

**BLU-001 Blue Peel RADIANCE™**

*obagi for life*

**FINAL ANALYSIS  
December 2012**

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OMPI DECEMBER 2012

## **A Single-Center Five-Week Open Label Study to Evaluate the Efficacy of a Series of Three Peel Procedures using Obagi Blue Peel RADIANCE™ in the Improvement of the Appearance of Facial Skin**

**INVESTIGATOR:**

Suzanne Bruce, MD

## STUDY DESIGN

Subjects (male and female) at one site in a 5 week study to evaluate the efficacy and improvement in the appearance of the facial skin after using the Obagi® Blue Peel RADIANCE™ peel in a series of 3 peel procedures in subjects with mild to moderate facial photodamage, fine lines and fine wrinkling, and /or mild superficial acne scarring. Study subjects had a series of 3 Obagi® Blue Peel RADIANCE™ peel procedures, approximately 2 weeks apart.

## MAIN INCLUSION CRITERIA

- Female or male subject, 21-45 years old, inclusive
- Have clinical diagnosis of mild to moderate facial photodamage, fine lines and fine wrinkling, and/or mild superficial acne scarring
- Baseline Investigator Assessment Facial Overall Integrated Photodamage Score 2-Mild or 3-Moderate
- Baseline Investigator Assessment Facial Overall Pigmentation Intensity Scale 1-Minimal or 2-Mild
- Glogau Photodamage Classification Type I or Type II
- Fitzpatrick Skin Type II through light VI

## STUDY TREATMENT REGIMEN

Obagi® Blue RADIANCE™ peel procedure done at Baseline Visit; Day 14 Visit; Day 28 Visit (One layer Obagi® Blue RADIANCE™ per peel procedure.)

Home Use Study Products	
AM	PM
<ul style="list-style-type: none"><li>• Nu-Derm® Gentle Cleanser</li><li>• Nu-Derm® Sun Shield SPF 50</li></ul>	<ul style="list-style-type: none"><li>• Nu-Derm® Gentle Cleanser</li></ul>
Subjects were provided with CLENZIderm™ Therapeutic Moisturizer and instructed to use as needed for post-peel dryness, itching or redness.	

## DEMOGRAPHICS

N	15
Gender Female (%)	86.7 (N=13)
Gender Male (%)	13.3 (N=2)
Age (Mean)	36
White/Caucasian (%)	86.7 (N=13)
Black/African American (%)	6.7 (N=1)
Asian (%)	6.7 (N=1)
Fitzpatrick Skin Type II (%)	46.7 (N=7)
Fitzpatrick Skin Type III(%)	26.7 (N=4)
Fitzpatrick Skin Type IV (%)	20.0 (N=3)
Fitzpatrick Skin Type VI (%)	6.7 (N=1)

## DIAGNOSIS FOR PEEL

N	15
Photodamage (%)	53.3 (N=8)
Photodamage/ Acne Scarring (%)	13.3 (N=2)
Hyperpigmentation (%)	13.3 (N=2)
Acne Scarring/ Hyperpigmentation (%)	6.7 (N=1)
Tactile Roughness/ Dyspigmentation (%)	6.7 (N=1)
Sun Damage (%)	6.7 (N=1)

## Investigator Assessments



## Investigator Assessment of Photodamage

Score	Overall Facial Photodamage
0	None
1	Minimal
2	Mild
3	Moderate
4	Severe

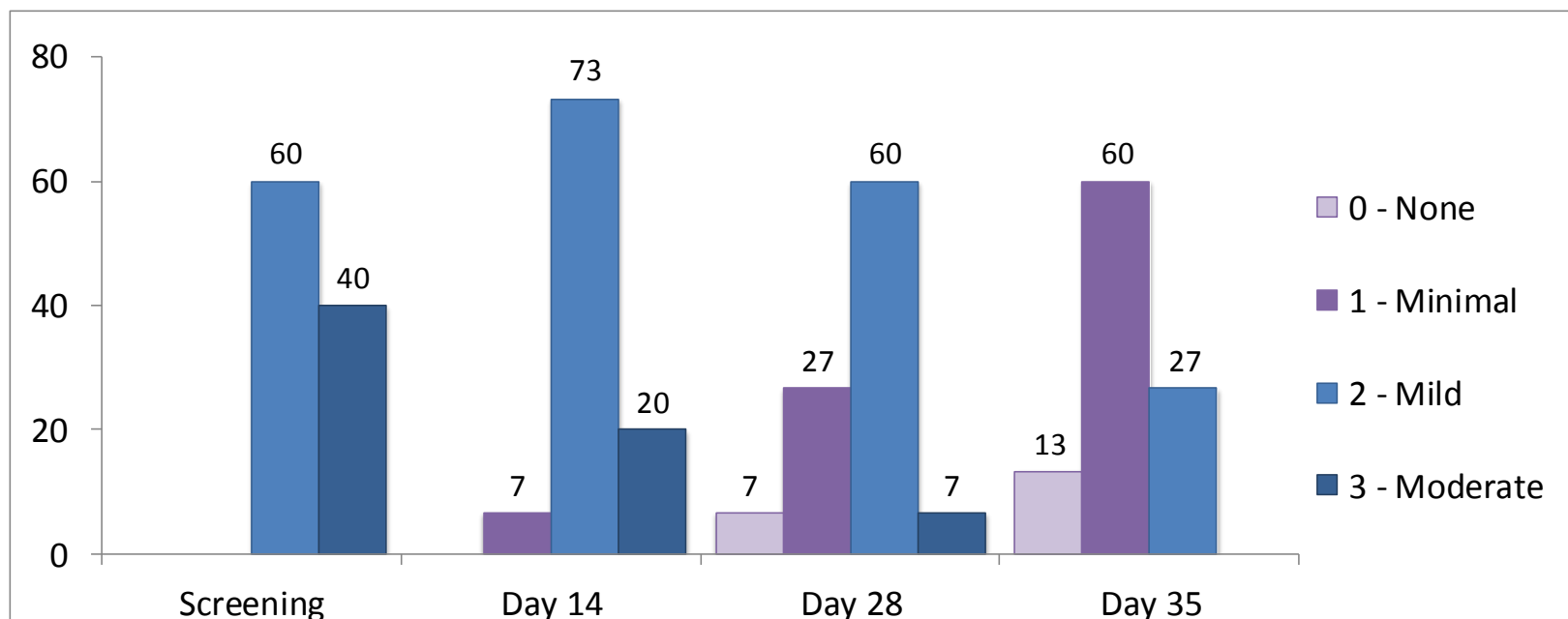
## Investigator Assessment of Pigmentation Intensity

Severity	Score	Overall Facial Pigmentation Intensity
None	0	No noticeable hyperpigmentation
Minimal	1	Localized deposits of pigment
Mild	2	Mild, diffuse deposits of pigment
Moderate	3	Moderate, diffuse deposits of pigment
Marked	4	Marked, dense deposits of pigment
Severe	5	Severe-dense deposits of pigment

## STATISTICAL ANALYSIS GRAPHS INVESTIGATOR ASSESSMENTS

### BASELINE THROUGH WEEK 5 VISIT

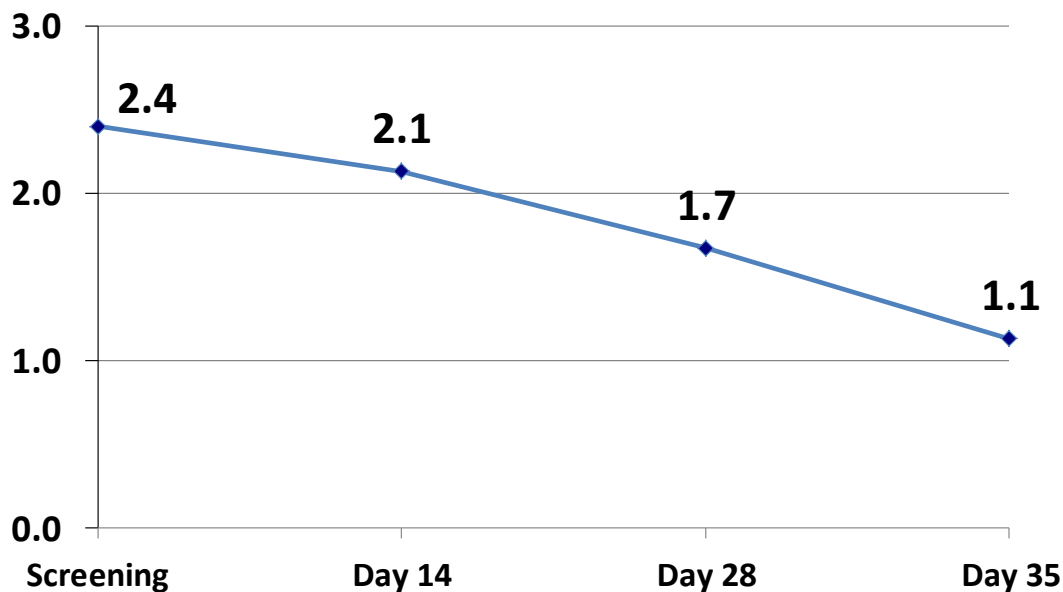
## INVESTIGATOR ASSESSMENTS FACIAL OVERALL INTEGRATED ASSESSMENT OF PHOTODAMAGE BY VISIT



Percentage of Subjects

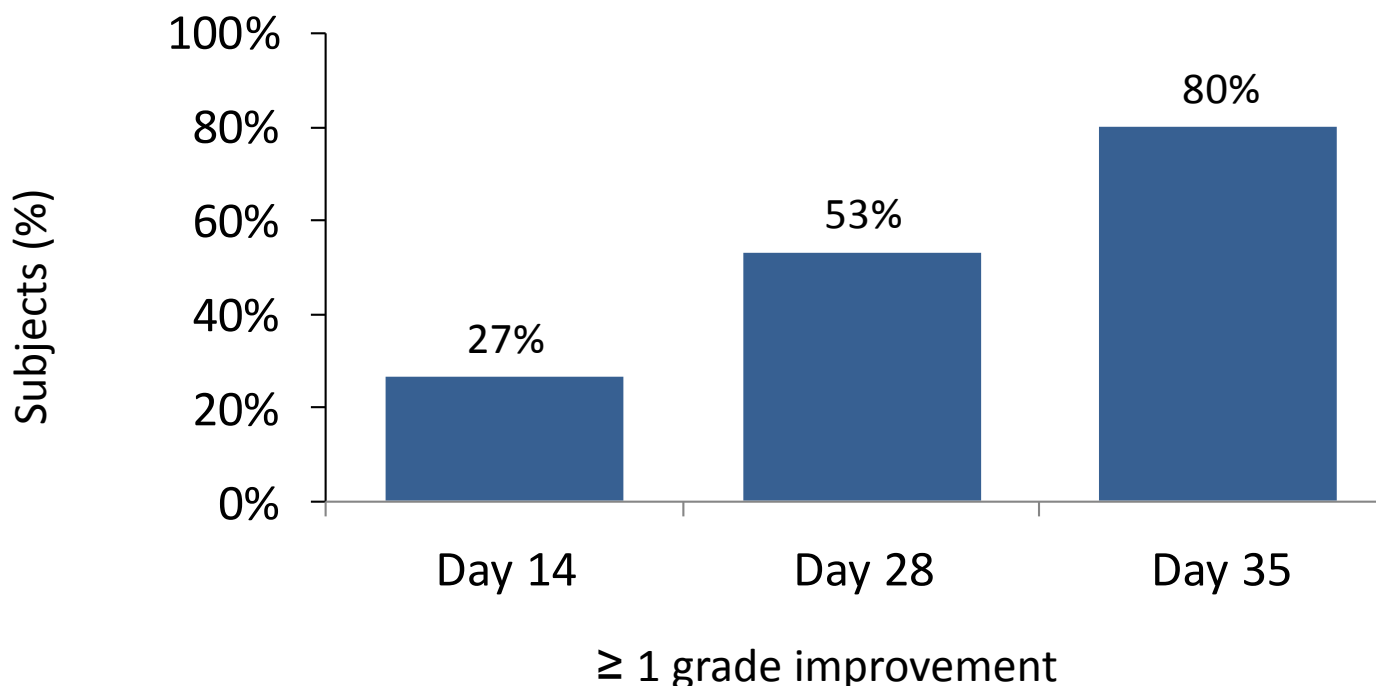
## INVESTIGATOR ASSESSMENTS FACIAL OVERALL INTEGRATED ASSESSMENT OF PHOTODAMAGE BY VISIT

Mean Scores

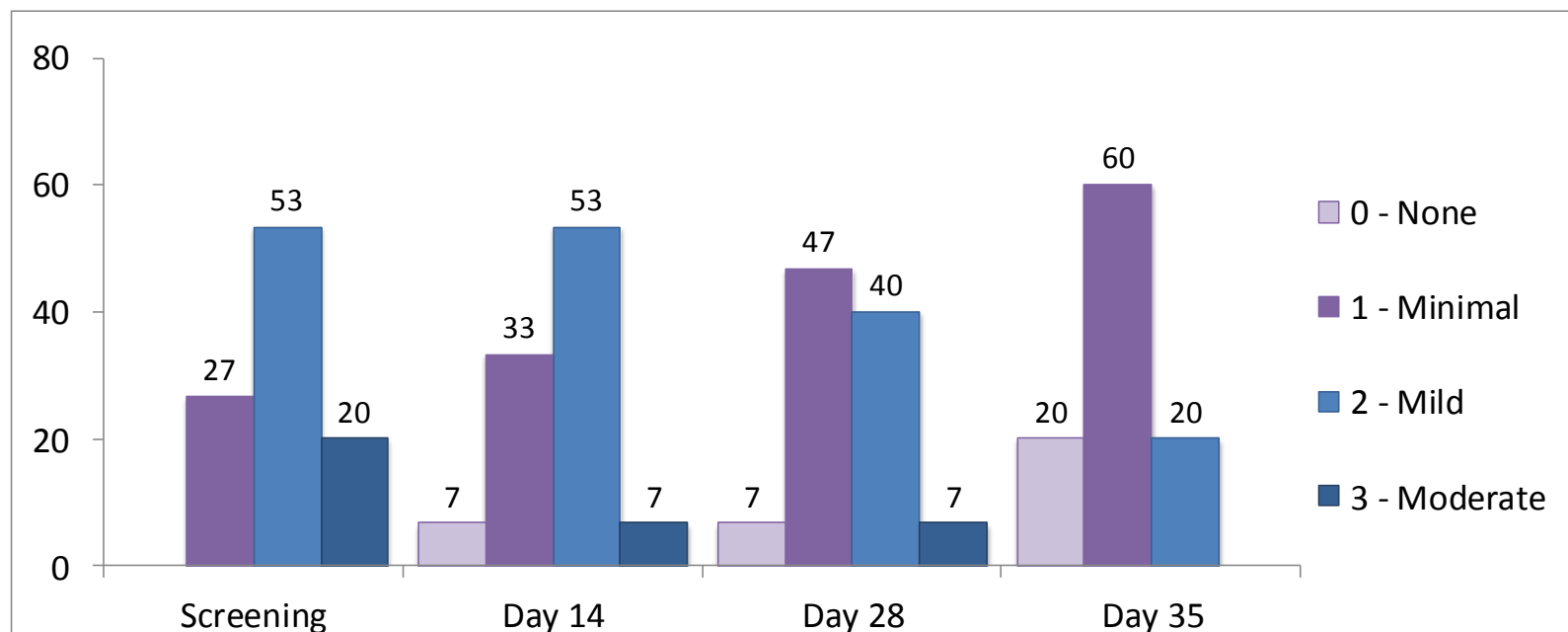


Scale  
None (0)  
Minimal (1)  
Mild (2)  
Moderate (3)

## INVESTIGATOR ASSESSMENTS FACIAL OVERALL INTEGRATED ASSESSMENT OF PHOTODAMAGE (IMPROVEMENT FROM BASELINE)



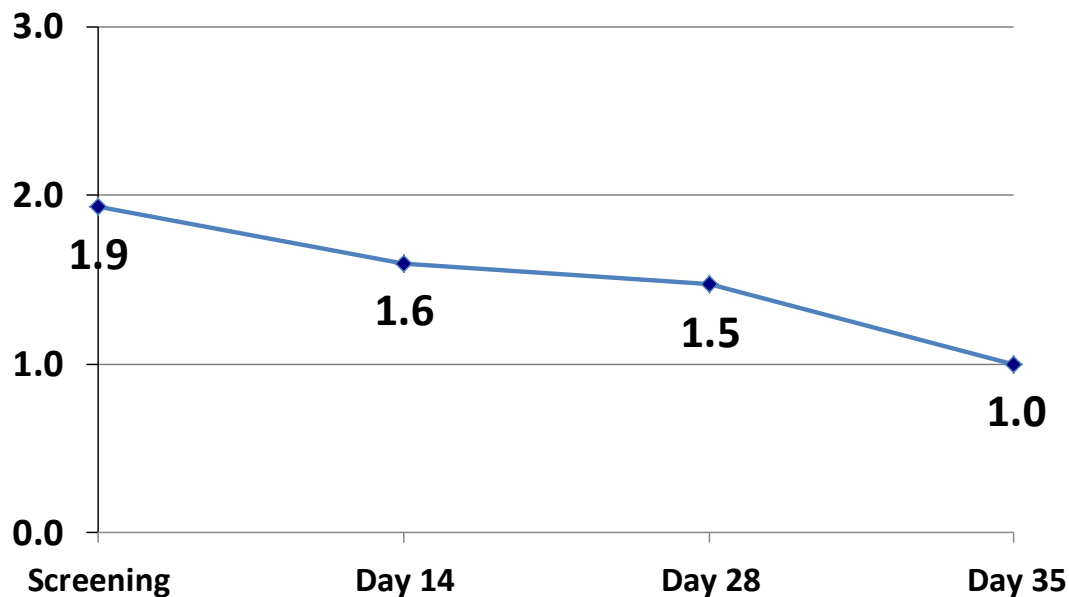
## INVESTIGATOR ASSESSMENTS PHOTODAMAGE CHARACTERISTICS – APPEARANCE OF FINE LINES AND WRINKLES BY VISIT



Percentage of Subjects

## INVESTIGATOR ASSESSMENTS PHOTODAMAGE CHARACTERISTICS – APPEARANCE OF FINE LINES AND WRINKLES BY VISIT

Mean Scores

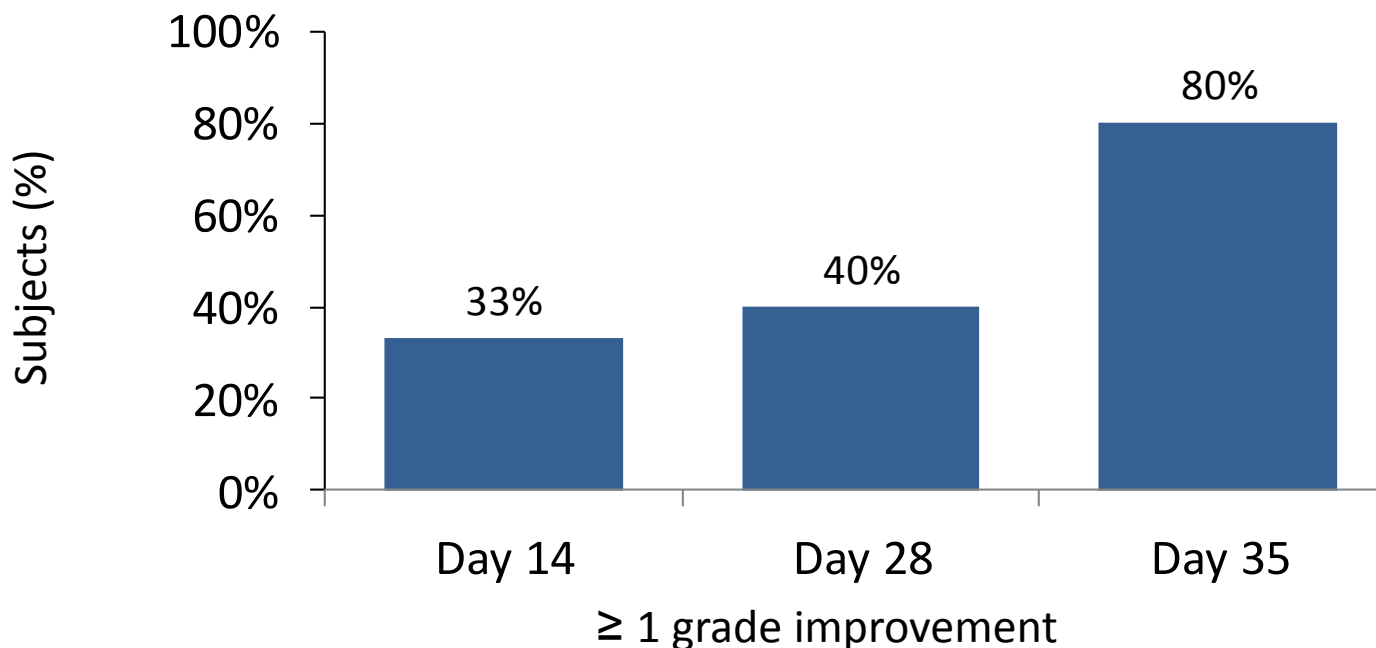


Scale  
None (0)  
Minimal (1)  
Mild (2)  
Moderate (3)  
Severe (4)

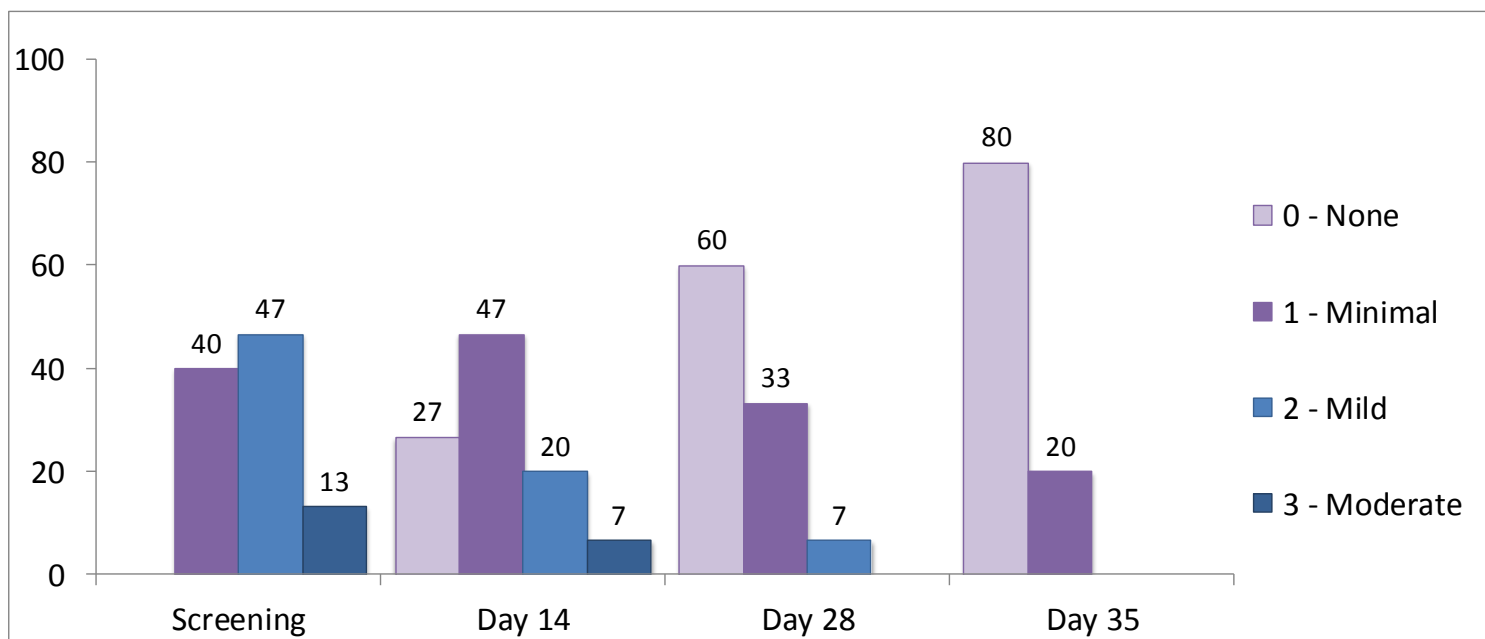


## INVESTIGATOR ASSESSMENTS PHOTODAMAGE CHARACTERISTICS – APPEARANCE OF FINE LINES AND WRINKLES BY VISIT

(IMPROVEMENT FROM BASELINE)



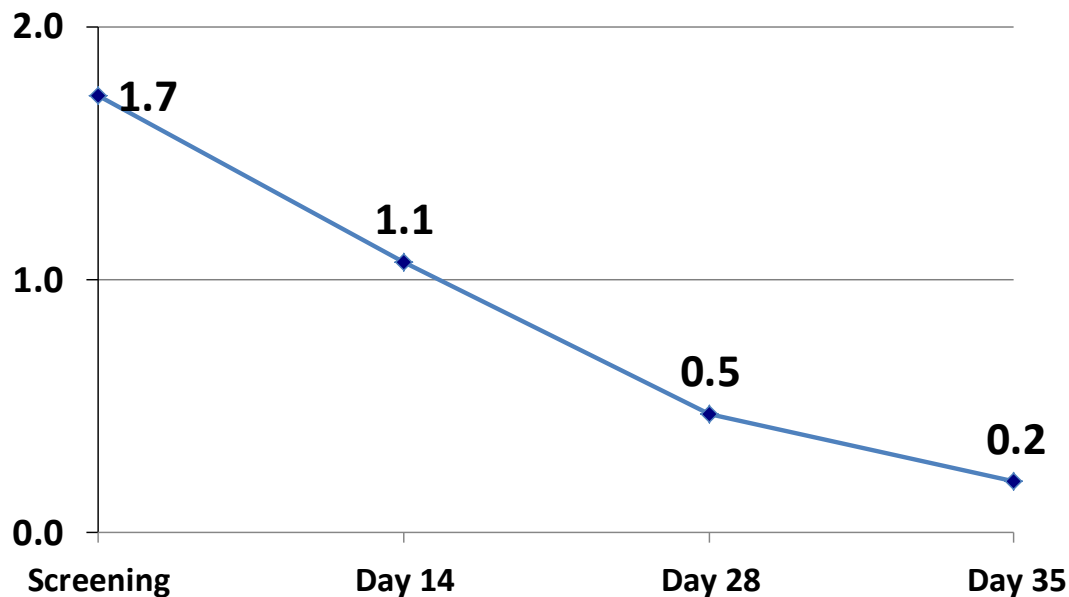
## INVESTIGATOR ASSESSMENTS PHOTODAMAGE CHARACTERISTICS – TACTILE ROUGHNESS BY VISIT



Percentage of Subjects

## INVESTIGATOR ASSESSMENTS PHOTODAMAGE CHARACTERISTICS – TACTILE ROUGHNESS BY VISIT

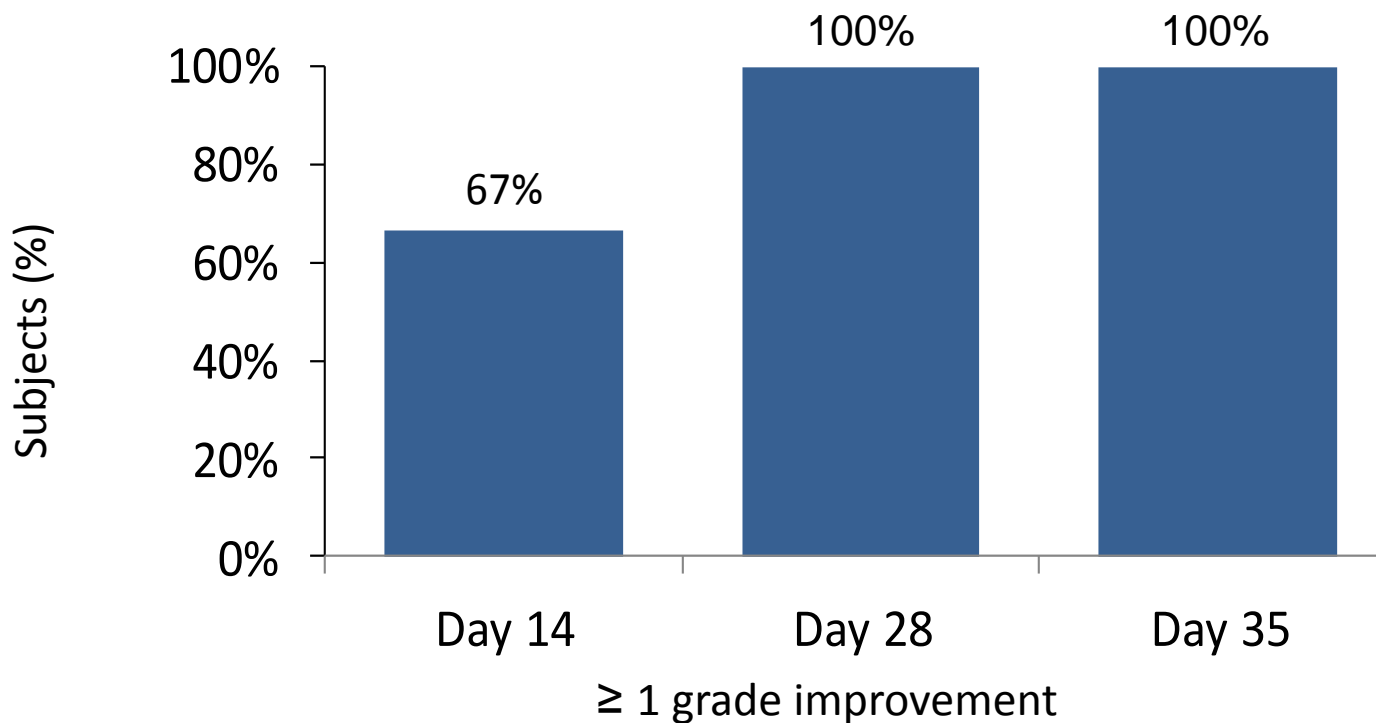
Mean Scores



Scale  
None (0)  
Minimal (1)  
Mild (2)  
Moderate (3)  
Severe (4)

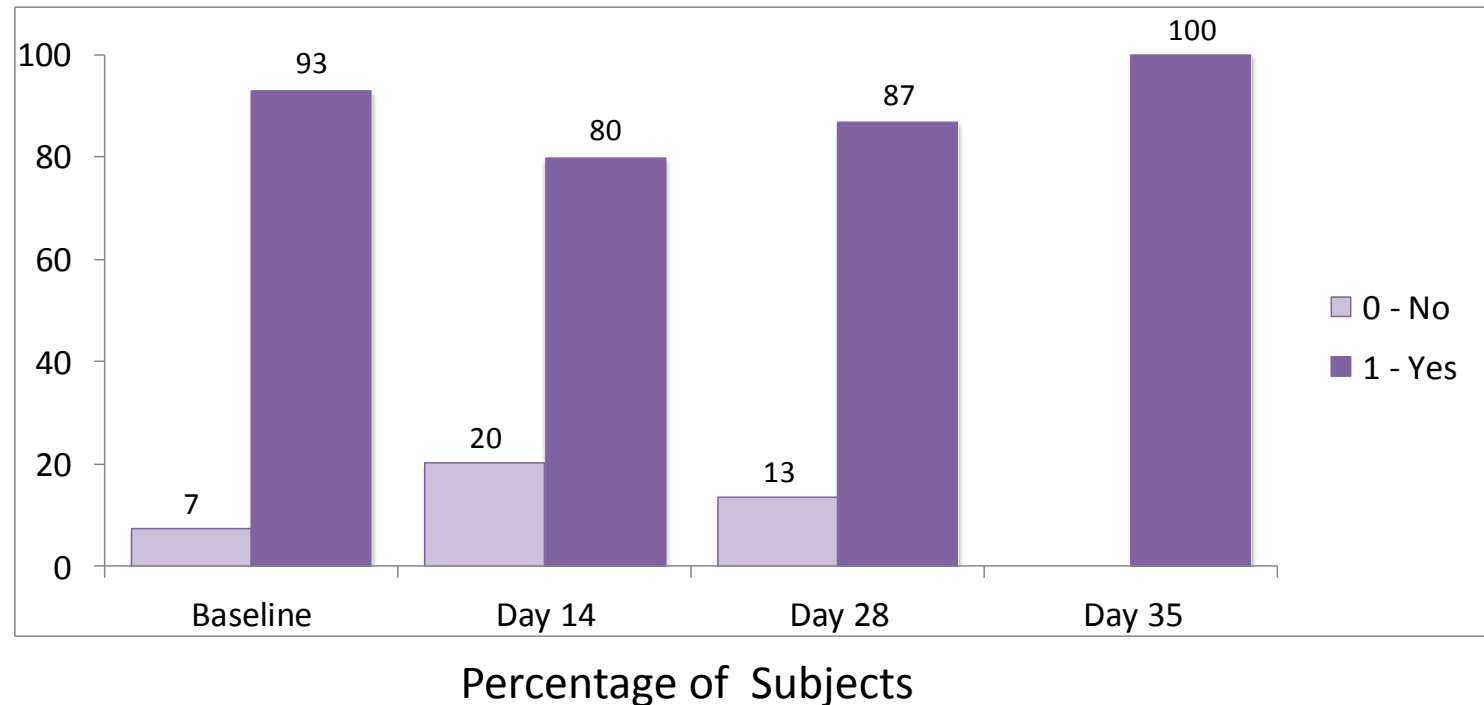
## INVESTIGATOR ASSESSMENTS PHOTODAMAGE CHARACTERISTICS – TACTILE ROUGHNESS BY VISIT

(IMPROVEMENT FROM BASELINE)

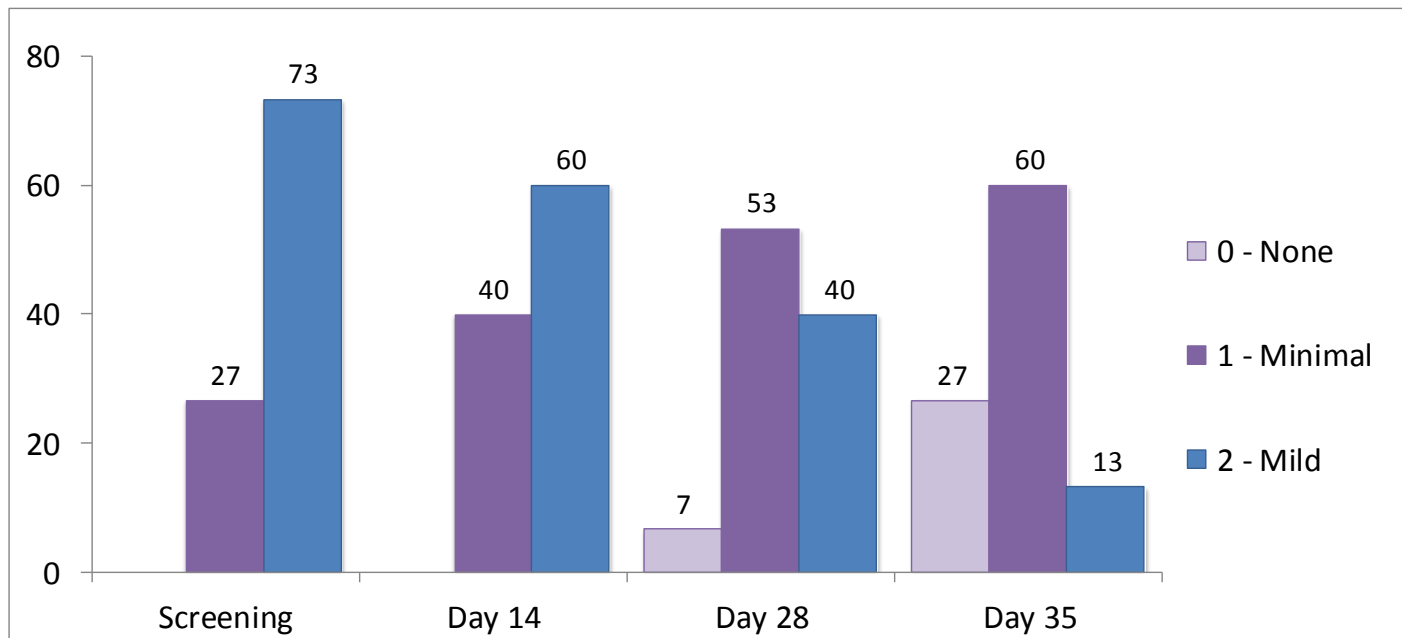


## INVESTIGATOR ASSESSMENTS

### APPEARANCE OF FACIAL SKIN FIRMNESS / INCREASE FIRMNESS CHANGE FROM BASELINE (ASSESSED FROM BASELINE PRE-PEEL PHOTO)



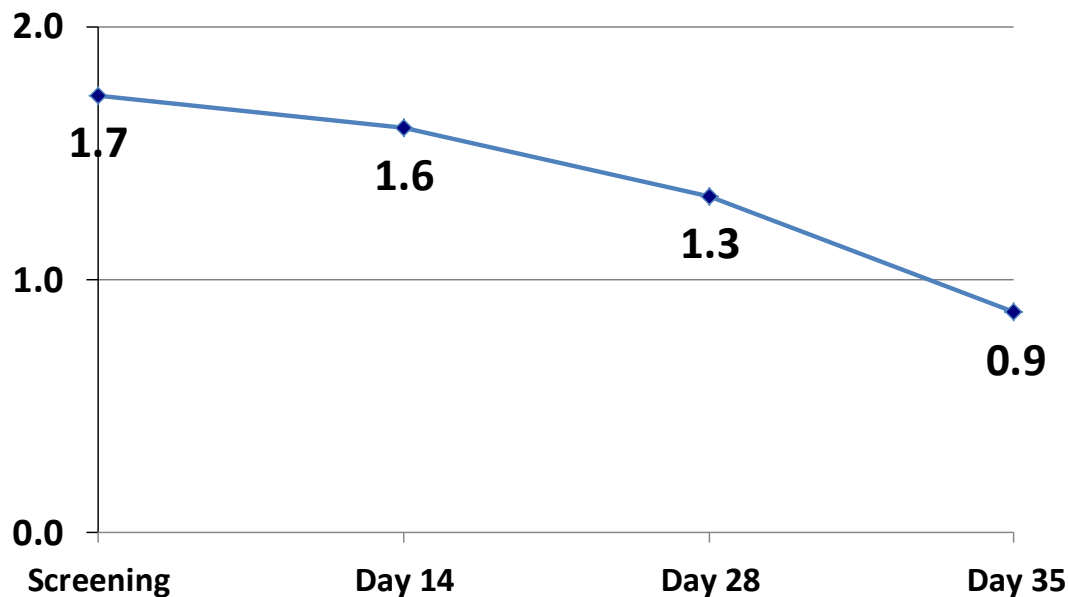
## INVESTIGATOR ASSESSMENTS OVERALL FACIAL PIGMENTATION INTENSITY BY VISIT



Percentage of Subjects

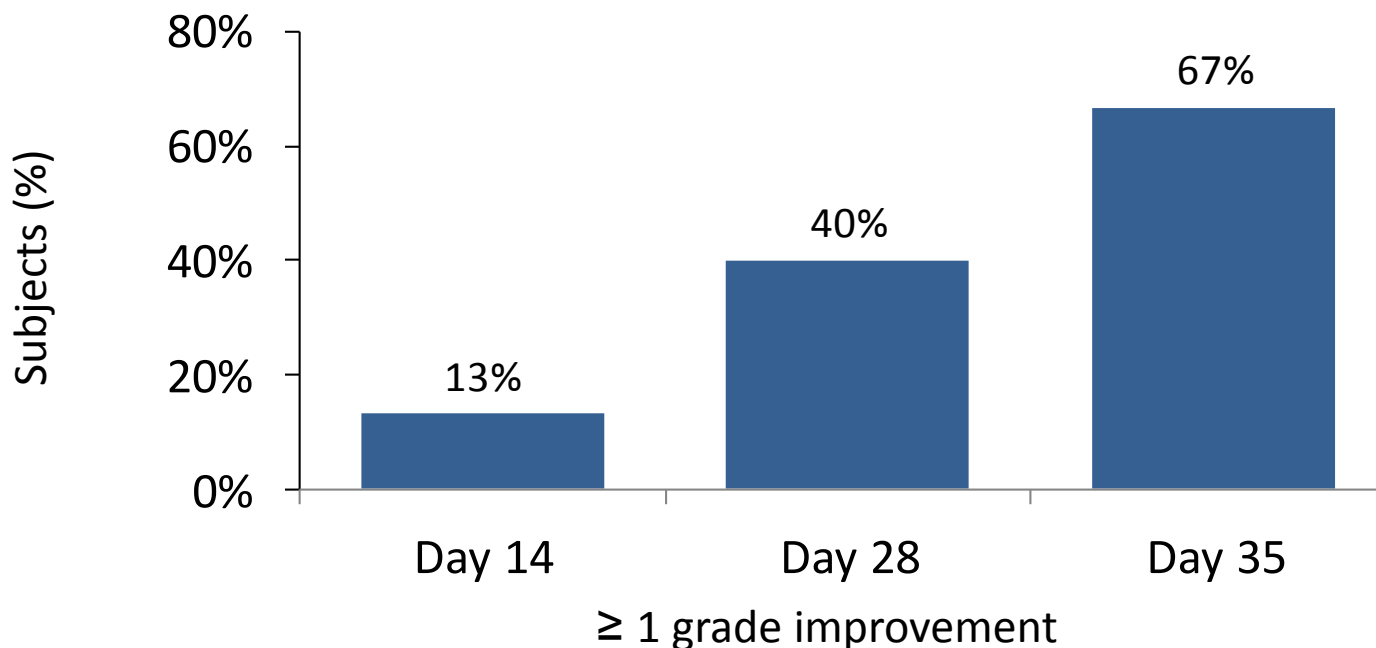
## INVESTIGATOR ASSESSMENTS OVERALL FACIAL PIGMENTATION INTENSITY BY VISIT

Mean Scores



Scale  
None (0)  
Minimal (1)  
Mild (2)  
Moderate (3)  
Severe (4)

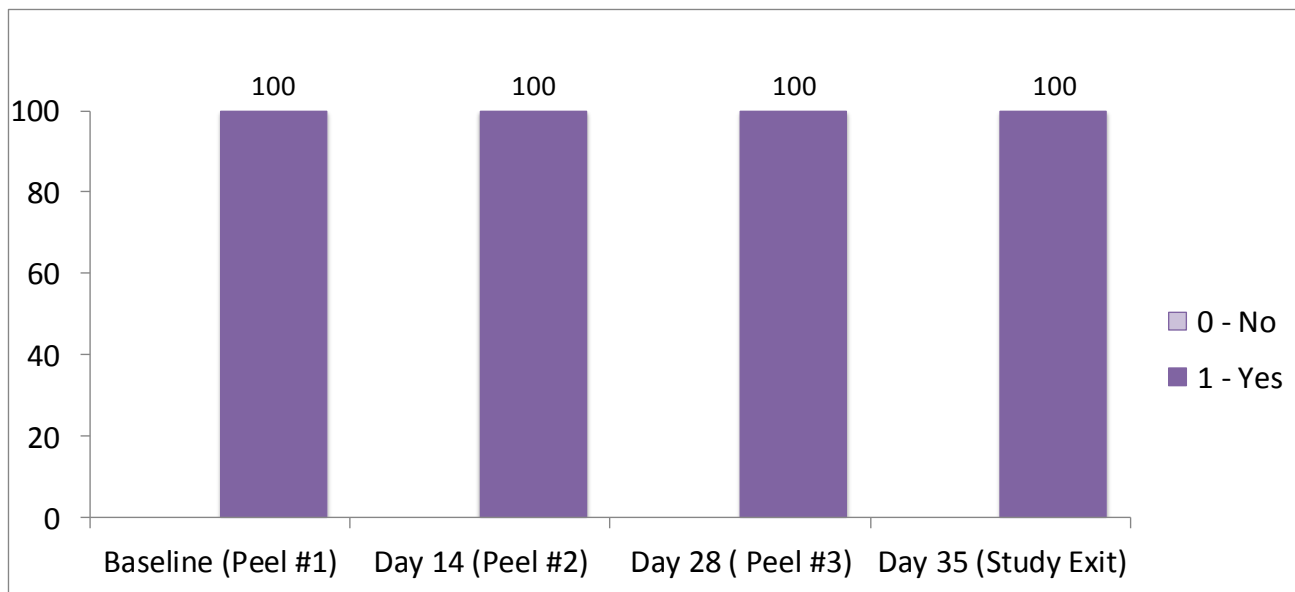
## INVESTIGATOR ASSESSMENTS OVERALL FACIAL PIGMENTATION INTENSITY BY VISIT





## INVESTIGATOR ASSESSMENTS

**SKIN APPEARS TIGHTER, SMOOTHER AND BRIGHTER LOOKING**  
**CHANGE FROM BASELINE (ASSESSED FROM BASELINE PRE-PEEL PHOTO)**



Percentage of Subjects

## TREATMENT RELATED ADVERSE EVENTS

TOTAL # SUBJECTS	ADVERSE EVENT DESCRIPTION	AE INTENSITY	COMMENTS
1	Acne Flare	Mild	Acne flare stopped 11/10/12.
1	Worsening of Acne, Face	Mild	Worsening of acne still ongoing 12/6/12.

No subjects discontinued due to treatment-related adverse events.

## **SUBJECT QUESTIONNAIRE RESPONSES BASELINE, DAY 14, DAY 18 AND DAY 35 VISIT**

## SUBJECT QUESTIONNAIRE RESPONSES CURRENT SATISFACTION WITH SKIN FEATURES

	BASELINE (compared to Baseline pre-peel photo) Percent (%) of Subjects						DAY 35 (compared to Baseline pre-peel photo) Percent (%) of Subjects					
	Extremely unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied	Extremely satisfied	Extremely unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied	Extremely satisfied
- Appearance of fine lines and wrinkles	6.7	<b>53.3</b>	26.7	6.7	6.7			13.3	26.7	26.7	<b>33.3</b>	
- Smoothness of skin		<b>40</b>	<b>40</b>	13.3	6.7				6.7	40	<b>53.3</b>	
- Firmness of skin		<b>60</b>	20	20					20	<b>46.7</b>	26.7	6.7
- Moisture level of skin		<b>40</b>	<b>40</b>	20					33.3	<b>46.7</b>	20	
- Consistent skin tone and coloration	26.7	<b>46.7</b>	20	6.7				6.7	20	<b>53.3</b>	20	
- Appearance of brown spots	40	<b>53.3</b>	6.7					26.7	<b>40</b>	26.7	6.7	
- Pore size	20	<b>40</b>	<b>40</b>					6.7	33.3	<b>40</b>	20	
- Glow/brightness of skin		<b>53.3</b>	40	6.7					6.7	<b>66.7</b>	13.3	13.3
- Overall appearance of skin	6.7	<b>66.7</b>	20	6.7				6.7	26.7	<b>40</b>	26.7	

## SUBJECT QUESTIONNAIRE RESPONSES SATISFACTION WITH PEEL PROCEDURE

	DAY 14 (compared to Baseline pre-peel photo) Percent (%) of Subjects						DAY 28 (compared to Baseline pre-peel photo) Percent (%) of Subjects					
	Disagree strongly	Disagree	Neutral	Agree some	Agree	Agree strongly	Disagree strongly	Disagree	Neutral	Agree some	Agree	Agree strongly
I would continue to have this facial peel procedure performed.			6.7		<b>46.7</b>	<b>46.7</b>			6.7	6.7	33.3	<b>53.3</b>
I would recommend this facial peel procedure to my friends.			13.3	13.3	33.3	<b>40</b>			20	13.3	<b>40</b>	26.7
The results of this facial peel procedure were what I expected.	6.7		20	<b>33.3</b>	26.7	13.3		13.3	6.7	20	<b>46.7</b>	13.3
The results of this facial peel procedure were better than I expected.		6.7	<b>33.3</b>	26.7	20	13.3	6.7	6.7	<b>33.3</b>	26.7	20	6.7
There was minimal downtime after this facial peel procedure.	6.7		13.3	6.7	26.7	<b>46.7</b>		6.7	6.7	20	13.3	<b>53.3</b>

## SUBJECT QUESTIONNAIRE RESPONSES SATISFACTION WITH PEEL PROCEDURE

	DAY 35 (compared to Baseline pre-peel photo) Percent (%) of Subjects					
	Disagree strongly	Disagree	Neutral	Agree some	Agree	Agree strongly
I would continue to have this facial peel procedure performed.			26.7	6.7	26.7	<b>40</b>
I would recommend this facial peel procedure to my friends.			13.3	13.3	33.3	<b>40</b>
The results of this facial peel procedure were what I expected.		13.3		26.7	<b>46.7</b>	13.3
The results of this facial peel procedure were better than I expected.		13.3	26.7	<b>40</b>	20	
There was minimal downtime after this facial peel procedure.		6.7		13.3	26.7	<b>53.3</b>

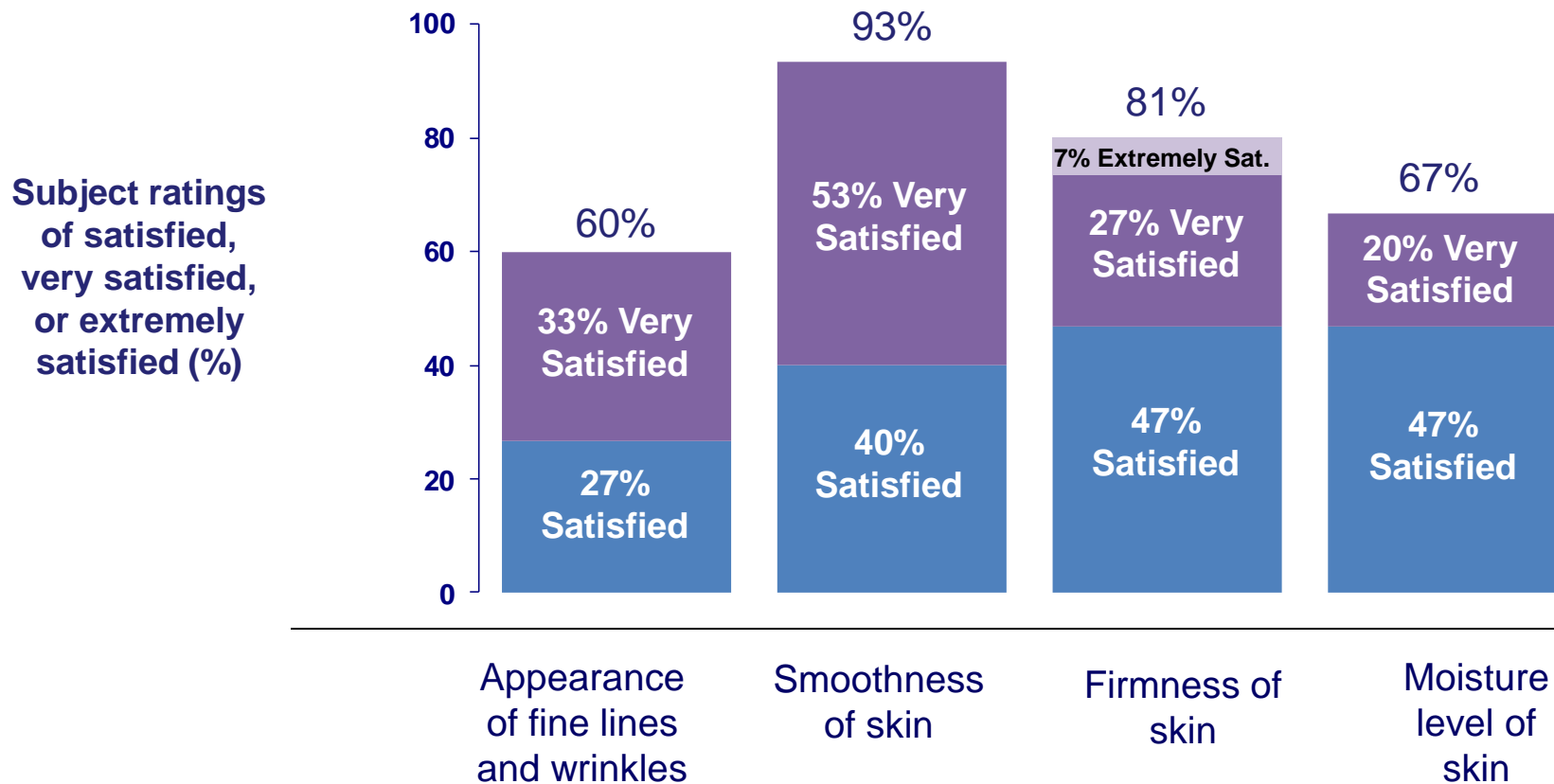
## SUBJECT QUESTIONNAIRE RESPONSES DAY 35 Percent (%) of Subjects

When did you <u>first</u> notice an improvement in your skin's appearance?	After the 1st Peel	After the 2nd Peel	After the 3rd Peel	I did not notice any changes
	40	<b>46.7</b>	6.7	6.7

Please rate your overall satisfaction with the peel procedures you received during this study.	Extremely unsatisfied	Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied	Extremely satisfied
				6.7	13.3	<b>40</b>	26.7

If you have received other facial aesthetic treatments before this study, how would you rate your results with this peel procedure compared to previous facial treatments?	N/A	Much worse	Worse	The same	Better	Much better
	<b>60</b>				13.3	20

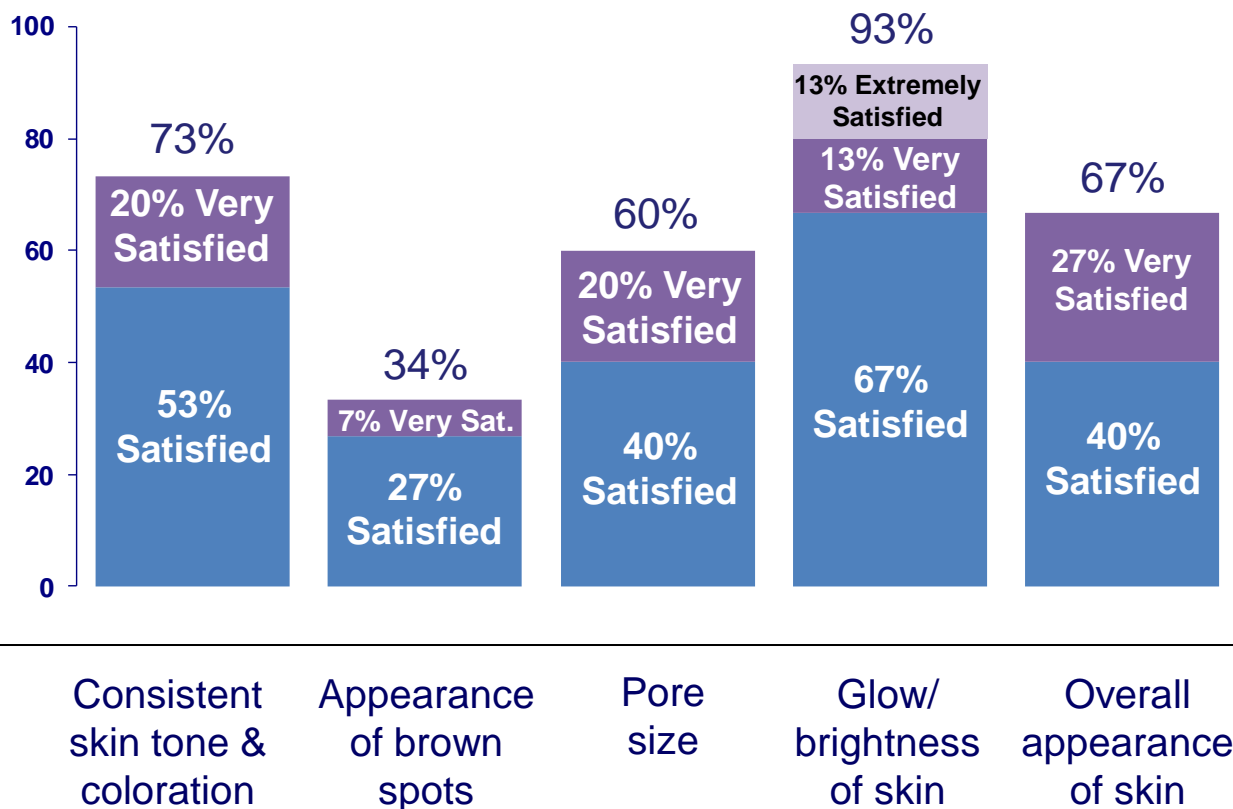
## Satisfaction with Skin Features at Day 35





## Satisfaction with Skin Features at Day 35

Subject ratings of satisfied, very satisfied, or extremely satisfied (%)



## SAMPLE SUBJECT PHOTOGRAPHS

**SUBJECT 001 KLJ  
OMP, INC. BLU001  
SUZANNE BRUCE, MD**



**BASELINE PRE-PEEL**



**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**

**SUBJECT 001 KLJ**



**BASELINE PRE-PEEL**



**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**



**SUBJECT 005 JKK  
OMP, INC. BLU001  
SUZANNE BRUCE, MD**



**BASELINE PRE-PEEL**



**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**

**SUBJECT 005 JKK  
OMP, INC. BLU001  
SUZANNE BRUCE, MD**



**BASELINE PRE-PEEL**



**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**

**SUBJECT 005 JKK**



**BASELINE PRE-PEEL**



**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**



**SUBJECT 006 APH  
OMP, INC. BLU001  
SUZANNE BRUCE, MD**



**BASELINE PRE-PEEL**



**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**



**SUBJECT 006 APH  
OMP, INC. BLU001  
SUZANNE BRUCE, MD**

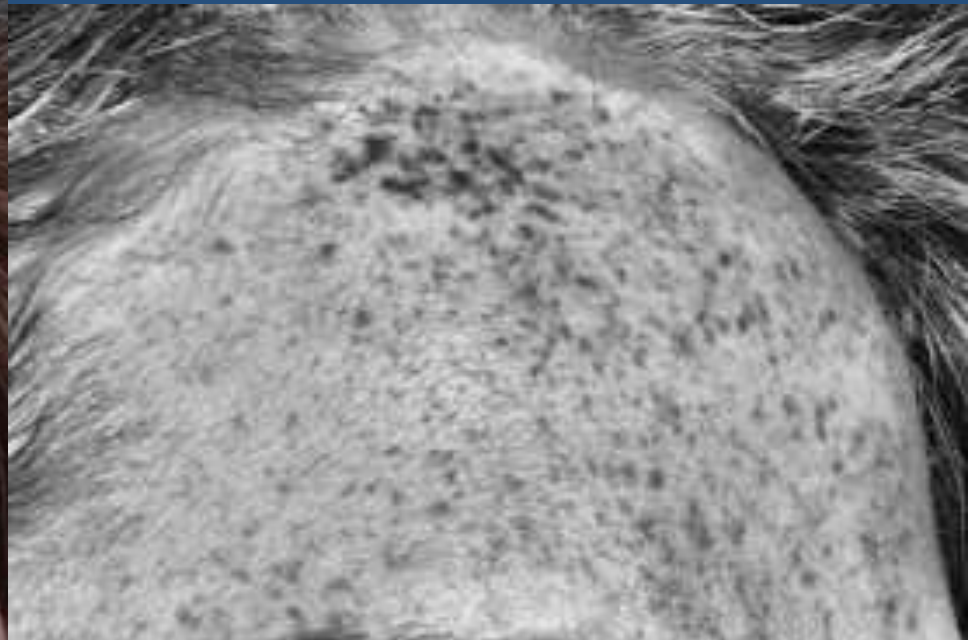


**BASELINE PRE-PEEL**

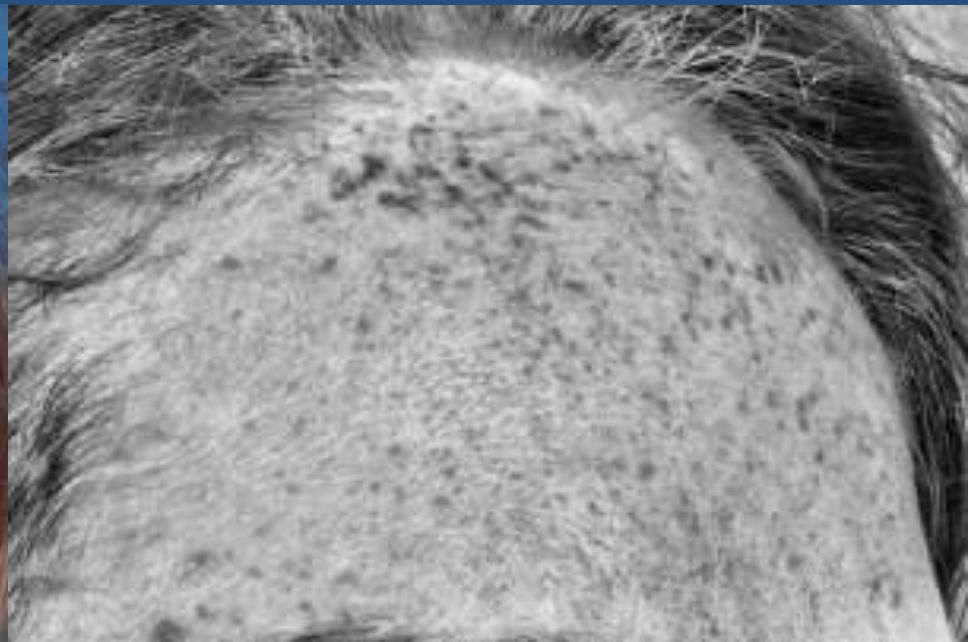


**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**

**SUBJECT 006 APH**



**BASELINE PRE-PEEL**



**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**

**SUBJECT 007 JEK  
OMP, INC. BLU001  
SUZANNE BRUCE, MD**



**BASELINE PRE-PEEL**



**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**



**SUBJECT 007 JEK  
OMP, INC. BLU001  
SUZANNE BRUCE, MD**

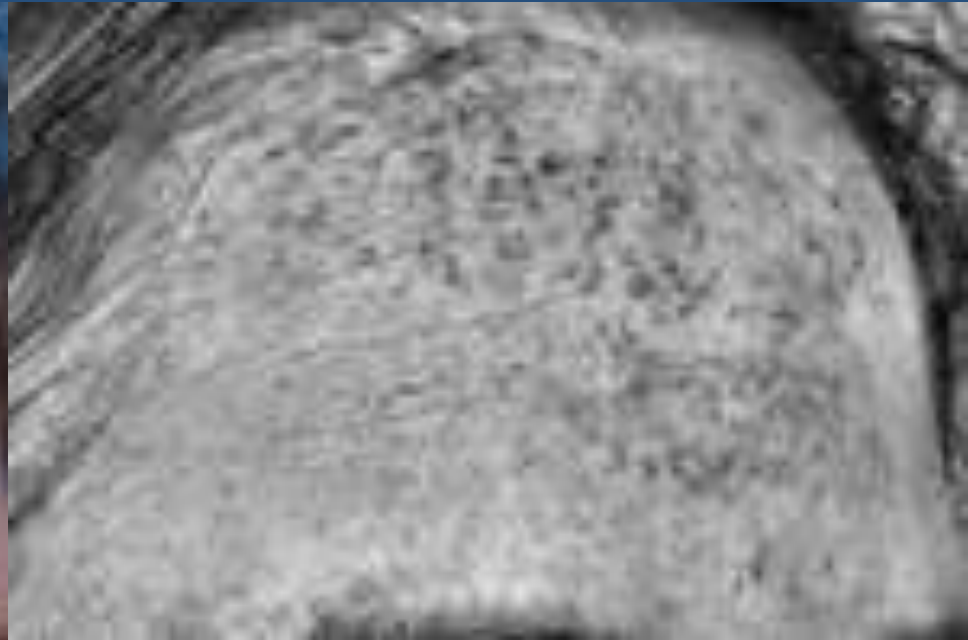


**BASELINE PRE-PEEL**

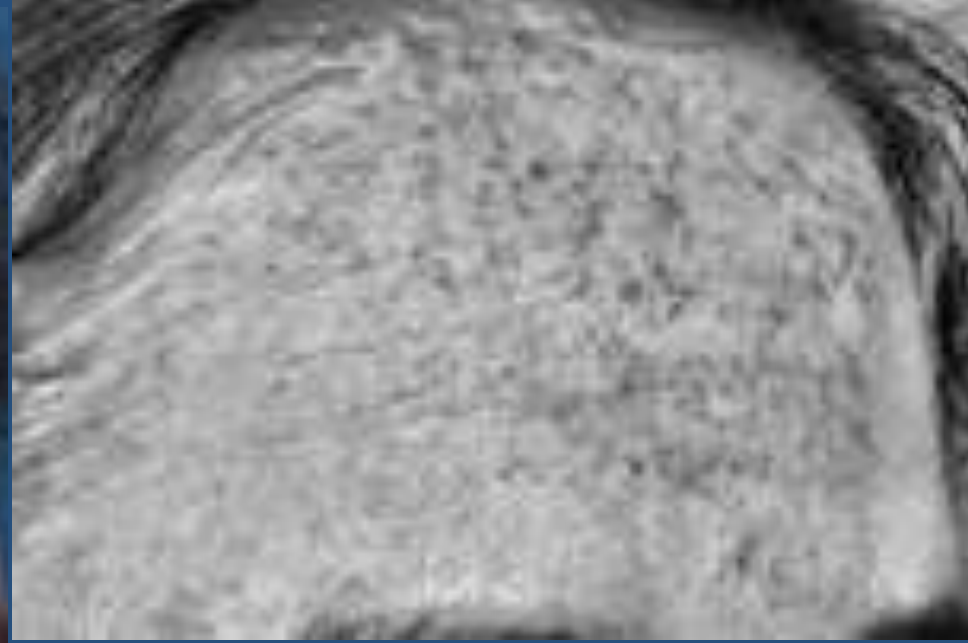


**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**

**SUBJECT 007 JEK**



**BASELINE PRE-PEEL**



**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**

**SUBJECT 009 YNC  
OMP, INC. BLU001  
SUZANNE BRUCE, MD**

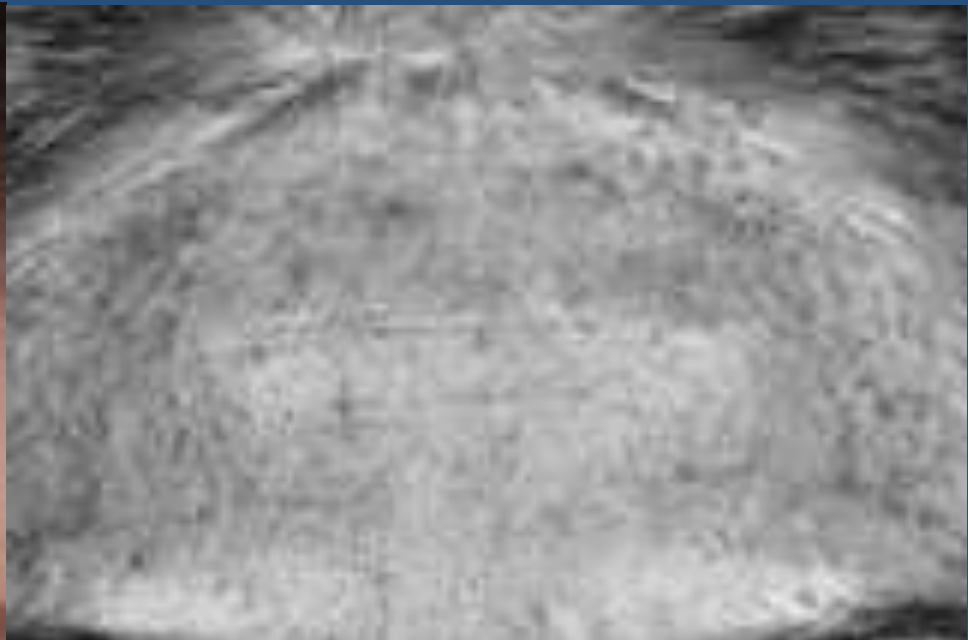


**BASELINE PRE-PEEL**

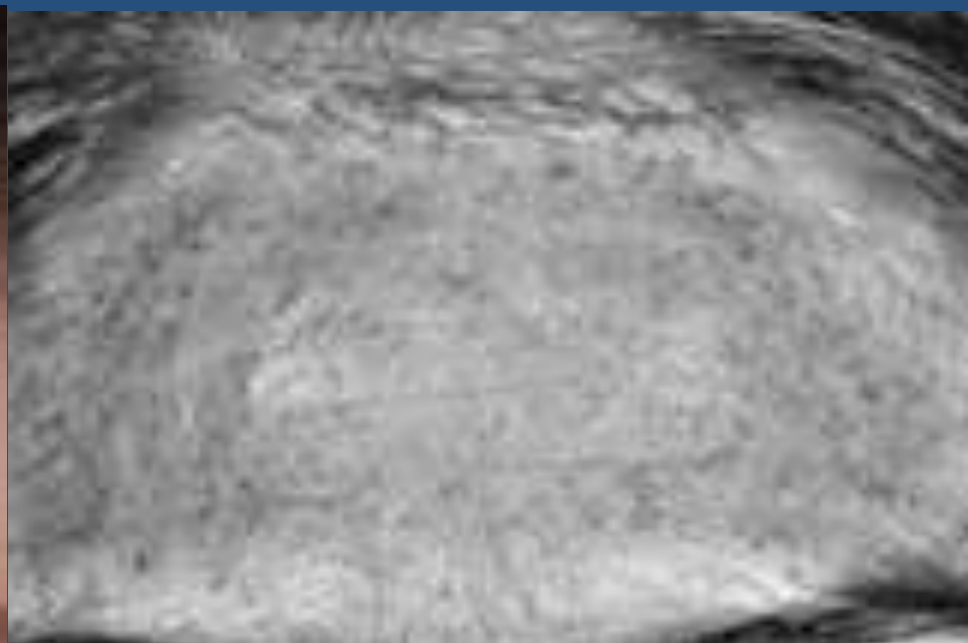


**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**

**SUBJECT 009 YNC**



**BASELINE PRE-PEEL**



**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**



**SUBJECT 010 ALR  
OMP, INC. BLU001  
SUZANNE BRUCE, MD**



**BASELINE PRE-PEEL**



**2 WEEKS AFTER PEEL #2**



SUBJECT 010 ALR  
OMP, INC. BLU001  
SUZANNE BRUCE, MD

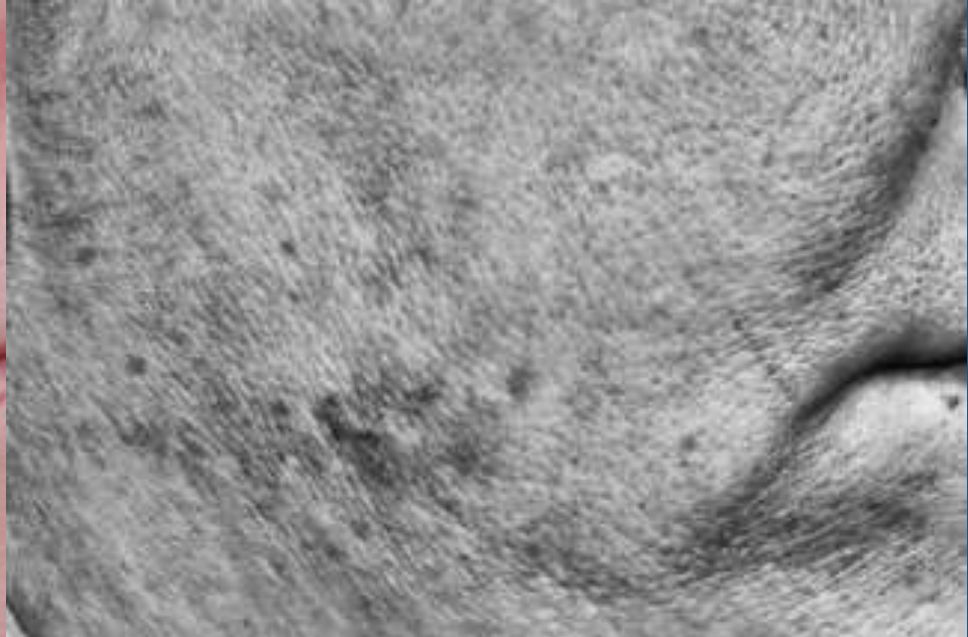


BASELINE PRE-PEEL

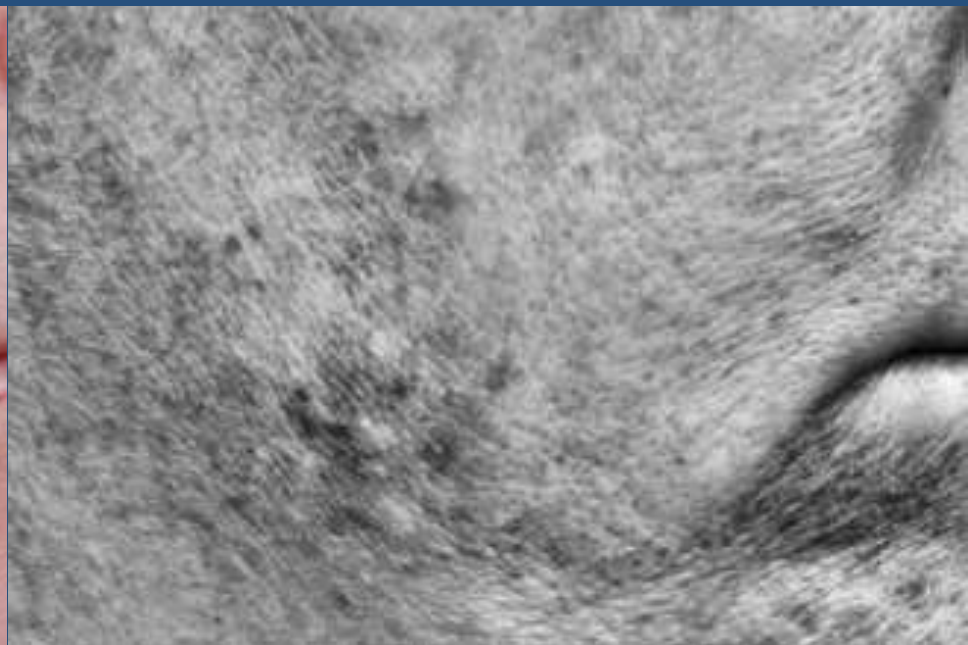


2 WEEKS AFTER PEEL #2

**SUBJECT 010 ALR**



**BASELINE PRE-PEEL**



**2 WEEKS AFTER PEEL #2**

**SUBJECT 012 JAE  
OMP, INC. BLU001  
SUZANNE BRUCE, MD**



**BASELINE PRE-PEEL**



**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**



**SUBJECT 012 JAE  
OMP, INC. BLU001  
SUZANNE BRUCE, MD**



**BASELINE PRE-PEEL**



**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**

**SUBJECT 012 JAE**



**BASELINE PRE-PEEL**



**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**

**SUBJECT 014 S-H  
OMP, INC. BLU001  
SUZANNE BRUCE, MD**



**BASELINE PRE-PEEL**



**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**

**SUBJECT 014 S-H  
OMP, INC. BLU001  
SUZANNE BRUCE, MD**



**BASELINE PRE-PEEL**



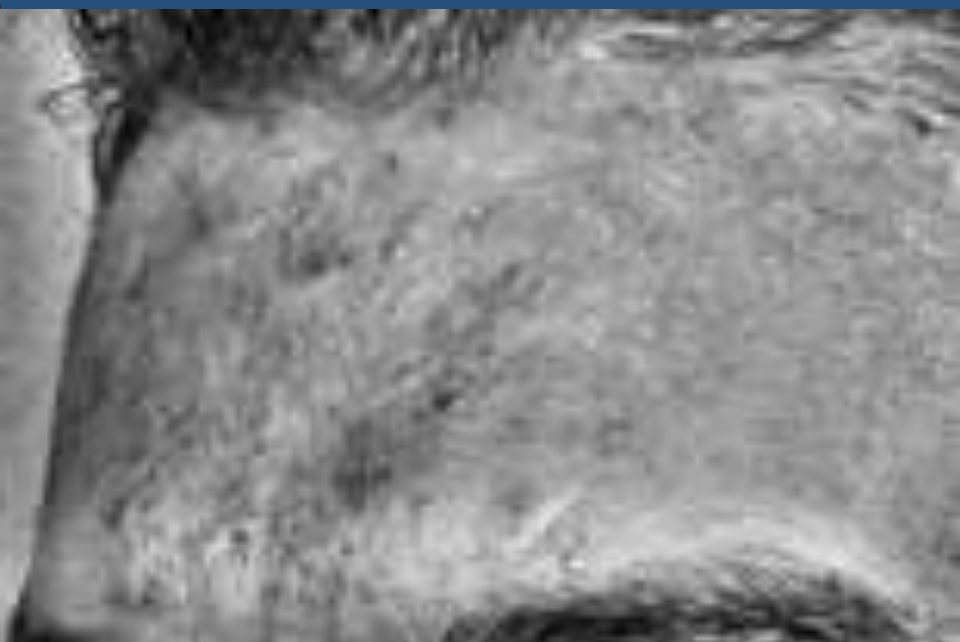
**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**



**SUBJECT 014 S-H**



**BASELINE PRE-PEEL**



**1 WEEK AFTER PEEL #3  
(35 DAYS FROM BASELINE)**



## CONCLUSIONS

- 100% subjects had tighter, smoother, brighter looking skin after peel #1
- 100% subjects had minimal or no tactile roughness after series 3 peels
- 100% subjects had at least 1 grade improvement tactile roughness after peel #2
- 93% subjects had firmer appearing skin after peel #1
- 80% subjects had at least 1 grade improvement in appearance of fine lines and wrinkles after series 3 peels
- 67% subjects had at least 1 grade improvement in pigmentation intensity after series 3 peels
- 80% subjects at least satisfied with series of 3 peels
- Most visible improvement seen in photo images after peel #3