

# Maximizing Pan-facial Aesthetic Outcomes: Findings and Recommendations from the HARMONY™ Study

Michael Kaminer, MD<sup>1</sup>; Joel L. Cohen, MD<sup>2</sup>; Vic Narurkar, MD<sup>3</sup>; Ava Shamban, MD<sup>4</sup>; Phil Werschler, MD<sup>5</sup>; Garrett T. Shumate, BS<sup>6</sup>; Conor J. Gallagher, PhD<sup>6</sup>

<sup>1</sup>SkinCare Physicians, Inc., Chestnut Hill, MA, USA; <sup>2</sup>AboutSkin Dermatology and DermSurgery, Englewood, CO, USA; <sup>3</sup>Bay Area Laser Institute, San Francisco, CA, USA; <sup>4</sup>AVA MD, Santa Monica, CA, USA; <sup>5</sup>University of Washington, School of Medicine, Seattle, WA, USA; <sup>6</sup>Allergan plc, Irvine, CA



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## BACKGROUND

- Aesthetic medicine has evolved from targeting individual treatment areas to a more global approach of facial rejuvenation (i.e. pan-facial treatment).
- A multimodal approach to pan-facial aesthetic treatment has not been systematically evaluated in controlled clinical studies. As a result, there is a paucity of universal best practices.
- HARMONY™ was the first clinical trial to evaluate the impact of combined treatment with hyaluronic acid fillers, onabotulinumtoxinA, and bimatoprost 0.03% using a range of validated measures
- Objective:** Understand the treatment strategies that enabled the clinical sites with the highest improvements on the Primary Endpoint (FACE-Q Satisfaction With Face Overall) to achieve incrementally greater results, as compared to those sites with the lowest improvements

## MATERIALS AND METHODS

### Study Design

- Data from the clinical sites with the lowest (2 sites) and highest (2 sites) improvements based on the primary endpoint (FACE-Q Satisfaction With Face Overall) were separated to understand "how" the highest improvements were achieved
- Note that all clinical sites exhibited a significant improvement
- A comparative analysis of the treatment characteristics (e.g. product selection, injection location, and injection volume) was performed to understand the factors enabling the highest performing sites to achieve incrementally greater improvements.

### Subjects

- Evaluation indicated similarity across most of the demographic characteristics:

Characteristic	HIGHEST SITES	LOWEST SITES
Gender	All Female	All Female
Age (mean)	51.8 years	52 years
Fitzpatrick Skin Phototype (mean)	2.9	3.2

- Evaluation indicated similar baselines across most of the endpoints:

Endpoint	LOWEST SITES (mean)	HIGHEST SITES (mean)
FACE-Q: Satisfaction with Facial Appearance Overall	22.7	22.4
FACE-Q: Aging Appearance Appraisal	19.2	18.5
FACE-Q: Social Confidence Scale	22.6	22.1
FACE-Q: Psych Well-Being Scale	28.4	27.8
Self-Perception of Age (years)	0.3	0.5
Overall Mid-Face Volume Deficit	3.0	3.1
Nasolabial Folds (NLFSS)	2.5	2.4
Oral Commissures (OCSS)	2.1	2.1
Perioral Lines (POLSS)	1.8	1.9
Glabellar Line Severity at Maximum Frown (FWS)	2.6	2.2
Crow's Feet Line Severity (FWS)	2.4	2.3
Eyelash Prominence (GEA)	1.9	1.6

## RESULTS

### Efficacy Outcomes

Category	LOWEST SITES (mean)	HIGHEST SITES (mean)	DIFFERENCE (%)
FACE-Q: Satisfaction with Facial Appearance	9.1	13.8	52
FACE-Q: Aging Appearance Appraisal	-4.3	-8.7	103
FACE-Q: Social Confidence Scale (Visual Analog Scale)	-3.6	-6.1	70
FACE-Q: Social Confidence Scale	4.2	7.3	75
FACE-Q: Psych Well-being Scale	5.1	8.2	60
Self-Perception of Age	-3.4	-6.3	89
Appearance of Periorbital Lines	-10.4	-14.2	37
Global Aesthetic Improvement (Subject)	1.5	1.7	16
Global Aesthetic Improvement (Evaluating Investigator)	1.1	1.6	55

- Highest sites exhibited greater improvement across all PROs
- Highest sites had less improvement in glabellar lines and eyelash prominence, which could be attributed to baseline differences
- Highest sites exhibited greater improvement in all other filler and toxin related outcomes

Category	LOWEST SITES (mean)	HIGHEST SITES (mean)	DIFFERENCE (%)
Glabellar Lines (max frown)	-1.70	-1.21	-29
Eyelash Prominence	1.90	1.47	-22
Crow's Feet Lines (max smile)	-0.88	-1.37	63
Midface	-1.20	-1.95	62
Nasolabial Folds	-0.90	-1.32	46
Perioral Lines	-0.72	-1.26	75
Oral Commissures	-0.68	-1.32	92

### Volume XC: Midface



Location	HIGHEST SITES (Mean volume injected per subject (% of subjects treated))	LOWEST SITES (Mean volume injected per subject (% of subjects treated))
Zygomaticomalar V1, V2	1.3 (100%)	1.0 (90%)
Anteromedial Cheek V3	0.9 (100%)	1.2 (90%)
Submalar V4	0.9 (53%)	0.7 (75%)
Overall Midface Total V1-V4	2.7 (100%)	2.9 (90%)

- Highest improvement was achieved with **greater** volume in the zygomaticomalar and **less** in the anteromedial cheek
- More overall volume did not translate into a higher improvement for the patient

### Ultra XC & Ultra Plus XC

Location	Product	HIGHEST SITES (Mean volume injected per subject (% of subjects treated))	LOWEST SITES (Mean volume injected per subject (% of subjects treated))
NLF	Total Ultra XC + Ultra Plus XC	2.0 (89%)	1.2 (95%)
	Ultra XC	2.0 (79%)	0.6 (20%)
Oral Commissures	Total Ultra XC + Ultra Plus XC	0.8 (100%)	1.0 (90%)
	Ultra XC	1.0 (40%)	0.5 (65%)
Marionette Lines	Total Ultra XC + Ultra Plus XC	1.2 (65%)	0.7 (75%)
	Ultra XC	0.3 (10%)	0.5 (40%)
	Ultra Plus XC	1.1 (53%)	0.8 (75%)

Location	Product	HIGHEST SITES (Mean volume injected per subject (% of subjects treated))	LOWEST SITES (Mean volume injected per subject (% of subjects treated))
Radial Cheek	Total Ultra XC + Ultra Plus XC	0.0 (0%)	0.8 (30%)
	Ultra XC	0.0 (0%)	0.5 (30%)
Perioral Region	Total Ultra XC + Ultra Plus XC	0.8 (79%)	0.6 (55%)
	Ultra XC	0.7 (65%)	0.6 (55%)
Overall Use	Total Ultra XC + Ultra Plus XC	4.0 (100%)	3.4 (100%)
	Ultra XC	3.0 (84%)	1.7 (65%)
	Ultra Plus XC	2.2 (68%)	2.4 (95%)

### Ultra XC & Ultra Plus XC Layering

Location	HIGHEST SITES (% of sites that rec'd both products (% rec'd both products in same visit))	LOWEST SITES (% of sites that rec'd both products (% rec'd both products in same visit))
Nasolabial Fold	17.6 (11.8)	15.8 (5.3)
Marionette Lines	20.0 (10.0)	53.3 (53.3)
Oral Commissures	5.3 (0.0)	55.6 (33.3)
Radial Cheek	0.0 (0.0)	50.0 (50.0)
Perioral	6.7 (0.0)	27.2 (16.2)

- Highest improvement was achieved when using only one product per location

### Use of Touch-Ups

Product	HIGHEST SITES (Mean volume injected per subject (% of subjects treated))	LOWEST SITES (Mean volume injected per subject (% of subjects treated))
Volume XC	1.3 (53%)	0.9 (70%)
Ultra XC	1.8 (68%)	0.9 (35%)
Ultra Plus XC	1.1 (48%)	0.9 (60%)

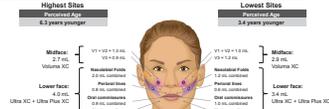
- Highest improvement was achieved using more touch-up volume for all fillers

## CONCLUSIONS

### Responder Rates:

- Subject satisfaction (age, social confidence, and psychological well-being) appeared to correlate with efficacy as assessed by blinded, independent raters

### Product usage that led to higher degrees of subject satisfaction:



Category	Ultra XC	Ultra Plus XC	Ultra XC + Ultra Plus XC	Volume XC
Zygomaticomalar				+
Anteromedial Cheek				+
Lower Face	+	+	+	+
NLF	+	+	+	+
Marionette Lines	+	+	+	+
Oral Commissure		+		
Radial Cheek				+
Perioral	+			
Touch Up	+	+	+	+

### Product Overlay:

- Highest improvements were achieved when using only one product per location

### Key:

- Highest sites used more volume
- Highest sites used less volume
- Product preferred by both highest and lowest sites

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