



Multimodal Facial Aesthetic Treatment on the Appearance of Aging, Social Confidence, and Psychological Well-being: HARMONY Study

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Abstract

Background: A global approach to facial rejuvenation involves multiple treatment modalities.

Objectives: The aim of this study was to evaluate the impact of multimodal facial aesthetic treatment on self-reported psychological and social outcomes.

Methods: HARMONY, a prospective, multicenter, 4-month study, enrolled patients aged 35 to 65 years to receive on-label treatment with a combination of hyaluronic fillers (VYC-20L, HYC-24L, and/or HYC-24L+), onabotulinumtoxinA, and bimatoprost. Fillers were injected on Day 1, with touch-ups performed on Day 14. OnabotulinumtoxinA was injected at Month 3 into glabellar lines and/or crow's feet lines. Patients applied bimatoprost to eyelashes once daily for 17 weeks. Mean change from baseline on FACE-Q Psychological Well-being and Social Confidence Scales, FACE-Q Aging Appearance Appraisal Scale, and FACE-Q Age Appraisal Visual Analog Scale were assessed.

Results: Of 100 patients treated, 93 were evaluated at 4 months posttreatment. Significant improvement vs baseline was observed on the FACE-Q Scales for Psychological Well-being (mean change, -19.9 ; $P < 0.00001$), Social Confidence (mean change, -18.2 ; $P < 0.00001$), and Aging Appearance (mean change, -28.5 ; $P < 0.0001$). On average, patients' self-assessed age was 0.1 years older than actual age at baseline and 4.5 years younger at Month 4 ($P < 0.001$ vs baseline). Forty-two patients experienced adverse events, all mild to moderate.

Conclusions: Multimodal, full facial aesthetic treatment improves patients' self-reported psychological well-being, social confidence, aging appearance, and perceptions of chronologic age.

Level of Evidence: 4

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Perception of facial appearance is a key factor for individuals selecting aesthetic surgery or minimally invasive procedures.^{1,2} A disparity between how old individuals may feel internally and the age that they see reflected in the mirror can be a source of tension and dissatisfaction that increases over time.³ Furthermore, facial appearance and age-related changes can impact an individual's interactions with others and may adversely affect their self-esteem.^{4,5} Evidence suggests that facial appearance strongly influences first impressions and that people with more attractive faces are perceived as being more socially competent, outgoing, intelligent, and financially successful.^{4,6-8} From an evolutionary perspective, youthful and attractive faces may serve as a signal that an individual is fertile.^{7,9} Such impressions based on facial appearance may result in preferential treatment in both personal and occupational relationships for people considered to be attractive.^{4,7} Thus, facial aesthetic treatments have the potential to both improve a person's overall feeling of well-being and facilitate more positive social interactions.

Accordingly, psychosocial benefits, including improvements in self-confidence, self-esteem, psychological symptoms of anxiety and depression, and quality of life, have been reported in individuals who underwent facial cosmetic surgery.^{10,11} Studies assessing patient-reported outcomes (PROs) following treatment with botulinum toxin A or hyaluronic acid (HA) fillers alone demonstrated benefits for patients' self-esteem, self-perception of age, and quality of life.¹²⁻¹⁹ However, these previous studies did not address the psychological and social impact of multimodal facial aesthetic treatment.

As the field of aesthetic medicine matures and a greater range of tools becomes available to address different areas of patient dissatisfaction with appearance, there has been an increased adoption of a holistic approach to assessment and treatment, which considers the entire face and at the same time utilizes various treatment modalities to address multiple aspects of facial appearance. Psychological research on perception demonstrates that people process faces quickly and comprehensively (ie, as a whole) rather than as a sum of individual features.²⁰⁻²²

Previous studies of multimodal facial aesthetic treatment generally focused on 1 or 2 facial areas, used only 1 type of product (eg, dermal fillers), and evaluated the efficacy and safety of specific products or devices based on clinician-assessed endpoints of physical changes in facial features.²³⁻²⁷ These endpoints did not capture the patients' perspective, including the extent to which treatments addressed their concerns and their psychosocial dissatisfaction with their facial appearance. To date, 1 published study reported psychosocial outcomes following a multimodal, full-facial rejuvenation approach. That 6-month, open-label study of a neuromodulator in combination with a range

of HA fillers reported high rates of patient satisfaction with overall full-facial aesthetic outcomes, as well as high rates of patient-rated global aesthetic improvements and modest yet statistically significant improvements in quality of life and self-esteem.²⁸

The HARMONY study aimed to evaluate various factors influencing patient satisfaction and well-being following multimodal facial treatment that incorporated endpoints assessing a range of outcomes based on PROs selected from the validated FACE-Q scales.²⁹⁻³³ Patient satisfaction with appearance measured by the FACE-Q Satisfaction With Facial Appearance Overall Scale (primary endpoint) was shown to almost double after treatment.³⁴ In this paper, additional findings from the HARMONY study are highlighted that demonstrate the impact of multimodal treatment on psychological and social outcomes and perceptions of appearance and age in patients seeking facial aesthetic treatment.

METHODS

Study Design

Details of the study design and eligibility criteria have been reported in prior publications.^{32,34} Briefly, HARMONY was a multicenter, single-blind, 4-month study (NCT02176356) conducted in the United States between July 1, 2014 and February 17, 2015. Patients received combined treatment with the following products for facial rejuvenation: onabotulinumtoxinA (Botox Cosmetic) for treatment of dynamic rhytids; HA dermal fillers VYC-20L (Juvéderm Voluma XC) for volume restoration and HYC-24L (Juvéderm Ultra XC) and/or HYC-24L+ (Juvéderm Ultra Plus XC) for lines and folds; and bimatoprost ophthalmic solution 0.03% (Latisse) for treatment of eyelash hypotrichosis (all products, Allergan Aesthetics, an AbbVie Company, Irvine, CA). The study was conducted in accordance with US FDA regulations and guidelines, the International Council for Harmonisation Good Clinical Practice guidelines, and local laws and regulations. A central IRB (Schulman Associates IRB, Cincinnati, OH) approved the protocol and all patients provided written informed consent before study participation. The study enrolled males and females aged 35 to 65 years who had not previously received treatment with neuromodulators, dermal fillers, and eyelash growth products. Subjects were included if they had moderate or severe glabellar lines and/or moderate or severe crow's feet lines; had at least 2 of the following, which, based on investigator and subject opinion, required treatment with dermal fillers: moderate or severe nasolabial folds, oral commissures, perioral lines, marionette lines, and/or radial cheek lines, and/or moderate to substantial midface volume deficit; and had minimal or moderate eyelash hypotrichosis

on the 4-point Global Eyelash Assessment (GEA) scale, as determined by the investigator.^{32,33} Patients received reimbursement for study-related expenses.

Treatment

Patients applied bimatoprost to the upper eyelid margins once daily in the evening from Day 1 for 17 weeks. On Day 1, patients received initial treatment with HYC-24L and/or HYC-24L+, injected as needed based on investigator assessment, with a maximum total volume of 6.0 mL. A maximum total volume of 4.0 mL of VYC-20L was also injected. Optional touch-up treatments were allowed on Day 14. Injected filler volumes used in the study have been reported previously.³⁵ At Month 3, onabotulinumtoxinA was injected for glabellar lines and/or crow's feet lines according to the FDA-approved injection pattern and doses for each indication.

Assessments

Four validated PRO instruments were used for patient assessments: the FACE-Q Psychological Well-being Scale, the FACE-Q Social Confidence Scale, the FACE-Q Aging Appearance Appraisal Scale, and the FACE-Q Age Appraisal Visual Analog Scale (VAS). Each of the FACE-Q Psychological Well-being and Social Confidence Scales measures a series of positively worded statements, with 8 to 10 statements per scale, each evaluated on a 4-point scale (definitely disagree, somewhat disagree, somewhat agree, and definitely agree). Patients were to answer questions keeping the last week in mind.³¹ The FACE-Q Aging Appearance Appraisal Scale is a 7-item scale designed to provide overall global assessment of a patient's perception of appearance in the context of facial aging; each item was evaluated on a 4-point scale (definitely disagree, somewhat disagree, somewhat agree, and definitely agree).³⁰ The FACE-Q Age Appraisal VAS comprises a single item asking patients to report their perceived age in comparison to their actual age.³⁰ FACE-Q scales with multiple items may be analyzed by individual items or by total score for all items. Scale questionnaires were distributed by study staff in the physician's office and were anonymous. Patients completed all questionnaires in writing and unaided at baseline and at Month 4.

Statistical Analysis

Efficacy analyses were performed on the modified intent-to-treat (mITT) population, comprising all patients who not only received treatment with all products but also who completed the 4-month posttreatment efficacy assessment. For the FACE-Q scales, except the FACE-Q Age Appraisal VAS, raw scores of the individual items for each

scale were summed to provide the total raw scores for the original scales. Raw data (individual and total scores) were transformed by Rasch unidimensional methods to a score ranging from 0 to 100, with higher scores reflecting a better outcome.^{36,37} Transformed score ranges for each response category for every item were calculated based on threshold estimates.³⁸ Data were analyzed with a paired *t* test (or Wilcoxon signed-rank test, depending on the distribution of the data). Analyses were performed with RUMM2030 software (RUMM Laboratory, Perth, Australia). The FACE-Q Age Appraisal VAS was analyzed as a continuous variable.

Effect size (Cohen's *d*), used to quantify the size of the difference between groups, was calculated based on mean change.^{39,40} As a general framework, effect sizes of 0.20, 0.50, and 0.80 were considered small, medium, and large, respectively, whereas effect sizes greater than 1.0 were considered substantial.

RESULTS

Patients

Of 116 patients enrolled, 16 failed screening and 100 received treatment (safety population). Seven patients were excluded from the efficacy analysis (4 were not treated with all products, and 3 discontinued early for personal reasons), resulting in an mITT population of 93. In previously reported demographics,³² 96% of patients were female (*n* = 96), 4% were male (*n* = 4), and the majority were White (86%), with a mean [standard deviation] age of 52.5 [7.4] years (range, 37-65 years) at baseline. Details of treatments, injection techniques, and HA filler volumes were published previously.³²

Psychological Impact

FACE-Q Psychological Well-being Scale

Overall mean scores for psychological well-being across the 10 items improved from 62.8 [22.5] at baseline to 82.7 [17.0] following treatment (mean change, -19.9 [20.6]; *P* < 0.0001) (Figure 1A). The change in psychological well-being scores was associated with a large effect size. For 8 of the 10 items on the Psychological Well-being Scale, responses improved from somewhat agree with each item at baseline to definitely agree following treatment (Figure 1B).

FACE-Q Social Confidence Scale

Overall mean scores for social confidence across the 8 items improved from 62.7 [21.7] at baseline to 80.9 [18.7] after treatment (mean change, -18.2 [23.0]; *P* < 0.0001) (Figure 2A). The change in social confidence scores was associated with a large effect size. For 6 of the 8 items

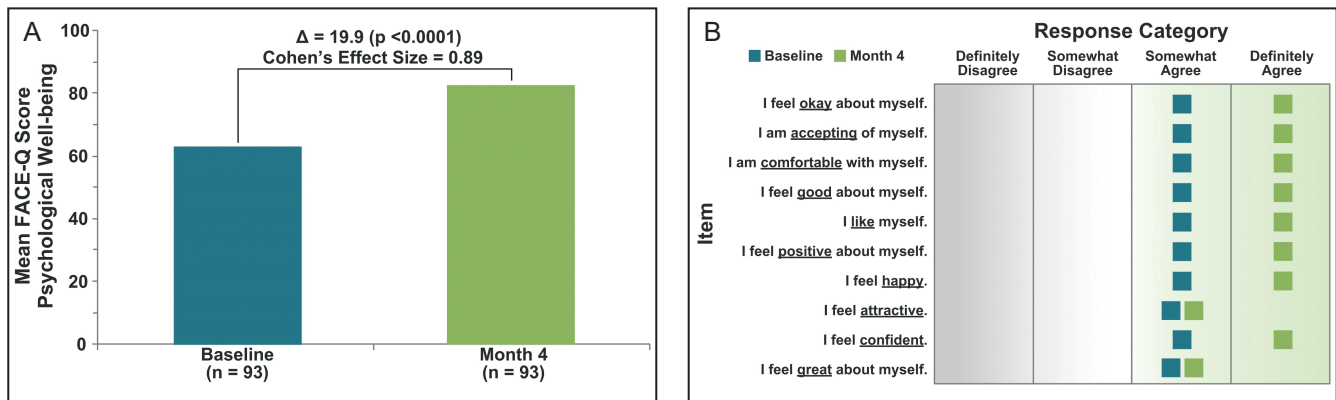


Figure 1. FACE-Q Psychological Well-being Scale mean scores at baseline and at Month 4. Data are presented as overall scores (A) and by individual items (B).



Figure 2. FACE-Q Social Confidence Scale mean scores at baseline and at Month 4. Data are presented as overall scores (A) and by individual items (B).

on the social confidence scale, responses improved from somewhat agree at baseline to definitely agree after treatment (Figure 2B).

FACE-Q Aging Appearance Appraisal Scale and Age Appraisal VAS

Overall mean scores for aging appraisal across the 7 items improved from 45.1 [18.9] at baseline to 73.5 [20.1] following treatment (mean change, -28.5 [21.5]; $P < 0.0001$) (Figure 3A). The change in Aging Appearance Appraisal scores was associated with a substantial effect size. For 6 of the 7 items, responses improved from somewhat disagree to somewhat agree (2 responses) or definitely agree (4 responses) (Figure 3B). On the FACE-Q Age Appraisal VAS, patients assessed themselves as appearing a mean of 0.1 [4.3] years older than their actual age at baseline and 4.5 [3.9] years younger than their actual age at Month 4 (mean difference, -4.6 [4.4]; $P < 0.001$). The change in Age Appraisal VAS scores was associated with a substantial effect size of 1.05. Overall, 75% of patients indicated at Month 4 that

they looked younger than their actual age (by a mean of 6.3 years), whereas 17% responded that they looked their age, and 6% believed they looked older (by a mean of 3.0 years) (Figure 4). Representative patient photographs at baseline and at Month 4 (Figures 5 and 6) demonstrate aesthetic outcomes following treatment.

Safety

As published separately in greater detail,³³ 42 of 100 patients in the safety population (42%) experienced adverse events (AEs), all of which were mild to moderate in severity. No serious AEs were reported, and no patients discontinued the study because of an AE. Of 91 procedure-related AEs, the most common AEs were bruising (61 events), injection site pain (12 events), injection site redness (8 events), and swelling (7 events). The number of patients who experienced a treatment-related AE attributable to one of the study products was 4/100 (4%) for bimatoprost, 12/96 (13%)

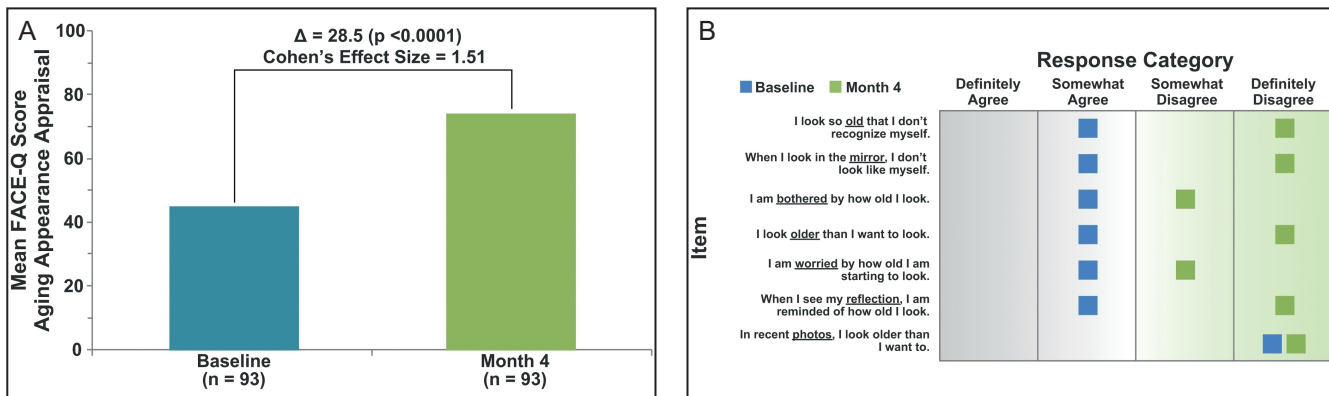


Figure 3. FACE-Q Aging Appearance Appraisal Scale scores at baseline and at Month 4. Data are presented as overall scores (A) and by individual items (B).

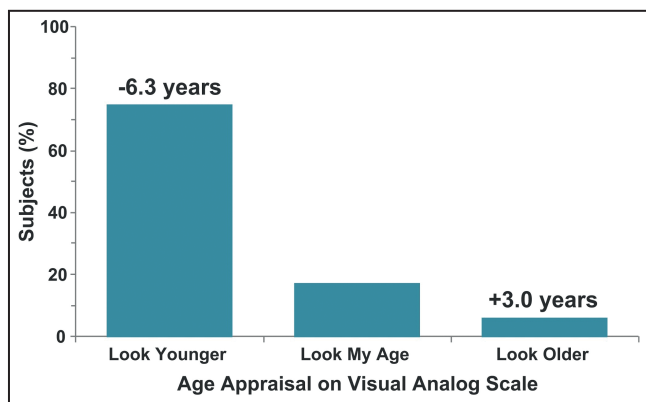


Figure 4. FACE-Q Age Appraisal Visual Analog Scale results at Month 4. Overall mean improvement from baseline was 4.6 years younger.

for VYC-20L, 16/80 (20%) for HYC-24L, 15/78 (19%) for HYC-24L+, and 2/96 (2%) for onabotulinumtoxinA.

DISCUSSION

HARMONY is a unique study demonstrating the considerable impact of a broad, multimodal approach to facial rejuvenation treatment on improvement in patients' self-reported psychological well-being, social confidence, and self-appraisal of improvement in aging appearance. The traditional tools for measuring treatment success (ie, quantifiable decreases in severity of aesthetic irregularities as assessed by clinicians and patients) are often inadequate to evaluate the impact of treatment on these psychosocial outcomes. Having assessments that provide insights into these psychosocial aspects is crucial for clinicians and patients to evaluate the full benefit of treatment. The development of validated PROs provides a vital tool to evaluate

outcomes that are meaningful, both in research and in clinical settings.^{29,31}

The item-level analyses of the psychological well-being and social confidence scales indicate that patients experienced improvements in feeling positive, confident, and happy with their facial appearance, and in feeling comfortable, confident, and positive in their interactions with others. In conjunction with the previously published HARMONY data on satisfaction with facial appearance, which showed a significant increase ($P < 0.0001$) from baseline scores and a substantial effect size of 2.7,³⁴ these findings indicate that a holistic, multimodal approach to facial aesthetic treatment may yield important benefits in multiple domains of improvement in body image. The results were associated with large and substantial effect sizes, similar in size to those reported after surgical aesthetic procedures.^{41,42} In total, the findings suggest that patients started out with realistic and well-adjusted perceptions of their appearance yet reliably achieved improvement in outcomes of psychological well-being and social confidence.

A multidimensional construct of body image comprises an individual's perceptions, thoughts, feelings, and behaviors related to his or her physical appearance.⁴³ It is this self-perceived mental image of one's face and body that may or may not align closely with the way that others view a person. Significant changes in facial structure occur with aging and, over time, psychosocial concerns about appearance focus increasingly on the face.^{2,44} Aging, in general, may result in negative psychosocial consequences, ranging from negative self-focused thoughts and feelings, such as shame, embarrassment, and anxiety, to perception of social discrimination or social neglect. Affected people report feeling ignored or "invisible" because of aging.^{45,46} Anxiety and concerns around facial aging are significant predictors of social motivations to pursue aesthetic intervention.⁴³



Figure 5. A 50-year-old female patient at baseline (A) and at Month 4 (B). Patient applied bimatoprost daily to eyelid margins and received 4.0 mL VYC-20L for midface volume deficiency, 3.7 mL HYC-24L for nasolabial folds, oral commissures, and perioral lines, and 1.6 mL HYC-24L+ for oral commissures and marionette lines; onabotulinumtoxinA was injected for glabellar lines (20 U) and crow's feet lines (12 U per side) at Month 3. At Month 4, Aging Appearance Appraisal Scale score improved by 15 points and Psychological Well-being Scale score by 12 points; Social Confidence Scale scores were similar to baseline (all FACE-Q scores noted here are raw, untransformed scores). The patient rated herself as looking 6 years younger than her actual age on the FACE-Q Age Appraisal VAS.

One study has demonstrated improvement in age appraisal with neuromodulator treatment of hyperdynamic facial lines according to the FACE-Q Age-Appraisal Scale.⁴⁷ Additional studies have shown improvement in age appraisal with the Self-Perception of Aging questionnaire following treatment with onabotulinumtoxinA,^{13,15,17,19,48} HA fillers,¹⁶ or combination therapy with onabotulinumtoxinA and HA dermal fillers.⁴⁹ However, the HARMONY study is unique in demonstrating a benefit of multimodal aesthetic treatment on age appraisal that includes treatment modalities beyond neuromodulators and HA fillers. Importantly, among the 75% of patients who reported an improvement in age appearance, the mean improvement was 6.3 years. Interestingly, the fact that not all patients reported looking younger postprocedure in this study may indicate that they sought to look better but not necessarily younger.

In recent years, there has been an increasing recognition that the benefits of facial rejuvenation procedures extend beyond physical appearances. Such procedures may serve as a catalyst for measurable improvements in the long-term emotional state of patients (eg, self-image) and allow these individuals to function better in their social

interactions. Given the importance ascribed to attractiveness, appearance has broad influences on self-confidence and social acceptance.⁵⁰ Accordingly, studies have reported significant correlations between patients' satisfaction with their own appearance and their sense of well-being, as well as between measures of facial self-perception and general self-esteem.⁵¹⁻⁵³ It is thus not surprising that surgical^{10,11} and nonsurgical^{12-14,16,18,19,28,49} facial aesthetic treatments have demonstrated benefits in self-confidence, self-esteem, and quality of life. This study shows, for the first time, that a multimodal, full-facial rejuvenation approach can impact not only patients' self-perception of age but may also significantly improve their psychological well-being and social confidence. A few individual items of the FACE-Q scales did not show improvement after treatment. This may reflect differences in patient expectations and goals for treatment, differences in perspectives based on patient age, and cultural factors.^{29,54} In a separate analysis of the HARMONY data, factors such as filler injection volume, product selection, and order in which facial areas are treated were shown to play a role in the degree of improvement in patient satisfaction with



Figure 6. A 63-year-old female patient at baseline (A, C) and at Month 4 (B, D). The patient applied bimatoprost daily to eyelid margins and received 4 mL VYC-20L for midface volume deficiency, 2.0 mL HYC-24L for nasolabial folds and marionette lines, and 3.0 mL HYC-24L+ for nasolabial folds and marionette lines. OnabotulinumtoxinA was injected for glabellar lines (20 U) and crow's feet lines (12 U per side) at Month 3. At Month 4, Aging Appearance Appraisal Scale score improved by 11 points; Psychological Well-being Scale score by 6 points; and Social Confidence Scale score by 3 points (all FACE-Q scores noted here are raw, untransformed scores). The patient rated herself as looking 5 years younger than her actual age on the FACE-Q Age Appraisal VAS.

appearance, social confidence, psychological well-being, and perception of younger age.³⁵ Nonetheless, all patients did improve on these measures.

The reasons underlying the psychosocial benefits of facial rejuvenation treatments are likely complex and multifactorial. The positive effect that may result from treatment-induced inhibition of negative facial expressions contributes to these benefits. Known as the facial feedback hypothesis, this concept emerged from research on the influence of peripheral physiological reactions, particularly facial muscular activity, on the experience of emotion⁵⁵ and was first articulated in 1980.⁵⁶ The main component of this hypothesis is that biofeedback from facial expressions has a causal effect on emotional experience and behavior. Accordingly, weakening of muscles associated with negative emotions (eg, “frown lines”) may improve mood by making it more difficult for people to produce or sustain negative emotions.⁵⁷ It seems probable that facial feedback contributes to psychological benefits following onabotulinumtoxinA treatment of facial lines. In 1 example, treatment of glabellar frown lines with botulinum toxin A was shown to correlate with a less negative mood.⁵⁷ Patients who did not receive onabotulinumtoxinA treatment were more anxious and depressed, based on the Irritability-Depression-Anxiety Scale, than those who did receive treatment. Demonstrations of positive effects of facial plastic surgery,⁶ neuromodulators,⁵⁸ and HA fillers⁵⁹ on first impressions suggest that facial rejuvenation procedures may also affect social interactions, a hypothesis that warrants further investigation.

This study had several limitations. Enrolled patients were primarily female, White, on average, middle-aged, and were treated with products from a single manufacturer. It is unclear whether findings may be generalized to males and to individuals of other races/ethnicities or age groups or to other aesthetic treatment regimens. Further, the lack of a control group prevented the determination of whether observed changes were attributable to the treatments being evaluated or to other unidentified factors. The current study used a self-report instrument to measure psychological outcomes. Self-report instruments may be subject to bias⁶⁰ and, ideally, will be corroborated by other measures in future studies. The 4-month study period prohibited assessment of the duration of effects of global treatment on psychological and social outcomes and perceptions of appearance and age. Finally, normative data were not available for the PROs used in this study. Although normative data may have facilitated interpretation of baseline and posttreatment scores on the FACE-Q scales, the lack of normative data does not impact the validity of our findings.

CONCLUSIONS

The HARMONY study used validated PROs to evaluate the impact of a personalized, multimodal, minimally invasive

treatment approach to aesthetic facial rejuvenation and assessed outcomes on multiple domains of well-being and age appearance. Patients in this study demonstrated significant psychological and social benefits of treatment, in addition to considerable improvements in their self-perceived appearance and age. Improvements in feeling accepting, happy, and confident about their appearance, as well as feeling comfortable and confident in social interactions, indicate the broad impact of this treatment approach, which complements the physical benefits and satisfaction achieved with these treatments. The HARMONY study provides clinicians with data that they can use when advocating for a more holistic and less piecemeal approach to facial aesthetic rejuvenation. The study also provides a convincing argument that the benefits of this holistic approach extend beyond mere physical improvements. Thus, increased awareness of the psychosocial benefits of facial rejuvenation may also prompt consideration of aesthetic treatment among segments of the population who may have heretofore dismissed it as being only for those who are vain.

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Disclosures

Dr Cohen has served as a consultant and/or clinical trial investigator for Allergan Aesthetics, an AbbVie Company (Irvine, CA), Galderma (Lausanne, Switzerland), and Merz (Frankfurt, Germany). Dr Rivkin serves as a consultant and investigator for Allergan Aesthetics, an AbbVie Company, and Merz Aesthetics. Dr Dayan has received research support or speaking/consultant fees from Allergan Aesthetics, an AbbVie Company, Galderma, Merz Aesthetics, and Valeant (Laval, Quebec, Canada). Dr Shamban serves as an investigator for Allergan Aesthetics, an AbbVie Company, Galderma, and Medicis (Scottsdale, AZ), and as a consultant for Allergan Aesthetics, an AbbVie Company, and Merz. Dr Werschler has served on an advisory board, as a speaker, and as a consultant and/or has received research funding from Allergan Aesthetics, an AbbVie Company, DermAvance (Malvern, PA), Galderma, Healion (Ijamsville, MD), Merz, Polyremedy (Concord, MA), Revance (Nashville, TN), Suneva (Santa Barbara, CA), and Thermi (Irving, TX). Dr Teller serves as an investigator and advisory board member and has received research funding from Allergan Aesthetics, an AbbVie Company. Dr Kaminer received research funding from Allergan plc (prior to its acquisition by AbbVie) for this study. Dr Weinkle serves as an investigator for Allergan Aesthetics, an AbbVie Company, Alphaeon (Irvine, CA), DermAvance, and Revance, and as a speaker for Sinclair (London, United Kingdom) and Teoxane

(Geneva, Switzerland). Dr Garcia is an employee of AbbVie and owns stock/options in the company. Dr Sykes declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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