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ORIGINAL INVESTIGATION

Nonsurgical Rhinoplasty Using Injectable Fillers: A Safety Review of 2488 Procedures

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Abstract

Background: Injectable fillers are used worldwide to improve the appearance of the nose by nonsurgical methods. The procedure is not without risks, as blindness and skin necrosis have been reported as a consequence of filler injections in the nose.

Objective: To determine an overall adverse event (AE) rate for the nonsurgical rhinoplasty (NSR) procedure and to assess whether previous surgical rhinoplasty increases the odds of an AE.

Methods: A retrospective chart review of 2275 patients and 2488 NSR procedures for a 10-year period from a single physician injector was conducted.

Results: The overall procedural AE rate was 7.6%, with five cases (0.20%) considered serious (ischemia and necrosis). Previous surgical rhinoplasty patients had a greater AE rate (10.8%) than those patients without previous surgery (7.4%), with a significant odds ratio of 1.51 (95% confidence interval: 1.03–2.18); $p = 0.032$. Injecting the tip and sidewall of the nose had the highest AE rates for both categories of patients.

Conclusions: NSR is a relatively safe procedure with the majority of AEs common injection site reactions. Patients with previous surgical rhinoplasty demonstrated significantly increased odds of an AE potentially due to surgical changes in anatomy.

Introduction

Surgical rhinoplasty remains one of the most popular cosmetic procedures performed in the United States with ~219,000 performed in 2017.[1] As with any surgical procedure, patients undergoing rhinoplasty are subject to significant risks, recovery time, and expense. Until recently, patients who wanted to avoid surgery have not had a viable alternative to accomplish the cosmetic goals of rhinoplasty noninvasively. With the advent of long-lasting injectable fillers, however, physicians and patients have embraced a nonsurgical surrogate.

The attraction of minimally invasive approaches to aesthetics is a function of today's demographics. Patients are increasingly refusing to sacrifice the time and resources necessary for postsurgical recovery. They desire significant aesthetic improvement but are seeking alternatives to traditional surgery. Although surgical rhinoplasty is still the gold standard for achieving permanent changes, the cost, risk, and recovery time place it out of reach for many patients. Moreover, some patients who have previously undergone rhinoplasty with less-than-satisfactory results are apprehensive to undergo additional surgery due to financial considerations, pain, fear, anesthesia, and/or failed expectations.

The current publication documents one physician's experience with the safety of the nonsurgical rhinoplasty (NSR) procedure for a 10-year period consisting of 2275 patients and 2488 procedures using injectable fillers. In addition, this study sought to determine whether previous surgical rhinoplasty increased the potential of an adverse event (AE) with the NSR procedure.

Methods

Patient population

This retrospective chart review examined all patients treated for NSR from January 2006 to August 2016 in a private practice in Los Angeles, California. Eligible patients must have had an aesthetic nasal concern that could be addressed with injectable fillers. Patients also had either no functional nasal concerns or an understanding that the procedure would not address functional issues. Patients excluded from NSR were those with a

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KEY POINTS

Question: Does previous surgical rhinoplasty increase the adverse event (AE) rate of nonsurgical rhinoplasty with injectable fillers?

Findings: Patients who previously had a surgical rhinoplasty had a significantly increased rate of AEs (10.8%) compared with those patients without previous surgery (7.4%; $p=0.032$). Injecting the tip and sidewall of the nose had the highest AE rates for both categories of patients.

Meaning: Potential changes in anatomy from previous surgical rhinoplasty significantly increase the odds of an AE.

large nose that required reduction surgery, a very ptotic nasal tip that could not be adequately lifted with filler, a high radix with a dorsal hump that would result in an unnaturally high radix, or 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 treated.

The aesthetic concerns addressed by NSR included dorsal hump camouflage, augmentation of an underdeveloped dorsum, elevation and definition of a ptotic tip, correction of asymmetries, and post-rhinoplasty contour irregularities. Areas injected included the ala, alar groove, columella, dorsum, radix, sidewall, and tip (Supplementary Figs. S1 and S2). A variety of fillers were used, including calcium hydroxylapatite (CaHA; Radiesse®; Merz Aesthetics, Raleigh, NC), polymethyl methacrylate (PMMA; Bellafill®; Suneva Medical, San Diego, CA), large particle non-animal stabilized hyaluronic acid (NASHA; Restylane® Lyft; Galderma, Fort Worth, TX), HYC-24L+, and VYC-20L (Juvéderm® Ultra Plus and Juvéderm® Voluma, respectively; Allergan, Madison, NJ), combination VYC-20L and CaHA (VYC-20L+CaHA), as well as a small number of other combinations.

All patients (and their parents if <18 years) were fully counseled during the informed consent process about the risks and benefits of NSR, as well as the off-label nature of this treatment. Risks reviewed included immediate or prolonged erythema, edema, tenderness, bruising or hematoma, acute and chronic infection, nasal skin irregularities, skin slough, skin necrosis, poor cosmetic result, and potential visual impairments, including blindness. Any AE, including typical injection site reactions (i.e., erythema, edema, bruising, and tenderness), was documented by the injector assessing the patient immediately postprocedure or during live follow-up 1–2 weeks later.

Data were analyzed by number of procedures or areas injected, as patients may have undergone more than one procedure over the years, and each procedure may have had multiple areas injected. Qualitative variables were summarized using frequencies and percentages and compared using Fisher's exact test. Procedures without live investigator follow-up were excluded from analyses. For patients with unknown previous surgical rhinoplasty status, demographic data, their number of procedures, and AEs were included in calculation of the overall AE rate, but eliminated from analyses stratified by surgery.

Data were initially stratified by year to account for injector experience; however, since no differences in AE rates were noted across time, data were collapsed across years. Logistic regression, estimated odds ratio (OR), and its 95% confidence interval (CI) were used to report the association between AE and previous surgery. The association between AE and area, as well as the association between AE and type of filler, were examined in two separate multivariable logistic regressions while controlling for previous surgery and its interaction term. The tip and CaHA were used as the area and filler reference, respectively, since they were used in the greatest number of procedures.

All tests were two sided and p-value <0.05 was considered statistically significant. All statistical analyses were conducted using SAS statistical software version 9.4 (SAS Institute Inc., 2013).

Results

Of the 2275 patients treated, the age range was 12–78 years, with a mean of 34.4 years. The majority of patients were female ($n=1737$; 76.4%), with 23.6% ($n=538$) male. The patients were ethnically diverse and included Caucasian (47.7%), Asian (24.3%), Hispanic (16.9%), African American (3.1%), and Middle Eastern (8.0%). Most of the patients ($n=1774$; 78%) had not had previous surgical rhinoplasty, whereas 340 (14.9%) had undergone a previous surgical rhinoplasty. A total of 5327 areas were injected in 2488 NSR procedures consisting of 1923 (77.3%) procedures in the no surgery group and 400 (16%) procedures in the previous surgery group. Information regarding a previous surgical rhinoplasty was not documented in the patient's medical history or chart and, therefore, unknown for 161 (7.1%) patients with 165 (6.6%) procedures and 4 AEs of mild erythema.

AE rate and rates stratified by surgery

The AE incidence per procedure was 189/2488, for an overall AE rate of 7.6%. Previous rhinoplasty patients were significantly more likely to experience an AE with a rate of 10.8%, whereas the AE rate for the no previous surgery group was 7.4%, OR = 1.51 (CI: 1.03–2.18), $p=0.032$.

A total of 216 AEs occurred in 142 procedures in the group without previous surgery, with 58 AEs occurring in 43 procedures in the group with previous surgery. The vast majority of AEs were mild and transient (180,185, 97.3%), consisting of bruising, erythema, edema, tenderness, infection, and telangiectasia (Table 1). Five AEs were considered serious adverse events (SAEs; 0.2% of procedures), all consisting of ischemia leading to necrosis

Table 1. Type of adverse events per procedure for patients with and without previous surgical rhinoplasty

Adverse event	*No surgery,* n *(%)*	*Previous surgery,* n *(%)*
Erythema	142 (7.4)	38 (9.5)
Edema	28 (1.5)	5 (1.3)
Bruising	21 (1.1)	6 (1.5)
Ischemia	2 (0.1)	4 (1.0)
Telangiectasia	5 (0.3)	0 (0)
Lump/bump	10 (0.5)	1 (0.3)
Tenderness	6 (0.3)	3 (0.8)
Infection	2 (0.1)	1 (0.3)

in patients both with and without previous surgical rhinoplasty (Table 2; Fig. 1).

Areas treated and AE rate by area

The majority of procedures involved injections in more than one area (83%). The radix alone or in combination was the most frequently injected area, included in 77% of procedures, followed by the tip (70%), dorsum (60%), side wall (26%), ala (2%), and columella (<1%). The most popular procedure included injecting the dorsum, radix, and tip.

Area was significantly associated with AE rate ($p < 0.001$), but the interaction between area × surgery was not significant (Table 3). Both the tip (8%) and sidewall (7.3%) were significantly more likely to result in an AE compared with the AE rate of other areas (dorsum 4.2%, radix 3.2%, and ala 1.9%) regardless of previous surgery status ($p < 0.05$).

Fillers used and AE rate by filler

The volume of filler used depended on the number of areas treated, with 0.4 cc the most commonly used amount for three areas. CaHA alone or in combination was the most frequently used filler, accounting for 58.3% of all areas injected, followed by VYC-20L alone or in combination (19%), and PMMA (18.6%).

Owing to low number of procedures performed with HYC-24L+, Mixed, and NASHA, these fillers were combined into one category as ''Other'' ($n = 245$, 4.6%). Filler was significantly associated with AE and previous surgery status ($p = 0.010$; Table 4). Patients with previous surgery were twice as likely to experience an AE when injected with the VYC-20+CaHA combination compared with patients without previous surgery, OR = 2.28 (CI: 1.08–4.80), $p = 0.031$. Previous surgery patients also had 70% greater likelihood of an AE when injected with CaHA compared with patients without previous surgery, OR = 1.70 (CI: 1.13–2.54), $p = 0.010$. For patients injected with PMMA, the odds of an AE was 94% lower for previous surgery patients compared with no surgery patients OR = 0.06 (CI: 0.01–0.41), $p = 0.004$, as there was only one AE in the previous surgery group. The association between AE and surgery when Other or VYC-20L fillers were used was not significant, $p = 0.975$ and $p = 0.788$, respectively.

Table 2. Serious adverse events

Area injected	*Previous rhinoplasty*	*Filler used*	*Area of AE*
Sidewall, tip	Yes	VYC-20L + CaHA	Sidewall
Dorsum, tip	Yes	CaHA	Ala, sidewall, tip
Radix	No	PMMA	Glabella
Ala	Yes	CaHA	Ala
Dorsum, radix, tip	No	VYC-20L	Sidewall, tip

AE, adverse event; CaHA, calcium hydroxylapatite; PMMA, polymethyl methacrylate.

Discussion

This large retrospective chart review provides evidence that the NSR procedure is relatively safe with an overall AE rate of 7.6%. Previous surgical rhinoplasty significantly increased the odds of patients experiencing an AE by 51%. In addition, although the SAE rate per procedure was low (0.20%), all five cases necessitated multiple modalities and treatments for resolution.

The vast majority of AEs in the current series consisted of mild and transient injection site reactions typical after treatment with injectable fillers, including erythema, edema, bruising, and tenderness occurring within 2 weeks of treatment. In the author's experience, delayed onset AEs after NSR are very rare and were, therefore, not assessed in this review. Six cases of ischemia developed, most of which were noted immediately after injection as painless blanching that resolved with massage, aspirin, and application of warm compresses. Five other cases of ischemia progressing to necrosis developed after the patient left the office and were considered SAEs. These patients were treated with combinations of aspirin, nitropaste, hyaluronidase (used regardless of filler in an attempt to decrease tissue pressure and aid perfusion), oral steroids, antibiotics, and hyperbaric oxygen therapy.

In three of five patients with an SAE, the SAE occurred at a touch up visit after the patients requested additional filler for increased correction. The five SAEs resulted in contour and pigmentation irregularities, which completely resolved in one patient after 4 months, resolved in another patient after 3 years, two patients were left with residual contour irregularities at 10 months then lost to follow-up, and one patient was lost to follow-up.

Injecting the tip or sidewall had the highest AE rates across both patient types, with the highest AE rate for the tip in the previous surgery group (9.7%). Blood supply to the tip is known to be tenuous[2] and there is less potential space in the tip between the skin and cartilage compared with the rest of nose. These two characteristics may set up the potential of a compartment effect with an over-injection of filler. In the author's opinion, the two

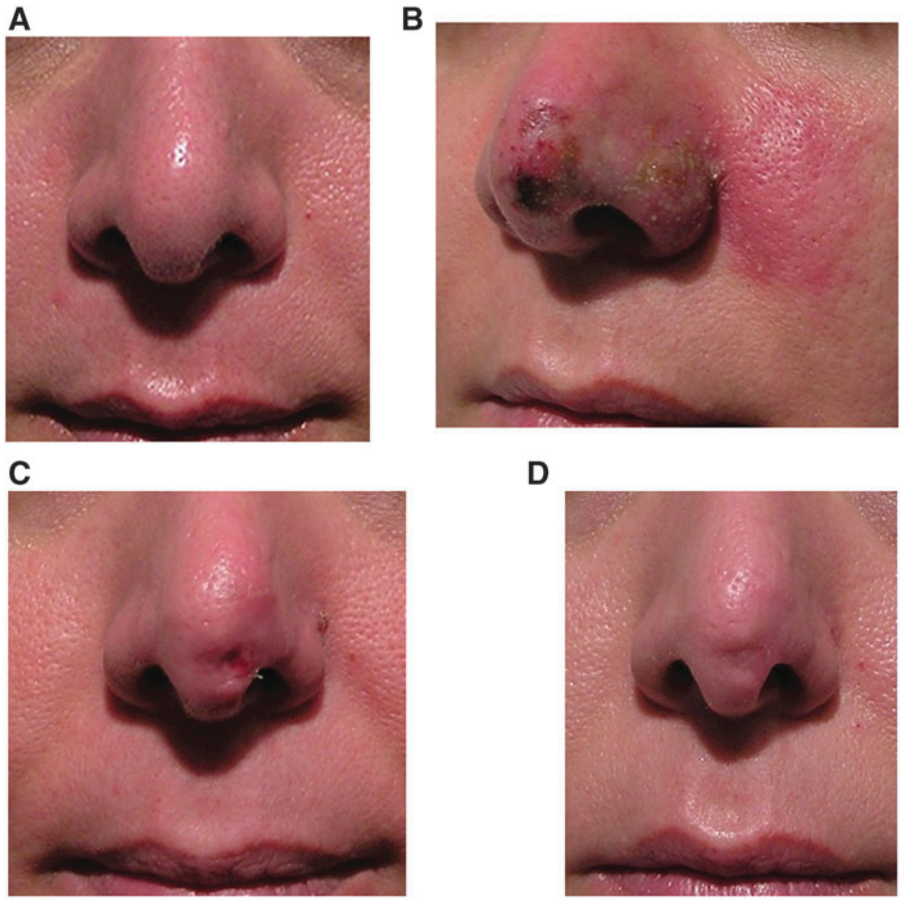

Fig. 1. Female NSR patient with ischemia leading to necrosis and contour irregularity. **(A)** Baseline, before NSR treatment. **(B)** One week post-NSR. **(C)** Three months post-NSR. **(D)** Eight months post-NSR. The patient had undergone four previous surgical rhinoplasties, resulting in an overly shortened nose with a hanging columella and notched ala. Calcium hydroxylapatite was placed in the infratip lobule to improve the profile with successful initial results. Two weeks post-treatment, the patient underwent a touch-up treatment and more filler was placed in the area in an attempt to improve the result. Transient blanching of the skin was observed upon injection that seemed to normalize within a minute. Over the next few days, the patient developed skin necrosis and cellulitis in the tip area, which was treated with warm compresses, nitroglycerin paste, massage, oral steroids, antibiotics, and hyperbaric oxygen. At 8 months, the patient was still left with a small depressed scar in the previously necrotic region. NSR, nonsurgical rhinoplasty.

Table 3. Adverse event rate per area for patients with and without previous surgical rhinoplasty [*n* (%)]

	No surgery		*Previous surgery*	
Area	*No AE*	*AE*	*No AE*	*AE*
Ala	49 (96.1)	2 (3.9)	55 (100)	0
Dorsum	844 (95.5)	40 (4.5)	274 (96.8)	9 (3.2)
Radix	1563 (96.8)	51 (3.2)	240 (96.4)	9 (3.6)
Sidewall	295 (91.6)	27 (8.4)	229 (94.2)	14 (5.8)
Tip	1198 (92.4)	98 (7.6)	298 (90.3)	32 (9.7)

Values represent the number of procedures with the specific area injected.

Table 4. Adverse event rate per filler for patients with and without previous surgical rhinoplasty

	No surgery		*Previous surgery*	
Filler	*No AE*	*AE*	*No AE*	*AE*
VYC-20L+CaHA	239 (88.8)	30 (11.2)	42 (77.8)	12 (22.2)
PMMA	682 (93.2)	50 (6.8)	244 (99.6)	1 (0.4)
VYC-20L	486 (89.8)	55 (10.2)	122 (89.1)	15 (10.9)
CaHA	2362 (96.7)	80 (3.3)	626 (94.6)	36 (5.4)
NASHA	141 (98.6)	2 (1.4)	53 (100)	0
HYC-24L+	9 (100)	0	1 (100)	0
Mixed*	30 (96.7)	3 (3.3)	8 (100)	0

Note: HYC-24L was excluded from statistical analysis due to too few injections. Values represent the number of procedures with the specific filler used.
*Mixed is all combinations other than VYC-20L+CaHA.
NASHA, nonanimal stabilized hyaluronic acid.

cases of SAEs involving the nasal tip were most likely a compartment syndrome rather than an embolic event since cannulation of the tiny tip vessels seems unlikely.

The sidewall had the highest AE rate in the no surgery group (8.4%) and second highest in the previous surgery group (5.8%). The angular artery and its branches are the largest vessels in the nose and are relatively easy to inadvertently puncture when injecting the sidewall. In this review, the majority of AEs in the sidewall consisted of bruising but the three SAEs involving the sidewall were most likely embolic in nature.

The results of the filler and AE analysis must be interpreted with some caution and the analyses warrant further studies investigating a possible association between filler type and AE rate. For many years, CaHA was the only filler used for almost all of the author's NSR procedures. CaHA lasted longer and provided more lift and definition than any other filler. Although the AE rates for CaHA in this review are low, in the author's experience, CaHA results in more edema, erythema, and tenderness immediately postprocedure than hyaluronic acid fillers. Once VYC-20L was approved by the Food and Drug Administration in 2013, it became the author's primary filler for the nose because it was reversible, durable, and robust enough for nasal sculpting.

Filler combinations were used when VYC-20L alone could not provide enough lift or definition. That the combination of CaHA and VYC-20L had the highest AE rate for both groups is, in hindsight, not surprising. These patients needed the most augmentation or definition, hence the additional layer of CaHA on top of VYC-20L. The patients who received VYC-20L+CaHA experienced more needle punctures resulting in increased bruising, their skin was more stretched leading to increased incidence of erythema, and they had a greater volume of filler injected leading to an increased incidence of ischemia.

That the VYC-20L+CaHA combination doubled the AE rate in the previous surgery group compared with the no previous surgery group suggests that postsurgical anatomic changes must be carefully evaluated before using an aggressive combination of fillers in postoperative patients. It is recommended that HA fillers be used for NSR whenever possible due to reversibility of the filler. Nondissolvable fillers such as CaHA and PMMA, as well as layering fillers, should be reserved for practitioners who are expert injectors and well versed in diagnosing and treating filler complications.

This review has several limitations. AEs were documented by the treating physician immediately after injection and during the live follow-up visit 1–2 weeks postprocedure, as well as in discussion with the patient. Patients were counseled during the consenting process about what to expect in terms of typical reactions and may not have considered these an AE. Thus, responses such as erythema, edema, bruising, and tenderness, as well as possible delayed onset AEs that occurred after 2 weeks, are probably under-reported here. More severe AEs may also be under-represented due to patient attrition.

No discussion of injectable filler SAE is complete without mentioning visual impairments. A recent consensus determined that the nose is the most common site of injection associated with vision loss especially in the radix/glabellar region.[3] A review of 98 cases of filler-induced visual changes found that 64% occurred after injection into the nasal or glabellar region.[4] Although the AE rate from the current data set was low, the potential for SAEs is considerable given the area, and injectors must be exceedingly cautious when injecting the nose.

Patient-reported satisfaction was not formally collected in this data series, however, 130 recent NSR patients were asked about satisfaction and whether they would recommend the procedure. Out of 104 responses, 88.5% were happy/extremely happy, 7.7% neutral, and 3.8% unhappy, with the results. Ninety-two percent of patients answered yes they would recommend the procedure, 5.8% said no, with 1.9% replying maybe. All of the unhappy patients and those who would not recommend the procedure stated the reason was that the results did not last as long as expected.

A recent chart review of NSR patients for a 2-year period found that all seven cases of vascular compromise were patients who had previously undergone a surgical rhinoplasty,[5] supporting the current results of increased odds of an AE with previous rhinoplasty. Surgical rhinoplasty certainly decreases blood supply to the skin, increasing the chances of ischemia in areas such as the tip. The scar tissue formed may also compromise the mobility of vessels, making them more at risk for perforation during the NSR procedure. Surgical rhinoplasty may also cause changes to the skin, soft tissue envelope, and lymphatic drainage system, leading to prolonged resolution of typical post-injection inflammatory responses.

Blood supply to the skin of the nose is less redundant than it is in other areas of the face, and large vessels such as the angular artery are located ≤1 mm under the surface. Nasal vessels are located within the SMAS and there is probably extensive communication between the internal and external carotid branches.[6] Therefore, the first rule of safety when injecting the nose is to keep the tip of the needle or cannula at the periosteum or perichondrium, below the SMAS. Injection pressure should be minimized to reduce the potential of sending retrograde emboli through the internal carotid arterial system into the eye. Needle diameter should be as small as possible to reduce the size of a potential bolus should the needle be intravascular.

A needle is recommended over a cannula due the ability for serial puncture. Serial puncture provides a more exact understanding of the needle tip location as well as maximum lift in all planes, whereas a cannula expands in only one plane, potentially leaving other planes

collapsed.[7] Whereas some practitioners recommend cannulas for nasal injections for presumably enhanced safety,[8] there have been reported cases of vascular puncture with smaller cannula sizes.[9] The author no longer uses a 27-gauge needle but rather backloads VYC-20L into a 31-gauge needle 0.3 cc BD syringe. Precise boluses of no more than 0.05 mL should be injected. The needle should be advanced through the skin slowly and filler should only be flowing in a retrograde manner, that is, when the needle is moving out of the skin. Thus, if the tip of the needle is inside the lumen of a vessel, only a tiny amount of filler will enter the vessel, as the needle will be out in the next moment. Although a blunt cannula may help decrease the risk of a direct puncture into a nasal artery, it is no guarantee for AE avoidance as vessel occlusion may also be due to a compression effect.[10–16] Trying to reflux blood before injection is not recommended as a safety maneuver. The chances that the needle tip is in exactly the same spot upon refluxing and injecting are low and the maneuver gives beginning injectors a false sense of security.[17]

Conclusions

This article reviews a large data set describing the overall complication rate, as defined in the broadest sense to include common short-term injection site reactions, of the NSR procedure as 7.6%. Previous surgical rhinoplasty increased the odds of an AE by 51%. Injecting the tip or sidewall was significantly more likely to result in an AE compared with other areas regardless of previous surgery status. The combination of VYC-20L+CaHA resulted in significantly higher AE rate compared with use of a single filler. Caution must always be taken when injecting the nose, regardless of surgical history and should only be performed by advanced injectors with a thorough understanding of nasal anatomy. Patients who are viable candidates report great satisfaction with the procedure and saves them the expense, risk, and downtime associated with surgical rhinoplasty.

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Supplementary Material

Supplementary Figure S1
Supplementary Figure S2

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