvéderm family provide predictable, highly satisfactory aesthetic outcomes. Within the Juvéderm family, products differ in a number of their properties (*Table 1*), providing clinicians with an array of options for meeting the diverse needs and goals of patients. For example, Juvéderm ULTRA 2 (Juvéderm ULTRA in the US) is often the best choice for lip enhancement and fine wrinkles, although some patients, including men, may achieve a more satisfactory result with the somewhat more viscous Juvéderm ULTRA 3 (Juvéderm ULTRA PLUS in the US)[12]. Additionally, the products can be combined to augment volume and restore and define the vermilion border depending on individual patient presentation. In general, the more viscous products are best suited for deeper defects, while the less viscous products can be

Table 1 Physical and chemical properties of the Juvéderm family of products

Property	Juvéderm® ULTRA 2 (Juvéderm® ULTRA; Juvéderm 24HV)	Juvéderm® ULTRA 3 (Juvéderm® ULTRA PLUS; Juvéderm 30 HV)	Juvéderm® ULTRA 4 (Juvéderm 30)	Juvéderm® VOLUMA™
Total HA concentration	24 mg/mL	24 mg/mL	24 mg/mL	20 mg/mL
High molecular weight HA	Major component	Major component	Major component	Minor component
Degree of crosslinking	≈6%	≈8%	≈6%	<5%
Indications/primary uses	Lips, NLFs, superficial lines	Deeper lines and folds	Areas with minor volume loss or requiring greater lift (e.g. severe or extreme NLFs)	Facial volume restoration

HA = hyaluronic acid; NLF = nasolabial fold
Data on file, Allergan, Inc

layered over more viscous products. This combination of attributes, including the high degree of crosslinking with a relatively low amount of soluble HA, provides clinicians and patients with a long-lasting outcome that is smooth and natural in feel and appearance.

Juvéderm VOLUMA: properties and performance

Juvéderm VOLUMA was designed to be more viscous and robust than other products in the Juvéderm family. It is therefore highly suitable for deep injection and volumising, but not for more superficial uses. In applications where an HA is used for volumising, a high lift capacity is essential. This property is a function of cohesivity and viscosity, as well as gel hardness, and can be achieved using different manufacturing methods. One approach is to increase gel hardness at the expense of cohesivity, a characteristic offered by the Restylane family of products. An altogether different way is to combine lower gel hardness with a high degree of cohesivity; a characteristic typified by the Juvéderm family of products.

By design, Juvéderm VOLUMA also demonstrates maximum lift capacity and retains its gel shape and structure as a result of its high cohesivity. Unlike the other Juvéderm products, however, Juvéderm VOLUMA is composed primarily of low-molecular-weight (LMW) hyaluronic acid, which results in increased thickness and viscosity when it is crosslinked. As the crosslinking is very efficient with LMW hyaluronic acid, the final product is of higher viscosity than other Juvéderm products (*Table 1*). Juvéderm VOLUMA, which is also homogenised during production, maintains the cohesivity and gel structure typical of the Juvéderm family of products (data from Allergan, Inc.). Thus, Juvéderm VOLUMA is both highly cohesive and viscous, two properties that are essential for an effective volumising agent.

These properties of Juvéderm VOLUMA may distinguish it from other products used for volumisation in clinical practice. For example, product mobility and lumpiness at the injection site have been reported with Restylane SubQ[14]. Additionally, Juvéderm VOLUMA retains the important properties of reversibility and resorbability, which differentiate it from calcium hydroxylapatite and poly-L-lactic acid, also used for volumising (data from Allergan, Inc.). Collectively, the attributes of Juvéderm VOLUMA make it an ideal agent for volumising and contouring larger areas of the face, such as the malar region and the chin.

Literature review

To the knowledge of the authors, clinical results with Juvéderm VOLUMA have been reported in two published clinical trials to date.

Retrospective aesthetic trial

Based on the results of a retrospective analysis of 102 patients, Juvéderm VOLUMA has shown to be effective and safe as a treatment for restoring facial volume[4]. The patients in this study were primarily female (*n*=93), who received midfacial injections of Juvéderm™ VOLUMA™. The injected dose of Juvéderm™ VOLUMA™ was based on the degree of volume loss (*Figure 3*)[4]. Most injections were in the central and lateral midfacial region (submalar/subpalpebral and malar areas). The mean total volume of Juvéderm VOLUMA injected was 4mL (range, 2–8mL). The investigator's assessments of the aesthetic benefits were based on the five-point Global Aesthetic Improvement Scale (GAIS: 1=very much improved; 2=much improved; 3=improved; 4=no change; 5=worse)[15]. Assessments were based on evaluated pre- and post-treatment standardised digital photography. Patients also rated effectiveness on a five-point scale (1=very good; 2=good; 3=not very good; 4=quite bad; 5=very bad).

Results of the GAIS at 1 month and 6–18 months post-treatment revealed that the majority of patients were very much or much improved; 98% at 1 month and 81% at the 6 and 18 month assessments (*Table 2*)[4]. Nearly all patients (98%) noted that they would recommend the treatment to friends. The vast majority also felt that the treatment was beneficial and helped them feel more attractive, better about themselves, and more confident. The nine adverse events that occurred in eight of the 102 patients (8%) were temporary. They included swelling (*n*=1; 1%), haematoma (*n*=3; 3%), over-correction (*n*=4; 4%), and hypersensitivity (*n*=1; 1%). Haematoma was considered to be related to the procedure, and the other events were deemed to be associated with the product. Overall, Juvéderm VOLUMA was well tolerated.

Figure 3 Staging volume loss on a four-point scale in which 1=normal (A); 2=evidence of early soft tissue ptosis or atrophy slightly visible (B); 3=visible depression or descent (C); and 4=severe depression or atrophy (D)

Prospective trial in HIV-associated lipoatrophy

The use of Juvéderm VOLUMA to treat HIV-associated lipoatrophy was investigated in an open-label study of 21 males who had at least a moderate degree of lipoatrophy[16]. The product was injected into the buccal, malar, and/or submalar areas. The total duration of the study was 12 months. Global improvement on the GAIS, patient satisfaction, quality of life, and safety were assessed.

Based on an evaluation of pre- and post-treatment standardised digital photography, 90.5% of patients were very much or much improved on the GAIS 3 months after treatment (*Table 3*)[16]. Note that at 6 and 9 months, of the patients evaluated, 100% were very much or much improved, and at 12 months, approximately 76% of patients retained this level of improvement. The mean total volume of Juvéderm VOLUMA injected was 5.3 mL±1.5 mL (range, 3-8 mL). In addition, patients exhibited statistically significant ($P<0.05$) improvements on a number of the quality of life assessments after treatment. These included improvements in aspects of daily living activities, symptoms and feelings, leisure, work and school, and personal relationships. Most patients (90.5%) stated that they would recommend this treatment, and 95.2% rated the treatment as beneficial. Adverse events were transient and included mild erythema (38%), swelling (19%), and discrete bruising (19%). None of the events were severe[16].

The results of the two trials, as well as the collective experience of the consensus participants, indicate that the clinical effect of Juvéderm VOLUMA can be expected to last from 12-18 months in most patients and longer in others. Based on 3 years of clinical experience and his 102 case studies, one of the authors (HR) noted that treatment effects may last at least as long as 22 months (*Figure 4d*).

Consensus recommendations

Before using Juvéderm VOLUMA, clinicians should refer to the instructions for use accompanying the product[17]. The following recommendations are based on the outcome of discussions among clinicians experienced in the use of Juvéderm VOLUMA for their patients.

Patient selection

A broad range of patients qualify for Juvéderm VOLUMA treatment, encompassing those with facial volume loss resulting from ageing, significant weight-loss, underlying anatomic defects leading to an appearance of midfacial volume loss, HIV-associated lipoatrophy, and patients with sequelae of hemifacial paralysis (*Table 4*). It was suggested that the guiding principle in patient selection be the aesthetic presentation of the individual, rather than specific age limits. For example, no specific age limits were set for treating patients with congenital conditions such as Parry-Romberg syndrome (progressive hemifacial atrophy) and maxillary hypoplasia. For aesthetic indications, it was recommended that patients be at least 18 years of age. If treating a younger patient—after parental assessment and informed consent is signed—a treatment plan might be discussed and explained clearly, as well as the potential for necessary repeated injections. Although no fixed upper age limit for treatment exists, it should be noted that substantial thinning of the skin and severe photoageing or environmental damage may make certain older patients unsuitable candidates. Injections must always be deep to avoid the product being visible or palpable as a result of thinner skin. In the absence of specific contraindications, patients of any skin colour (Fitzpatrick I-VI) and those

Table 2 Results on the GAIS at 1 month and 6-18 months post-treatment with Juvéderm™ VOLUMA™

GAIS	Categories	1 month post-treatment *n* (%)	6-18 months post-treatment *n* (%)
1	Very much improved	73 (71.6)	65 (64.4)
2	Much improved	27 (26.5)	17 (16.8)
3	Improved	1 (0.9)	18 (17.8)
4	No change	1 (0.9)	1 (0.9)
5	Worse	0 (0)	0 (0)

GAIS=Global Aesthetic Improvement Scale
Source: Raspaldo[4]

who wish to avoid a surgical facelift, are also appropriate candidates for treatment with Juvéderm VOLUMA.

Regardless of the patient's presentation, the first step in developing a treatment plan is to conduct a comprehensive aesthetic evaluation and stratify the degree of volume loss. For this, a four-point stage has been proposed (Raspaldo Scale) and may prove useful (*Figure 3*)[4]. Expert consensus was that new users of Juvéderm VOLUMA, after appropriate training, should begin treating patients who are categorised as stage 2 on the four-point scale, and advance to the treatment of more severe volume loss as experience and proficiency are developed. It was noted that a five-point scale has also been used to describe facial volume loss[18]. On this scale, grades 2 and 3 include moderate degrees of facial volume loss, and grades 4 and 5 include more severe degrees of lipoatrophy, including progressively increasing visibility of underlying musculature and prominence of bony landmarks.

As with other aesthetic treatments, patients with unrealistic expectations (e.g. those who may expect results equivalent to those of a surgical facelift) are not suitable candidates for treatment with Juvéderm VOLUMA. From an aesthetic perspective, neither patients with high cheekbones nor those with heavy or drooping skin are ideal candidates for volumising treatment in the malar area. However, it is possible to inject more medially or in the temporal area to reduce the impression of high cheek bones[23]. Patients with heavy skin may benefit from surgical facelift, deep chemical peel, or laser resurfacing. In addition, clinicians should be alert to signs of body dysmorphic disorder as such patients are also unsuitable for treatment.

The Juvéderm VOLUMA Instructions for Use recommend that the product should not be used in sites previously treated with permanent implants, as more data are needed to confirm the safety of this clinical scenario[17]. The product is not indicated for patients who are pregnant or lactating, or those who have other conditions that contraindicate treatment. This includes patients with a tendency to develop hypertrophic scars, those with known hypersensitivity to HA, or patients whose skin exhibits inflammation and/or infection, such as acne or herpes.

Facial treatment areas

Juvéderm VOLUMA is indicated for facial volume restoration and is not intended for more superficial use or where other Juvéderm products would be more suitable, such as the tear troughs, lips, or glabellar areas[23]. Consensus recommendations for the use of HA dermal fillers in these areas have recently been published[1]. The primary treatment sites for Juvéderm VOLUMA are the malar area and the chin. Volume loss in these areas becomes apparent with ageing, and volume restoration can provide results with a long duration and highly satisfactory outcomes.

A 55-year-old woman with facial volume loss

This 55-year-old woman presented for aesthetic evaluation and recommendations for treatment (*Figure 4a*). Before treatment, the patient's aesthetic appearance was typified by the loss of the inverted triangle and the ogee curve in the malar area (*Figure 4b*).

Table 3 Results of the GAIS (*n* [%])

GAIS Rating	Time (months)			
	3	6	9	12
Very much improved	17 (81)	17 (81)	16 (76.2)	11 (52.4)
Much improved	2 (9.5)	4 (19)	5 (23.8)	5 (23.8)
Improved	2 (9.5)	0 (0)	0 (0)	4 (19)
No change	0 (0)	0 (0)	0 (0)	1 (4.8)
Worse	0 (0)	0 (0)	0 (0)	0 (0)

GAIS=Global Aesthetic Improvement Scale. Very much improved=optimal cosmetic result for the implant. Much improved=marked improvement in appearance, but not completely optimal for this patient; a touch-up would slightly improve the result. Improved=obvious improvement in appearance, but a touch-up or retreatment is indicated. No change=the appearance is essentially the same as the original condition. Worse=the appearance is worse than the original condition. Repeated-measures comparison of time points: P>0.05 (Friedman's test). Source: Bechara et al[15]

Table 4 Patient selection: candidates for Juvéderm™ VOLUMA™ treatment

Potential candidates*	Potential exclusions
■ Age-related facial volume loss (>18 years of age) ■ Weight loss-associated facial volume loss ■ HIV-associated lipoatrophy ■ Congenital anatomical defects: • Parry-Romberg syndrome • Maxillary hypoplasia ■ Patients with sequelae of hemifacial paralysis ■ Patients wishing to avoid surgical facelift ■ Patients of any skin colour (Fitzpatrick I–VI)	■ Patients <18 years old (aesthetic indications only) ■ Older patients with substantially thinned skin (injections must be very deep or in combination with Juvéderm™ Ultra)[23] ■ Patients with body dysmorphic disorder or unrealistic expectations ■ Patients with very high cheekbones, round big visage or heavy, drooping skin ■ Patients with previous permanent implants ■ Patients with specific contraindications to the product as specified in Juvéderm™ VOLUMA™ Directions for Use[17] (e.g. pregnant, lactating, tendency to develop hypertrophic scars, those with known hypersensitivity to HA, or patients whose skin exhibits inflammation and/or infection, such as acne or herpes)
	*Patients of any age unless otherwise specified

Malar volume loss is particularly apparent in the profile views. After discussion of treatment options and expected results, the patient received 2mL/side of Juvéderm VOLUMA. *Figures 4b–4d* demonstrate the results 3, 12, and 22 months post-treatment. Treatment with Juvéderm VOLUMA provided substantial volume restoration and helped restore the triangle of beauty. The results had a long duration with improvements in volume remaining apparent after 22 months post-treatment. These results are consistent with the physicochemical properties of the products and are particularly noteworthy as the ageing process and loss of volume would be expected to continue in an untreated woman of this age. Furthermore, the patient was very satisfied and returned every 6 months for botulinum toxin type A treatments of her upper face. She has received no additional hyaluronic acid treatments since Juvéderm VOLUMA.

Other appropriate areas for treatment include the jawline and pre-jowl sulcus. Some experienced clinicians inject a small quantity of Juvéderm VOLUMA at the very

superior fold of the nasolabial areas. In general, however, the consensus participants preferred other members of the Juvéderm family for treating the nasolabial folds, temporal hollow, tear troughs, nose, and marionette lines. It was suggested that Juvéderm VOLUMA may prove valuable for rejuvenation of the hands, but further research is warranted to support use in areas outside the malar region and chin. It was recommended that new users begin by initially restricting treatment to the lateral portions of the malar area and chin, with the goal of achieving a smooth, natural aesthetic balance. Overall, it is essential to understand facial anatomy and formulate an overall treatment plan that considers the aesthetics of the entire face. Juvéderm VOLUMA can be used in combination with other Juvéderm products as well as with BOTOX® Cosmetic to provide optimal outcomes[1,2,5,23].

Procedures and protocols

Pre-treatment: evaluation, counselling and preparation

Before treatment, taking a complete patient history to uncover the full details of previous aesthetic treatments and potential contraindications to treatment is essential. This is the time to fully explore the patient's expectations and ensure the patient's complete understanding of the benefits and risks of a variety of treatment choices, to select from the range of options, and to develop a comprehensive treatment plan. Standardised photography is a valuable tool in this process and 3D photography is optimal if available[5]. Consensus participants strongly recommended pre-treatment photography under standardised conditions of lighting and positioning. This serves the purpose of documenting pre-treatment appearance, as well as helping stage volume loss and describing it to the patient. It also serves as a baseline for comparison with post-treatment photography used to document treatment effects. It was noted that overhead lighting is very effective in demonstrating the extent of volume loss.

Patients must be informed of all details of the procedure and of the potential side-effects. For example, consensus participants apprise their patients of the potential for oedema and discomfort that may occur 24–72 hours post-treatment. Based on clinical experience and trial data, the most likely side-effects are transient bruising and swelling, that are mild to moderate in severity. It is most important that patients be educated about the differences between volumising and line filling or dermal filling, so that they are aware of the somewhat greater risk of swelling with volumisers. In addition, although the risk of haematoma is relatively low (e.g. observed in fewer than 3% of patients in the retrospective case analysis[4], patients should be informed that it can occur as a result of the procedure itself. Some clinicians recommend that patients also receive written information along with pre-treatment instructions. As is standard for any medical treatment, patients should be asked to provide written informed consent before any procedure, including photography, is undertaken and after they have been made aware of all details, including the potential risks and benefits.

Although pre-treatment instructions vary across clinical practices, it was agreed that patients should discontinue the use of any anticoagulant agents, such as aspirin, antivitamin K therapy, and vitamin E, 1 week before treatment. Also, patients with a history of herpes simplex virus infection (cold sores) should receive prophylactic treatment with antiviral therapy, such as acyclovir. These recommendations are consistent with those for other soft tissue augmentation procedures[1,19-22].

A variety of herbal remedies can be used by patients both before and after treatment. For example, some patients and clinicians use topical and/or oral arnica preparations in the belief that it may help reduce swelling and bruising. Additional research is needed to evaluate the benefits of these products and dosing recommendations supplied with the agents should be followed carefully. One regimen is to use arnica granules for 2–3 days before treatment and for approximately 1 week after treatment in combination with a topical formulation. Some consensus participants also advocated the use of antioxidants, but again, this is optional.

The procedure

The proposed treatment area should be thoroughly cleaned with antiseptic according to standard surgical

Figure 4 Restoration of the malar area in a 55-year-old woman. This 55-year-old patient with malar volume loss received 2 mL of Juvéderm™ VOLUMA™ in each malar area of her face with a 21-gauge needle (local anaesthesia with 1.5 mL lidocaine plus adrenaline). Results were evaluated at 3 months, 12 months, and 22 months post-treatment. (A) Before treatment, (B) 3 months post-treatment, (C) 12 months post-treatment, and (D) 22 months post-treatment

practice because it is a deep tissue injection that comes in contact with fat. Anaesthesia recommendations depended largely on clinician experience and preferences, and include topical and local anaesthetic agents, nerve blocks, and combinations of these. Some of the consensus participants also recommended the use of pre-injection cryotherapy, such as a Zimmer MedizinSystems cooling device. Patient preferences should also should be considered. Clinicians should not undertake treatment with Juvéderm VOLUMA until they have been trained specifically in the use of this product. As it is a volumising agent, the proper techniques for its use differ substantially from the techniques used for dermal fillers. As with all procedures, a thorough knowledge of facial anatomy is essential for proper use. The fundamentals of the technique are described below, but should not be considered a substitute for specific training.

Juvéderm VOLUMA is supplied as one prefilled 2mL syringe together with two single-use, 23-gauge, 1 inch needles and two single-use, 18-gauge, 70mm cannulae[17]. While both needle length and diameter (gauge) can have an effect on the extrusion force required, physicians have some freedom with regard to needle gauge (e.g. 21–23) or cannula gauge (e.g. 18–25) (data from Allergan, Inc.). The selection of needle or cannula for injecting the product is highly dependent on the experience and preference of each treating clinician, and successful outcomes can be obtained with either technique. Regardless of technique, the product should be injected subcutaneously, intra- or submalar fat pad, and always above the periosteum[17,23].

When the cannula technique is used for midface volume restoration (*Figure 5*), the skin lateral to the malar area is first punctured with a needle to create a subcutaneous channel approximately 1cm in length. Once the needle is withdrawn, a round-tipped cannula is inserted through the incision. Pushing the cannula through the subcutaneous plane extends the channel, and Juvéderm VOLUMA is injected using the anterograde and retrograde technique. This step can be repeated using the fanning technique to create multiple channels to inject the required volume of product. When the injection is completed, the area should be massaged to mold the product to create a natural-looking result.

To restore midface volume using the needle technique, Juvéderm VOLUMA is injected following lines from the most prominent edge of the malar bone toward the nose and strictly inferior to the orbital rim, and always deeper than the orbicularis muscle (*Figure 6*). For more effective filling, the advanced injector familiar with periorbital rejuvenation may add additional perpendicular vectors for midface injections, from a point at the top of the nasolabial fold, 2mm away from the nostril junction, fanning up to the malar eminence, and again, strictly inferior to the orbital rim. The fanning technique can be used to create multiple channels to create a heart-shape, until the desired volume of product is injected. If the subpalpebral area also needs filling, injections should be performed upwards in a fan-shaped pattern to recreate the appearance of youthful suborbicularis oculi fat pad (SOOF) and a malar pad. The product should be injected horizontally using an anterograde and retrograde technique, with continuous pressure on the piston of the syringe and always keeping the needle under the orbicularis oculi muscle[4].

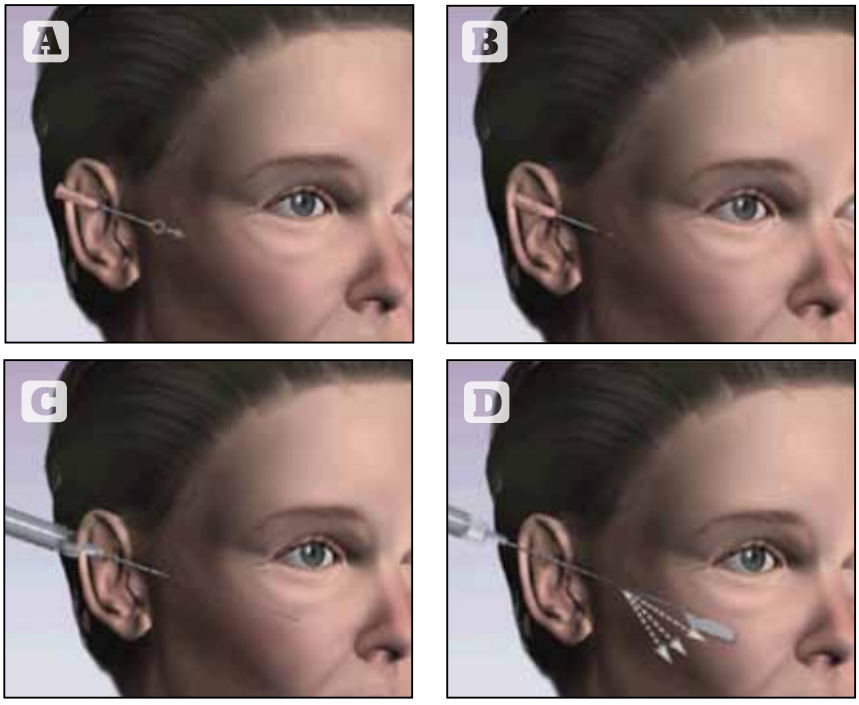

Figure 5 Physician-recommended technique for injecting Juvéderm™ VOLUMA™ with a cannula for malar volumisation. (Photos courtesy of Allergan, Inc., Irvine, CA)

Anterograde deposition of Juvéderm VOLUMA will gently dissect the tissue and minimise injury to deep facial components. When using a needle or cannula, the clinician can use an advanced technique to administer Juvéderm™ VOLUMA™ by creating multiple tunnels that cross each other in different planes (e.g. under the orbicularis muscle and under or into the malar and SOOF pads)[4]. Although these injections are very deep, they are always above the zygomaticus muscle. Performing a gentle massage at the end of the injection procedure helps spread the product evenly into all the tunnels, creating a smooth, natural appearance.

The cannula and needle techniques each have advantages and limitations, but both can yield highly satisfactory outcomes. Proponents of the cannula technique find it to be rapid and associated with little tissue damage; it results in possibly less bleeding and bruising than the needle technique. On the other hand, it may be somewhat less precise and associated with a potential risk of haematoma. Additionally, the cannula technique may appear more aggressive as the blunt tip must break through the subcutaneous septum, in contrast to the effect of using a sharp needle. The cannula technique may also be more difficult for new injectors to master than the needle technique, which may also offer greater precision. The needle allows control of both anterograde and retrograde deposition of material. A slight risk of haematoma formation and a higher risk of tissue trauma is associated with multiple injection sites. Clinicians should decide which technique to use based on their experience and comfort level with using volumising agents and after they have undergone specific training with Juvéderm VOLUMA.

Figure 6 Physician-recommended advanced technique for injecting Juvéderm™ VOLUMA™ with a 21- or 23-gauge needle[16]

Volume recommendations

Injection volumes are highly dependent on the nature and extent of the volume defect. As an example, aesthetic patients with stage 2 volume loss may need a volume ranging from 1–2 mL per side. It was recommended that clinicians begin by injecting 1–2 mL per malar treatment area in a single session and retreat as needed. Patients with greater volume deficits, such as those with HIV-associated lipoatrophy, may ultimately require as much as 6–8 mL per side. Regardless of the required volume, however, no more than 4 mL per midface area should be injected in a single session for any patient. In a study of patients with HIV-associated lipoatrophy, the mean total volume injected at a baseline visit was 5.3 mL ± 1.5 mL (range, 3–8 mL)[16]. For the jaw area and jowl deformities, recommended volumes were 1–2 mL per side. It was noted that the chin should receive at least 2 mL, which is appropriate for a first visit, although more than 2 mL is the typical mean volume necessary for this area. All patients should be evaluated after 1 month, at which time touch-up injections can be performed if they are deemed necessary. Waiting 1 month allows swelling and bruising to subside so that an accurate evaluation can be made. Also, it provides patients time to live with the results and assess their satisfaction with their outcomes. At that time, discussions and decisions about the use of other products can occur.

Post-treatment recommendations and patient counselling

Post-treatment recommendations for patients receiving Juvéderm VOLUMA were similar to those for other hyaluronic acids and dermal fillers. Should a haematoma occur, it will be immediately apparent, and patients should be advised to expect bruising and discolouration a few days after treatment, and be assured that it will resolve over time. Consensus participants recommended the use of ice or cryotherapy on the treatment areas for at least 10 minutes in the office after treatment. Post-treatment instructions should be reviewed directly with patients and then provided in writing. Many of the participants advised conducting a telephone follow-up to provide reassurance to the patient and to uncover any potential problems. Regardless, patients should be encouraged to call with any questions or concerns. They can be advised to continue intermittent use of ice for at least an additional 10–30 minutes and up to approximately half a day after treatment, but some consider this additional use of ice optional.

It was agreed that patients should avoid massaging or touching the area. Patients who use arnica can continue to do so according to the instructions for the specific product(s). As a general precaution, sun exposure should be avoided, and patients should not undertake strenuous activities or exercise for approximately 24 hours. Clinicians should provide patients with their usual recommendations regarding exercise after treatment with any hyaluronic acid product. Patients can also benefit from sleeping with their heads elevated for 1–2 days to prevent compression of the injected areas. No specific food or dietary restrictions were noted.

Adverse events and precautions

Consensus meeting participants, who were all experienced users of Juvéderm VOLUMA, reported minimal adverse events in clinical practice. Although swelling was reported to be common within the first 48 hours after treatment, bruising was minimal, particularly when using the cannula technique. Product migration, lumping, or infection were not reported.

To reduce potential adverse events, it is recommended that the midface and tear troughs not be treated in the same session because of the likelihood of increased swelling. Patients who are not suitable candidates for treatment should not be treated and can be reassessed later if the conditions precluding treatment are temporary. It is also important not to overcorrect, as with other hyaluronic acids. This can be avoided by careful prior aesthetic assessment, relatively conservative treatment at the first session, and subsequent retreatment if necessary to achieve the ultimate desired result.

Using Juvéderm VOLUMA as part of a multimodal comprehensive approach

Consensus participants described a variety of protocols used in clinical practice to provide comprehensive facial rejuvenation. Aesthetic evaluation of the entire face was stressed as being important in developing a comprehensive treatment plan to provide a harmonious and natural look. Specific methods depended largely on patient presentation and clinician experience. Some of the participants recommended first using a neurotoxin to reduce

hypertrophic muscle activity, followed by Juvéderm™ VOLUMA™ treatment up to 1 month later. At that time, other Juvéderm products can be used to treat lines and folds. One of the benefits of that approach is to enable the clinician to assess the effect of malar enhancement with Juvéderm™ VOLUMA™ on the appearance of the nasolabial folds and periorbital area before embarking on treatment with other hyaluronic acids. The most important principle is to assess each patient as an individual and develop a tailored treatment plan[4,16].

Summary

Juvéderm VOLUMA is a smooth, highly cohesive, volumising 20 mg/mL hyaluronic acid gel indicated for the restoration of facial volume. The importance of volume loss in facial ageing and its aesthetic consequences in patients with congenital defects or HIV-associated lipoatrophy is now well appreciated. This understanding focused attention on the key role of soft tissue augmentation in facial aesthetic procedures. The properties of Juvéderm VOLUMA make it an ideal hyaluronic acid for volume restoration or volume creation in congenital defects for a number of reasons. It was designed for deeper injections with higher viscosity and robustness than that of other Juvéderm products. Initial results suggest that the effects of treatment with Juvéderm VOLUMA last longer (for at least 12–18 months) than do those of other Juvéderm products, while retaining all of the benefits of the other Juvéderm products, such as smooth and even flow, malleability, resorbability, and reversibility. It is also considered easy-to-use and is highly satisfactory to patients[4,16] (*Figures 4* and *5*; *Tables 2* and *3*).

Juvéderm VOLUMA is supplied with cannulae and needles, and thus provides options to suit the preferences and experience of the clinician. Pre- and post-treatment recommendations are similar to those of other Juvéderm products and hyaluronic acid fillers in general. Unlike most other hyaluronic acids, Juvéderm VOLUMA is intended for subcutaneous, sub- or intra-fat pad, and above the periosteum use. It combines the smooth, cohesive features of other members of the Juvéderm family with its volumising properties. No migration has been observed either in published clinical trials or in the experience of the consensus group participants[4, 16]. This differentiates Juvéderm VOLUMA from Restylane SubQ, which participants noted to be potentially unstable at injections sites. For more superficial treatments, other hyaluronic acids may be more appropriate and can be used either before or after treatment with Juvéderm VOLUMA. Experienced clinicians consider Juvéderm VOLUMA suitable for a broad range of patients who require volume restoration or creation. They recommend using the product primarily in the malar area, chin, jaw, and pre-jowl sulcus. Further, it is suggested that new users begin with malar enhancement in patients with a mild to moderate degree of volume loss.

Conclusions

As a highly robust, smooth, viscous, and cohesive hyaluronic acid gel formulation, Juvéderm VOLUMA is one of the foundations of the current aesthetic treatment paradigm that considers volume restoration and contouring a paramount goal in facial rejuvenation—whether the volume deficits result from ageing, weight-loss, congenital defects, or HIV-associated lipoatrophy. As Juvéderm VOLUMA is a volumising agent, technical considerations concerning use differ substantially from dermal fillers. Therefore, potential users should undergo specific training in the use of Juvéderm VOLUMA before treating patients. It is also recommended that less experienced users begin treatments with patients who exhibit less severe volume loss, and restrict their treatments to the malar area. Overall, the most suitable facial areas for treatment with Juvéderm VOLUMA are the malar–midface area, chin, jaw, and pre-jowl sulcus.

The use of Juvéderm VOLUMA and facial volumising is also consistent with a multimodal approach to address the spectrum of changes associated with ageing. Within this framework, neurotoxins play an essential role in managing dynamic changes associated with hypertrophic muscle activity, and a range of dermal fillers can be used to reduce the appearance of static lines and folds. As a volumising agent, Juvéderm VOLUMA retains the reversible and resorbable qualities of hyaluronic acids, while offering a high level of effectiveness, characterised by long-lasting outcomes, a lack of migration and stability at the injection site, and an excellent safety profile.

“Neurotoxins play an essential role in managing dynamic changes associated with hypertrophic muscle activity, and a range of dermal fillers can be used to reduce the appearance of static lines and folds.”

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