

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">• Nu-Derm® Gentle Cleanser• Nu-Derm® Sun Shield SPF 50	<ul style="list-style-type: none">• Nu-Derm® Gentle Cleanser
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

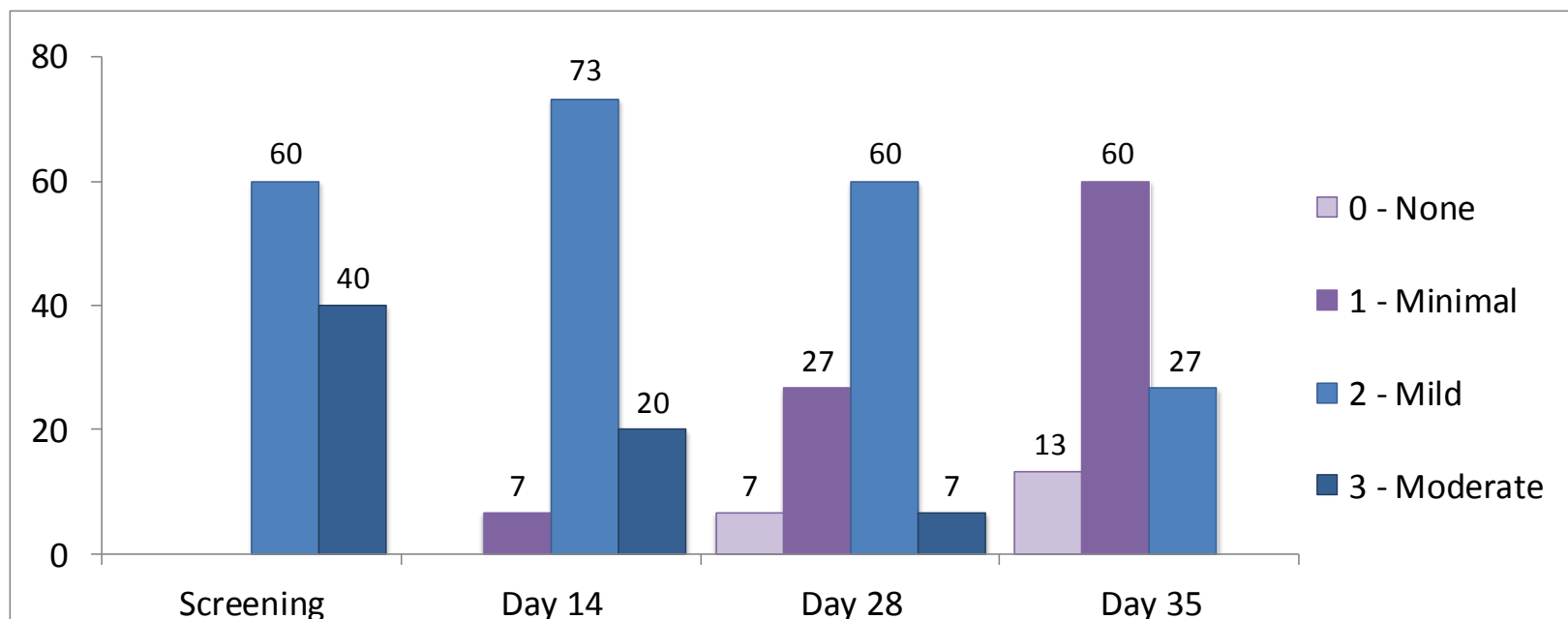
Investigator Assessment of Pigmentation Intensity

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

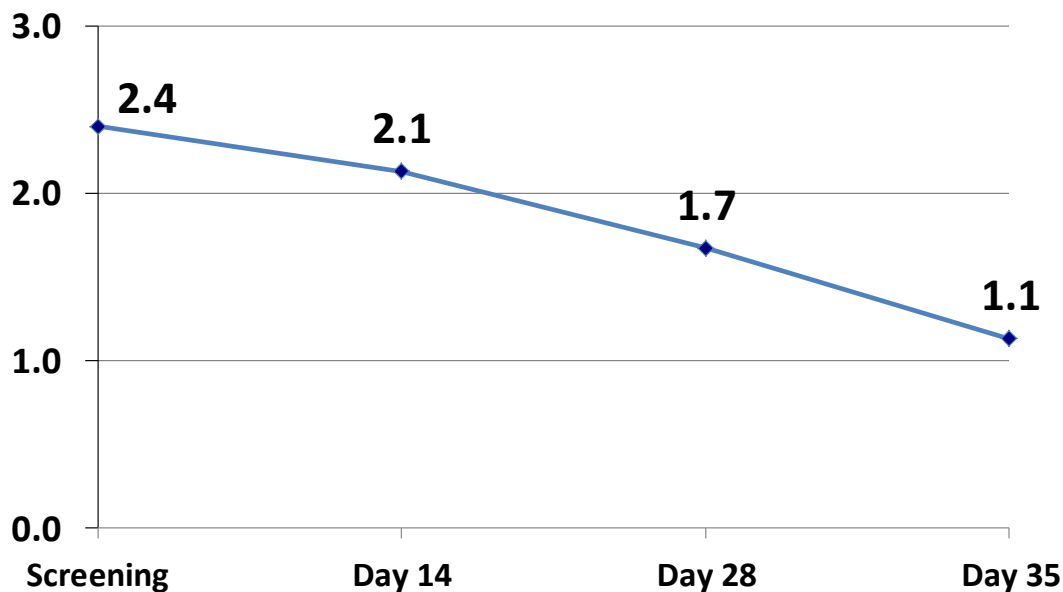
INVESTIGATOR ASSESSMENTS FACIAL OVERALL INTEGRATED ASSESSMENT OF PHOTODAMAGE BY VISIT



Percentage of Subjects

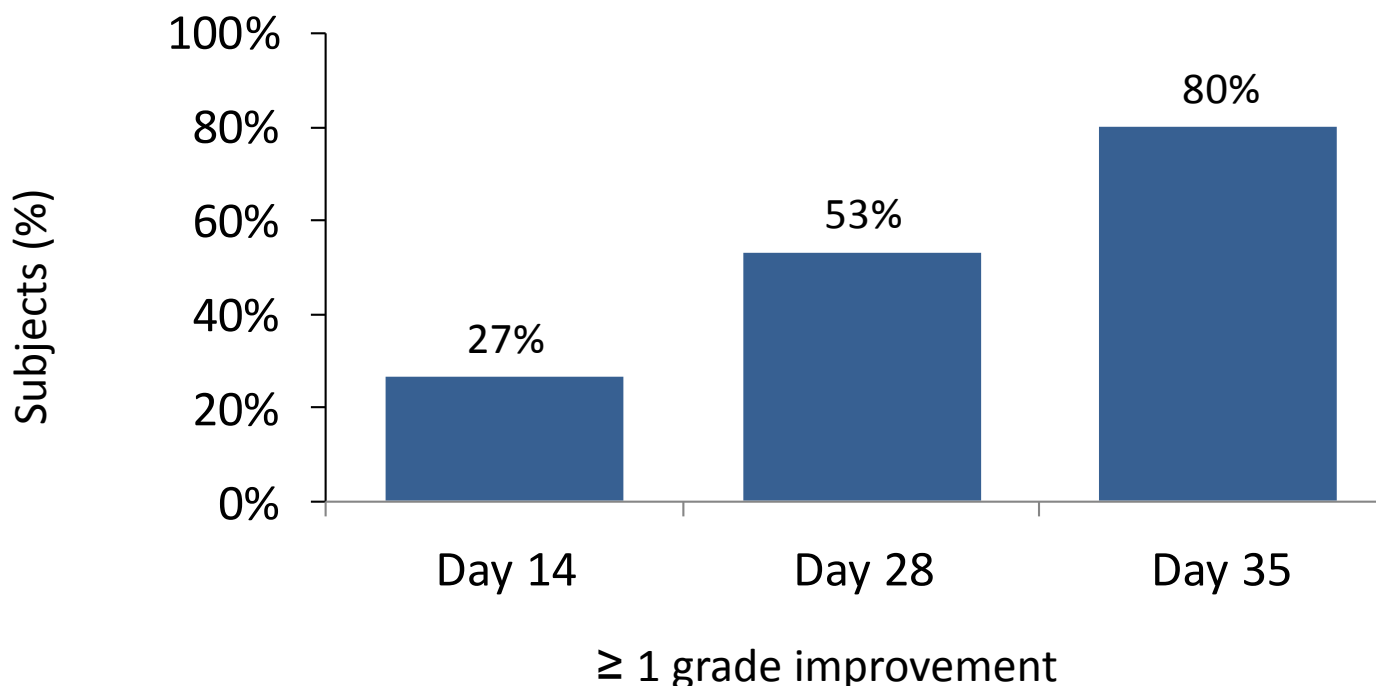
INVESTIGATOR ASSESSMENTS FACIAL OVERALL INTEGRATED ASSESSMENT OF PHOTODAMAGE BY VISIT

Mean Scores

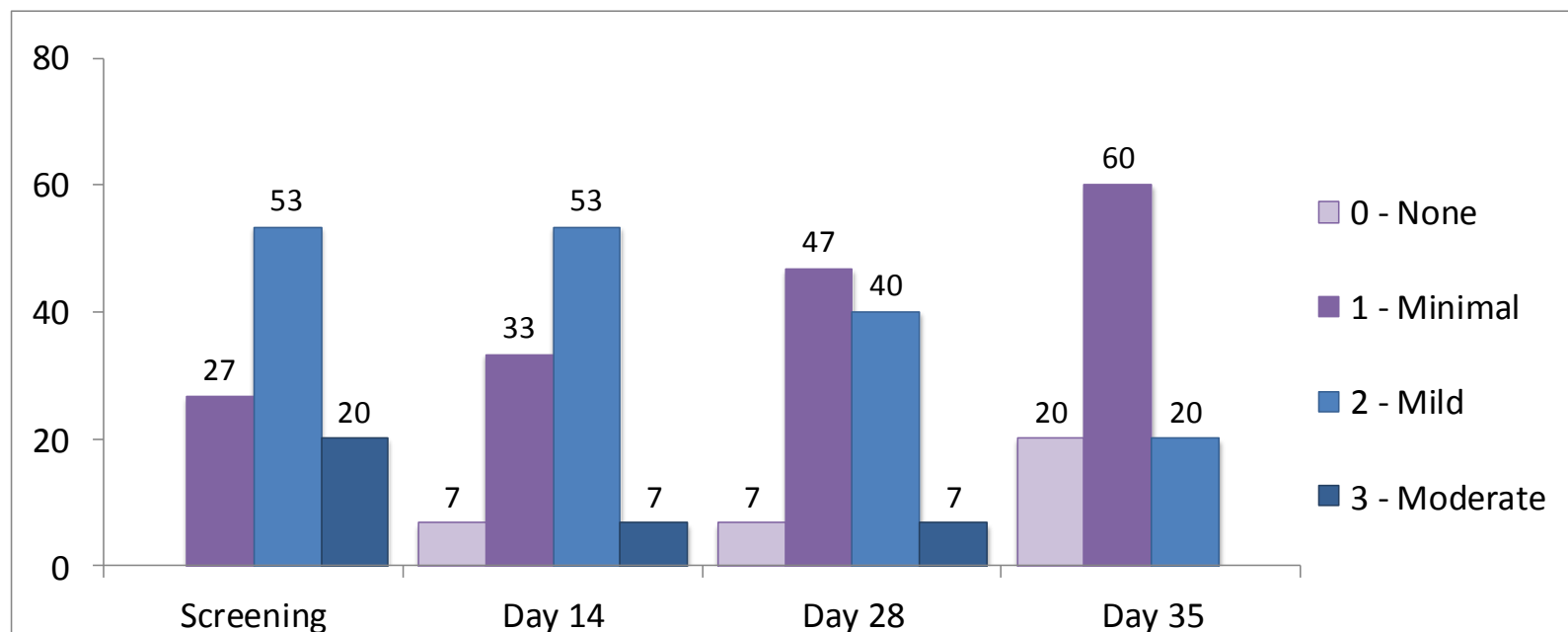


Scale
None (0)
Minimal (1)
Mild (2)
Moderate (3)

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



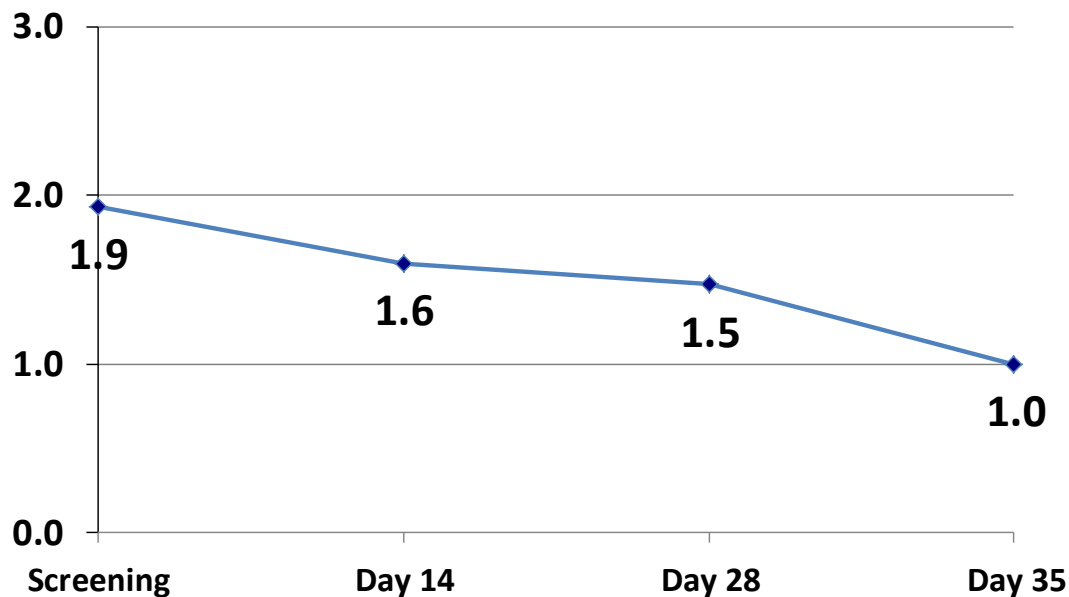
INVESTIGATOR ASSESSMENTS PHOTODAMAGE CHARACTERISTICS – APPEARANCE OF FINE LINES AND WRINKLES BY VISIT



Percentage of Subjects

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

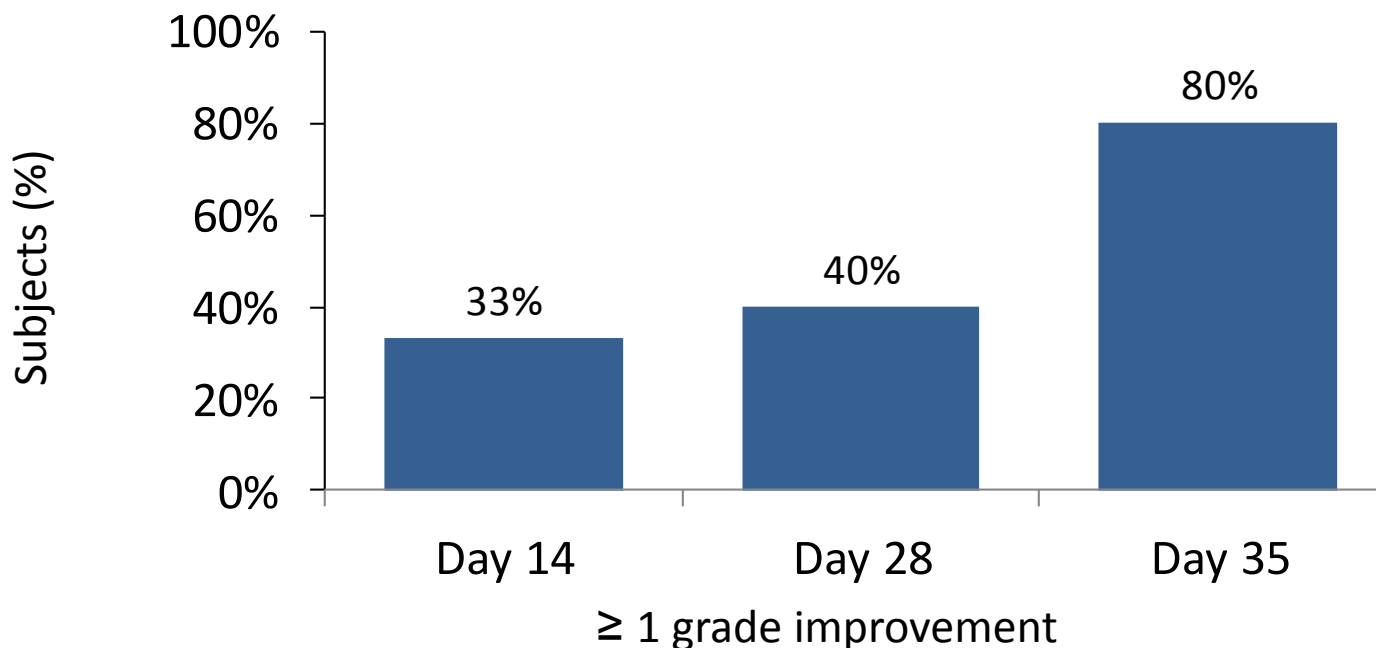
Mean Scores



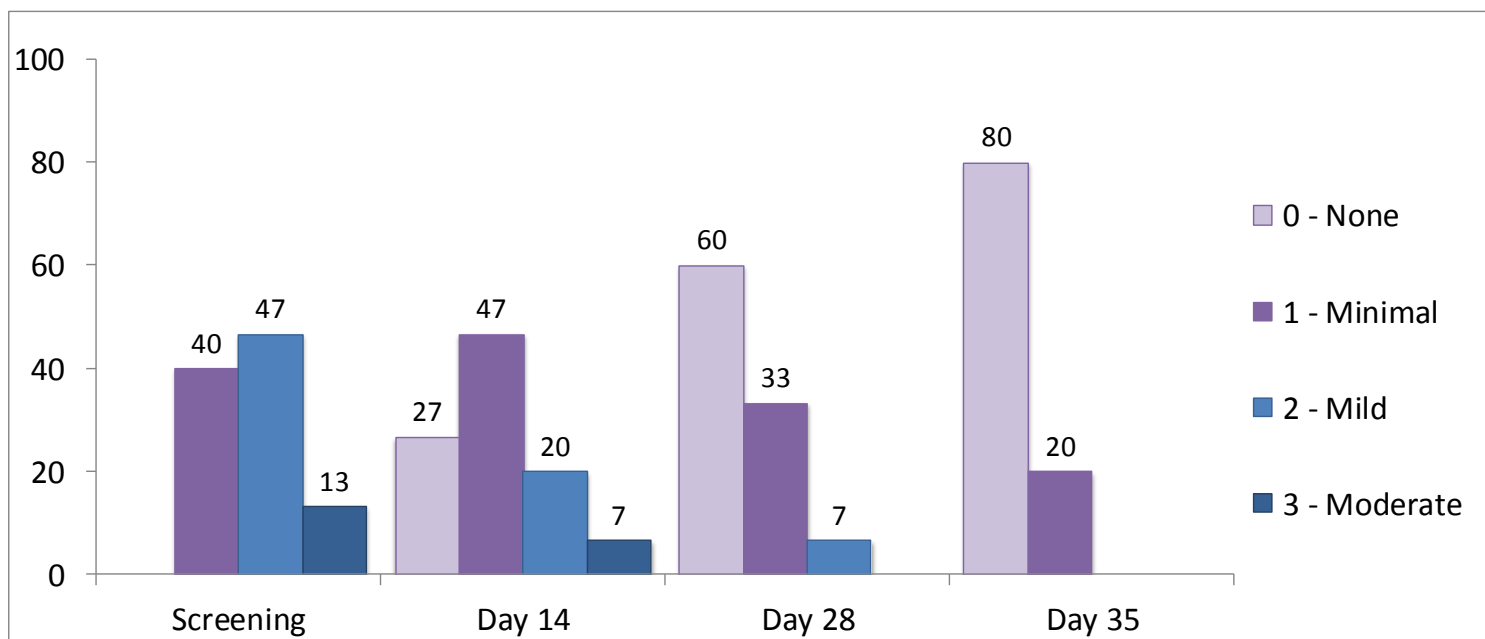
Scale
None (0)
Minimal (1)
Mild (2)
Moderate (3)
Severe (4)

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

(IMPROVEMENT FROM BASELINE)



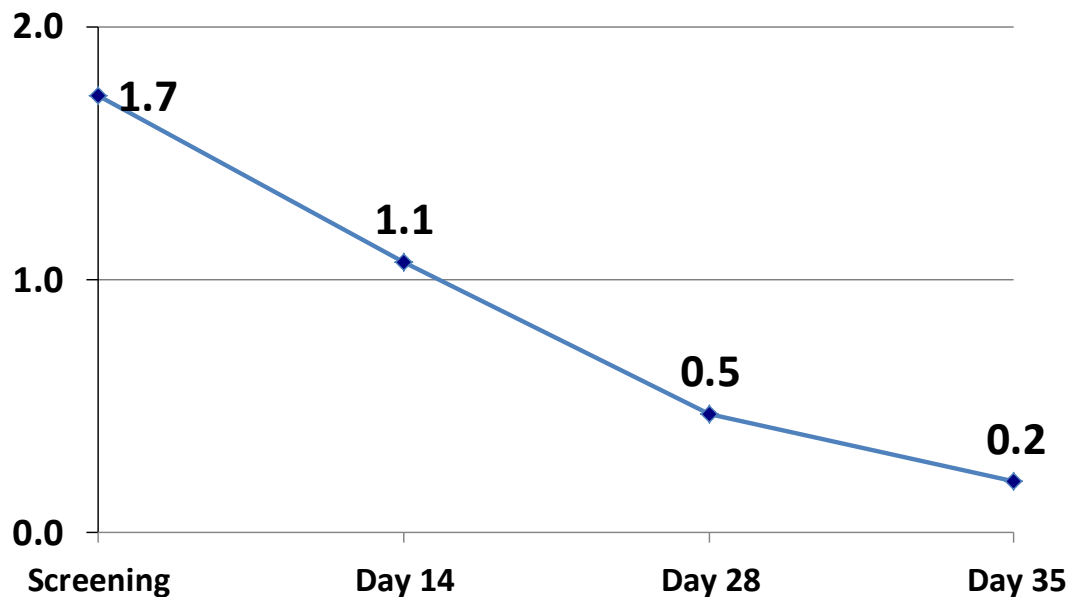
INVESTIGATOR ASSESSMENTS PHOTODAMAGE CHARACTERISTICS – TACTILE ROUGHNESS BY VISIT



Percentage of Subjects

INVESTIGATOR ASSESSMENTS PHOTODAMAGE CHARACTERISTICS – TACTILE ROUGHNESS BY VISIT

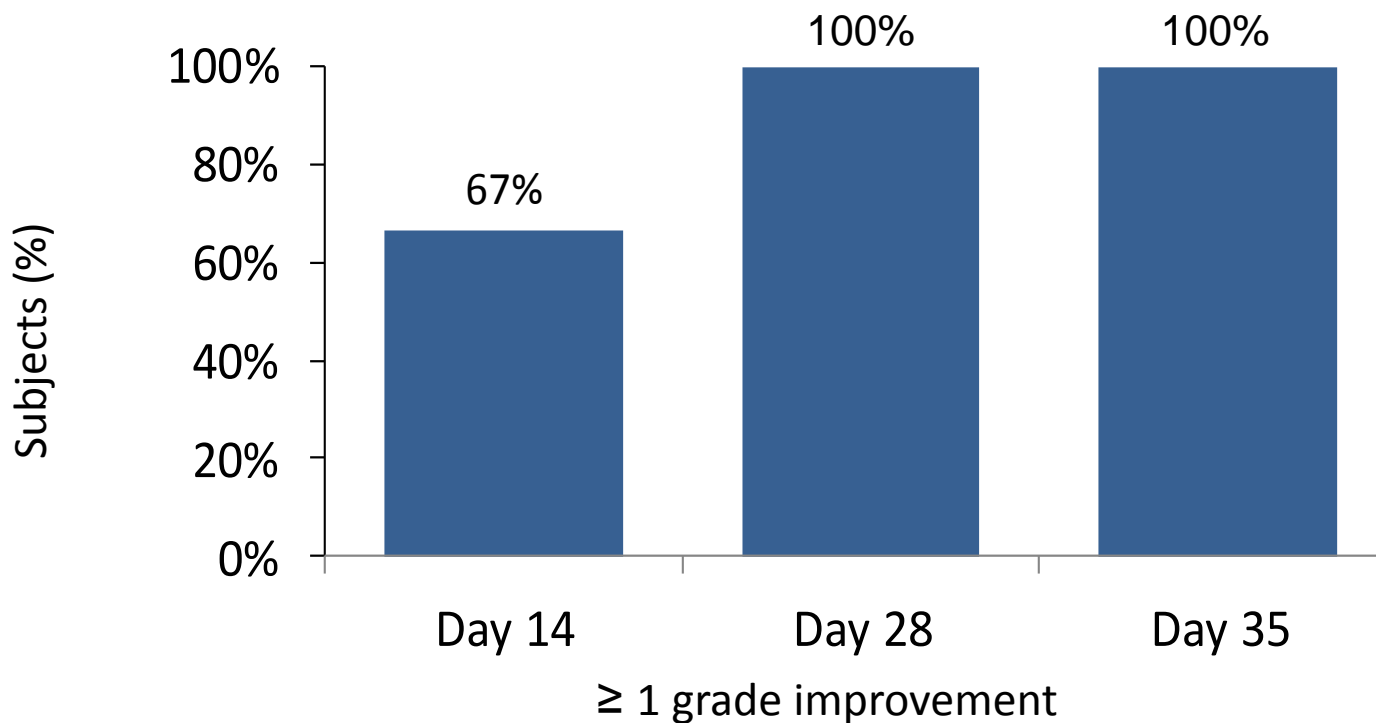
Mean Scores



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

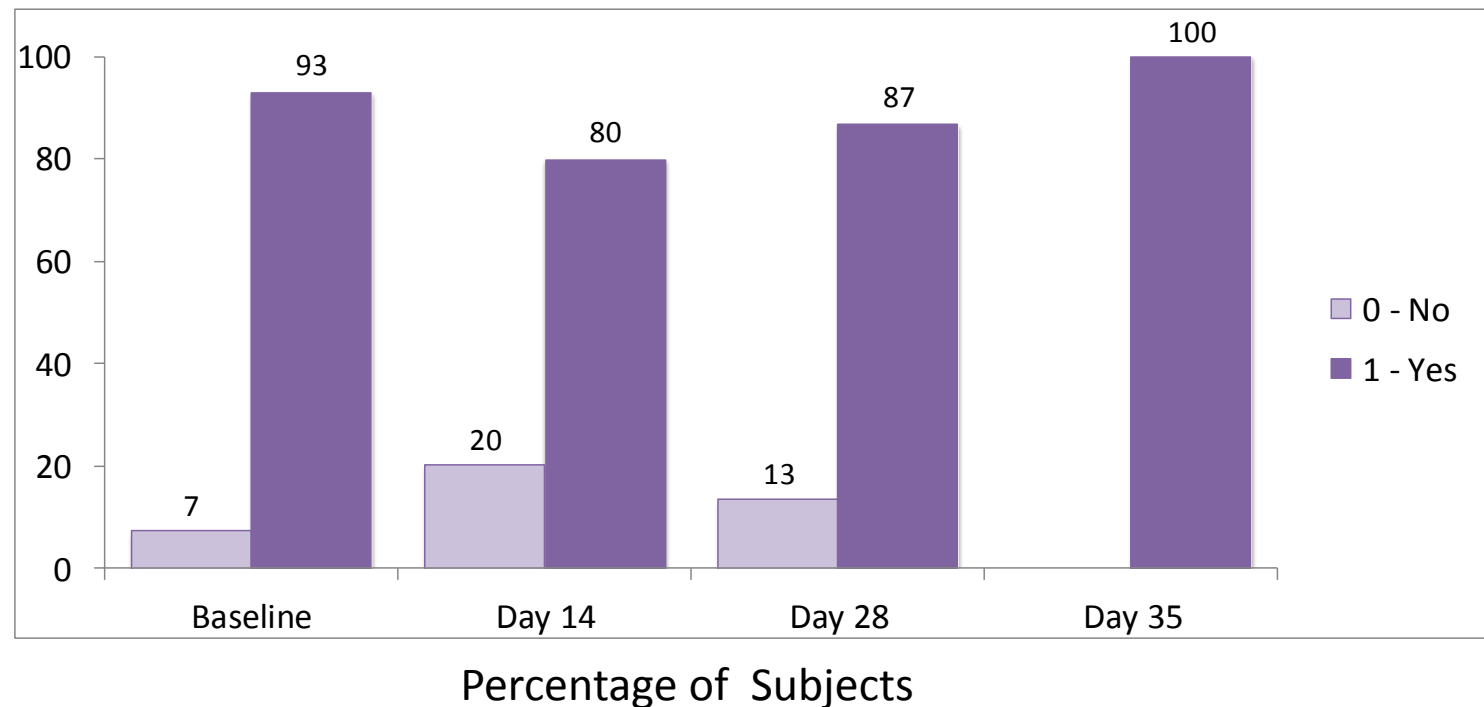
INVESTIGATOR ASSESSMENTS PHOTODAMAGE CHARACTERISTICS – TACTILE ROUGHNESS BY VISIT

(IMPROVEMENT FROM BASELINE)

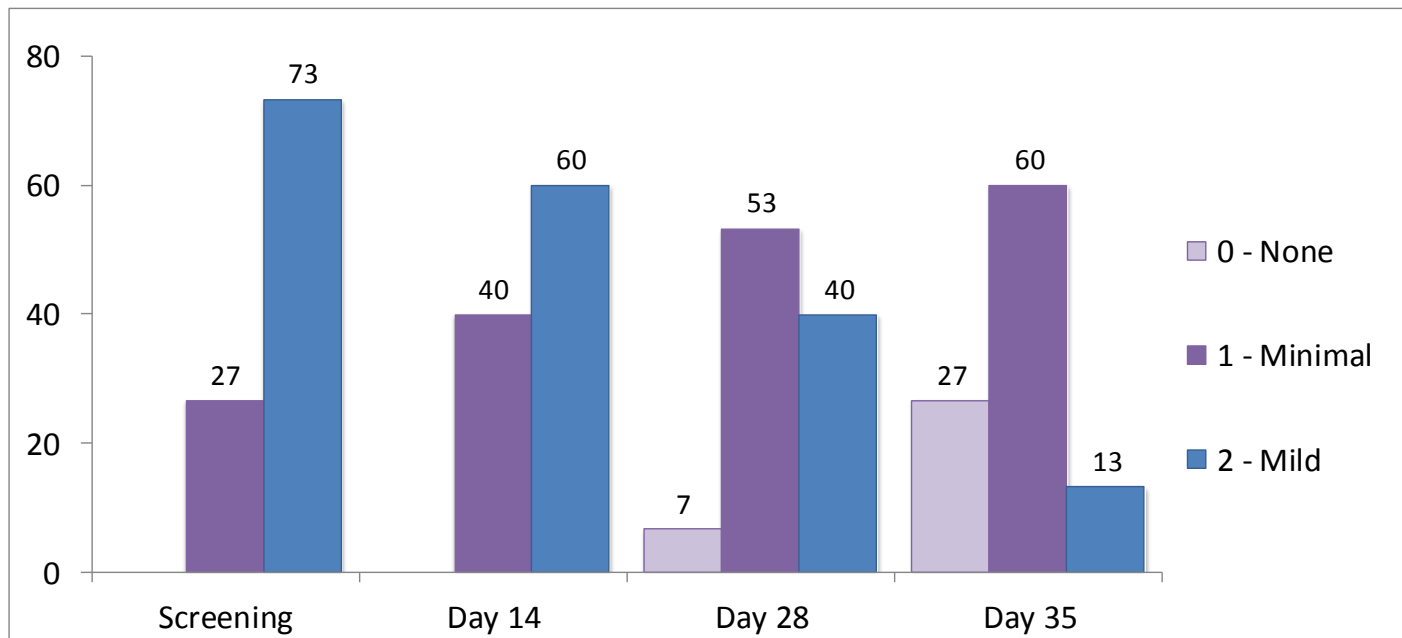


INVESTIGATOR ASSESSMENTS

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



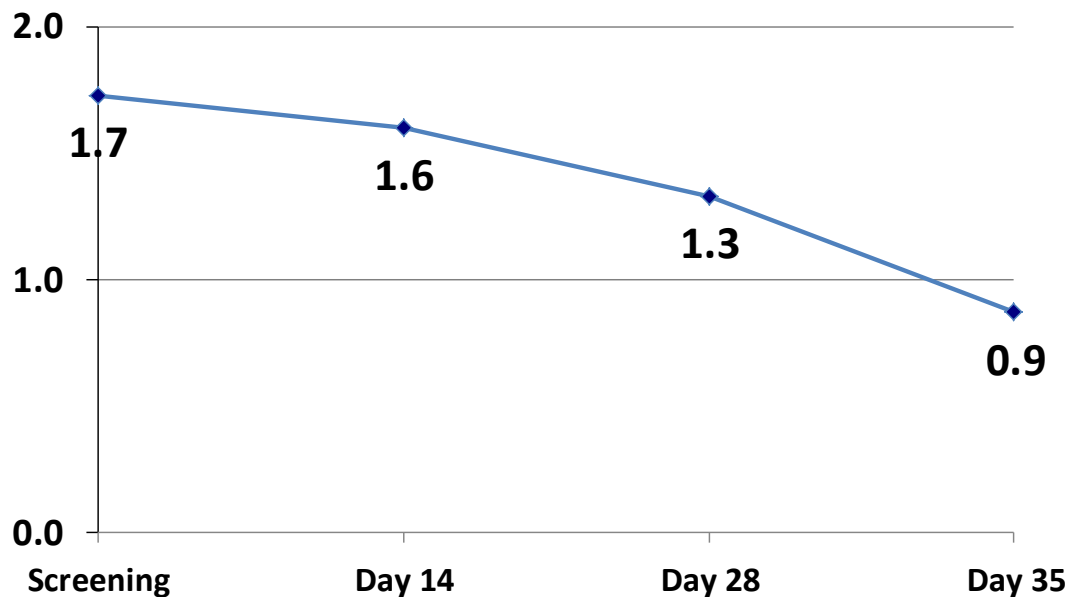
INVESTIGATOR ASSESSMENTS OVERALL FACIAL PIGMENTATION INTENSITY BY VISIT



Percentage of Subjects

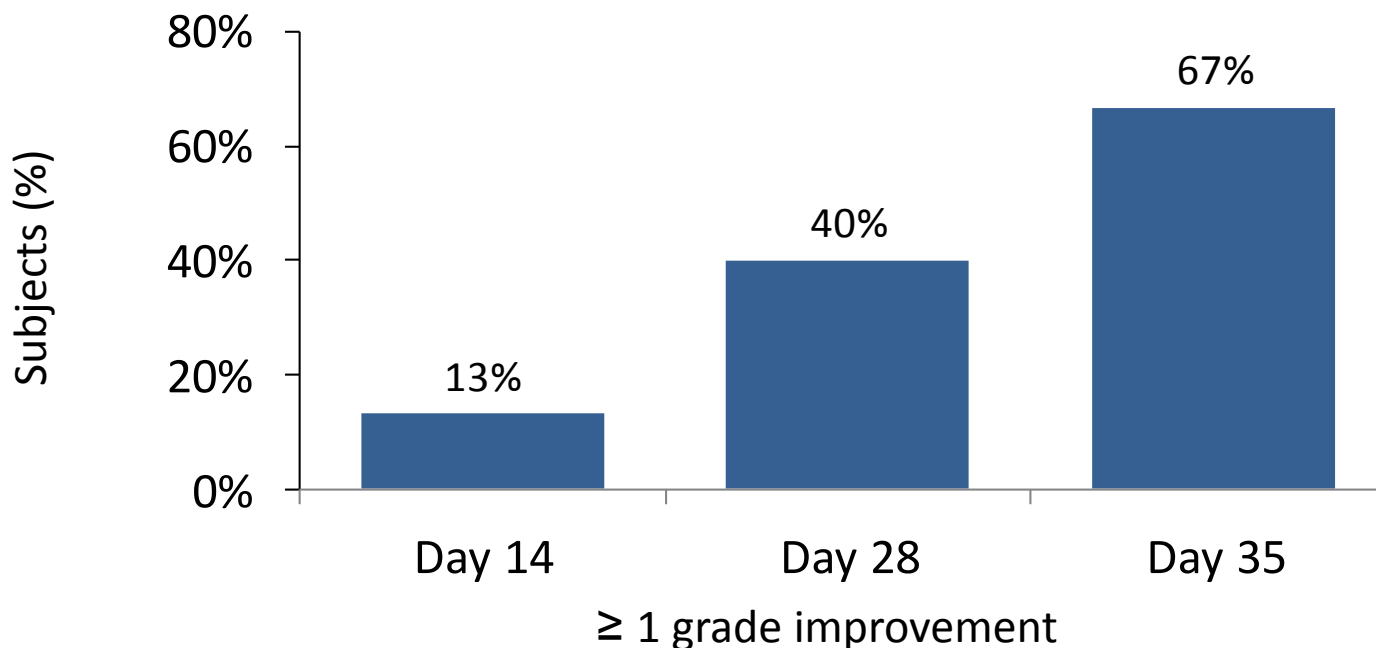
INVESTIGATOR ASSESSMENTS OVERALL FACIAL PIGMENTATION INTENSITY BY VISIT

Mean Scores



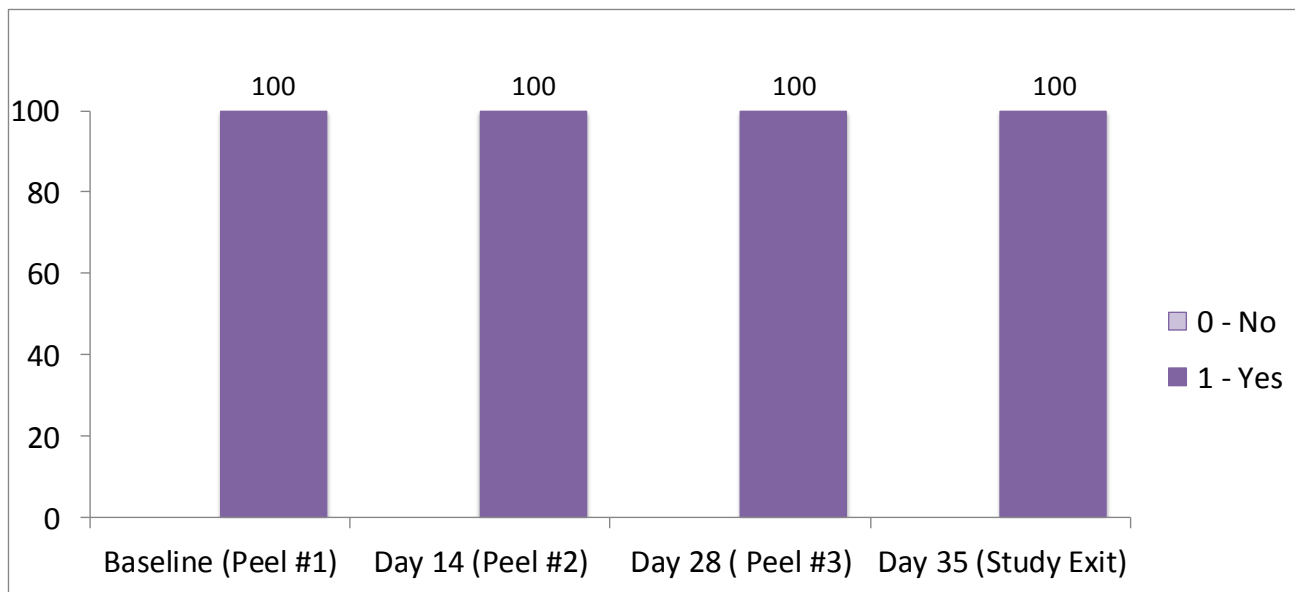
Scale
None (0)
Minimal (1)
Mild (2)
Moderate (3)
Severe (4)

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	53.3	26.7	6.7	6.7			13.3	26.7	26.7	33.3	
- Smoothness of skin		40	40	13.3	6.7				6.7	40	53.3	
- Firmness of skin		60	20	20					20	46.7	26.7	6.7
- Moisture level of skin		40	40	20					33.3	46.7	20	
- Consistent skin tone and coloration	26.7	46.7	20	6.7				6.7	20	53.3	20	
- Appearance of brown spots	40	53.3	6.7					26.7	40	26.7	6.7	
- Pore size	20	40	40					6.7	33.3	40	20	
- Glow/brightness of skin		53.3	40	6.7					6.7	66.7	13.3	13.3
- Overall appearance of skin	6.7	66.7	20	6.7				6.7	26.7	40	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		46.7	46.7			6.7	6.7	33.3	53.3
I would recommend this facial peel procedure to my friends.			13.3	13.3	33.3	40			20	13.3	40	26.7
The results of this facial peel procedure were what I expected.	6.7		20	33.3	26.7	13.3		13.3	6.7	20	46.7	13.3
The results of this facial peel procedure were better than I expected.		6.7	33.3	26.7	20	13.3	6.7	6.7	33.3	26.7	20	6.7
There was minimal downtime after this facial peel procedure.	6.7		13.3	6.7	26.7	46.7		6.7	6.7	20	13.3	53.3

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	40
I would recommend this facial peel procedure to my friends.			13.3	13.3	33.3	40
The results of this facial peel procedure were what I expected.		13.3		26.7	46.7	13.3
The results of this facial peel procedure were better than I expected.		13.3	26.7	40	20	
There was minimal downtime after this facial peel procedure.		6.7		13.3	26.7	53.3

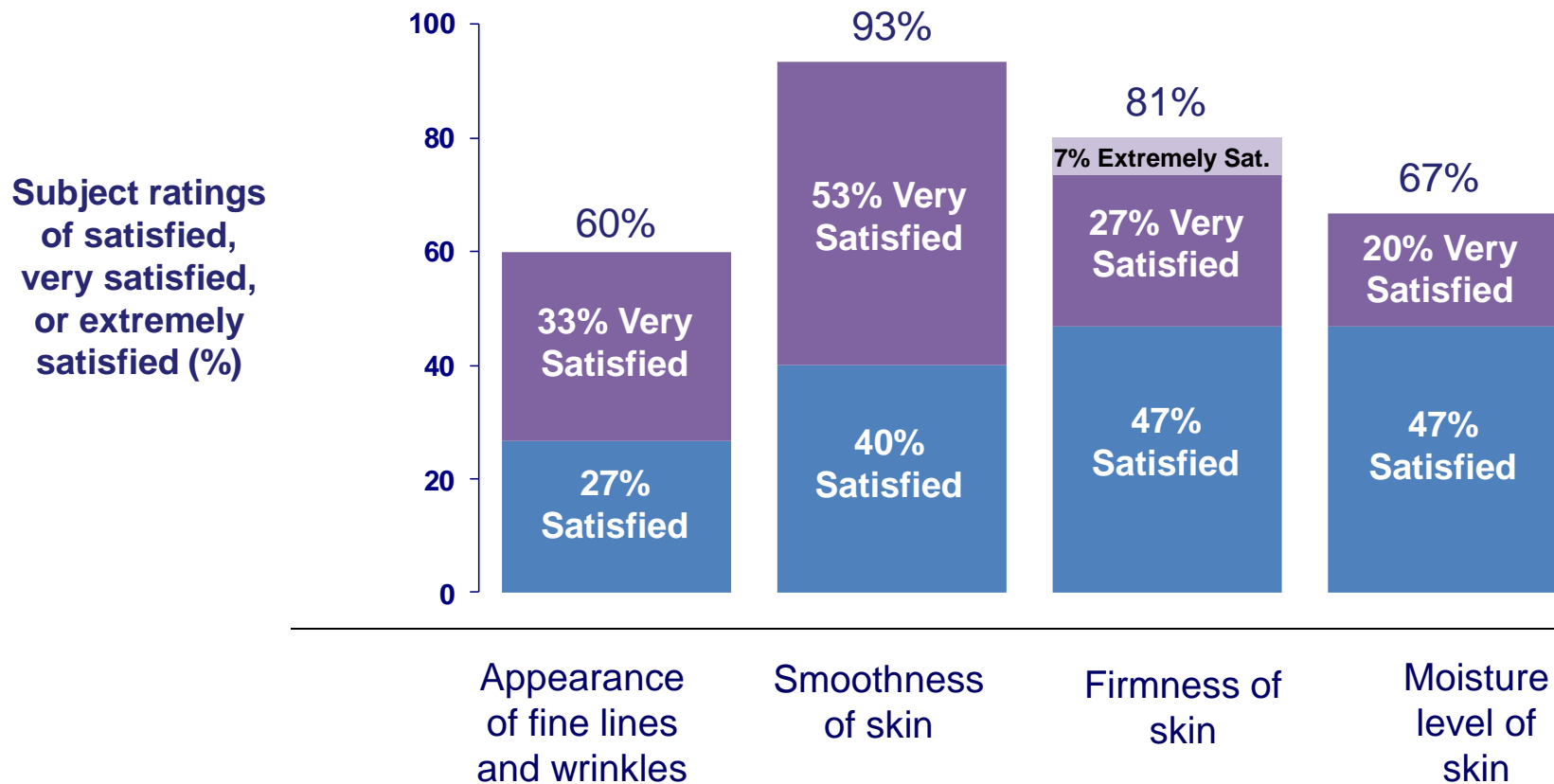
SUBJECT QUESTIONNAIRE RESPONSES DAY 35 Percent (%) of Subjects

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	46.7	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	40	26.7

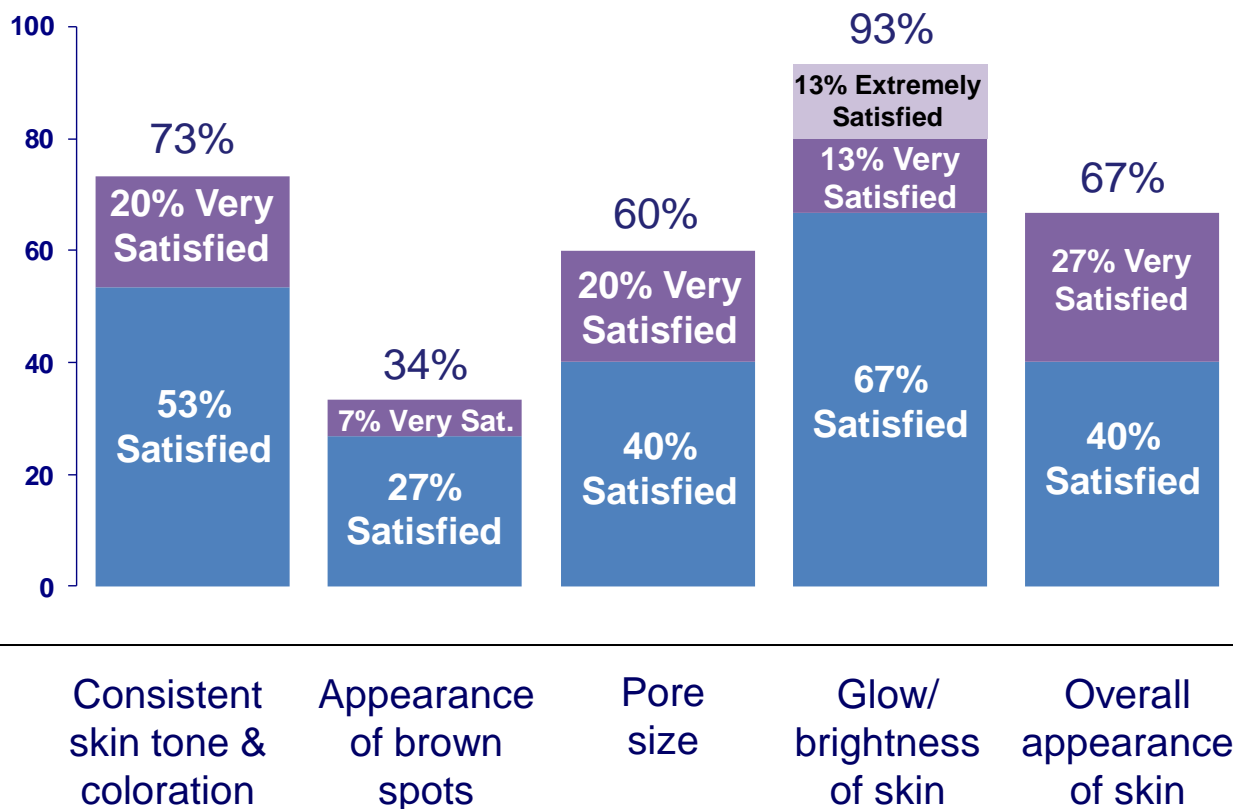
If you have received other facial aesthetic treatments before this study, how would you rate your results with this peel procedure compared to previous facial treatments?	N/A	Much worse	Worse	The same	Better	Much better
	60				13.3	20

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**

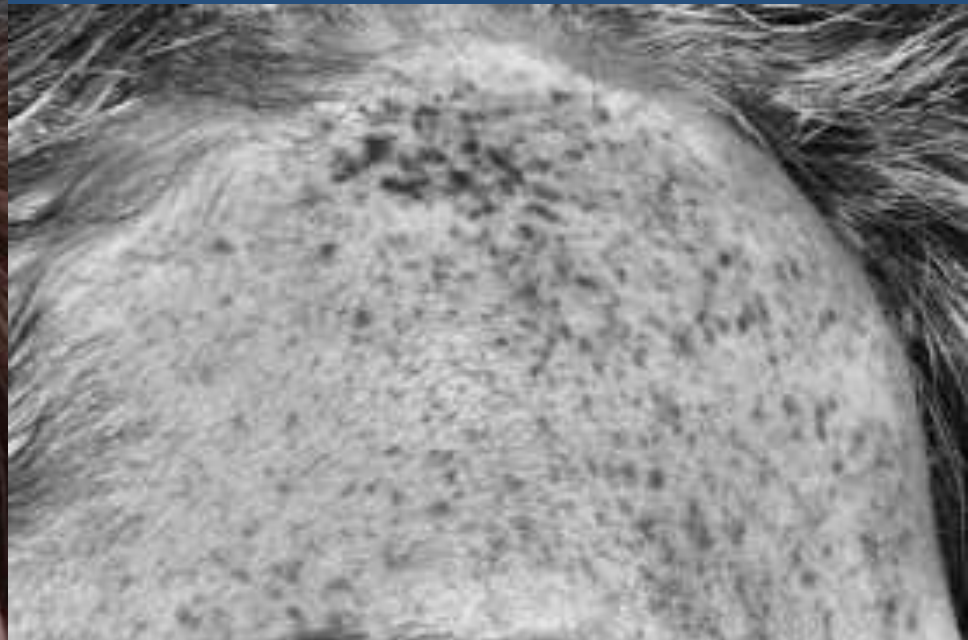


BASELINE PRE-PEEL

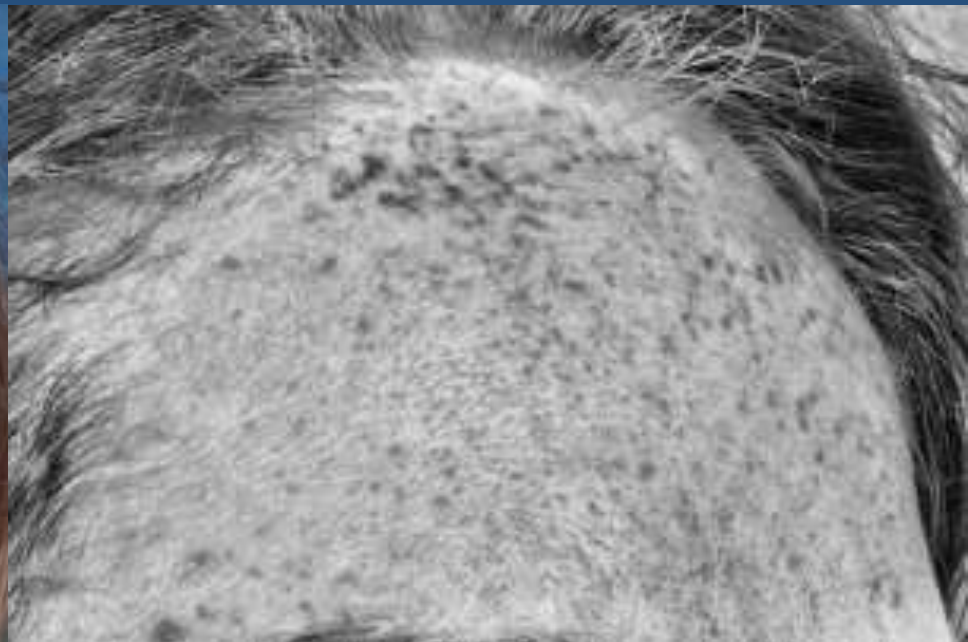


**1 WEEK AFTER PEEL #3
(35 DAYS FROM BASELINE)**

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**

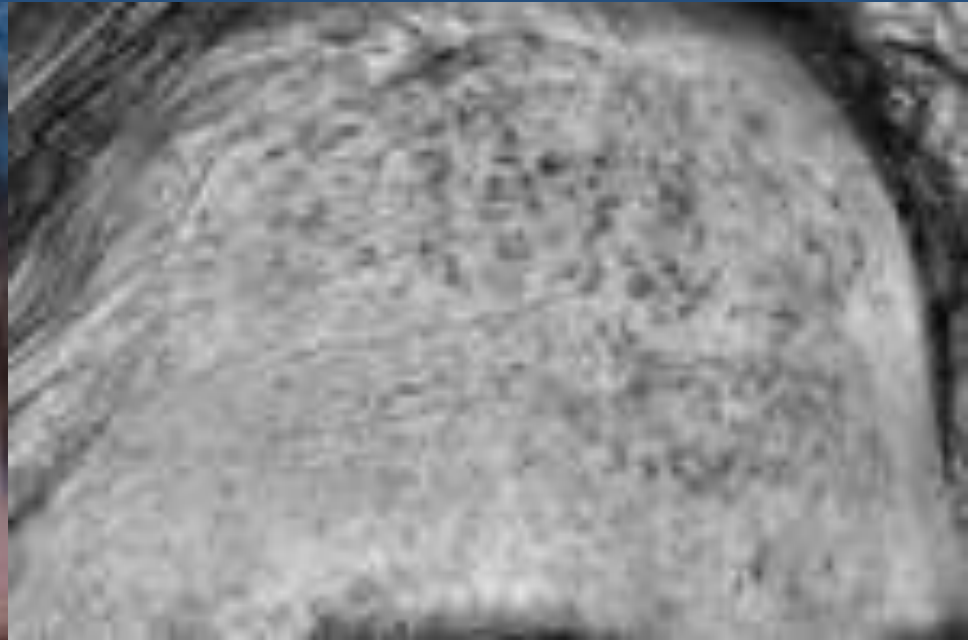


BASELINE PRE-PEEL

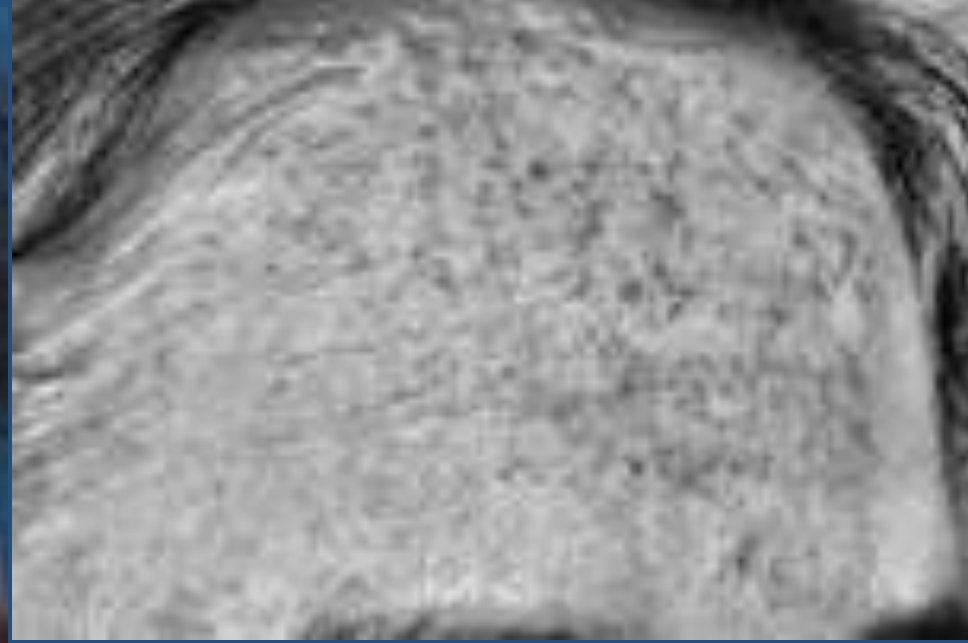


**1 WEEK AFTER PEEL #3
(35 DAYS FROM BASELINE)**

SUBJECT 007 JEK



BASELINE PRE-PEEL



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

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

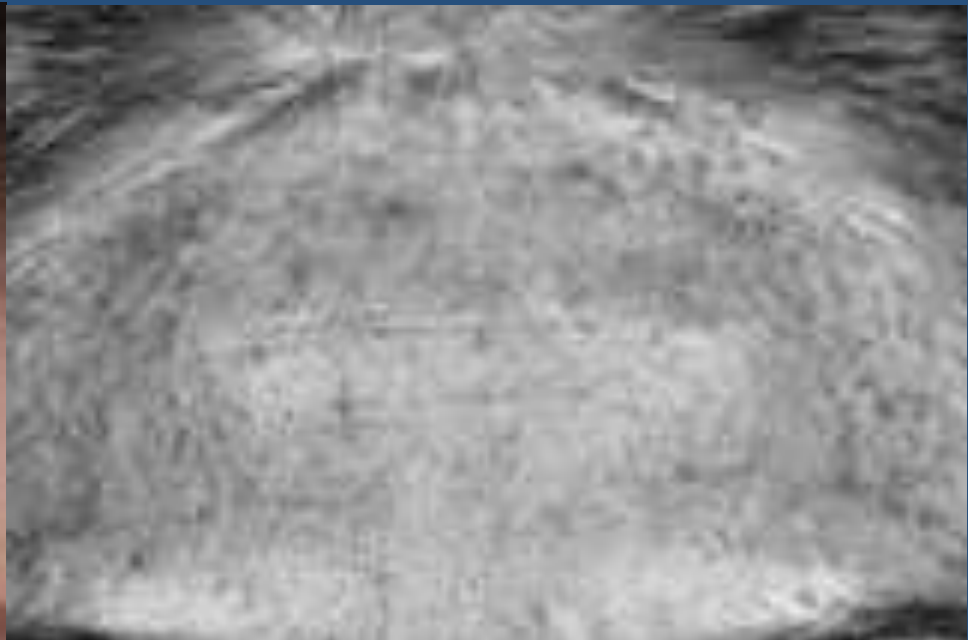


BASELINE PRE-PEEL

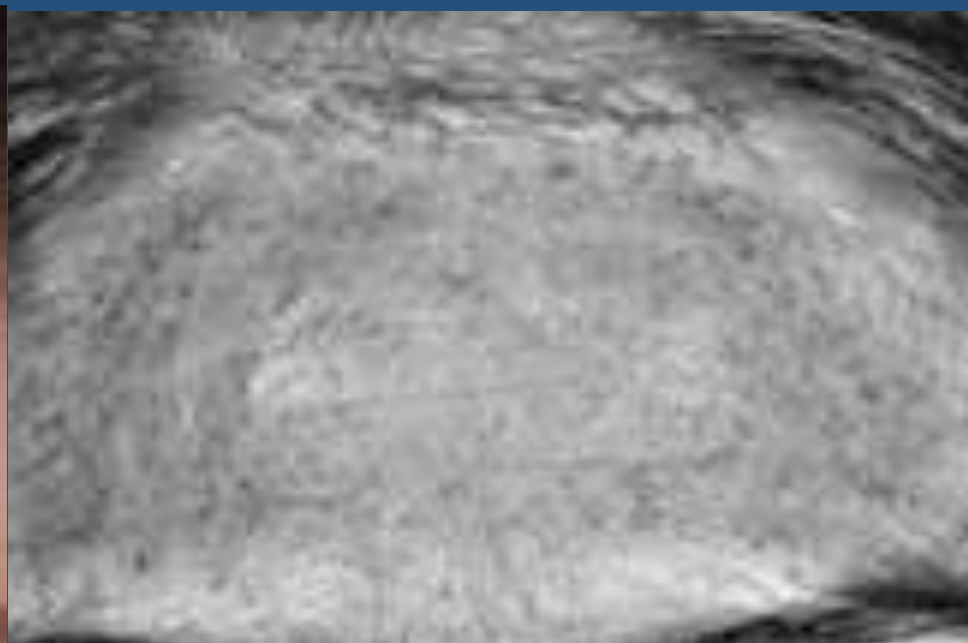


**1 WEEK AFTER PEEL #3
(35 DAYS FROM BASELINE)**

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**

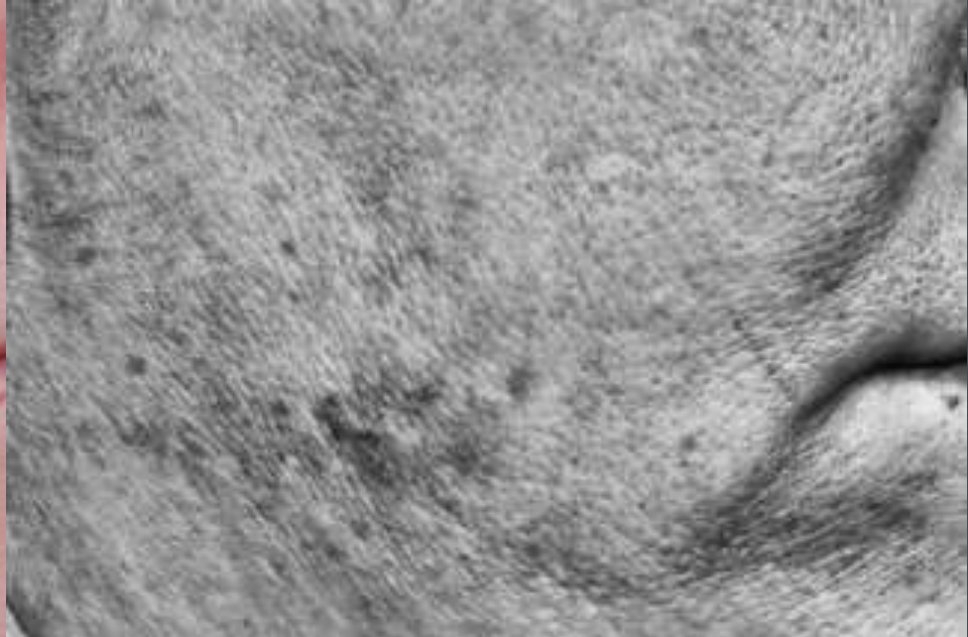


BASELINE PRE-PEEL

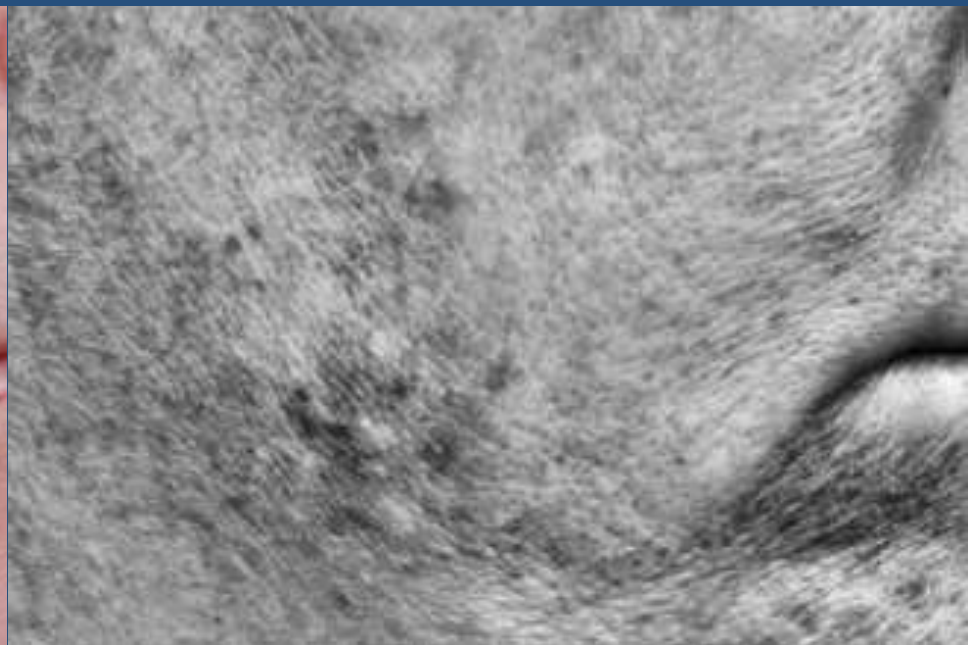


2 WEEKS AFTER PEEL #2

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

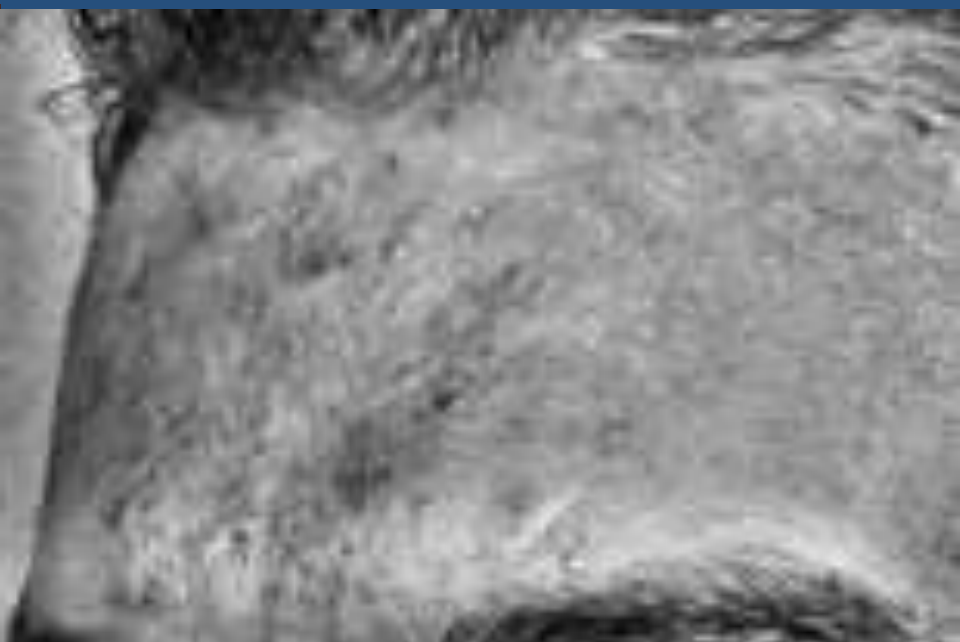


**1 WEEK AFTER PEEL #3
(35 DAYS FROM BASELINE)**

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