

# Calcium Hydroxylapatite for Augmentation of the Posterior Mandibular Angle in Men

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Since its introduction, clinical literature is already replete with studies of calcium hydroxylapatite (CaHA). With the exception of a few articles on lipoatrophy, however, the vast majority of the studies have been conducted on women. In this article, the author reports his findings on the open-label protocol use of CaHA in male participants who were seeking a more prominent jawline. These men received injections of CaHA in the area of the posterior mandibular angle. Treatment results described herein were quite satisfactory, both to the participants and to the physician-investigator.

Ever since its approval for facial use in late 2006, Radiesse dermal filler (RDF), which contains calcium hydroxylapatite (CaHA), has become an integral component of treatment regimens for many aesthetic physicians. Although there are some exceptions, the use of RDF in the face has typically been associated with treatment in female populations. Published studies on areas of treatment have included the nose; the cheeks and submalar space in the midface; and the nasolabial folds, marionette lines, and prejowl sulcus in the lower third of the face.<sup>1-5</sup> Populations in these studies have been overwhelmingly female and are likely representative of the populations seen in clinical practice.

In contrast to areas of treatment for women, large scale studies of dermal fillers in men have tended to cluster around treatments associated with facial lipoatrophy.<sup>6-8</sup> In this study with male participants, lipoatrophy was not an overt consideration. Instead, the author was curious

about the use of RDF for augmentation of the posterior mandibular angle. The objective of this open-label protocol study was to assess the effectiveness of RDF for augmenting the posterior mandibular angle in men seeking a more prominent jawline, the presence of which is seen by many men as masculine and cosmetically appealing.

## METHODS AND MATERIALS

### Participant Population

Male participants were assessed for inclusion in the study using the following criteria: a desire for a more pronounced or square jawline (mandible); met the study criteria in the judgment of the physician study director; were aged 18 to 53 years; signed a written informed consent; understood and accepted the obligation not to receive any other facial procedures throughout the 6-month follow-up; and understood and accepted the obligation and was logistically able to present for all scheduled follow-up visits.

Of the 25 participants initially considered, 21 male participants enrolled in the study. One participant was subsequently withdrawn prior to initial injection. Another participant was lost to follow-up after the initial injection, leaving 19 participants for a 6-month evaluation. Age range of the participants was 27 years to 53 years, with a median age of 40.

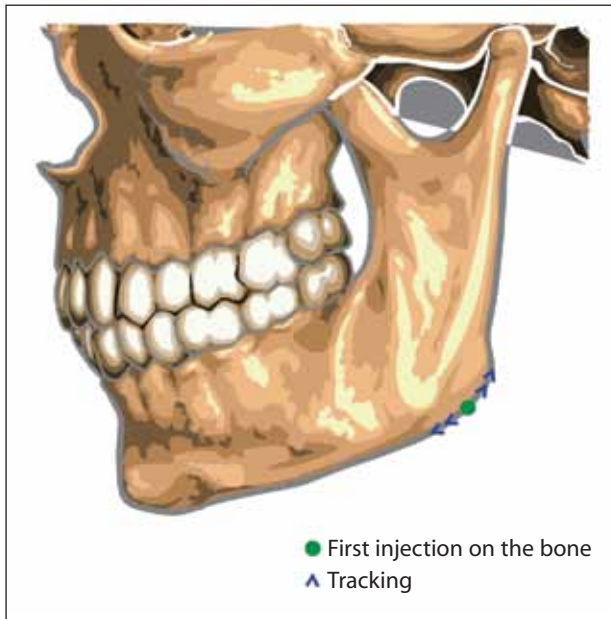
Exclusion criteria included known bleeding disorder, recent or anticipated antiplatelet therapy, anticoagulant

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**Figure 1.** Tracking method for injecting Radiesse into the deep dermis to supraperiosteum.

therapy, thrombolytic therapy, vitamin E intake, anti-inflammatory therapy, or all criteria combined. Other exclusion criteria included a recent history of systemic corticosteroid or anabolic steroid use; history of infection or inflammation; history of injection of collagen, hyaluronic acid, or CaHA within the mandible area; permanent implants within the mandible area; allergies manifested by anaphylaxis; any contraindications in RDF product labeling; any interfering study; any history of keloid formation or hypertrophic scarring; and treatment with any over-the-counter products for wrinkles 4 weeks prior to commencement of the study.

### Procedure

After being informed of the risks and benefits of the off-label procedure and signing the appropriate documents, 21 participants enrolled in the study. Standardized pretreatment photographs of the entire face (frontal and oblique views) were taken prior to the initial injection. Because the improvement seen following injection required an assessment of the participant's entire face, postinjection photographs of the entire area were also taken.

Anesthetization of the posterior mandibular area was performed at the discretion of the treating physician. The RDF was injected with a 1¼-in, 27-gauge needle into the deep dermis to supraperiosteum using the tracking method (Figure 1). Tracking was defined as depositing as many strands as necessary in a retrograde manner to provide optimal correction. Injection material was cross-hatched to provide a long-lasting effect and to ensure

even material placement. The injected volume of RDF sufficient for optimal augmentation was at the discretion of the treating physician. The distance from the inferior margin of the earlobe to the angle of the mandible was measured and marked with povidone-iodine on the first side to be treated. The same distance was targeted for treatment on the other side.

Injection was perpendicular to the angle of the jaw at a supraperiosteal depth, with injection continuing in a track as the needle was withdrawn to the lower dermis and then terminated. Subsequent injections were in the dermis, superiorly and inferiorly to the original injection, to gradually create a contoured mound of dermal filler, rather than a stark bolus of product protruding from the angle of the jaw.

Postinjection, patients were informed that they should minimize exposure of the treated area to excessive sun, UV lamps, extreme heat or cold, significant movement or massage, and application of makeup until initial swelling and redness resolved.

### Follow-up Visits

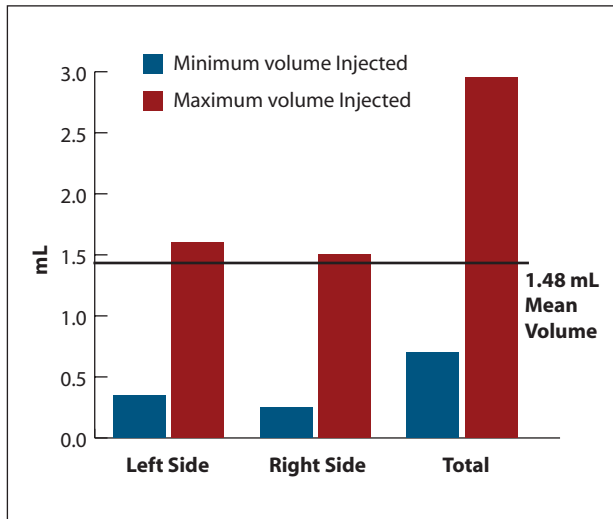
At the 1-, 3-, and 6-month follow-up from initial injection, all participants returned for an evaluation. During each follow-up, the participant was evaluated by self-assessment and by the treating physician. At each visit, the Global Aesthetic Improvement Scale<sup>9</sup> (GAIS) and participant assessment ratings were made. Photographs of participants' upper faces were taken using the same photography procedure deployed for enrollment photographs. If a participant desired a touch-up, RDF could be administered into the mandible area at 1 month, 6 months, or both. Prior to touch-up in either time point, however, photographs of the participants' faces were taken using the same photographic procedure used for enrollment photographs. The participants' involvement in the study ended after the 6-month follow-up.

### Effectiveness

Effectiveness was determined by GAIS and patient assessment ratings at 1, 3, and 6 months from initial CaHA injection. These ratings were conducted live by the physician-investigator, using the participants' baseline photographs as a comparison.

### Participant Self-assessment

Participant self-assessment included statements used in other cosmetic facial procedures,<sup>10</sup> which, when extrapolated, connote a range of sentiments from unsatisfied to neutral and satisfied to very satisfied. These included statements regarding participants' feelings on whether they looked less, the same, or greater than their ages.



**Figure 2.** Volumes of Radiesse initially injected into the left and right sides of male participants for augmentation of the posterior mandibular angle.

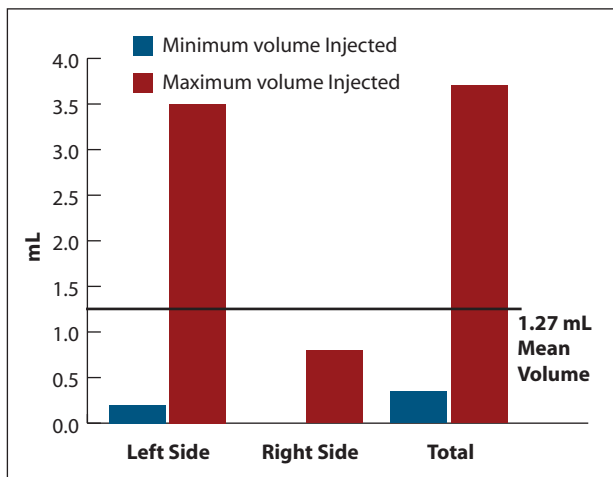
**Safety**

Adverse events were recorded for all participants at all time points. Safety was assessed by the recording of all adverse events, including any or all at the local implant site, observed for all participants from initial injection through 6-month follow-up.

**RESULTS**

**Volumes Injected**

Volumes injected initially and then at 1 and 6 months were tabulated by injected side, total volume, and mean volume. At the initial injection session, 20 participants received RDF in the mandible. In the left side, volumes ranged from 0.35 mL to 1.6 mL. In the right side,



**Figure 3.** Volumes of Radiesse injected at 1-month follow-up into the left and right sides of male participants for augmentation of the posterior mandibular angle.

volumes ranged from 0.25 mL to 1.5 mL (Figure 2). Total volumes ranged from 0.7 mL to 2.95 mL, with a mean volume of 1.48 mL.

At 1-month follow-up, 12 participants received RDF in the mandible; 7 participants did not receive any additional RDF at 1-month follow-up (1 patient was lost to follow-up before the 1-month visit). In the left side, volumes ranged from 0.2 mL to 3.5 mL. In the right side, volumes ranged from 0 mL to 0.8 mL (Figure 3). Total volumes injected in the 12 participants ranged from 0.35 mL to 3.7 mL, with a mean volume of 1.27 mL.

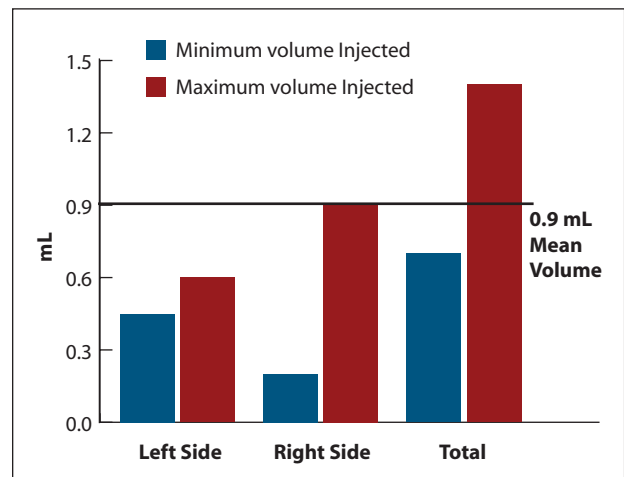
At 6-month follow-up, 6 participants received additional RDF in the mandible; 13 participants did not receive any additional RDF at 6-month follow-up. In the left side, volumes ranged from 0.45 mL to 0.6 mL. In the right side, volumes ranged from 0.2 mL to 0.9 mL (Figure 4). Total volumes injected in the 6 participants ranged from 0.7 mL to 1.4 mL, with a mean volume of 0.9 mL.

**Physician-Investigator Assessment**

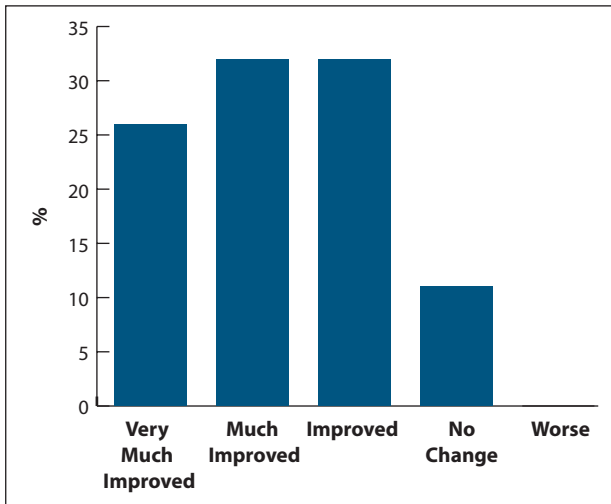
Using the GAIS options of very much improved, much improved, improved, no change, and worse, the physician-investigator examined the 19 participants at each time point. At 6 months, 5 of the participants (26%) remained very much improved; 6 of the participants (32%) remained much improved; 6 of the participants (32%) remained improved; and 2 of the participants (11%) were evaluated as no change by the physician-investigator (Figure 5).

**Patient Self-assessment**

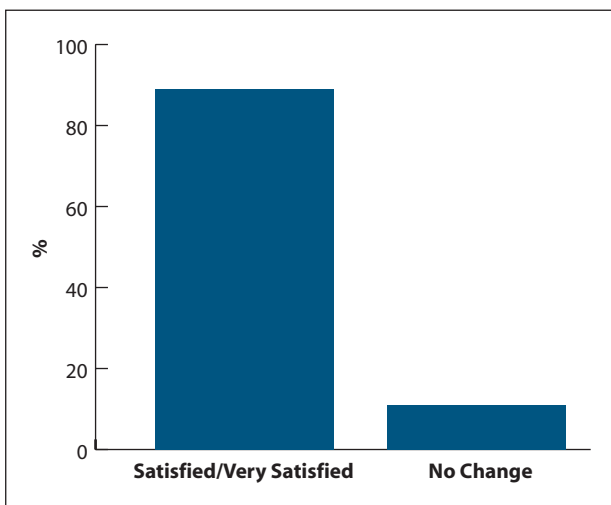
Using a series of statements about perception of change, 17 of the 19 participants (89%) rated their level of contentment as satisfied/very satisfied. The same 2 participants (11%) who were rated as no change by the



**Figure 4.** Volumes of Radiesse injected at 6-month follow-up into the left and right sides of male participants for augmentation of the posterior mandibular angle.



**Figure 5.** Physician-investigator assessment of male participants who received Radiesse for augmentation of the posterior mandibular angle.



**Figure 6.** Participants' self-assessment of their level of satisfaction with Radiesse for augmentation of the posterior mandibular angle.

physician-investigator also rated their improvement as no change (Figure 6).

Figures 7 and 8 are representative results of the participants treated for augmentation of the posterior mandibular angle. In Figure 7, the 53-year-old participant rated as very much improved by the physician-investigator, received a total of 2.3 mL of RDF. Of this amount, 1.1 mL was in the right posterior mandible and 1.2 mL was in the left posterior mandible. In Figure 8, the 47-year-old participant rated as very much improved by the physician-investigator received a total of 1.5 mL of RDF. Of this amount, 0.7 mL was in the right posterior mandible and 0.8 mL was in the left posterior mandible. Neither participant received any additional RDF at the 1- or 6-month follow-up.



**Figure 7.** A 53-year-old male participant before (A), 1-month post-injection (B), and 6-months postinjection with a total of 2.3 mL of Radiesse for augmentation of the posterior mandibular angle (C).

## DISCUSSION

Calcium hydroxylapatite, a key component of RDF, has specific properties that make it the ideal dermal filler for certain regions of the midface and lower face. In particular, its pliability allows physicians to inject it with confidence because it can be massaged across a fairly large area. Additionally, the microspheres of CaHA and gel carrier support a firm platform for contouring over bone. While earlier studies have detailed the success of RDF in prejowl sulcus, marionette lines, and other areas of the lower face, this study of the lower face using RDF is the first to be seen in healthy male participants. A few other studies of RDF in men have described its use in





**Figure 8.** A 47-year-old male participant before (A), 1-month post-injection (B), and 6-months postinjection with a total of 1.5 mL of Radiesse for augmentation of the posterior mandibular angle (C).

treatment of facial lipoatrophy. The men in this study sought augmentation of their jawline so that it would be more masculine and aesthetically appealing. The author believes that the results reported here provide ample evidence of the applicability of RDF in treating the male jawline and looks forward to reading other studies on the use of RDF in men.

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