Injectable Hyaluronic Acid Implant for Malar and Mental Enhancement

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BACKGROUND The use of a thicker injectable implant version of one of the hyaluronic acid dermal fillers (Restylane SubQ, Q-Med, Uppsala, Sweden) is described.

OBJECTIVE A group of treated patients has been studied for more than 1 year. Restylane SubQ was injected to the submuscular plane of the upper cheeks and chin to observe efficacy of augmentation and side effect profile, and further observations were made of the duration of benefit.

METHODS Patient details—72 patients were treated, 68 for upper cheek augmentation, 2 for chin augmentation, and 2 for both areas. Four patients received second injections 8 weeks after the first to increase augmentation.

RESULTS Patients all showed a persistence of benefit during the posttreatment observation period of up to 64 weeks. Four patients had minor side effects that resolved with local treatment and time. Four patients had second injections to complete augmentation without complications.

CONCLUSIONS Restylane SubQ is a useful injectable agent to augment and lift upper cheeks and recontour chins. Further efficacy studies seem justified.

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Hyaluronic acid–based fillers have been utilized since approximately 1995 in Europe, and various modifications have subsequently taken place with some fillers.[1–5] Most uses of these fillers have been in the nasolabial lines, for lip augmentation and for treatment of atrophic scars, and some of the thinner, less viscous hyaluronic acid fillers have been utilized for the forehead, periorbital area, and glabelar lines.[1,2,4,5] Refinements to manufacturing and formulation of Restylane products in 2000 have led to a reduced incidence of delayed reactions.[1,4]

A recent development is a more viscous, longer-lasting version of Restylane termed Restylane SubQ (Q-Med, Uppsala, Sweden). The literature from the company shows that this contains 1,000 molecules per 1 mL compared to 10,000 molecules per 1 mL for Perlane (Q-Med) and 100,000 for Restylane. It is the larger molecular size that increases the thickness and viscosity of the SubQ compared to Perlane and Restylane. There is no difference in cross-linking.

We believe that this injectable device may have safety and delivery advantages over some alloplastic implants previously described.[6–11]

Methods and Patients

Patient details are presented in Table 1. Patients treated were those who requested augmentation of upper cheeks or who desired a change of chin contour. An inquiry was made on general medical conditions and ease of bruising. Medications such as aspirin and nonsteroidal anti-inflammatory agents were discontinued at least 5 days before the procedure.

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The injection procedure adopted was via a percutaneous route; 1% xylocaine and epinephrine anesthesia was injected to the upper cheeks with an infraorbital nerve block, via the buccal mucosa. This was followed by deep submuscular injection and superficial subdermal injections that gave complete anesthesia. A total of 6 mL anesthesia was used for both cheeks. Three milliliters of submuscular and subdermal were injected for mental SubQ.

Incision was by an 18-gauge No-Kor needle (NJL) or with the tip of a No. 11 Blade (RG) that was inserted through the skin and fascia approximately 2.5 cm anterior to the preauricular area immediately below the level of the lateral zygomatic bony prominence.

Minimal distortion occurred before local anesthesia injections; the patient was marked using appropriate skin markers to delineate the area of required augmentation before anesthesia. Photographs were taken both from the frontal, from the lateral-frontal, and from above the face looking vertically downward on both sides of the face (Figures 1–4A).

The Restylane SubQ was injected through a disposable blunt-ended trocar with its exit port on one side of the tip of the trocar (Canulle Fillin, Thieband, Thonon, France; size 18 gauge × 70 mm). The trocar was introduced to the furthest point of requirement of the filler in the submuscular plane and immediately above the periosteum below the zygomatic and over the maxillary bone. The Restylane SubQ was slowly injected with palpation by the other hand over the tip of the trocar. As the trocar was withdrawn, the material was deposited in the area required into the space created by the removal of the trocar. Between five and eight tunnels were made with deposition of Restylane SubQ on withdrawal per side when augmenting a cheek.

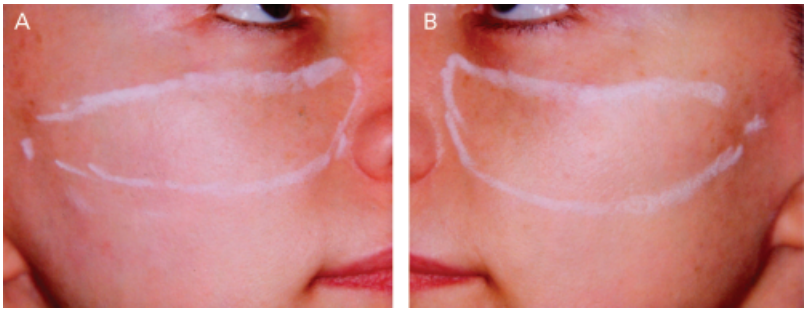

Figure 1. Showing a planned area outlined for introduction of the SubQ. A stab incision is made on the lateral cheeks (see marked dots after 1% xylocaine and epinephrine local anesthesia is infiltrated). The blunt trocar is introduced and inserted below the muscle and close to the maxillary bone below the zygoma. The SubQ is deposited in the submuscular plane as the syringe and trocar are slowly removed.

Following this, external molding of the material was achieved by hand massage. On removal of the trocar, the entry areas were cleaned and local pressure was applied for hemostasis. Following hemostasis, they were sprayed

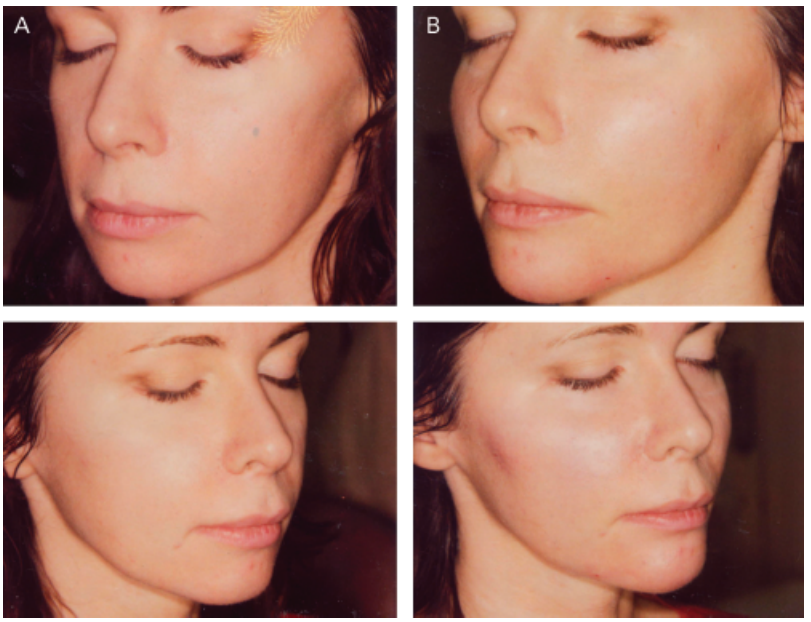

Figure 2. Traverse angled photographs before (A) and after (B) maxillary SubQ. A more rounded contour can be seen.

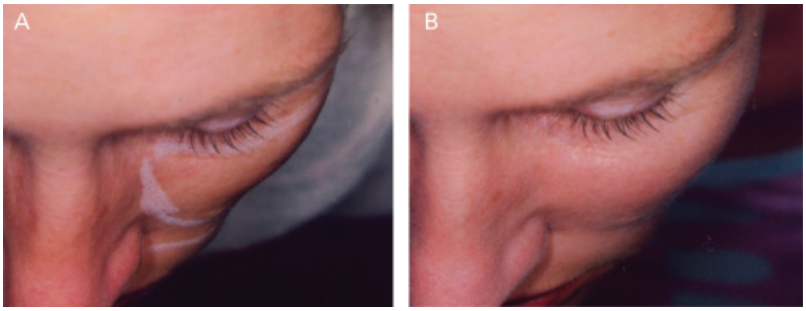

Figure 3. Vertical views from above showing improved and fuller cheek contours before (A) and after (B) administration of 2 mL Restylane SubQ.

with a plastic waterproof dressing (Opsite, Smith & Nephew, Hull, England). No sutures were required using the NoKor needle for incision.

Results

The patients and injectors observed augmentation of the areas injected. On subsequent clinic visits, patients were asked whether they felt they had sufficient or insufficient augmentation. Six patients decided to have further augmentation, where between 1 and 2 mL of further material was injected in the same location as the first implant.

All injected patients were satisfied with the procedure. Injectors graded the results as good improvement in all cases. Four patients requested additional filler to the malar areas which was given 8 weeks after first injection with no problems observed.

Duration

Duration of improvement remained for the time of observation of this preliminary treatment study, i.e., up to 64 weeks. The authors anticipate continued persistence for varied times among the treated patients and see no reason to not re-treat.

Side Effects

Transient bruising and swelling occurred in 15% of patients (Table 2). There was little discomfort following the procedure, and any swelling and bruising resolved over a 7-day period. This treatment is technique-dependent, and minimum side effects have been observed by following a consistent deep submuscular injection detailed in this article.

Four patients developed minor side effects. One had a small-volume local extrusion of material at the medial aspect of one cheek. This was successfully incised, and a small volume of SubQ from the subdermal space was removed via a small (2-mm) incision made by a NoKor needle (Figure 4B). This was approximately 3 months after implantation. Another patient noted some mobility of the implant which gradually resolved with massage and time. Two other patients developed transient hematoma which resolved without complications.

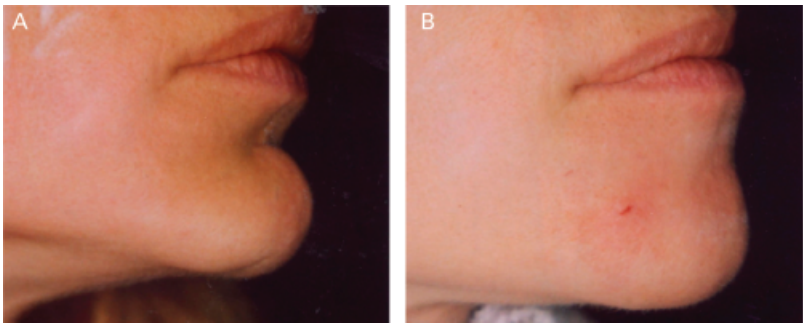

Figure 4. Views before (A) and after (B) placement of 1 mL of SubQ to the middle chin area to reduce the pretreatment "bulbous" chin appearance by injections of SubQ below the muscle layer immediately above mentalis.

Discussion

A variety of alloplastic implants have been used for enhancing the malar and mental facial zones.[6–11] These implants have been of a variety of materials including silicone rubber[9,10] and Silastic (Dow Corning, Midland, MI) material.[11] There have been a variety of techniques used including a transbuccal approach. Some of these solid implants have also been noted to lead to underlying bone resorption.[6]

The use of this more viscous injectable implant has proved to be successful in the patients treated,

TABLE 1. Details of Patients Treated with Restylane SubQ to the Malar and Mental Facial Zones

Gender	*Mean Age (Years)*	*Sites Injected**	*Volume Injected (Mean)*	*Posttreatment Observation Times*
69 female 3 male	43.50	Malar 66 Mental 8	3.9 mL	4–64 weeks

*Two patients had both malar and mental zones injected.

leading to enhancement of the upper cheek with secondary lifting and elevation of parts of the lower face. These features can be observed in Figures 2 and 3A for the cheeks and Figures 4A and 4B for the chin. SubQ has specific use as a deep submuscular level filler in contrast to Perlane, which is optimally at a deep dermal level.

The use of Restylane and Restylane Perlane since 2000 has been associated with very few (less than 1:2,000) delayed reactions.[1,4] The authors are hopeful this will also be the case with SubQ.

Other potential complications not seen in this series of patients might include injury to nerve and vessels, persistent swelling, hematoma formation with possible seroma, and misplacement of the injectable material. No immediate or delayed allergic reations were observed in this group of patients.

The authors anticipate a very low rate of allergy based on experiences with Restylane and Perlane.[5] One minor extrusion was seen in one patient, probably because the injection became too superficial at the medial cheek during injections. The injections were made into a defined area of the upper cheek, with the upper limit being the zygoma (Figure 1).

Other practitioners have suggested that a transbuccal route of injection as an alternative to the transcutaneous route, with injection through the sulcus of the upper buccal mucosa.[6] This has been used to inject silicone and place solid implants, but further experience is needed to determine whether this has advantages over the percutaneous route described in our patients.

In summary, Restylane SubQ is an effective injectable implant that can be used on the upper cheeks, resulting in some lifting of the lateral face. It is also proved useful in remodeling of some chin abnormalities by injection under the mentalis muscle. Further studies are suggested to examine different areas of treatment and to follow more patients for a longer time period to observe duration and effects of repeat treatments.

TABLE 2. Side Effects of Restylane SubQ in 72 patients

Side Effect	*Early (3 Days)*	*Delayed (8 Weeks)*	*Outcomes*
Hematoma	3	—	Resolved, no treatment
Swelling	4	—	Resolved, no treatment
Migration and swelling	—	2	1 incised and raised, 1 resolved with massage

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COMMENTARY

Restylane SubQ is the most robust of the Q-Med products. The particle size is close to double that of Perlane, and initially it was suggested to be used subcutaneously or supraperiosteally. In the initial studies performed by Q-Med, even though the study was 12 months in length, at 3 months, 46% of patients were merely somewhat improved or worse, with 64% better or significantly improved. According to Brian M. Kinney, a Clinical Professor of Plastic Surgery at USC and UCLA Schools of Medicine, the effects of Restylane SubQ last twice as long as collagen, usually 6 months. "Initially," he says, "there were really enthusiastic results from Europe indicating that it lasted nine months or more, but now the expectations are less optimistic than the expected duration of one year." Dr. Haneef Alibhai, the medical director of MD Cosmetic Laser Clinic in Abbotsford, BC, Canada, who has been using it for more than 5 years and has conducted training of physicians for 2 years, confirms that the effects last "at least six months," although there may be isolated patients in whom the results may last longer. This is very difficult to believe in that the SubQ product has only been here for 2 years (e-online journal April 2006).

So why the variation in response? The critical factor appears to be site of implantation. Duration of effect appeared to be longest when the product was placed superperiosteally. Those physicians who placed the product in the subcutaneous space (fat) did not see the 1-year or greater improvement seen in the ongoing clinical trials in Canada. This would be consistent with the late Dr. Sam Stegman's observations with bovine collagen. As it descended to a lower plane it lost its ability to correct. Thus, by putting a temporary agent close to the bone, it will have a greater longevity. On the other hand it could be the metabolic activity of the subcutaneous space. As per anesthesia and placement, I would prefer a block rather than the 4 to 6 mL used by the authors in that distortion might result. Additionally, when augmenting the cheek, I stay over the zygoma rather than placing material in the lateral face. Furthermore, the addition of botulinum toxin at the sites of implantation could certainly prolong the results. Indeed, this is an exciting time in minimally invasive aesthetics, and I will best be able to talk about Restylane SubQ when I get my hands on it.

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