

An Early Experience with Novuma®, A Calcium Hydroxylapatite Filler for Hand Rejuvenation

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Abstract

The aging hand is characterized by cutaneous and dermal atrophy, grooves between intermetacarpal spaces, prominent bones, tendons, and engorgement of reticular veins. Dermal fillers are a viable option available for physicians to restore the lost volume in aging hands. In this article, the use of the new calcium hydroxylapatite (CaHA; Novuma), for hand rejuvenation is reported. One-year follow-up results, dilution, and injection techniques have been described. Five female subjects with volume loss in the dorsum of their hands were enrolled in this study. A solution of 1.5 mL of Novuma mixed with 1.5 mL 2% lidocaine and a total amount of 3 mL was injected into the areolar plane between the subcutaneous layer and superficial fascia of the hand with a 25-G and ultra-thin cannula through one entry site. The injected dorsum was massaged to achieve an even hand dorsum surface without irregularities. Subjects were reviewed in controls at 1, 6 and 12 months. With a single injection, all patients were satisfied without requiring any touch-up injections afterwards. Patients and the physician were all satisfied according to the questionnaire scores in the follow-up period. Nodule or granuloma was not noted. A few adverse events such as transient oedema and ecchymoses were observed. Novuma, a % 35 CaHA-containing, filler is effective, safe, easily injectable, longlasting, and versatile option for creating youthful appearance in the aging hands.

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Aging hand is another popular problem as well as facial aging. Changes in skin pigmentation, thinning of skin and loss of elasticity, soft tissue atrophy due to reduced collagen, elastin, and fat, and alterations in skin hydration are general features of hand aging. As a result of decrease in collagen content and loss of hydration, skin becomes loose, and wrinkles appear (1). Consequently, further thinning and atrophy of the hand skin results in visibility of extensor tendons and veins, and grooves between them (2). Usually, these changes result in hands to be perceived as “old”. These signs of aging are difficult to conceal, and concomitant changes in the face bothers the patients to seek treatments to reverse the signs of hand aging.

Current hand rejuvenation procedures involve topical agents, resurfacing laser and peeling procedures, sclerotherapy, fillers, and fat injections to reverse the volume loss related to fat atrophy (3). Fat injection is the best autogenous option for creating youthful hands; however, this is an invasive, donor site and anesthesia-dependent, time-consuming, and inconsistent procedure with frequent post-operative additional requirements for touch-ups (4). Dermal fillers are a viable option available for physicians to restore lost volume in aging hands. Hand rejuvenation by injectable fillers, and combinations of mesotherapy has been quite popular in the last two decades (5). CaHA filler-containing fillers have been more frequently used for the treatment of hand aging since the approval of Food and Drug Administration (FDA) for calcium hydroxylapatite treatment for this anatomical region (5,6). Hyaluronic acid, poly-L-lactic acid, polycaprolactone have all been used for hand rejuvenation with varying success and shortcomings (7,7,9). Objective of this study was to assess the safety and effectiveness of the new CaHA-containing filler, Novuma (Burgeon Biyoteknoloji ve Sanayi Tic. AŞ, Ankara, Turkey) for the correction of volume loss in the hands until twelve months after treatment. The CaHA concentration in Novuma is 35%. A 1:1 dilution of Novuma with lidocaine was used for

volume restoration in the hand dorsum.

Methods

Patient population

Five female patients (aged 42 to 68, mean=54.6) were enrolled in this study. All patients had soft tissue atrophy of the dorsum of their hands and decrease in skin texture due to hand aging. Exclusion parameters included prior soft tissue filler injections at the same sites, acute or chronic local infections, current or history of systemic collagen diseases, bleeding disorders or patients who are unable to pause stop the use of anti-coagulant drugs, Raynaud’s syndrome and other circulation disorders. Informed consent was obtained from all subjects after detailed explanation of the procedure and the follow-up protocol. The explanation involved the selection of Novuma CaHA for hand rejuvenation. Photographs were taken before (baseline), immediately after the treatment and after one year that involved both hands and each hand separately.

Treatment Protocol

Each Novuma syringe (1.5 mL) was mixed with 5-cc injector containing 1.5 mL of 2% Lidocaine (Jetokain Simplex 2-mL ampul, Adeka İlaç San. ve Tic., İstanbul, Turkey). To prepare a homogenous solution, the lidocaine was first withdrawn into the 5-mL syringe. The lidocaine-containing syringe was then connected to the CaHA syringe using the special Luer-lock connector (Novuma, Burgeon Biyoteknoloji ve San. Tic. AŞ, Ankara, Turkey). After attachment, pressing the CaHA in the syringe forced the material into the 5-mL syringe and by back-and-forth movements at least 15-20 times mixed the lidocaine with CaHA. We think that at least 15 passes are good enough to create an adequate mixture without compromising the rheology of the product. The CaHA was then withdrawn back into the 5-mL syringe and injected into the areolar plane between the subcutaneous layer and superficial fascia of the hand using a 25-gauge and 5-cm long nano (ultra-thin) cannula (JBP, FEEL

TECH Co. Ltd., South Korea).

Before each procedure, the skin was prepped with a chlorhexidine-containing antiseptic and one central- dorsal hole was used to inject CaHA with a fanning technique. In every subject, 1.5 mL Novuma: 1.5 Lidocaine mixed solution was injected per hand. An entry hole for cannula insertion was opened with an 18-G needle in the middle of dorsal wrist crease. A special attention was paid to the dorsal vein anatomy to avoid unnecessary bleeding. The distant border for injection was the horizontal line connecting the metacarpophalangeal joints. The skin was lifted a little to pass underneath the vessels and the grooves between the tendons and engorged veins were retrogradely injected with CaHA. After completing the soft tissue augmentation, skin was gently massaged to spread the material evenly in all the treated areas. The massaging was done several times until optimal distribution is visible in the hand dorsum. Patients are advised to wear non-tight cloth gloves in the following three days and keep

their hands elevated, if possible. Table 1 gives a step-by-step and brief explanation of hand injection procedure.

Digital photographs were taken pre-injection and immediately after injection, using standard photographic setup. The patients were followed up in the post-operative period for ecchymosis, swelling, erythema, filler leak, infection, keloid formation, hypertrophic scarring, pigmentation problems, nodules and other side effects. All the treated patients were seen in the follow-up period in the office after six and twelve months. Photographs were taken at twelve months.

At each follow-up time-points, the injecting physician evaluated the degree of improvement and standardized photographs were taken (Figure 1 and 2). A questionnaire was also filled at each visit concerning the possible adverse effect. Both physician and patient were asked to evaluate the hand ((appearance) contour and/or volume replacement) by Novuma® filler using Patient

Table 1: Steps of CaHA injection for treatment of the aging hand in the office

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- 1 Identifying the areas of treatment at the dorsum of the hand. The space that is injected is delineated laterally by the fifth metacarpal bone, medially by the second metacarpal bone, proximally by the dorsal wrist crease, and distally by the metacarpophalangeal joints.
 - 2 Marking the outlines of injection area by the skin marker
 - 3 Mixing 1,5-mL of CaHA with lidocaine, using a Luer-Lock connector for the CaHA syringe and a 5-mL syringe containing 1.5 mL of 2% plain lidocaine
 - 4 Insertion of an 18-G needle to create an entry hole for the cannula at the middle of the dorsal wrist crease
 - 5 Pinching and lifting the skin over the hand dorsum with the non-injecting hand to facilitate separation of the skin from vascular and tendinous structures at the entry hole
 - 6 Linear injection of CaHA-lidocaine mixture into areolar plane between the subcutaneous layer and superficial fascia of the hand using a 25-gauge, 1.5-inch cannula.
 - 7 Gently massaging the injection site until the filler is evenly spread
 - 8 Advising patients to wear non-tight cloth gloves in the following 3 days and keep their hands elevated, if possible
 - 9 Scheduling follow-up with patient in the office at six and twelve months
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Figure 1: A 48-year-old patient, before treatment (1A) and one year after treatment (1B). Hand augmentation with 3 cc of 1:1 diluted CaHA filler with lidocaine, using a 25-gauge and 5-cm long nano cannula

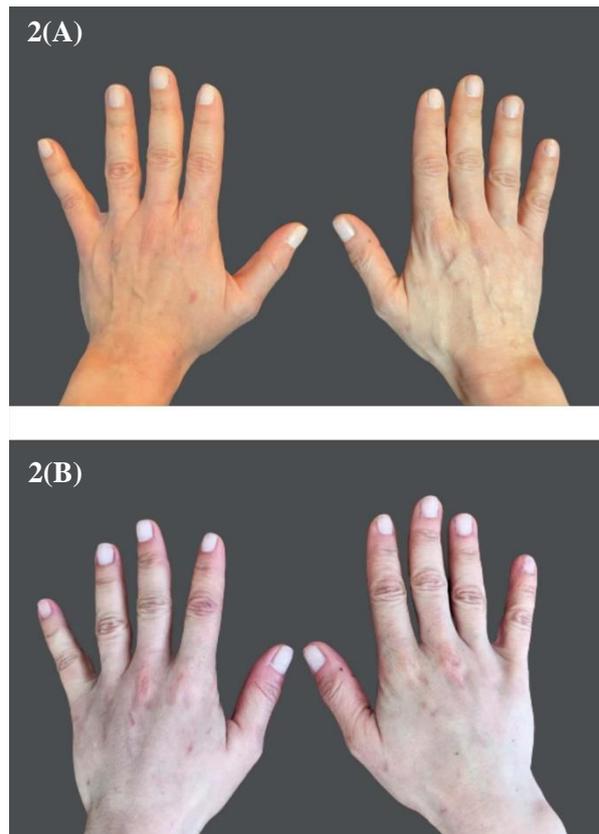


Figure 2: A 58-year-old patient, before treatment (2A) and one year after treatment (2B). Hand augmentation with 3 cc of 1:1 diluted CaHA filler with lidocaine, using a 25-gauge and 5-cm long nano cannula

Satisfaction Scale at sixth and twelfth months. Satisfaction was self-reported using the following scale: 1=unsatisfactory, 2= poor, 3=satisfactory, 4= very good, and 5= excellent.

Results

Cosmetic results

Five patients were all followed up in the study until twelve months. One injection session was done in all the patients and no touch-up injections of CaHA were deemed as necessary. One syringe of 1.5-mL Novuma was mixed with 1.5 mL of lidocaine in 1:1 dilution to inject a total of 3 mL per hand, which was very pleasing for the youthful appearance after one year.

Adverse events

Relevant data about the adverse events just after the treatment and at each follow-up visit was

collected. The staff nurse also proceeded with the follow-up of the patients through telephone calls about any adverse events. No serious complications were observed, and the post-injection period was uneventful. None of the patients had any discomfort after the procedure; however, a painkiller, usually of paracetamol type, was prescribed after the hand rejuvenation procedures. A mild swelling can be considered as standard after soft tissue augmentations in the hand dorsum. The swelling lasted for three to seven days and resolved without any further medication and intervention, apart from Arnica montana cream massaging twice a day. Ecchymosis in small patches was observed, beginning from the completion of injection, which was observed in one patient. These ecchymosis islands resolved after one week with hand elevation, intermittent application of ice packs and

application of Arnica montana cream to ecchymotic patches twice a day on the hand dorsum. There were no any other adverse events. No papules, nodules or granulomas were noted or reported.

Efficacy Rating by Treating Surgeon and by patient

Efficacy ratings were performed for all (n=5) patients. All patients were evaluated during the six-month follow-up visit. The patients' mean ratings of the appearance of the hands was 4.8. The physician's mean rating for the appearance of the hands at six-months was also 4.8. The scoring at twelve months after hand rejuvenation was also evaluated with the same scale. The patients' mean ratings of the appearance of the hands was 4.4. The physician's mean rating for the appearance of the hands at six months was still 4.6.

Discussion

Results of this study showed that Novuma, %35 CaHA-containing filler, results in significant improvement in the appearance of hands. Patient and physician scores were assessed using the Patient Satisfaction Scale. Novuma was delivered as a single injection, and 1:1 diluted with lidocaine. Overall appearance of the hand dorsum was satisfactory for the patients and the physician immediately and through the follow-up period. Several previous authors have reported marginal decrease in satisfaction scores both by the subjects and the physician near the end of the follow-up (6). We also observed a similar but minor decline in the evaluation scores at one year after the initial treatment, though scores were still high. The safety profile was good, and no serious adverse events were encountered. Novuma was an effective therapy for hand rejuvenation with comparable success. The treatment was well tolerated by patients.

Since 2015, calcium hydroxyapatite is currently the only dermal filler approved by the FDA for hand rejuvenation. However, several

other new fillers such as hyaluronic acid (HA), and poly-L-lactic acid (PLLA) for volume restoration of the hands has been reported in several articles (9,10). The treatment of hands with PLLA has been shown to result in marked aesthetic improvements lasting more than one year (2). However, multiple treatment sessions with varying dilution ratios may be required. Furthermore, PLLA is reported to have a higher potential for complications, such as nodule formation (2). Studies reporting the use of HA fillers for hands also show improved results within one year after the treatment (2,9). Use of HA fillers for the hands usually do not display the same longevity as CaHA-containing fillers. Aesthetic improvement in hands usually decline after six months with HA fillers (1). Thus, among available fillers for improving hand volume and texture, only PLLA can be compared with CaHA for the maintenance of the improvement over one year.

Since the first report by Busso et al in 2007 (11), there have been at least eight articles, demonstrating the efficacy of CaHA for aesthetic improvement of the hands in many patients. However, there is still no consensus on the number of entry sites, selection of injection techniques, use of cannula or needle, and dilution ratios (1). We have been using 25-G cannula through one entry site at the dorsal wrist crease without any adverse events. This technique can be performed with reproducible good results in the treatment of hand aging. Our technique has been given in detail in this article. We have one-year follow-up results of a limited number of patients, but several authors have reported the durability of results with CaHA, ranging from one to two years (3,12,13).

Safety profile in this study was favorable in all control time-points, with no serious adverse events. However, the number of patients enrolled in this study is limited and further studies with larger number of patients will be more meaningful to reach solutions. Most adverse events were related to the injection technique and were mild in severity.

Mild oedema and erythema can be considered as routine in the first few days. Injection volume and dilution ratios can also be an important determinant in the incidence of adverse events. None of the patients in this study complained of any functional limitation for three days after the 1:1 diluted injection of CaHA. In the first few days, patients were given gloves to wear for decreasing the procedure-related oedema and possible ecchymosis. Thereby, an even distribution of diluted filler was achieved in the hand.

Several factors limit to draw generalizable inferences from the current study. The number of patients was small, making it unlikely that probability of adverse events is very low; one-year follow-up period might also be insufficient to observe any late-appearing safety concerns. The study was open-label and not active- or sham-controlled; thus, the potential for assessment bias cannot be ruled out. The study population lacked men, young patients, and people from different Fitzpatrick types. Furthermore, choice of techniques, dilution ratio, and methods of delivery, either through cannula or needle, may affect the outcomes as well as the experience level of the injector.

Conclusion

Novuma, CaHA filler, was safe and well-tolerated in all the subjects. Mixing lidocaine with CaHA was an easy and suitable anesthetic modality that enabled pain-free hand injections. The product was found to be safe, easily injectable, and devoid of any serious adverse events. Clinical improvement was still visible after twelve months after single injection. In addition, enhancement of hand volume was immediate secondary to the rheological composition of the filler with sustaining results because of collagen stimulation. Patient satisfaction was high after initial injection and remained so until one-year time point, despite a minor decrease.

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