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Initial experience in transdermal administration of Restylane SubQ for augmentation of the cheek and chin suggests that the product is easy to administer via this route and that it provides a stable aesthetic result. Local adverse reactions are consistent with those expected of an alloplastic filler material and appear to be related to the injection procedure/site rather than to the product itself. In the event of overcorrection or the appearance of superficial irregularities (nodules), any excess material can readily be removed by needle aspiration.

Several measures can be taken to increase the likelihood of a satisfactory aesthetic outcome and minimize the risk of treatment complications with Restylane SubQ. One such measure is to deposit the product in small aliquots at multiple sites (using a multiple tunneling technique) to avoid pooling within the soft tissues. Treatment sites with poor soft-tissue cover pose a challenge because of the high risk of surface irregularities. In cheek augmentation procedures, Restylane SubQ should be placed below the zygomatic arch where the subcutaneous tissue is more fibrous, thereby providing a possible barrier to implant mobility. The chin appears to be particularly well suited to volume augmentation with Restylane SubQ because its dense fibrous tissue creates naturally occurring pockets for product placement. In summary, transdermal administration of Restylane SubQ is a convenient, noninvasive procedure for chin and cheek contouring and for rejuvenation of the mid and lower face. (Aesthetic Surg J 2006;26(suppl):S28-S34.)

Aging of the midface is characterized by inferior displacement of intraorbital fat over a weakened orbital septum coupled with descent of ptotic cheek fat, thereby creating a cheek concavity that is further accentuated by depletion of malar and perioral fat deposits.[1] In addition, age-related weakening of the lateral nasal cartilages leads to progressive nasal tip ptosis. In the lower face, resorption of mandibular bone contributes to ptosis of the chin pad and loss of definition of the chin and jawline.[2]

Facial rejuvenation involves correction of the skin, correction of facial skin and tissue laxity, and most importantly, restoration of soft-tissue volume.[3] Standard face-lift procedures, based on lifting and tightening of the skin in areas prone to atrophic sagging, are excellent for the treatment of the jawline but are of limited effectiveness in rejuvenating the midface. The subperiosteal midface lift provides good aesthetic results in the area between the lower eyelid and angle of the mouth, but at the expense of increased morbidity and complications.[4,5] Modifications of this technique include the extended subperiosteal face lift,[6] the endoscopic full face lift,[7] the subperiosteal cheek lift[8] and the SMILE face lift.[9] However, these procedures are essentially limited to 2-dimensional manipulation of the facial soft tissues and largely fail to restore the volumetric features of the youthful face. In contrast, the recently developed 3-dimensional endoscopic midface enhancement technique[10] and the minimal access cranial suspension (MACS) lift[11] provide volume to the rejuvenation of the midface, but have the relative disadvantages of being invasive surgical procedures.

Similarly, numerous procedures have been developed to correct the ptotic chin, including soft-tissue approaches that resect or tighten the apparent excess soft tissue over the mandible.[12] However, successful correction of chin ptosis requires reapproximation of the chin pad to the mandibular skeleton and elevation of the soft tissues above the lower border of the mandibular symphysis.[13]

Dermal and subcutaneous fillers, used either alone or as an adjunct to surgical and nonsurgical facial rejuvenation techniques, are a logical and effective treatment choice for "lifting and filling" the facial soft tissues. Resorbable soft tissue fillers such as collagen and hyaluronic acid are widely used for intradermal treatment of facial wrinkles and

folds. Non-animal stabilized hyaluronic acid (NASHA) offers a longer-lasting aesthetic effect than bovine collagen or avian hyaluronic acid, and a potentially lower risk of immunogenicity and hypersensitivity reactions.[14] Some injection-related reactions, mainly mild and anticipated, have been reported with Restylane SubQ. Reactions may include erythema, swelling, tenderness, pain, bruising, and pruritis. Less commonly, nodules, lumpiness, and local product mobility within the site of injection have occurred. In such cases, evacuation of the implant material by needle aspiration has been shown to resolve the problem. There have been no documented cases of granuloma to date. Restylane SubQ is a new NASHA product intended for deep subcutaneous or supraperiostal administration to replace lost volume in the cheeks and chin, thereby creating a more sculpted facial contour. We present here our recommendations for, and experience in, the transdermal application of Restylane SubQ for mid and lower face rejuvenation through cheek and chin augmentation.

Transdermal Injection of Restylane SubQ for Facial Rejuvenation and Augmentation of the Midface

A number of measures can be taken to increase the likelihood of a satisfactory aesthetic outcome and minimize the risk of treatment complications when administering Restylane SubQ via the transdermal route. As a preliminary measure, the skin overlying the proposed treatment area should be cleansed with a topical antiseptic (eg, Savlon solution). The proposed area for volume augmentation should be clearly outlined on the face with the patient in an upright position (with gravity acting on the facial soft tissues). Care should be taken to ensure that the upper limit of this treatment area lies at least 1 cm below the inferior orbital margin, so as not to breach the orbital septum while injecting and, therefore, inadvertently allow the product to infiltrate into the lower eyelid tissues. The proposed incision site for insertion of the injection cannula is marked on the skin some 2.5 cm from the border of the treatment area. For malar augmentation procedures, this insertion point should lie below the zygomatic arch, as the subcutaneous tissue here is more fibrous and, therefore, has a more restrictive effect on the mobility of the implant than the tissue above the zygomatic arch. In this latter location, the plane between the temporalis fascia and deep temporal fascia is loose, so there is little obstacle to movement or even migration of the implant.

The treatment area is prepared by infiltration of a local anesthetic into the proposed site of skin incision, the entry route (insertion tunnel) for the injection cannula, and the soft tissues overlying the area for volume augmentation with Restylane SubQ. A small superficial incision is made in the skin with the tip of a No. 11 blade, and the injection cannula is inserted via this entry point to a position beyond the limit of the proposed augmentation area. The position of the cannula tip can be verified by touch, using the opposite hand for guidance. Restylane SubQ injection is performed while withdrawing the cannula from the insertion tunnel; during this procedure, possible deposition of product above the orbital rim may be physically prevented by applying downward pressure with the fingers of the opposite hand.

A number of tunnels (approximately 5 to 8) should be created with the injection cannula throughout the entire augmentation area, and Restylane SubQ should be injected while withdrawing the cannula from each tunnel. It is important that these tunnels be physically discrete (noncommunicating), so that the product is deposited at separate sites and does not pool within the tissues. Once the injection is completed, any residual product in the vicinity of the entry incision should be removed by digital expulsion, leaving a clear/empty zone from the point of incision to the point of product deposition of at least 2.5 cm. Treatment of the contralateral side of the face follows the same procedure. Both treatment areas are then gently massaged with the patient in the upright position to ensure that the augmentations are symmetrical. Finally, the incision points are covered with a sterile plaster.

To minimize the risk of implant mobility, patients should be advised to sleep on their backs rather than on their sides for the first few days after treatment and discouraged from massaging the treated area(s). To reduce the risk of bruising or bleeding at the treatment site, the use of aspirin and nonsteroidal anti-inflammatory drugs should be avoided for 10 days immediately prior to treatment and for 3 days following treatment.

Preliminary Experience in Restylane SubQ Use for Facial Rejuvenation and Augmentation of the Midface

We present here a selection of case studies that illustrate the aesthetic results obtained with Restylane SubQ in malar augmentation via the transdermal route.

A male-to-female transsexual presented with a request for enhancement of the female appearance of her face. Deep implantation of Restylane SubQ, using a tunneling technique to place 1.1 mL of product above the zygomatic periosteum on each side of the face, enhanced the

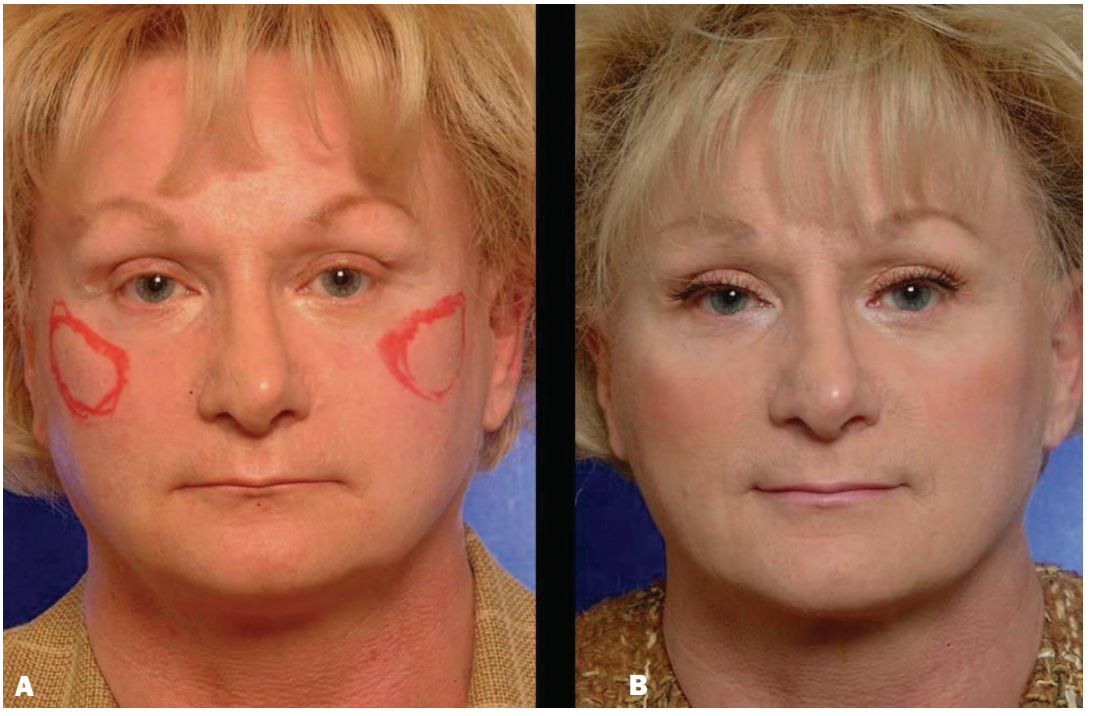

Figure 1. *Before* **(A)** *and after* **(B)** *(5 months) photographs of a male-to-female transsexual who underwent malar augmentation with 1.1 mL Restylane SubQ on both sides. The augmentation zone is outlined in red.*

Figure 2. A, *Pretreatment view of a female patient.* **B,** *The patient was dissatisfied with the cosmetic result after treatment with 1.8 mL of Restylane SubQ on each side of the face.* **C,** *The patient was satisfied with the final result after 0.1 mL of product was aspirated from each side of the face 3 weeks after the initial treatment.*

facial triangle and resulted in a more feminine appearance (Figure 1).

In the event of overcorrection of the cheeks with Restylane SubQ, any excess material can be readily removed by needle aspiration. A female patient desired very prominent malar eminences (Figure 2, *A*) and, consequently, after subcutaneous infiltration anesthesia, was treated with 1.8 mL of Restylane SubQ on each side of the face. However, this degree of volume augmentation proved excessive, and the patient was dissatisfied with the cosmetic result (Figure 2, *B*). Three weeks after the initial treatment, 0.1 mL of product was aspirated from

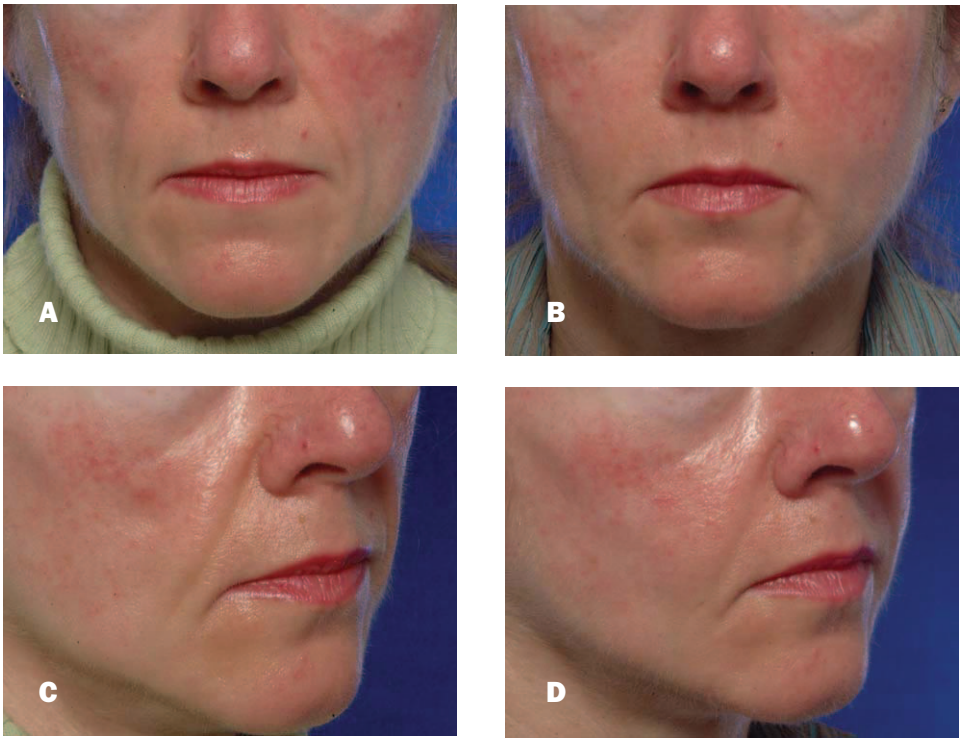

Figure 3. A, C, *Pretreatment views of a 41-year-old woman with HIV-associated facial lipoatrophy.* **B, D,** *Posttreatment views showing corrections 3 months after injection of 1.8 mL of Restylane SubQ in each cheek.*

each side using a 16-gauge needle, resulting in the desired degree of malar enhancement (Figure 2, *C*).

The patient depicted in Figure 3 is a 41-year-old woman who underwent cheek augmentation with Restylane SubQ for correction of HIV-associated facial lipoatrophy. Stab incisions were made over the zygomatic area and parabuccal area in the nasolabial groove and 1.8 mL of Restylane SubQ was injected into each cheek. On each side 0.1-mL aliquots of product were placed in 8 to 10 physically discrete insertion tunnels in the deep subcutaneous layer of the cheek. Larger volumes were required for cheek augmentation than for chin augmentation because, unlike the chin, the soft tissue of the cheek has no underlying bony support to restrict inward volume distribution.

Transdermal Injection of Restylane SubQ for Chin Augmentation

In the mental region, the soft tissues are divided into 3 layers: the skin, adipo-muscular layer, and periosteum. The adipo-muscular layer is composed of 3 muscles—the triangular depressor muscle of the labial commissure (*depressor anguli oris*), the square depressor muscle of the lower lip (*depressor labii inferioris*), and the mentalis muscle—together with bundles of platysma. In the midline, the chin dimple, formed by a fibroelastic lamina extending from the symphysis menti to the deep skin, provides an important landmark for placement of the skin incision and insertion of the injection cannula.

In one way to establish the appropriate area for local anesthesia and skin incision, the patient is seated in an upright position and 2 lines are marked on the chin: a vertical line in the midline, extending from the lower lip to the inferior margin of the chin, and a bisecting horizontal line at 90° to the former (Figure 4, *A*). Local anesthetic (2% xylocaine solution) is then infiltrated into the lower chin at the proposed incision site; in cases of severe volume loss in the lower face, small aliquots of local anesthetic (<1 mL in total) are additionally injected along the mandibular margin. A small midline incision is made in the lower chin with a No. 11 blade to facilitate entry of an 18-gauge injection cannula; this is inserted in a lateral direction to sufficient depth to bring the tip into direct contact with the underlying bone. Restylane SubQ is then placed immediately above the periosteum, using a deep tunneling technique along the mandibular bone (Figure 4, *A*). An alternative approach is to place the incision point laterally and use a tunneling technique directed toward the midline (Figure 4, *B*).

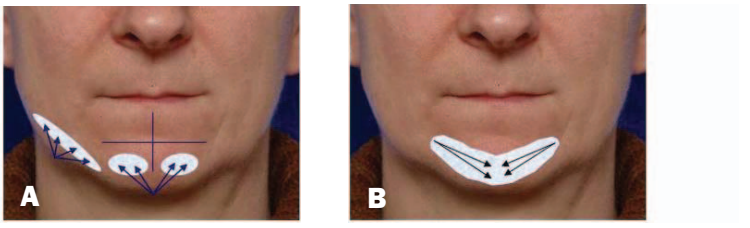

Figure 4. *Sites of injection for chin augmentation with Restylane SubQ.* **A,** *The incision site is located at the midline at the point of intersection of the 2 guide lines. Tunnels are inserted in a medial-to-lateral direction to place product bilaterally at the depicted sites. For injection along the mandibular bone, the incision point is placed laterally and a tunneling technique along the bone directed toward the midline is used.* **B,** *The incision points are made laterally and product injected using a lateral-to-medial tunneling technique.*

Preliminary Experience in Restylane SubQ Use for Chin Augmentation

Initially, Restylane SubQ was administered in a volume of 1 mL on each side of the chin or chin plus mandible. However, in later series of patients, the injection volume was increased to 2 mL on each side (1 mL for the chin and 1 mL for the mandible) to provide optimal chin augmentation and mandibular contouring. The injection technique involved multiple (typically 8 to 10) passes of the cannula at each treatment site, with a small aliquot (~0.1 mL) of Restylane SubQ injected at each pass. No overcorrection with Restylane SubQ was applied. After injection, the treated area was massaged to give the desired aesthetic contour; this is particularly important in volume augmentation of the mandibular region. The treatment procedure is quick, lasting no more than 20 to 30 minutes, and is performed on an out-patient basis.

The initial 11 patients (3 men and 8 women), aged 26 to 56 years, treated by Dr. Belmontesi have undergone chin augmentation using the technique illustrated in Figure 4, *A*. The first 2 patients received 1 mL of Restylane SubQ on both sides of the chin; however, the subsequent 9 patients received 2 mL of Restylane SubQ on each side of the chin because this larger injection volume appeared to provide more satisfactory aesthetic correction. In all cases, treatment was confined to a single treatment session, and no touch-up injections were applied.

Patient-assessed evaluation of aesthetic outcome at 3 months after treatment with Restylane SubQ indicated that 5 patients were very much improved in appearance (1 patient had received 2 mL, and 4 patients had received 4 mL of product), whereas the remaining 3 patients were moderately improved (1 patient had received 2 mL and 2 patients had received 4 mL of product). Corresponding investigator-based evaluations at this time indicated that 6 patients were very much improved (1 patient had received 2 mL and 5 patients had received 4 mL of product), and the other 2 patients were moderately improved (1 patient had received 2 mL and 1 patient had received 4 mL of product). Observed adverse reactions appeared to be due to the injection procedure rather than to the product. These included local swelling, tenderness and redness (n = 3), bruising (n = 1), and moderate injection-site pain (n = 3). These reactions did not appear to be related to the injection volume and were generally transient, typically resolving within 4 to 8 days of Restylane SubQ treatment. No product mobility or migration, as evidenced by superficial nodularity, was noted in any patient.

Figure 5 depicts a representative case study that illustrates the aesthetic results obtained with Restylane SubQ in chin augmentation using the transdermal route of administration. The patient shown in Figure 5 is a 38-year-old woman who underwent an extended MACS lift, followed by rhinoplasty and a temporal brow lift. In conjunction with the MACS face lift procedure, chin augmentation was performed by injecting 2.0 mL of Restylane SubQ on both sides, using a lateral-to-medial tunneling technique. The volume augmentation was well maintained at 17 months posttreatment, and the implant remained stable and immobile.

Conclusion

Initial experience in transdermal injection of Restylane SubQ for augmentation of the cheek and chin suggests that the product is easy to administer via this route and that it provides a stable aesthetic result. Local adverse reactions are consistent with those expected of an alloplastic filler material and appear to be related to the injection procedure/site rather than to the product itself. In the event of overcorrection or the appearance of

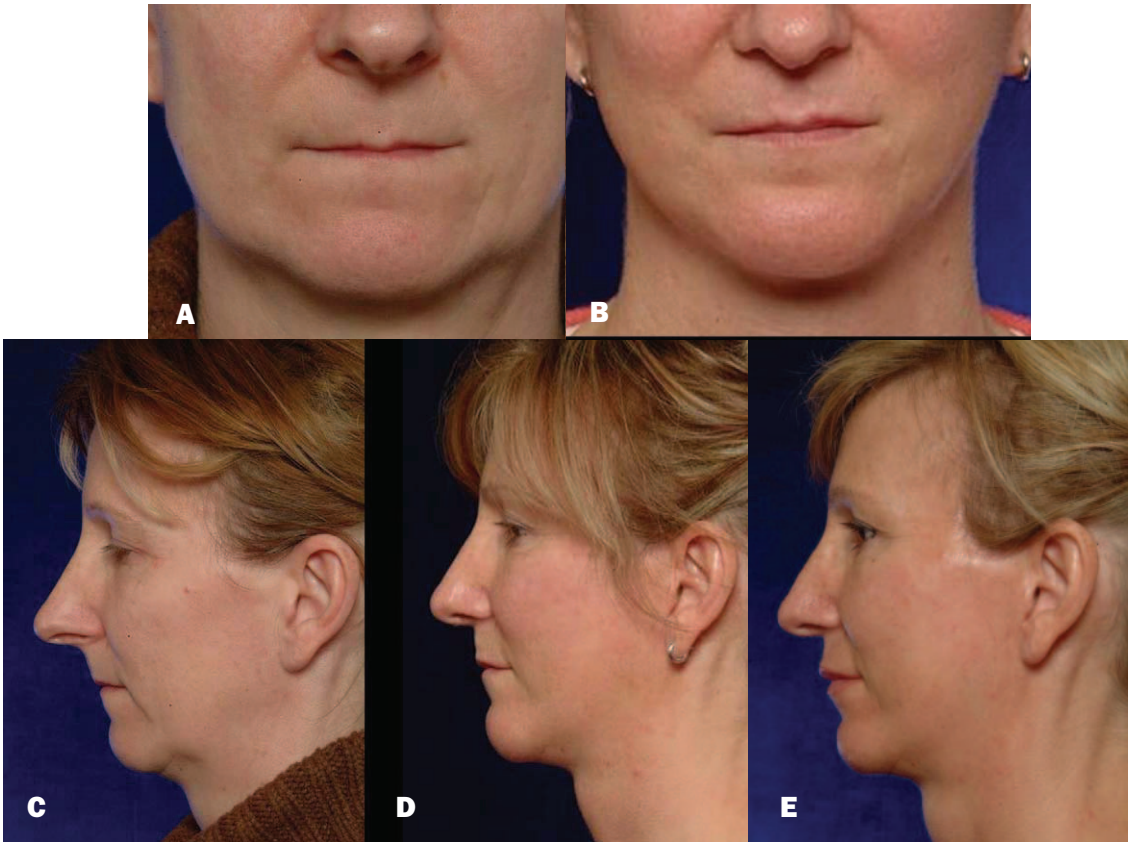

Figure 5. A, C, *Pretreatment views of a 38-year-old woman.* **B, D,** *Posttreatment views 6 months after receiving 2 mL of Restylane SubQ on both sides of the chin, using a medial-to-lateral tunneling technique. The patient also underwent an extended MACS lift, rhinoplasty, and a temporal brow lift.* **E,** *The volume augmentation was well maintained at 17 months postoperatively.*

superficial irregularities (nodules), any excess material can readily be removed by needle aspiration. Several measures can be taken to increase the likelihood of a satisfactory aesthetic outcome and minimize the risk of treatment complications with Restylane SubQ. Based on our initial findings, it is important that the product be deposited in small aliquots at multiple sites (using a multiple tunneling technique) to avoid pooling within the soft tissues. Treatment sites with poor soft tissue cover pose a challenge because of the high risk of surface irregularities. In cheek augmentation procedures, Restylane SubQ should be placed below the zygomatic arch, where the subcutaneous tissue is more fibrous and provides a barrier that reduces the risk of possible implant mobility. The chin appears to be particularly well suited to volume augmentation with Restylane SubQ because its dense fibrous tissue creates naturally occurring pockets for product placement.

In summary, transdermal administration of Restylane SubQ is a convenient, noninvasive procedure for chin and cheek contouring and for rejuvenation of the mid and lower face. ■

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Restylane SubQ is not approved for any use by the US Food and Drug Administration.

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