Nonsurgical Injection Rhinoplasty With Calcium Hydroxylapatite in a Carrier Gel (Radiesse): A 4-Year, Retrospective, Clinical Review

Alexander Rivkin, MD; Peyman Soliemanzadeh, MD

The field of facial plastic surgery is experiencing explosive growth in noninvasive and minimally invasive procedures. We describe our experience with a new nonsurgical treatment using calcium hydroxylapatite (CaHA; Radiesse dermal filler [RDF]) injected off label for correction of mild to moderate cosmetic irregularities in patients who do not want to undergo surgical rhinoplasty.

This was a 4-year, retrospective, clinical review of a large sequential series of nonsurgical rhinoplasty patients (385) treated in a private practice setting. The charts of all patients who underwent the nonsurgical rhinoplasty procedure were reviewed. Patients' records of outcomes and adverse events were independently reviewed by a nonblinded observer. Primary outcome measures included recovery time, duration of correction, adverse occurrences, and need for repeat treatment.

Of the 385 patients, follow-up data were available for 295. Of these, 136 patients (46%) had some resorption requiring touch-ups more than 2 months after their initial procedure. Eighty-two patients (28%) had partial resorption requiring touch-ups between 2 and 6 months after their initial procedure; another 54 (18%) patients had touch-ups after 6 months and before 1 year. Prolonged erythema was the only complication, except for 2 patients with partial skin necrosis. Incidence of erythema was higher in patients with previous surgical rhinoplasty history.

We have found that injecting the semipermanent filler RDF can result in relatively safe correction of patients' aesthetic deficiencies. However, the RDF did not last as long as expected, and the need for touch-ups was more frequent than expected.

Dr. Rivkin is in private practice, Los Angeles, California. Dr. Soliemanzadeh is Codirector, Profiles Surgery Center, Los Angeles, California.

Dr. Rivkin is a member of the medical education faculty for Bio-Form Medical and has received compensation for presentations about Radiesse within the medical community.

Correspondence: Alexander Rivkin, MD, 1033 Gayley Ave, Ste 104, Los Angeles, CA, 90024 (arivkin@westsidemedicalspa.com).

Dermal fillers have brought about a revolution in the fields of cosmetic dermatology and plastic surgery. Originally approved by the US Food and Drug Administration for filling nasolabial folds, injectable fillers are increasingly being used to achieve a younger, more symmetric appearance not just by filling in wrinkles but also by restoring lost volume. As a result, we are seeing these fillers used for an array of procedures, including

reshaping the jawline and chin, filling the cheeks, and, most recently, reshaping the nose.[1-5]

The attraction of minimally invasive approaches to facial aesthetics is partially a function of today's demographics. Increasingly, patients who do not have the time or resources for postsurgical recovery are seeking alternatives to surgery as they look for the aesthetic improvement they desire. While surgical rhinoplasty is the gold standard for achieving long-lasting aesthetic changes in the nose, the procedure is out of reach for many patients due to the considerable financial cost and associated recovery time. Many patients considering primary improvements are young and either cannot afford the cost of surgery or are simply unwilling to bear the risks involved with general anesthesia. Moreover, some patients who have previously undergone rhinoplasty with less than satisfactory results are apprehensive to undergo another round of surgery due to financial considerations, pain suffered, fear of further surgery, anesthesia, and/or failed expectations.

Since 2003, the lead author, Alexander Rivkin, MD, has had the opportunity to perform over 1000 nonsurgical injection rhinoplasty (NIR) procedures using calcium hydroxylapatite (CaHA; Radiesse dermal filler [RDF]). The filler is injected into the deep supraperiosteal/supraperichondreal layer of the nasal skin to correct mild to moderate cosmetic irregularities. This paper describes a significant case series with this NIR technique and includes details of injection technique, outcomes, and complications using RDF.

ELIGIBILITY AND PATIENT POPULATION

Eligibility Criteria

To be eligible for NIR treatment, the patient must have had an aesthetic nasal concern that could be addressed by injection rhinoplasty and have had either no functional nasal concerns or an understanding that the procedure does not address functional problems. Exclusion criteria included patients with (1) large noses that require reduction surgery; (2) very ptotic nasal tips; (3) a high radix with a dorsal hump; or (4) a twisted nose, which, if injected, would result in an overly wide dorsum. Patients with previous rhinoplasty or with silicone or other alloplastic nasal implants were not excluded.

Patient Population

This retrospective, clinical review examines all patients treated from November 2003 through April 2007 with NIR by a single physician, Alexander Rivkin, MD, in a private practice setting in Los Angeles, California. Of the 385 patients treated, the age range was 12 to 88 years, with 41% aged 21 to 30 years and 29% aged 31 to 40 years. Twenty-one percent of patients were male and 79% were female. Two hundred thirty-seven (62%) patients had no previous rhinoplasty history, 121 (31%) patients had undergone surgical rhinoplasty at some point prior to receiving the injection rhinoplasty procedure, and no information on previous rhinoplasty was available for 27 patients (7.0%).

The patients in the review were ethnically diverse: 52% classified themselves as white, 19% Asian, 16% Hispanic, 6% African American, 5% Middle Eastern, and 2% Southeast Asian (Figure 1). Cosmetic concerns among patients of various ethnicities closely paralleled the concerns of patients desiring surgical rhinoplasty. Asians tended to want maximal bridge height augmentation from the radix down the length of the dorsum; they also tended to want better tip definition. For white individuals with no previous rhinoplasty, the predominant request was for camouflage of a dorsal hump. In those who had undergone rhinoplasty, requests were for minor corrections of asymmetry, dorsal augmentation for saddle nose deformities, and augmentation and camouflage in the middle vault due to upper lateral cartilage collapse. These patients were instructed that the filler would only camouflage the defect and would not help with any nasal obstruction. African Americans, like Asians, wanted bridge augmentation, whereas Hispanic Americans generally presented for correction of a droopy nasal tip or a dorsal bump.

In keeping with the Department of Health and Human Services Regulations for the Protection of Human Subjects, all patients (and their parents if under 18) were fully counseled during the informed consent process about the risks and benefits of RDF, as well as the off-label nature of this treatment. Specifically, the investigator reviewed risks including, but not exclusive of, immediate or prolonged erythema, bruising or hematoma, acute and

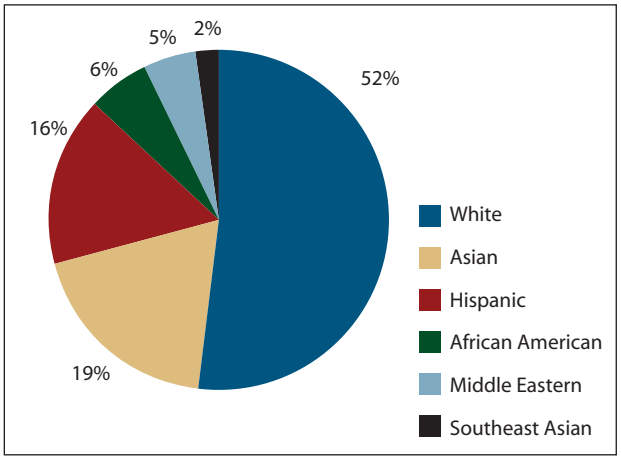

Figure 1. Breakdown of patients receiving injection rhinoplasty by ethnicity.

chronic infection, nasal skin irregularities, skin slough, and poor cosmetic result.

TREATMENT

Standard preprocedure photographs were taken in frontal and both profile views. The procedure was performed in a designated injection room with the patient sitting upright. The patient's nasal skin was cleansed with alcohol and a topical triple anesthetic cream was applied. If RDF injection was to be performed on the nasal tip, a superior alveolar nerve block was placed using bupivacaine along the gumline. Immediately prior to injection, the area was iced for 1 minute to mitigate bruising.

Injections with RDF were administered using the standard, sterile, prefilled 1.3-mL syringes, with a 27-gauge, ½-in needle. Injection points were chosen based on the irregularity to be corrected. The RDF was delivered by entering into the skin deeply until bone or cartilage was palpated and then withdrawing slightly so as to be in a supraperiosteal/supraperichondreal layer. After injection, the product was gently massaged and molded into place. Along the dorsum and sidewall, a standard retrograde injection technique was performed; no bolus injections in the dorsum were permitted. In the tip, when refinement was needed, a small bolus was placed at the tip-defining points. Undercorrection was always preferred to overcorrection.

Radiesse dermal filler has a malleable consistency. Firm pressure in one or another direction causes the filler to shift in that direction. This malleability allowed the investigator to adjust the position of the filler material postinjection and make sure that the contour was smooth.

Postprocedure, patients were encouraged to use ice and *Arnica montana*. They were also instructed not to wear sunglasses for 10 days to allow time for the material to settle. Postprocedure pain was controlled with acetaminophen. Ibuprofen and aspirin were discouraged for several days after the procedure to reduce bruising tendencies. No other restrictions were given.

POSTTREATMENT

Patients were instructed to follow up 2 weeks after the procedure at which time a touch-up treatment was offered if needed. Further follow-up visits were encouraged as needed. Patients were informed at their initial procedure that all touch-ups within a 1-year time frame would be performed at no cost.

DATA COLLECTION

Primary outcome measures included duration of correction, adverse occurrences, and need for repeat treatment. Primary outcomes and adverse events were assessed and recorded at any time interval when patients came for follow-ups or touch-ups. For the purpose of this review, we defined any patient who presented for reinjection 2 months or more after the initial procedure as needing correction of partial resorption; those who presented within the initial 2 months following their procedure were defined as needing a touch-up for undercorrection. Patients failing to follow up were telephoned as part of the protocol in order to capture as much data as possible. Patients' records were independently reviewed by a nonblinded observer (Peyman Soliemanzadeh, MD) to record outcomes and adverse events.

RESULTS

A total of 385 patients were treated with the NIR procedure from November 2003 through April 2007. Two hundred ninety-five patients (77%) came back for a follow-up at some point.

Areas Treated

The problems addressed included dorsal humps and asymmetries, deficiencies of dorsal height and definition, sidewall asymmetries, tip ptosis or underprojection, tip and lateral alar asymmetries, and collapse in the scroll region in postrhinoplasty patients (Figures 2 and 3). In most patients, more than one area was treated (Figure 4). In total, there were 235 injections into the radix area, 229 injections into the tip area, 229 injections into the area of the dorsum, 92 injections into the sidewall, and 17 injections into the alar crease (to fill in postsurgical depressions in the scroll area). The most common treatment combination involved the radix, the dorsum, and the tip; 92 patients (25%) received this combination. Total amounts of RDF injected averaged approximately 0.3 to 0.5 mL, depending on the areas injected.

Touch-ups

Of the 295 patients, 129 (44%) had a touch-up within 2 months of the initial procedure, with the vast majority of these patients requiring touch-ups in the first weeks after the initial procedure due to undercorrection. One hundred thirty six patients (46%) had some resorption with touch-ups after the 2-month period. Of these, 82 (60%) patients had touch-ups between 2 and 6 months after their initial procedure; the remaining 54 (40%) patients had injections after 6 months and before 1 year.

Adverse Events

Investigators evaluated the incidence of complications in all follow-up patients by assigning them into 3 groups: no previous surgical rhinoplasty (group A), patients with previous surgical rhinoplasty (group B), and those whose

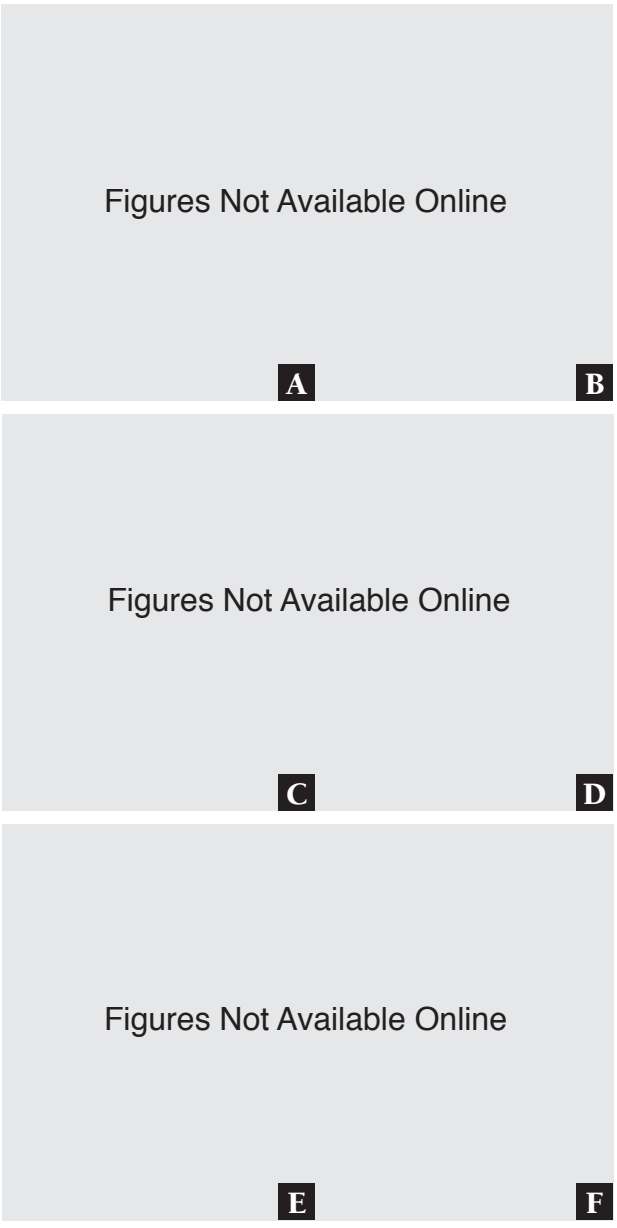

Figure 2. Male patient who received nonsurgical injection rhinoplasty in the radix, upper dorsum, and tip before (A,C,E) and after (B,D,F).

status preprocedure was unknown (group C; Figure 5). Adverse events (AE) in group A (237) included 2 telangiectasias; 6 sensitive tips; 12 prolonged swelling (defined as >2 weeks); 13 prolonged erythema (defined as >2 weeks); 4 bruises (relatively severe bruising >1 week and those with possible mini hematomas); 2 cellulitis; 1 skin necrosis; and 0 with visible skin irregularities. In group B (31), AEs included 3 telangiectasias, 3 sensitive tips, 6 prolonged swelling, 20 prolonged erythema, 3 bruises, 4 cellulitis, 1 skin necrosis, and 2 with visible skin irregularities/bumps. In group C (27), AEs included 2 telangiectasias and 1 prolonged swelling.

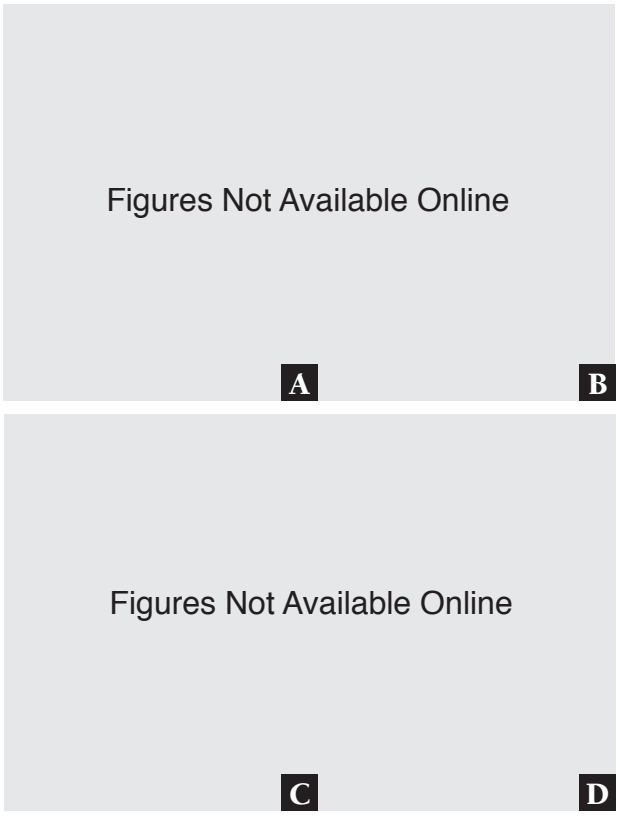

Figure 3. Female patient who received nonsurgical injection rhinoplasty in the radix and tip before (A,C) and after (B,D).

Of the patients with prolonged swelling, 14 required injection of triamcinolone for resolution. In 12 of 14 patients, only 1 injection of triamcinolone was needed for resolution. The other 2 patients needed 2 to 3 injections and took 1 to 2 months for complete resolution. There were 7 patients who had relatively severe bruising lasting more than a week. One out-of-state patient appeared on photographs to have suffered a hematoma due to the nature of the bruising and swelling; she did not return for proper evaluation to confirm this. There were 6 patients who had cellulitis, requiring a 10-day course of antibiotics (generally levofloxacin) for resolution.

In 1 patient with several previous surgical rhinoplasty procedures that had resulted in an overshortened nose with a hanging columella and notched ala, RDF was placed in the infratip lobule to improve the profile, and initial results were good. Unfortunately, more RDF was placed into the area 2 weeks later in an attempt to improve on the result. Some transient blanching of the skin was observed, but it seemed to normalize within 1 minute. In the subsequent few days, the patient developed skin necrosis and cellulitis in the tip area that took a few weeks to resolve with antibiotics and topical care. The patient was ultimately left with a small depressed scar in the necrotic region of the nasal tip. One other

patient suffered skin necrosis arising from cellulitis; the necrosis resolved on antibiotics with conservative management and little visible consequences.

DISCUSSION

For injection rhinoplasty, the issue of safety is still unclear, especially long term since this is the first large cohort review of the procedure. Our study shows that in nearly 300 patients with a desire for nasal contour changes, NIR with the semipermanent RDF filler caused relatively few complications. To our surprise, a history of previous rhinoplasty did not significantly predispose our patients to a higher rate of complications. The exception was that post-rhinoplasty patients tended to have more prolonged erythema. Perhaps patients who have had previous rhinoplasty have already experienced some damage to the overlying skin soft tissue envelope and to the lymphatic drainage system. As a result, there may be an increase in the time necessary to resolve the usual postinjection inflammatory response.

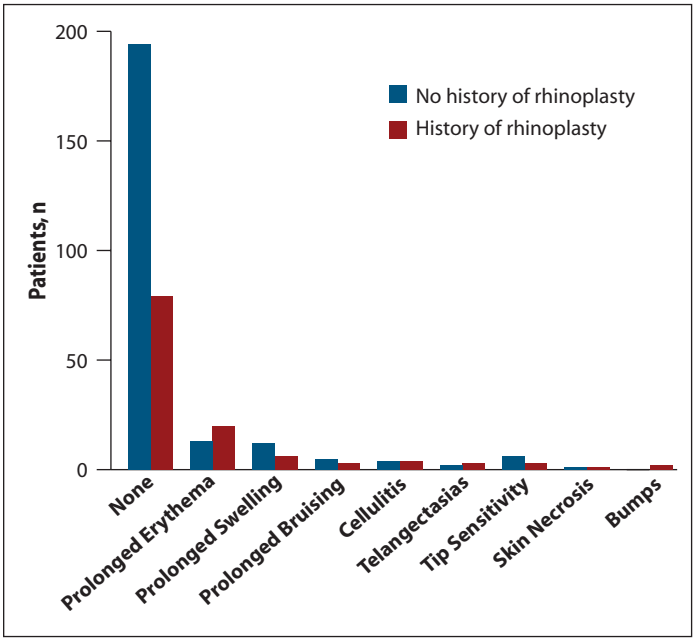

Figure 5. Breakdown of patients' history of rhinoplasty.

Patient selection and an understanding of the limitations of NIR are both critical aspects of this procedure. Any physician performing injection rhinoplasty needs to understand which patients can undergo this procedure and which should undergo surgery. Some examples include large dorsal humps that need to be reduced, not camouflaged. Tip ptosis, functional problems, and all but minimal tip asymmetries can only be addressed surgically.

We acknowledge that one possible weakness of this study, as with many retrospective reviews, is that a significant number of patients (23%) could not be reached for a follow-up. However, based upon the large number of patients for whom we have follow-up data, we have found that using a technique of injecting the semipermanent filler deep into the supraperichondreal/supraperiosteal layers results in relatively safe correction of their aesthetic deficiencies. We were, however, surprised that the RDF did not last as long as expected and the need for touch-ups was more frequent than expected.

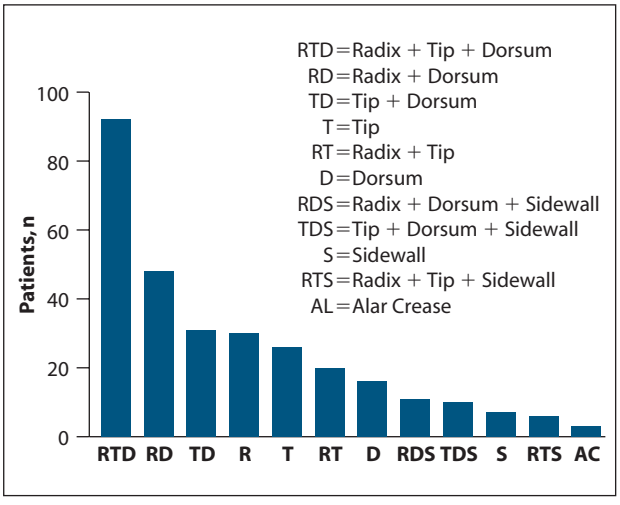

Figure 4. Breakdown of patients receiving nonsurgical injection rhinoplasty by combination areas of injection.

Outside of the relatively low occurrence of complications, the other major but surprising finding was how many patients needed touch-ups between 2 and 6 months after the procedure. In those presenting for touch-ups closer to the 1-year mark, there may have been some bias, since our protocol allowed for free touch-ups within the first year after treatment. Overall, we had expected that RDF would last significantly longer in the nasal bridge than hyaluronic acid (HA), especially since the nasal bridge is an area that experiences relatively little motion. Based on our results, we would advise doctors to inform their patients that resorption is variable and may occur, to some degree, relatively early after the procedure.

Nevertheless, we have always preferred to undercorrect rather than risk skin irregularities, pollybeak deformity, or other sequelae of overcorrection. We were cognizant that, with the right patient selection, any undercorrection could be addressed simply by placing more filler at a later date upon reevaluation. We found that those patients who did have overaugmentation, while few, were more problematic than those who simply needed a little touch-up due to undercorrection.

One key element regarding technique in NIR is that the person who performs the injection must be cautious

to inject deeply against the bone or cartilage and avoid injecting into the dermal layer, as this can permanently damage the skin envelope. A handful of patients manifested skin irregularities due to unduly superficial injection of the material. These patients, for the most part, had undergone previous surgical rhinoplasty and had thinner skin than was initially suspected.

Regarding the safety of this technique, more prospective studies with long-term follow-up are needed. We join the proponents for caution like Dean Toriumi, MD, and Russell Kridel, MD, who, as experts in revision rhinoplasty, see a disproportionate number of those cases where complications arose from injection rhinoplasty. It has been advocated that the use of a temporary HA filler is a reasonably safe option for individuals who have undergone previous nasal surgery because these materials are reversible with the use of hyaluronidase and resorb more rapidly.[6] Especially in the hands of physicians who are only starting to inject the nose, HA may be a better option.

That being said, the only real way to reduce complications is to make sure that physicians who are doing this procedure are well trained in the anatomy, aesthetics, and limitations of the technique. Surgeons experienced in facial aesthetics and nasal anatomy, regardless of the specialty, need to take the lead in studying, teaching, and performing this procedure in the appropriate patients. This procedure should not be one of the litany of procedures being performed by injectors with little experience in rhinoplasty or nasal filler injection.

CONCLUSION

Future studies would do well to evaluate long-term follow-up of filler injection into the skin of the nose to identify any potential delayed complications. Nasal injection of RDF by highly experienced physicians should be done very carefully during a couple of sessions to minimize the chances of overcorrection, asymmetry, or bumpiness. In addition, information on patient satisfaction would be highly useful for follow-up studies in this area, both short term and long term. We anecdotally note that most patients are satisfied with this procedure, but given the shorter than expected duration of effect, it would be interesting to note whether patients remain satisfied over time, or whether many eventually migrate to the surgical side of the equation.

As a final note, we would admonish physicians eager to inject the nose with semipermanent and permanent fillers that these fillers still have not been formally evaluated for their safety in the nose. Based on this study, carefully injected RDF appears safe, but more prospective studies are needed and long-term follow-up will be important. As responsible physicians, we should learn from past experiences and pay heed to the old proverb: The more one learns, the less one believes.

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