Nonsurgical Rhinoplasty: a Safety of Calcium Hydroxyapatite Filler Used for Nose Sculpt

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INTRODUCTION

The use of dermal fillers for a nonsurgical rhinoplasty requires a medical knowledge of nasal anatomy. The deep fatty layer is targeted as it is known as the safe plan for filler deposition. Therefore, the filler should be injected exactly underneath the fibromuscular layer and above the perichondrium/periosteum layer in order to avoid a superficial injection or an inaccurate injection into the nose's major blood vessels and artery systems [1–5]. The advantages of a calcium hydroxyapatite filler used for nose sculpt arise from its ability to alter the shape of the nose at the anatomic region where it was positioned [6–8]. Also, when injected directly, the filler has the ability to correct aesthetic deformities without having the patient go through a complicated rhinoplasty procedure [9,10]. Moreover, it can also be used for the correction of postrhinoplasty deformities [11]. The dermal filler of choice used in this study was Crystalys, a calcium hydroxyapatite injectable filler (Panaxia Ltd.). Crystalys is a sterilized, apyrogenic, long lasting and non-permanent injectable facial implant. It is a homogenous, semi-solid implant, intended for sub- and deep-dermal use, it is provided in a 1.25 mL pre-filled graduated, glass syringe. The filler is based on synthetic calcium hydroxyapatite, the major material of teeth and bones [12]. It consists of microspheres of calcium hydroxyapatite formulated to a concentration of 55.7% CaHA, suspended in an aqueous gel carrier of glycerol and sodium carboxymethylcellulose. When injected, the CaHA microspheres form a framework for ingrowth by fibroblasts, which steadily substitute the carrier vehicle. As the fibroblasts grow, they generate collagen fibers, which anchor the microspheres in place [13,14]. CaHA is biodegradable, it follows the same metabolic pathway of common bone fracture as it turns into bone debris. After 2–3 months, collagen replace the absorbed carboxy-methylcellulose [12]. As a CaHA dermal filler Crystalys has high elasticity (G prime) and high viscosity properties. A product having a high elasticity characteristic results in the ability to resist deformation when undergoing pressure and to produce a precise lifting effect during injection [7,15,16] even while small volumes are used (0.1–0.15ml). Its high viscosity translates into molding ability and results in a smooth sculpting property. There are different injection techniques when approaching nonsurgical rhinoplasty [11,17,18]. The direct approach used here is a type of technique by which the physician performs an injection perpendicular to the skin with a sharp 27-gauge needle, resulting in a more accurate filler placement and a minimal shape distortion or aberration [1,19]. This nonsurgical rhinoplasty study gathers a multidisciplinary team of physicians. The study was conducted by Dr. David Mor-Yosef MD, aesthetic physician for over a decade, who has performed over 1500 nonsurgical rhinoplasty procedures using dermal fillers since 2012. Dr. Konstantin Konfino, MD PhD, a dermatologist who practices aesthetic medicine for over 20 years and Dr. Roni Moscona, MD, which is a senior plastic surgeon with a vast experience.

MATERIALS AND METHODS

A one-center, post-market, retrospective study

was conducted on 82 patients injected with Crystalys used for nose sculpt between July 2012 and May 2016. The study comprised both retrospective and prospective elements. Safety and performance (retrospective element) data was collected from all treated patients' medical records for analysis (n = 73). Additionally, telephone follow ups were made in order to collect any missing data. Performance data (prospective element) was collected after patients signed an informed consent form. Data included patients photographs (n = 65) which had a "before treatment" photo and an „after treatment" photo in their patient medical files. The „after treatment" photo was taken within six months of initiation of the study. An investigator then assessed the photos, and they were rated on a scale of 1–5 (1 – Very Much Improved, 2 – Much improved, 3 – Improved, 4 – No change, 5 – Worse, respectively) using the Global Aesthetic Improvement Scale.

Also, 22 patients filled out a 5-point Likert scale User Satisfaction Questionnaire. Patients ages ranged between 19–68 years. Follow ups ranged between one to more than 6 months, time from treatment and number of patients is as follows: total number of patients who attended follow ups was 82. At 1–2 months from treatment 13 patients (16%) attended, at 3–4 months from treatment 14 patients (17%) arrived, at 5–6 months the same number of patients (17%) attended the follow up, at 6 months or more than 6 months since first received treatment 41 patients (50%) attended. Patients inclusion criteria set for treatment eligibility were: the minimum limit of age was 18 years, and upon a signed informed consent submission. The study protocol was originated in accordance with the ethical principles of the Helsinki Declaration and of the ICH Harmonized Tripartite Guideline for GCP. The study protocol as well as the informed consent forms (ICFs) were reviewed and approved by the Institutional Review Board (IRB) and explained during patient consultation. Crystalys was injected at six specific anatomic regions designated for nose sculpt (Figure 1, p. 194). The most injected region of the nose in this study was the columella with 25.37% which is corresponding to 68 injections out of 268 total injections given.

The infra tip region on the other hand represents the least injected region with only 4.1% of injections (Table 1, p. 193). Each region was injected with a specific volume according to its aesthetic deformity.

Mean and median total injected volumes per patient were 0.68 ml and 0.65 ml, respectively. The maximum volume injected to a single patient in one session was 1.25 ml whereas the minimum was 0.25 ml. Total injection volume per patients' nose was determined by the physician according to need of all treated regions (Table 2, p. 195) Regarding the study retrospective element; patient's safety, an assessment was made according to reported adverse events (AEs) collected from the consent report questionnaire answers filled during either a follow up visit at the clinic or through a telephone call follow up. The data was then incorporated into a summarizing table which included the AEs severity and duration.

Performance level was evaluated according to 65 patients for whom both a "before treatment" and an "after treatment" photos were available. The photos were then rated by an investigating physician equating the patients' nose baseline to its post-treatment outcome. The photos GAIS ratings were statistically analyzed using the Kolmogorov-Smirnov test for two null hypotheses. Hypothesis 1 – the treatments resulted in "no change". Hypothesis 2 – the treatments resulted in merely "improved". As for the statistical analysis, a p-value of < 0.05 was considered statistically significant. Additionally, treatment performance data was collected from 22 patients' 5-point Likert Scale User Satisfaction Questionnaires (Table 5, p. 199).

RESULTS

Patient's Safety

First, all nose sculpts treatments using Crystalys for nonsurgical rhinoplasty were well tolerated by the patients. Second, no severe nor serious or long-lasting AEs were reported. In fact, all the reported AEs were related to local injection site reactions and were mild, short-termed, and self-resolved (Table 3, p. 196). Also, there were no device-related AEs reported. Last, the mostly common (CaHA-based dermal filler) side effects, such as granulomas, nodules, pruritus, erosion, necrosis, allergic reaction or infection were not reported. Pain was the most common 57.14% of all AEs reported, then erythema at 16.67%. AEs mean duration for pain was 4.5 days while edema and erythema lasted 2.7 days on ave-

rage, ecchymosis lasted 3.5 days. Pigmentary change AEs was only 4.65% and its mean duration was the longest since it lasted 14 days on average following treatment. All AEs were self-resolved.

Treatment performance

Sixty-five patients with a "before treatment" and an "after treatment" photos were evaluated using GAIS. The GAIS ratings validate the treatment clinical effectiveness as 38.46% of the patients (25 out of 65) were evaluated as "very much improved", 55.38% (36) as "much improved", 4 patients 6.15% as improved and 0 showed "no change" or "worse" according to an investigating physician rating scores determined by equating the patient's' nose baseline to its post-treatment outcome (Table 4, p. 197). The statistical data analysis calculated using the Kolmogorov-Sminrnov test for the two null hypotheses resulted in "no change" ($p\text{-value} < 1.0 \times 10^{-6}$) for Hypothesis 1 and in merely "improved" ($p\text{-value} < 1.0 \times 10^{-6}$) for Hypothesis 2. Both hypotheses were rejected ($p\text{-value} < 0.05$) Hence, the deduction that Crystalys substantially improved ("much improved") the aesthetic deformities of the nose. Twenty-two patients filled out a 5-point Likert scale User Satisfaction Questionnaire. Their answers were analyzed in order to evaluate treatment performance. All questions scores were ranked high, with a mean above 4. The patient overall satisfaction topped a 4.318, and the likeliness to repeat the treatment as well as to recommend it to others was ranked at 4.364 and 4.391 respectively (Table 5, p. 199).

Treatment performance can be seen in Figure 2 (p. 196). Images a–h contain four patients' lateral view comparison of before and after nose sculpt treatment with Crystalys. Figure 2a is showing a 25-year-old female patient before treatment. Figure 2b was taken approximately one month after Crystalys treatment. The patient was injected with a total volume of 1ml. The nose anatomic regions treated were: supra-tip (0.1 ml), infra-tip (0.1 ml), columella (0.25 ml), tip (0.2 ml) and radix (0.35 ml). Figure 2c is showing a 19-year-old female patient before treatment. Figure 2d was taken two months after treatment. A total of 0.9 ml was used to treat the following regions; supra-tip (0.15 ml), columella (0.2 ml), tip (0.25) and radix (0.3 ml). Figure 2e shows a 40-year-old female patient before treatment. Figure 2f was taken four months after treatment. The patient was injected in the supra-tip (0.1 ml), infra-tip (0.1 ml), columella (0.2 ml), tip (0.25) and radix (0.35 ml) with a total of 1 ml of Crystalys. Figure 2g is showing a 49-year-old male patient before treatment. Figure 2h was taken one year and one month after treatment. The patient was injected in the supra-tip (0.15 ml), columella (0.2 ml), tip (0.25), radix (0.45 ml), and the dorsum (0.2 ml) resulting in the maximum amount per patient injected with Crystalys during in this study, a total of 1.25 ml.

Another aspect regarding the use of dermal fillers for a nonsurgical rhinoplasty is the ability to provide a contour defects nose sculpt Crystalys treatment for patients which had already gone through a rhinoplasty procedure. Figure 3a (p. 198) is showing a 57-year-old female with a nasal tip deformity as a result of rhinoplasty. Figure 3b was taken 3 months after the patient received a corrective treatment. The patients' nose regions injected with filler were: the tip (0.3 ml) and the infra-tip (0.1 ml) resulting in a total of 0.4 ml Crystalys injected.

DISCUSION

The use of Crystalys for nose sculpt is considered new in the product category used for nonsurgical rhinoplasty. In this post-marketing study, we show that the product has the ability to correct aesthetic deformities of the nose and alter its shape directly at the anatomic region where it was injected. Deformities of the nose which qualify for a nonrhinoplasty procedure include frontonasal angle deformity, nasal tip ptosis, upward rotation of dropping tip, alar sidewall depression/retraction, nostril asymmetries, dorsum irregularities, dorsal hump defects, dorsum narrowing and saddle nose deformity ("ski-slope" nose). Such deformities maybe related to a genetic predisposition, to an injury or due to a rhinoplasty procedure [20]. The use of a CaHA dermal filler for nose sculpt can resolve such deformities without causing the nose to appear as if it was enlarged, the physician uses the euclidean geometry postulate to create a stright line between two points located upon the nose dorsum. He injected the filler along the dorsum making the nose appear shorter and smaller than before due to distance shortening between the two points. In some cases when using a filler would not serve the patient's best interest

meaning deforming the shape of his nose the physician can decide that the patient should go through surgery. However, in this study all of the patients selected were chosen by the physicians since they were qualified, as good candidates for a nonsurgical treatment. Meaning that these patients were evaluated and were found suitable for an injection and not a surgical procedure. Upon conducting this study, we acknowledged the fact that the use of Crystalys for nose sculpt treatment demonstrated safety results.

There were no severe nor serious or long--lasting AEs reported by the patients or by the physician. In addition, all the related treatment common AEs (common AEs for all injectable treatments including CaHA, hyaluronic acid or collagen fillers) [22] which appeared on this study, such as ecchymosis, edema, erythema, pain and even a pigmentary change, all were self-resolving within 1–21 days.

Regarding Crystalys treatment performance outcomes showed a significant improvement. We have found that such scores depend not only on the high quality of the product but also on the qualified administrating hand. That being said, the reasoning behind Crystalys shown to be both safe and effective for nose sculpt should also be linked to the fact that the treating physician is a well- trained facial aesthetics virtuoso, who conquer his knowledge in nasal anatomy, the rules of aesthetics, dermal fillers usage and limitations, and the wide range of injection techniques.

The Crystalys treatment given for a nonsurgical rhinoplasty demonstrated here has all the desired characteristics of a nose sculpt dermal filler. The advantages of a calcium hydroxyapatite filler, when compared with a hyaluronic acid dermal filler, is due to the fact that it has a long-lasting effect (especially when injected in the nasal bridge area – an area of the nose experiencing relatively slight motion [21]) and that it allows an accurate placement of the filler.

Finally, the treatment given for nose sculpt is safe with a high-performance level and on top of all it is user friendly, and cost-effective.

CONCLUSION

► The results of this study demonstrate that the use of Crystalys for nose sculpt is safe and has minimal risks upon administration. It is very common these days to treat nasal defects such as a slightly strayed nose, a nose having a mild dorsal hump or a high nasal tip with a flat radix, by the use of a CaHA dermal filler. Physicians prefer, when possible, to use nonsurgical rhinoplasty procedure over going through a complicated rhinoplasty surgery. By doing so they help their patients avoid high complication rates resulting from undergoing surgery and gain a short recovery time.
► The use of Crystalys in nonsurgical rhinoplasty has been shown to hold a constant high level of performance in all patients. The overall satisfaction with Crystalys, used for the ability to contour defects by nose sculpt, according to the user satisfaction questionnaire was ranked as a high-performance product.
► Based on this study the use of Crystalys for nose sculpt is safe. However, a wider range of patients' age, skin type, gender and a longer follow up period of time will be very beneficial for such a study.

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ABSTRACT

Nonsurgical Rhinoplasty: A Safety of Calcium Hydroxyapatite filler used for Nose Sculpt

Objective: The primary aim of this study was to assess the safety of Calcium Hydroxyapatite (CaHA) injectable filler used in nonsurgical rhinoplasty. The study secondary aim was to assess treatment performance within a six months' period.

Materials and Methods: 82 patients at 19–68 years of age participated in this study. The patients were evaluated by the physician examining aesthetic deformities at six specific anatomic regions of the nose. The total volume injected was 55.85 ml. On average, 0.68 ml was used. Patients' safety was evaluated according to the reported adverse events (AEs). Patients' treatment performance was assessed by using the Global Aesthetic Improvement Scale (GAIS).

Results: 73 patients were assessed for whether they have experienced any adverse events. There were no severe nor serious or long-lasting AEs reported. Additionally, all the events were self-resolving. The common AEs reported were: pain, edema, erythema, ecchymosis, pigmentary changes. With regards to the treatment performance, ratings were attained based upon a subset of 65 patients using the GAIS validated clinical scales. In addition, a 5--point Likert scale User Satisfaction Questionnaire was filled out by 22 patients. Crystalys, the CaHA injectable filler used in this study, demonstrated excellent efficacy results according to the GAIS and the user satisfaction ratings.

Conclusions: The results of this study demonstrated that the use of Crystalys for nose sculpt is safe and holds a constant high level of performance. Moreover, the use of Crystalys in nonsurgical rhinoplasty has been shown to have no risks upon its administration.

► **KEY WORDS:**

nonsurgical rhinoplasty, calcium hydroxyapatite, injectable dermal filler, safety, performance, adverse events, clinical scale

Table 1. Total number of injections per region

OSTRZYKIWANY OBSZAR NOSA NOSE INJECTION REGION	ŁĄCZNA LICZBA INIEKCJI TOTAL NUMBER OF INJECTIONS
Nasada/Adix	65
Koniuszek/ Tip	65
Słupek nosa/ Columella	68
Dolna część wierzchołka nosa/Infra-Tip	11
Grzbiet/Dorsum	14
Górna część wierzchołka nosa/Supra-Tip	45
Wszystkie obszary/All sites	268

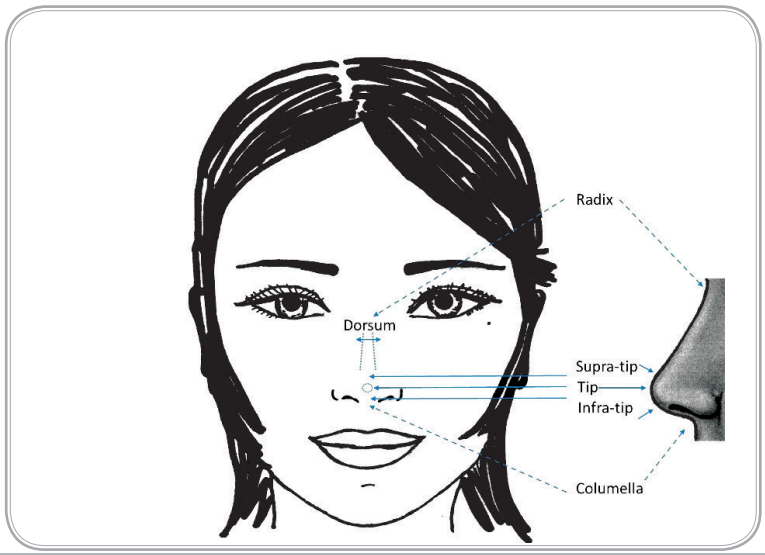

Fig. 1. The treated nose injected regions marked by arrow heads from top to bottom: The Radix, the Dorsum, the Supra-Tip, the Tip, the Infra-Tip and the Columella

Table 2. Anatomic regions of the nose treated and amount of exposure

OBSZAR NOSA NOSE REGION	Wstrzyknięta objętość ml Injected volume ml (SD)	Średnia ml Mean ml	Mediana ml Median ml	Min ml	Max ml
Górna część wierzchołka nosa Supra-Tip	6.65 (0.05)	0.15	0.15	0.1	0.35
Grzbiet Dorsum	3.95 (0.09)	0.28	0.3	0.15	0.4
Dolna część wierzchołka nosa Infra-Tip	1.35 (0.06)	0.12	0.1	0.1	0.3
Słupek nosa Columella	13.7 (0.05)	0.2	0.2	0.1	0.3
Koniuszek Tip	12.6 (0.05)	0.19	0.2	0.1	0.3
Nasada Radix	17.6 (0.13)	0.27	0.25	0.1	0.7
Łączna objętość Total Vol	55.85 (0.21)	0.68	0.65	0.25	1.25

Table 3. Related treatment AEs

ZDARZENIE NIEPOŻĄDANE ADVERSE EVENT	LICZBA AE (N = 42) (*%) NUMBER OF AES (N = 42) (*%)
Podbiegnięcia krwawe n (%)/Ecchymosis n (%)	3 (7.14%)
Obrzęk n (%)/Edema n (%)	6 (14.29%)
Rumień n (%)/Erythema n (%)	7 (16.67%)
Ból n (%)/Pain n (%)	24 (57.14%)
Zmiany barwnikowe/Pigmentary change	2 (4.76%)

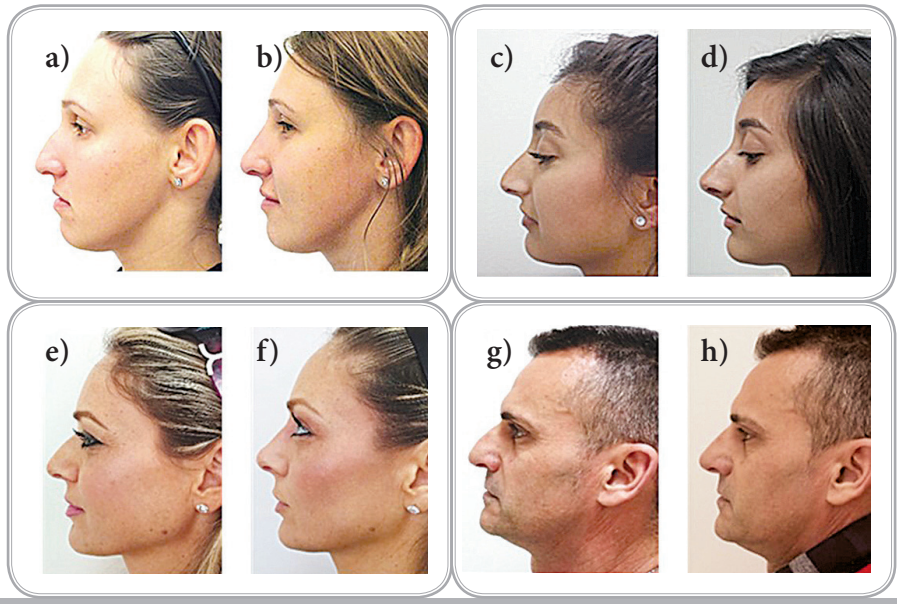

Fig. 2. Photographs of four patients at two time points: before treatment (a, c, e, g) and after Crystalys treatment (b, d, f, h)

Table 4. GAIS scores (Performance cohort)

SKALA I ROZKŁAD WYNIKÓW W SKALI GAIS GAIS SCALE AND DISTRIBUTION	WYNIKI W SKALI GAIS (N = 65) GAIS SCORES (N = 65)
Bardzo znaczna poprawa (%)/Very Much Improved (%)	25 (38.46%)
Znaczna poprawa (%)/Much Improved (%)	36 (55.38%)
Poprawa (%)/Improved (%)	4 (6.15%)
Bez zmian (%)/No Change (%)	0
Pogorszenie (%)/Worse (%)	0
poziom istotności p (wobec „bez zmian”)/p-value (vs. "no change")	$< 1.0 \times 10^{-6}$
poziom istotności p (wobec „poprawa”)/p-value (vs. "improved")	$< 1.0 \times 10^{-6}$

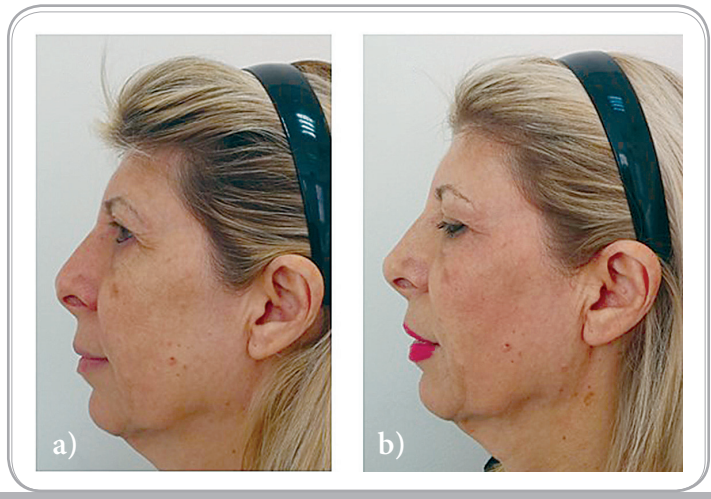

Fig. 3. A lateral view of a postrhinoplasty female patient at two time points: before Crystalys corrective treatment of nose tip (a) and 3 months after treatment (b)

Table 5. Performance as per User Satisfaction

PYTANIE/QUESTION	Wynik (n = 22) średnia* Score (n = 22) mean*
Odniosłem(-am) korzyść z zabiegu z wykorzystaniem preparatu Crystalys. Being treated with Crystalys injections was beneficial to me.	4.318
Jestem zadowolony(-a) z wyglądu mojej twarzy i tego, jaka jest w dotyku po zabiegu. I am happy with the look and feel of my face after having had this treatment.	3.818
Po zabiegu czuję się bardziej atrakcyjny(-a). I feel more attractive after having had this treatment.	4.000
Po zabiegu zyskałem(-am) dodatkową pewność siebie w kwestii wyglądu zewnętrznego. I now have more self-confidence with regard to my appearance after having had this treatment.	3.773
Moje samopoczucie psychiczne poprawiło się po zabiegu. My emotional well-being has improved since having had this treatment.	4.455
Ogółem, jestem zadowolony(-a), że poddałem(-am) się zabiegowi. Overall, I am satisfied with having had this treatment.	4.318
Ogółem, wynik zabiegu spełnia moje oczekiwania. Overall, the treatment outcome meets my expectations.	4.091
Wrócił(a)bym do kliniki na kolejny zabieg z wykorzystaniem tego produktu. I would be likely to return to the clinic to receive additional treatment with this product.	4.364
Polecił(a)bym zabieg z wykorzystaniem tego produktu innym osobom. I would recommend treatment with this product to others.	4.391

** Skala oceny: 1. Bardzo się nie zgadzam; 2. Nie zgadzam się; 3. Ani się nie zgadzam, ani zgadzam; 4. Zgadzam się; 5. Bardzo się zgadzam*
** Score scale: 1. Strongly disagree; 2. Disagree; 3. Neither agree or disagree; 4. Agree; 5. Strongly Agree*