A Prospective, Open-label, Post-marketing Study of the Safety and Effectiveness of HArmonyCa Injectable Gel for Midface Soft Tissue Augmentation: Interim Analysis

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OBJECTIVE

To report interim safety and effectiveness data from a prospective open-label study of HArmonyCa (Allergan Aesthetics, an AbbVie Company, Irvine, CA) for midface soft tissue augmentation

CONCLUSIONS

- Treatment with HArmonyCa achieved clinically meaningful improvement in midface volume deficit that was maintained through 9 months
- Most participants treated with HArmonyCa had improved investigator- and participant-assessed GAIS ratings and substantial improvements in FACE-Q scores
- HArmonyCa was well tolerated

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INTRODUCTION

Background

- HArmonyCa is an injectable facial soft tissue filler containing calcium hydroxyapatite (CaHA) microspheres (55.7% w/w) embedded in cross-linked sodium hyaluronate (HA) gel (20 mg/mL).[1] The lidocaine version includes 0.3% (w/v) lidocaine HCl
- HArmonyCa, in a single ready-to-use syringe, provides an immediate filling and lifting effect from HA[1,2] along with endogenous collagen production and a sustained lifting effect from CaHA[3]
- Although HArmonyCa is marketed in more than 30 countries, limited published prospective safety and effectiveness data are available
- This open-label study in France collected prospective data on HArmonyCa (HArmonyCa and HArmonyCa Lidocaine) to support ongoing registration in Europe and other areas

METHODS

Study Design: Prospective Open-label Post-marketing Study

Screening
Up to 30 days
Inclusion criteria: adults with moderate to severe midface volume deficit: grades 3–5 on the validated 6-point Allergan Midface Volume Deficit Scale (MFVDS): 0=none, 5=severe

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Initial Treatment
HArmonyCa or HArmonyCa Lidocaine in midface and lateral face

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Optional Touch-up Treatment
14 days after initial treatment

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Follow-up Visits
Months 1, 3, 6, 9, and 12

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Study Exit

Assessments

Primary Endpoint

- Rate of responders, participants with MFVDS ≥1-grade improvement from baseline at month 1

Secondary Endpoints

- Rate of participants with "improved" or "much improved" on Global Aesthetic Improvement Scale (GAIS) at month 1 as rated by investigators and participants
- Change from baseline on FACE-Q Satisfaction with Cheeks and Satisfaction with Facial Appearance at month 1

Safety

- Injection site responses (ISRs), adverse events (AEs)

RESULTS

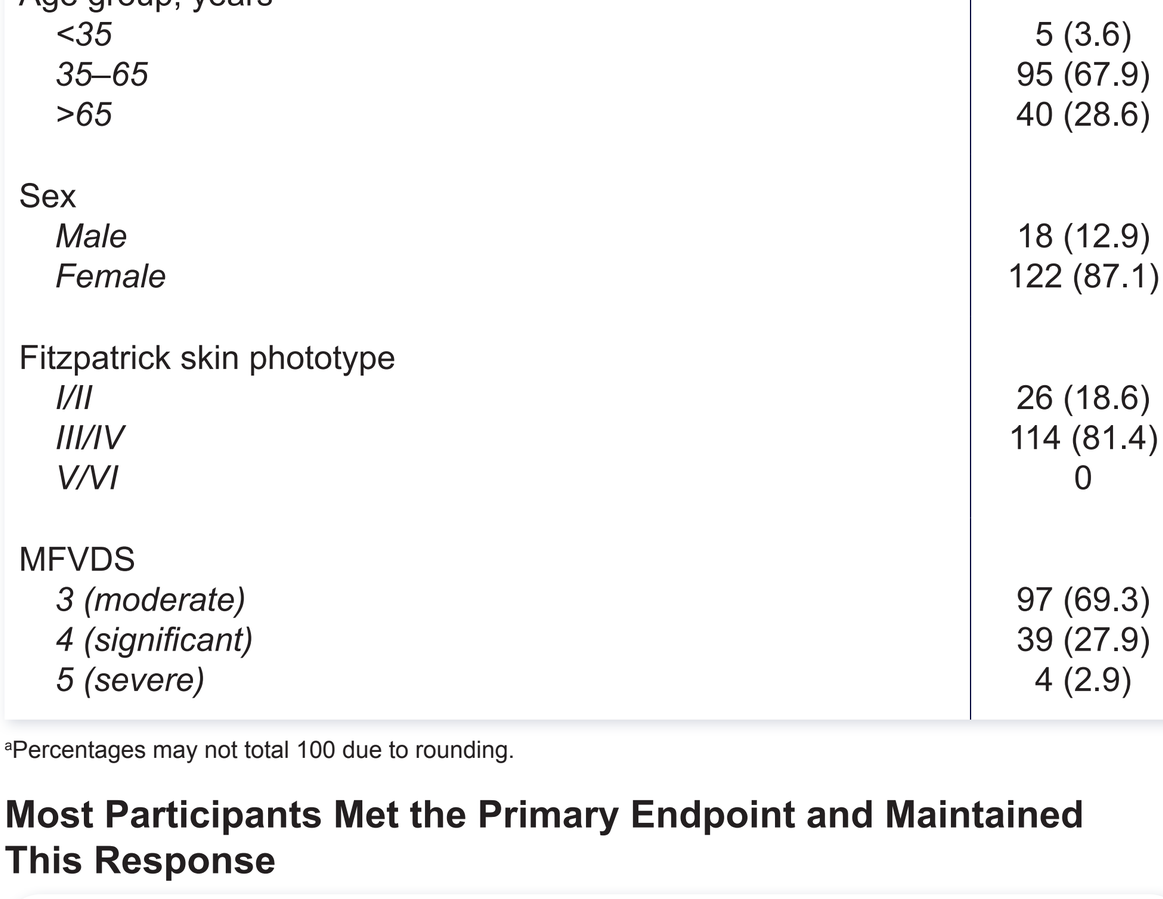
Most Participants Had Moderate Midface Volume Deficit

Baseline demographics and characteristics (N=140)	n (%)[a]
Age group, years	
<35	5 (3.6)
35–65	95 (67.9)
>65	40 (28.6)
Sex	
Male	18 (12.9)
Female	122 (87.1)
Fitzpatrick skin phototype	
I/II	26 (18.6)
III/IV	114 (81.4)
V/VI	0
MFVDS	
3 (moderate)	97 (69.3)
4 (significant)	39 (27.9)
5 (severe)	4 (2.9)

[a]Percentages may not total 100 due to rounding.

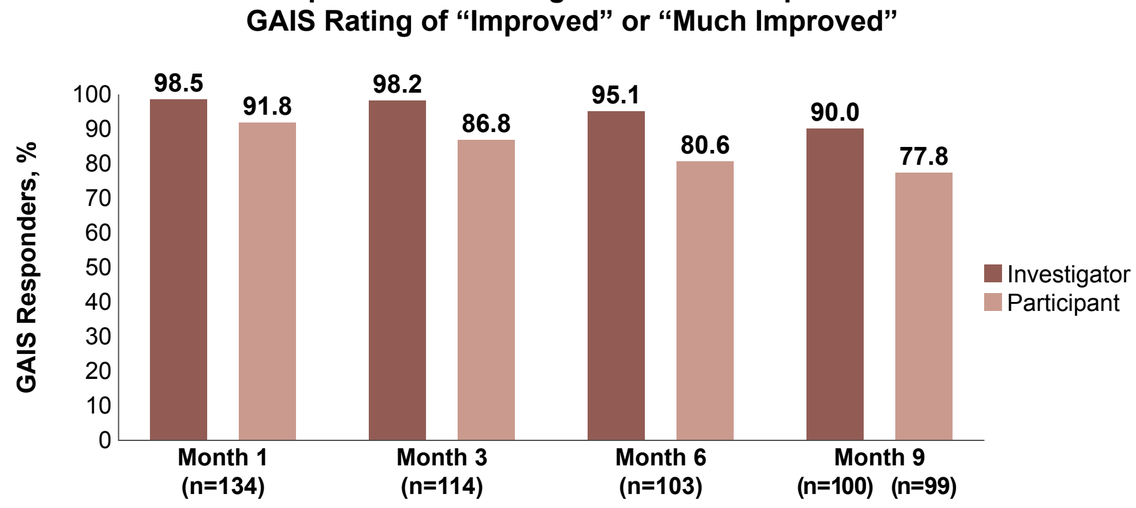
Most Participants Met the Primary Endpoint and Maintained This Response

Participants with MFVDS ≥1-Grade Improvement from Baseline



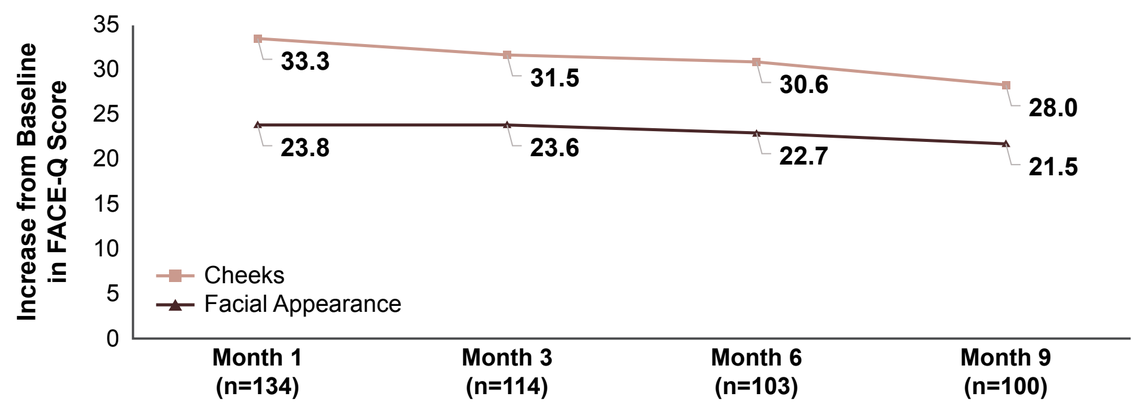
Investigator- and Participant-rated GAIS Improved for Most Participants

Participants with Investigator- and Participant-rated GAIS Rating of "Improved" or "Much Improved"



Participants Had Substantially Increased FACE-Q Scores Compared with Baseline

FACE-Q Satisfaction with Cheeks and Satisfaction with Facial Appearance Questionnaires: Change from Baseline



HArmonyCa Was Well Tolerated

- Overall, a total of 89/140 participants (63.6%) had treatment-emergent AEs (TEAEs) and 52/140 participants (37.1%) had treatment-related TEAEs
- 3/140 participants (2.1%) had treatment-emergent serious AEs; none were considered to be treatment related
- The most common treatment-related TEAEs were injection site pain (10.7%), injection site mass (10.7%), headache (7.9%), injection site bruising (4.3%), and injection site hematoma (3.6%)
  - All were mild (90%) or moderate (10%) in severity
  - 38% resolved in ≤1 week; 65% resolved in ≤30 days
- 95.7% (132 of 138 participants with initial treatment diary data) experienced ISRs consistent with injections of HA or CaHA filler
  - The most common ISRs after initial treatment were tenderness to touch (87%), pain after injection (73.7%), and firmness (71%)
  - 91.3% of ISRs were minimal or moderate
  - 54.3% of ISRs resolved in ≤1 week

References: 1. HArmonyCa Lidocaine [instructions for use]. Muenster, Germany: MedNet EC-REP GmbH; 2021. **2.** Hee CK, et al. *Dermatol Surg*. 2015;41(suppl 1):S373-81. **3.** Gonzaga da Cunha M, et al. *Surg Cosmet Dermatol*. 2020;12:109-17.

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