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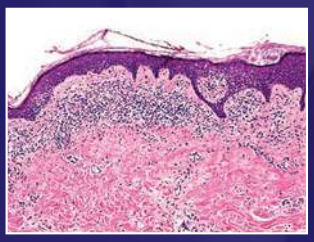

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Real-World Clinical Experience with an Allograft Adipose Matrix for Replacing Volume Loss in Face, Hands, and Body

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SUPPLEMENT ARTICLE OPEN ACCESS

Real-World Clinical Experience With an Allograft Adipose Matrix for Replacing Volume Loss in Face, Hands, and Body

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Keywords: allograft | cosmetic formulation | cosmetic procedure | dermal filler

ABSTRACT

Introduction: Real-world experience using an allograft adipose matrix (AAM) (Renuva) is presented as a series of seven cases demonstrating successful use of the matrix by nine expert cosmetic physicians across the United States. AAM is donated tissue that is aseptically processed without terminal irradiation into a transplantable adipose matrix that functions as a natural, versatile, and nonimmunogenic cushioning and volume-restoring tissue. When injected, the adipose matrix is replaced with the body's own fat cells and provides the cellular scaffold required for volume restoration and retention.

Methods: Nine expert dermatologists were selected to share and discuss real-world patient cases using AAM. The experts discussed a variety of cases and selected 7 cases that demonstrated successful, novel use of AAM to present in this manuscript.

Results: Experts agreed that the novel AAM is an easy-to-use, effective, and safe alternative to traditional fillers and fat grafting.

Conclusion: The use of the AAM is recommended for the face, hands, and other adipose tissue-containing parts of the body. The presented real-world cases provide guidance on how to identify ideal candidates to ensure optimal volume restoration results.

1 | Introduction

Aging is characterized by natural changes in the skin, soft tissue, and skeletal support structures of the human face [1]. Intrinsic skin aging occurs in response to inherent factors such as sex, ethnicity, hormones, or hyperdynamic facial expressions that are unique to an individual [1, 2]. These factors lead to dermal atrophy, reduction in dermal fibroblasts, blood vessels, and loss of elastic tissue as well as reduction in type I and type III collagen production, a lower epidermal turnover rate, and reduced melanocyte activity [1]. Extrinsic factors of skin aging include predominately solar ultraviolent (UV) ray exposure as well as diet and smoking [1]. These environmental exposures lead to loss of skin elastin and overgrowth of abnormal elastic fibers accompanied by dilated, tortuous blood vessels, and thickened basement membrane [1]. The culmination of both intrinsic and extrinsic factors leads to looser, wrinkled skin as well as loss of soft tissue volume [1, 2]. More specifically, the aging face also undergoes bony changes such as craniofacial skeletal growth and changes in musculature, which results in a mature appearance in contrast to that of youth [2]. At a molecular level, aging affects the ability of the extracellular matrix (ECM) to synthesize and catabolize components of the dermis, such as collagen, elastin, and glycosaminoglycans,

which results in reduction in soft tissue and ECM richness [3]. This can also be seen throughout the body as sagging or loose skin may be observed in an aging adult (Table 1).

Autologous fat grafting (AFG) and dermal fillers are used in plastic surgery and cosmetic medicine to restore volume and reconstruct areas of the body after age-related changes, trauma, congenital malformations, or in the treatment of burn scars [4]. While collagen-based bio-stimulatory filler products have long been used for the correction of soft tissue defects, AFG is considered ideal for soft tissue augmentation [3, 4]. AFG is biocompatible, versatile, natural-looking and nonimmunogenic, which make it the preferred choice for reconstruction [4]. In addition to aesthetic contouring, AFG can also improve wrinkling, radiation damage, pore size, and pigmentation [4]. Drawbacks to this technique include low graft survival, resorption rates ranging from 25% to 80%, donor site morbidities, insufficient harvest, or excessive harvesting times (Table 2) [4, 5]. In a pivotal trial, Kølle et al. demonstrated that enrichment of AFG with adipose tissue-derived stem cells (ASC) increased fat graft retention and volume, which is thought to occur due to improved vascularization as well as immunomodulatory and trophic effects of ASC [4]. Further, studies identified that nutrient-rich environments were required for survival and retention of AFG [4, 5].

In response to the challenges of AFG, an AAM was developed as an off-the-shelf alternative to either augment or replace AFG. AAM (Renuva®) mimics physical and physiological attributes of autologous fat to restore natural cushioning and volume loss in the face, hands, and body [5]. The AAM preparation relies on donated tissues that are subsequently processed as Human Cell and Tissue/Products (HCT/P) allograft that may be placed anywhere in the body where native adipose tissues exists [5]. When transplanted into the body, AAM is an adipose-derived architecture that supports vascularization and provides a three-dimensional scaffold for adipocytes to adhere to, differentiate, and proliferate [5–7]. Over time, the natural tissue structure is replaced with the individual's own body fat [5–7].

Kokai et al. [7] first demonstrated use of AAM as a structural human allograft adipose scaffold. AAM was injected into the dorsal hands of 15 patients and monitored over 16 weeks [7]. At 16 weeks, the average graft retention was approximately 47% relative to the initial injection volume with clinically visible reduction in veins and tendons of the dorsal wrist after injection [7]. In presurgical abdominoplasty patients, AAM was injected into the pannus to assess safety and host cellular response, which revealed that AAM had no severe adverse effects and remained within the confines of the patient's native surrounding adipose tissue [8]. In addition, AAM was shown to be noninflammatory and supportive of angiogenesis, which aids in fat graft retention and aesthetic reconstruction [8]. Further clinical studies also demonstrated that AAM injection for temple atrophy led to approximately 75% increase in volume retention at 6 months with 71% patient satisfaction and a favorable safety profile [5]. Another clinical study investigating the effects of AAM in the midface revealed 86% improvement in facial appearance satisfaction and 82% and 64% improvement in investigator and patient Global Aesthetic Improvement Scale (GAIS), respectively [9]. Herein, we present a series of real-world cases that demonstrate use of AAM for a variety of conditions in a diverse set of patients under real-world conditions. Unlike previous studies, our cases demonstrate use of AAM under real-world conditions in the hands of various experts. It demonstrates a variety of usages from the face, breast, and hands. These cases provide invaluable experience from experts to serve as a field-guide for patient selection for AAM treatment.

TABLE 1 | Comparison of allograft adipose matrix vs. adipose fat grafts and other fillers.

Type of injectable	Allograft adipose matrix (AAM)	Autologous fat graft (AFG)	Biodegradable polyer-based fillers	Permanent fillers
Composition	Human matrix proteins and growth factors	Adipose tissue from self	Cross-linked hyaluronic acid, poly-l-lactic acid, calcium hydroxyapatite filler	Polymethylacrylate microspheres, hydrogel polymers, and silicone
Durability	Lifetime	Lifetime	Up to 1 year	Up to 2 years
Advantages	Contains matrix proteins and growth factors	Contains adipocytes from self Allows for a more natural look	Reversible (with hyaluronidase) Low viscosity makes it amenable to molding and improving fine lines	Long lasting Quick procedure
Drawbacks	Expensive Novel technology with few clinical studies	Requires two procedures to harvest and process adipocytes for implantation Low graft survival Donor site morbidities Risk of irregular fat accumulation, fat necrosis and visible lumpiness	Risk for nodule formation Bruising and edema	Permanent without any reversible agents Risk for nodule formation

TABLE 2 | Overview of selected patient cases using allograft adipose matrix.

Case #	Patient demographics	Body site	Quantity of AAM injected	Outcome at 12 weeks	Key features
1	F60, FST III	Face	1 mL per side of mid-face	1 point improvement in MMVSA score	Successful AAM use with a 1:7 dilution and 22-gauge canula
2	F70, FST III	Face	3 mL per side of mid-face	Reduction in jowl appearance at 6 months	Use of AAM in a patient with a lengthy history of cosmetic procedures
3	F69, FST I	Face	1.5 mL per side of mid-face at baseline and 7 weeks (total 3 mL per side at 12 weeks)	Improvement in midface volume at 12 weeks without any reported side effects	Safe and successful use of AAM in geriatric patient
4	F67, FST II	Hands	1.5 mL per hand at baseline	Dorsal hand fullness at 12 weeks	Effective alternative to standard collagen-based fillers for treatment of hand aging
5	F43, FST III	Breast	Treatment #1 (Baseline): 1.5 cc of AAM blended with 1.5 cc of saline and 0.5 cc of lidocaine on a 1.5 in. and 2-in. cannula Treatment #2 (12 weeks): 1.5 cc of AAM blended with 1.5 cc of saline and 0.5 cc of lidocaine on a 1.5 in. and 2-in. cannula Treatment #3 (16 weeks): 1.5 cc of AAM blended with 2 cc of saline and 0.5 cc of lidocaine on a 1.5 in. and 2-in. cannula	Even, soft tissue volume in both breasts at 12 weeks	AAM is advantageous product for patients in cancer remission as it has less risk to interfere with future monitoring scans
6	M70, FST II	Face	1.5 mL per side of mid-face at baseline and 8 weeks (total 3 mL per side at 12 weeks)	Distinct improvement in midface volume at 12 weeks, 3-point decrease in MMVSA score	Effective in durable treatment of HIV-associated lipoatrophy
7	F40, FST I	Face	0.75 mL per side of midface at baseline	Distinct improvement in midface volume at 12 weeks, 3-point decrease in MMVSA score	Concomitant use of AAM and neuromodulator use led to safe and effective results for facial rejuvenation

2 | Methods

This is a real-world case series highlighting the use of AAM in an adult population aged 40–70 years. These cases demonstrate how expert cosmetic physicians choose ideal candidates for AAM transplantation and document the outcomes and results of these patients over 12-week follow-up evaluations. Expert clinical reasoning and rationale are described in each case to serve as a guide for future healthcare providers (HCP) to aid in selecting ideal candidates for AAM treatment. The following series is presented with a case-based approach including steps in diagnosis/patient presentation, treatment options, management and specific tips, special considerations, and advantages of AAM for these cases.

2.1 | Steps in the Process

The real-world cases were compiled and selected in the following steps: (1) project definition and expert panel selection, (2) data collection and preparation of patient cases, (3) patient case discussion and selection for publication, (4) literature review to support selected cases, and (5) drafting, review, and finalization of the manuscript.

2.2 | Role of the Panel

The selected expert panel consisted of nine internationally recognized American dermatologists with experience in cosmetic, reconstruction, and rejuvenation procedures. Panelists represented clinical practices in six states across the United States (Tennessee, New York, California, South Carolina, Colorado, and Texas) with high patient volume and a wide variety of skin concerns. Each panelist presented two cases of patients over the age of 40 that received AAM during a meeting. The meeting took place on February 10, 2024, in Miami Beach, Florida, and expert discussions highlighted the use of AAM in variety of settings under real-world conditions. After all cases were presented, the panelists collectively chose seven cases that best represented AAM use under real-world conditions.

2.3 | Allograft Adipose Matrix

Allograft adipose matrix (AAM) (Renuva®; MTF Biologics, Edison NJ, USA) is a safe and effective, natural, off-the shelf solution for restoring natural cushioning and fat volume loss in the face, hands, and body. The matrix maintains the natural tissue structure while providing a scaffold to support adipogenesis and volume restoration. Syringes are available in 1.5 and 3 cc for injection into the face, body, or another adipose tissue containing site.

The patients received instructions from the injector on how to massage the treated areas for 5 min, five times a day, for 5 days following the injection procedure. Patients were informed that anti-inflammatories to manage any potential pain associated with the treatment should be avoided and were prescribed Tylenol only. For the first few days following injections, patients were instructed not to wear clothing, hats, scarves, or headbands, which might encounter, rub, or irritate the injected areas. Patients were advised to contact their study team for any serious issues or issues that do not resolve within the first 48 h following the injection procedure.

2.4 | Mid-Face Volume Scale Assessment

Face Volume Scale Assessment (MMVSA) is a validated, 4-point investigator assessment of the midface volume loss. The scale measures facial volume deficit with scores ranging from 1 (full midface) to 4 (severe/substantial loss of fullness in the midface area). Thus, lower values represent better outcomes.

2.5 | Global Aesthetic Improvement Scale

Global Aesthetic Improvement Scale score is a physician scale that measures aesthetic improvement of patients at follow-up visits. GAIS rates a patient's response to treatment as: very much improved (3), much improved (2), improved (1), no change (0), worse (−1), much worse (−2), and very much worse (−3).

2.6 | Data Gathering and Outcome Measures

Suggested information to present included patient demographics, clinical features, cosmetic treatment goals, and qualitative and quantitative outcome measures.

The panel used the same template to gather insight through a case-based approach, comprising cosmetic evaluation and alignment of treatment goals. Information on the patients' skincare routine and facial injectable/procedure history was recorded. The reason for AAM selection was also presented as well as the AAM treatment preparation details and quantity chosen for each patient and body site. If appropriate, a MMVSA and GAIS scores were recorded at baseline and 12 weeks. A physician evaluation that evaluated skin tone, skin texture, erythema, and irritation on a scale of 1 (minimal) to 4 (severe) was also conducted at baseline and 12 weeks. Photographs were taken at baseline and 12 weeks to compare volume retention. Patients were also asked to evaluate the impact of facial skin condition on their daily activities, professional life, social life, and self-image. Special considerations and lessons learned were discussed at the end of the evaluation.

3 | Results

Seven cases were selected by the expert panel to illustrate the use of AAM for a variety of skin concerns under real-world conditions. The cases demonstrate how AAM is used in a diverse population with differing medical histories, skincare regimens, and cosmetic treatment history. Real-world experience with AAM in the hands of expert cosmetic dermatologists is a valuable illustration of AAM's use as an effective

FIGURE 1 | Case 1. 60-year-old woman. AAM 1 mL injection into bilateral midface in 60-year-old woman after significant weight loss (*Photograph courtesy of Ava Shamban M*).

and safe alternative to AFG or fillers. The selected cases are summarized in Table 2.

3.1 | Case 1. Recent Weight Loss

A 60-year-old woman with Fitzpatrick Skin Type (FST) III presented with reported volume loss in her midface after significant weight loss. The patient reported that the facial volume loss impacted many parts of her life. At baseline, her MMVSA score was 3. The patient's skincare routine comprised facial wash, vitamin C serum, moisturizer, and sunscreen in the morning and facial wash and night-time moisturizer in the evening. At baseline, the patient was injected with 1 mL of AAM in each side of her midface. The product was used at a 1:7 blending and injected with a 22-gauge canula. After injection, the physician instructed the patient to massage the treatment area 5 min, five times a day for 5 days following the injection procedure. No adverse events were reported. The patient returned at 12 weeks with a noticeably fuller face. Her midface had gained in soft tissue volume improving her MMVSA score to a 2 (Figure 1).

3.2 | Case 2. Filler, Neuromodulator, Rhytidectomy-Experienced Patient

A 70-year-old woman with FST III presented with concern of worsening jowls and facial drooping. She had a rhytidectomy 24 years prior and received neuromodulator injections every 3–4 months. In the past, the patient had also been treated with hyaluronic acid fillers and chemical peels. Despite prior treatment, the patient still felt that the soft tissue distribution in her face was sinking creating prominent jowls. The patient received 3 cc of AAM into each side of her mid-face. The injector used a 22-gauge canula. At 6 months, the increase in volume of the patient's midface led to reduction in facial and jowl drooping (Figure 2). The patient tolerated the procedure without any adverse events.

FIGURE 2 | Case 2. 70-year-old woman. AAM 3 mL injection into bilateral midface in 70-year-old woman (*Photograph courtesy of Suneel Chilukuri M*).

3.3 | Case 3. Patient With Severe Loss of Midface Volume

A 69-year-old woman, FST I, presented with significantly aged skin and soft tissue volume loss in her face. The patient denied any direct impact of her appearance on her daily life; however, she requested enhancement in the volume of her face. In the

past, the patient had Dysport (obobotulinumtoxinA) injected into her glabella. AAM was considered for this patient as it was thought to be the best option for enhancing her cheek volume. At baseline, the patient was injected with 1.5 mL of AAM on each side of her face. Seven weeks later, the patient returned for another round of 1.5-mL AAM injections on each side of her face. At 12 weeks, the patient returned to clinic with a fuller midface (Figure 3). Notably, results appeared very natural, and the patient denied any adverse effects and was satisfied with results.

3.4 | Case 4. AAM for Dorsal Hands

Soft tissue loss and appearance of hands are strong indicators of age [10]. Atrophy of soft tissue and dermal elasticity is specifically noticeable on the dorsal hands of an individual [10]. To treat the loss of volume, injection of dermal fillers and adipose tissue have been utilized with success [10]. Here, a 67-year-old woman, FST II, presented with significant atrophy of subcutaneous tissue in her hands. Having already received fillers and neuromodulators in the past, AAM was chosen in the hopes to improve retention of volume and help restore adipose tissue production in her dorsal hands. At 12 weeks, the patient saw a considerable increase in volume of her dorsal hands (Figure 4) without any reported adverse effects. She had a natural correction of the hand without any downtime. The patient tolerated the procedure well with minimal discomfort and no reports of damage or irritation to the hands or skin.

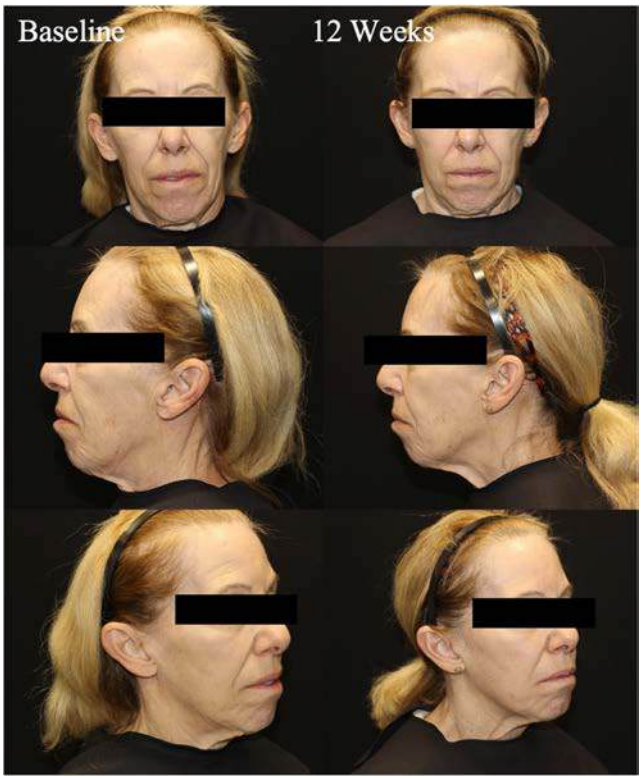

FIGURE 3 | Case 3. 69-year-old woman. AAM 3 mL (2×1.5 mL) injection into bilateral midface in 69-year-old woman (*Photograph courtesy of Joel Cohen MD*).

3.5 | Case 5. AAM Postlumpectomy in Breast Cancer Survivor

A 43-year-old, FST III, woman presented with uneven breasts secondary to a lumpectomy. She had a history of breast cancer that was removed by a lumpectomy 5 years prior to presentation. AAM was chosen to treat an area that naturally contains fat, the breast. It was also considered the ideal product given its natural fat composition that would not interfere with future cancer image monitoring. The patient was treated with 1.5 cc of AAM into her right lateral breast divot caused by surgery and radiation treatment. At baseline, the skin overlying the right breast had a skin tone and texture score of 1 with scores of 0 for erythema and irritation. Twelve weeks later, she had a GAIS score of 3 with scores of 0 for skin tone, texture, erythema, and irritation (Figure 5). The patient tolerated the AAM injection without any adverse events.

3.6 | Case 6. HIV-Associated Lipoatrophy Treatment

A 70-year-old man, FST I, with a 30-year history of HIV presented with HIV-associated lipoatrophy in his face. At presentation, the patient had a MMVSA score of 4 with a BMI of 29. Despite past filler and RF microneedling treatments, the patient remained unsatisfied with results and continued to be bothered by volume loss in his midface. Physician assessment of the patient's skin at baseline revealed a skin tone and texture of 3 and an erythema and irritation score of 1. AAM was injected bilaterally into his midface at baseline and Week 8 (Table 2). In total, by Week 12, the patient had received 3 mL to each side of his face and saw significant improvement in midface fullness. The

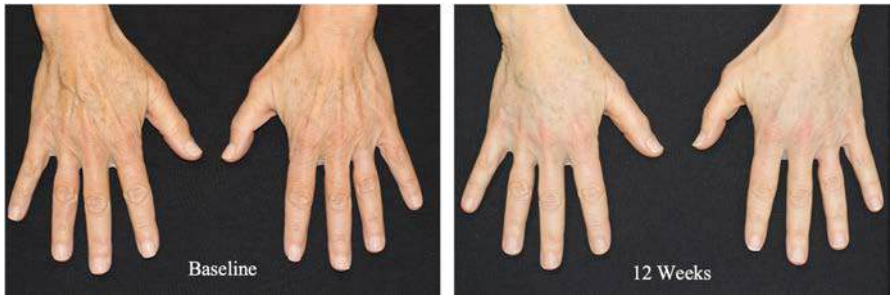

FIGURE 4 | Case 4. 67-year-old woman. AAM 3 mL (2×1.5 mL) injection into dorsal hands in 67-year-old woman (*Photograph courtesy of Joel Cohen MD*).

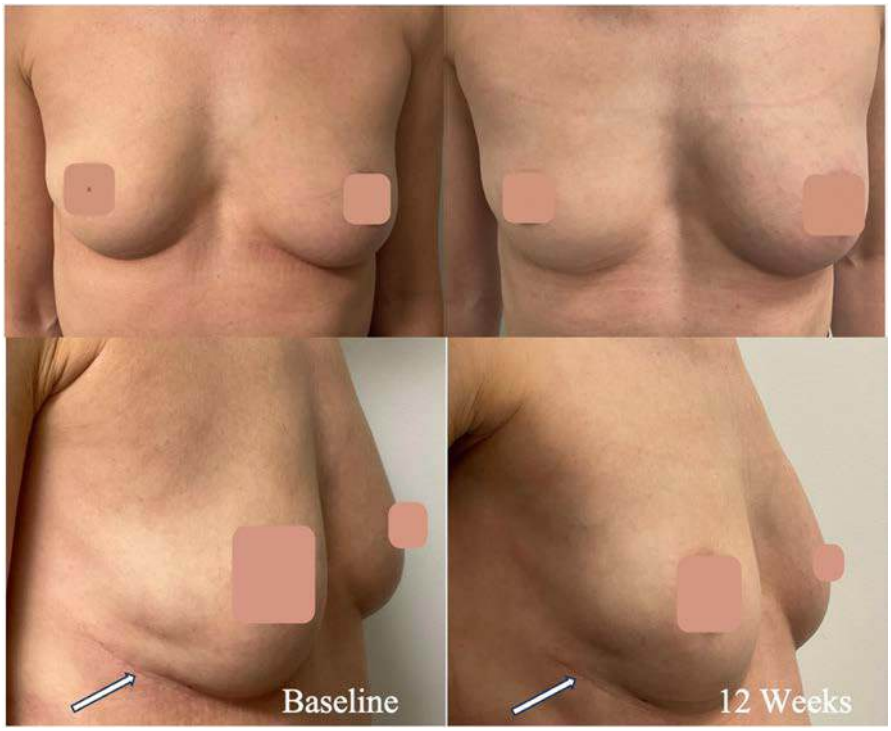

FIGURE 5 | Case 5. 43-year-old woman. AAM 1.5-mL injection into right lateral breast of 43-year-old woman before and after 12 weeks (*Photograph courtesy of Doris Day MD*).

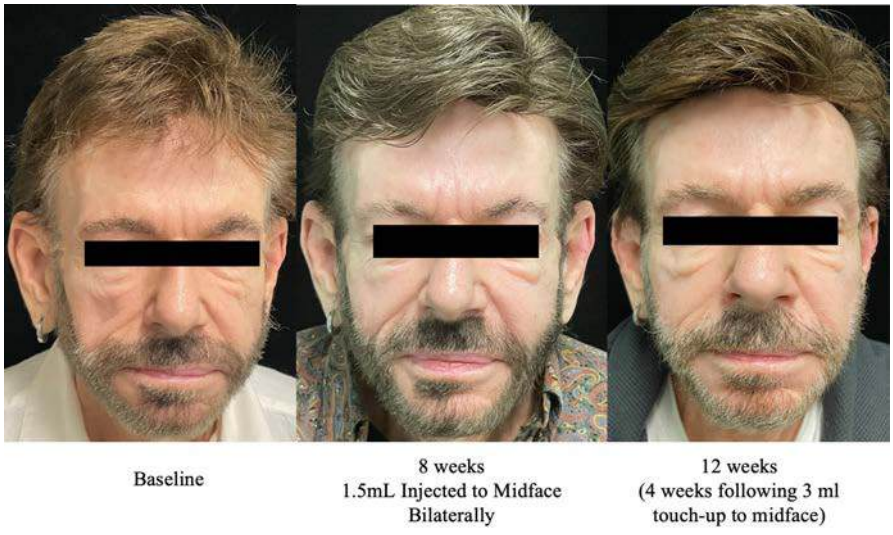

FIGURE 6 | Case 6. 70-year-old man. AAM 1.5-mL injection into midface bilaterally in 70-year-old man with HIV-associated lipoatrophy (*Photographs courtesy of Michael H. Gold, MD, Marci Kleinrock, PA-C, and Collette Utley, DNP, NP-C*).

patient had a MMVSA score of 1 at the end of the treatment period (Figure 6). He was very satisfied with the AAM treatment and tolerated the treatment without any adverse events.

3.7 | Case 7

A 40-year-old woman, FST I, presented to clinic for significant loss of midface volume. The patient felt that since turning 40, she noticed facial volume loss, which resulted in prominent nasolabial folds and marionette lines. Upon evaluation, her MMVSA score was 3, at which time AAM treatment was proposed for its natural-appearing results and efficiency in treatment. In the past 12 months, the patient had already tried neuromodulators (Botox and Dysport) and continued to receive treatment every 12 weeks into her forehead, crow's feet, glabella, and bunny lines. AAM, 0.75 mL, was injected to both sides of her midface. At 12 weeks, the patient had noticeable filling of her midface, which reduced the visible marionette lines and nasolabial folds (Figure 7). MMSVA and GAIS scores at 12 weeks were 1 and 4, respectively. The treatment was well-tolerated without any reported adverse events over the treatment period.

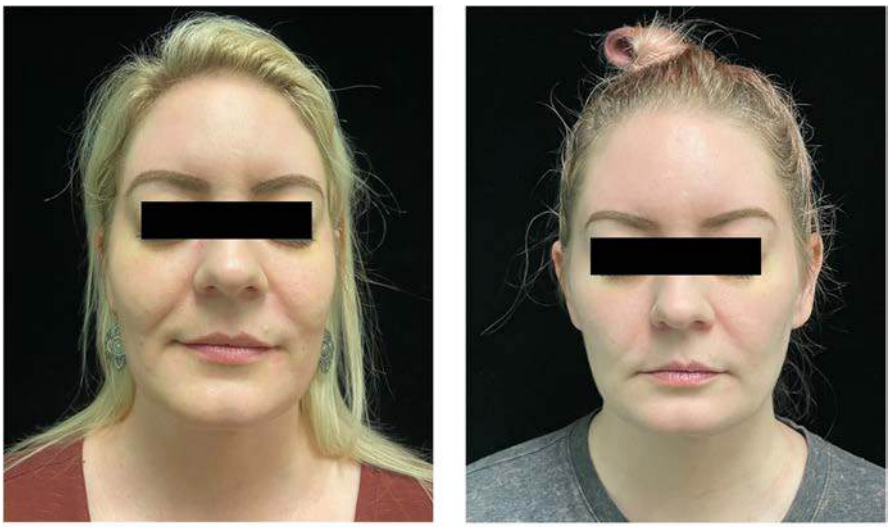

FIGURE 7 | AAM 0.75-mL injection into midface bilaterally in 40-year-old woman concerned with aging face (*Photographs courtesy of Michael H. Gold MD, Marci Kleinrock PA-C, and Collette Utley, DNP, NP-C*).

4 | Discussion

Allograft adipose matrix is a natural, treatment that supports volume restoration and acts as a safe and effective scaffold for adipose tissue in volume-depleted areas of the body [3–8]. The presented cases illustrate the successful use of the matrix in the fat-containing regions of the face, hands, and breast. Experts noticed significant volume restoration, which was attributed to the ability of the body to replace its own fat cells supported by the presence of natural allograft adipose. Having seen many complications from fat grafting, experts appreciated that this matrix yielded a uniform, predictable amount of fat that did not accumulate, "clump", or become "wavy". Massaging the injected material also helped ensure homogeneity of the matrix distribution. When injected into fatty areas of the body, the matrix does not migrate and stays within adipose tissue [8].

Allograft adipose matrix provides a natural scaffold and microenvironment of proteins and growth factors that are beneficial to the natural skin rejuvenation process [6]. It will also be valuable to study the AAM durability over longer periods of time and analyze type I versus type III collagen production as well as quantify and describe expected skin changes after AAM treatment.

Through this case series, experts trialed different injection techniques to yield optimal results with AAM. There was expert consensus that a 22-gauge canula was ideal for injection with one expert suggesting use of a 25-gauge canula and blending the AAM with 1 cc of saline and 0.5 cc of lidocaine. Clogging of the canula was reported as an obstacle in injection, which could be avoided by using a 2:1 AAM to saline blend. Most experts found that use of AAM was easier and smoother than fat grafting, highlighting that needle use made the process more precise. As the matrix product becomes more widely used, consensus among experts on key variables such as blending preparation, volume, swishing technique, injection depth, caliber of needle, adaptor, and canula for AAM treatment will be necessary to ensure uniform results across all patient populations.

Allograft adipose matrix is a novel and versatile natural allograft tissue form, which can help with soft tissue volume loss or deformation secondary to aging or scarring. The expert panel discussed other unexplored uses of the matrix to address soft tissue atrophy in a variety of clinical conditions. For instance, Adem et al. [11] have recently demonstrated effective use of AAM to alleviate radiation-induced skin fibrosis. The AAM was found to augment the regenerative potential of human skin and improve both soft tissue atrophy and morphological characteristics of irradiated skin [11]. Injecting AAM into irradiated, fibrotic skin led to increased dermal thickness, collagen density, collagen fiber networks, and skin vascularity, which resulted in greater volume retention than traditional fat grafts [11]. One panel expert also highlighted the ideal use of AAM in a breast cancer survivor that undergoes frequent, routine scans. AAM appears as natural adipose tissue on imaging; thereby, sparing patients from any unnecessary worry or anxiety. Other experts also suggested using AAM as a hyperdilution for pan-facial treatment for enhancing dermal thickness.

5 | Limitations

The cases demonstrate successful use of AAM in a variety of patient cases and body sites. At 12 weeks, all patients saw retention and improvement in soft tissue volume; however, it will be important to follow these patients for a longer period to mirror AFG studies and determine how long AAM results last [5]. In addition, it will be important to include controls and comparator products to best evaluate the efficacy and safety of AAM. Our results represent data from patients under real-world conditions and do not represent data from a controlled, clinical trial setting.

6 | Conclusion

Allograft adipose matrix is a novel, allograft treatment that restores adipose soft tissue atrophy and volume loss. Experts'

cumulative experience and insight suggest that AAM is a powerful option that acts as a scaffold for the patient's own fat cells to infiltrate, remodel, and restore lost volume. These real-world cases demonstrate the successful use of AAM for volume loss in the face, hands, and breast across various clinical practices nationwide. The use of AAM may be a safe and more effective alternative to fat grafting for improving outcomes in patients seeking volume restoration.

Author Contributions

All authors contributed to the collection, selection, and discussion of the real-world cases. All authors contributed to developing the manuscript, reviewing this work, and agreeing with the content.

Consent

All authors obtained written informed consent from the individuals who participated in the real-world case series. The participants in the real-world series allowed the recording of their photographs to be used for the manuscript and its publication.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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