

Obagi NuDerm + Retinol Melasma/Photo damage Study

Week 24 Final Results

July 1, 2015

Design

- One-arm, single-center, CRO-run (Stephens & Associates), Investigator-blinded, 24-week study
- N=35 female subjects age 35-65 with mild-to-moderate melasma, mild-to-moderate photo damage, and Fitzpatrick Skin Types III-VI
- Test products: Obagi NuDerm System with Retinol:
 - Foaming Gel (morning & evening)
 - Toner (morning & evening)
 - Clear (4% HQ) (morning & evening)
 - Exfoderm Forte (morning)
 - Sunshield Matte SPF50 (morning)
 - Retinol 1% (evening)
 - Blender (4% HQ) (evening)
- Evaluation time points: BL, week 4, 8, 12, 18, 24 and option to add week 48 (tbd)
- Clinical parameters (identical to original NuDerm study):
 - Melasma disease severity (0 to 8 scale)
 - Melasma pigment intensity (0 to 8 scale)
 - Melasma area severity index (MASI; 0-48 possible score)
 - Melasma improvement (0 to 7 scale; Evaluation at all time points except baseline)
 - Overall photo damage (0 to 6 scale)
 - Specific photo damage characteristics (0 to 5 scale): Lentigines, Tactile roughness, Laxity, Mottled hyperpigmentation, Fine wrinkling, Coarse wrinkling, Crepiness
- Tolerance parameters (0 to 3 scales): erythema, dryness, peeling, burning, stinging
- Photographs with Visia CR
- Consumer questionnaire regarding current skin condition, regimen performance, product aesthetics, tolerance, and quality of life measures

Clinical Benefits - Week 4

	% Clinical Improvement (average change in condition)	% of Panel Improved
Melasma Pigmentation Intensity	8.1*	39.4
Melasma Area Severity Index (MASI)	8.5*	57.6
Overall Photodamage	3.2*	12.1
Mottled Hyperpigmentation	10.9*	36.4

*Mean grading score, statistically significant ($p < 0.05$) improvement when compared to baseline. N=33

Note: Only attributes with significant changes at week 4 are shown. Other attributes evaluated include: Melasma Disease Severity, Lentigines, Tactile Roughness, Laxity, Fine Wrinkling, Coarse Wrinkling, and Crepiness.

Clinical Benefits - Week 8

	% Clinical Improvement (average change in condition)	% of Panel Improved
Melasma Disease Severity	11.3*	39.4
Melasma Pigmentation Intensity	22.4*	78.8
Melasma Area Severity Index (MASI)	28.4*	84.8
Overall Photodamage	12.1*	39.4
Mottled Hyperpigmentation	24.5*	72.7
Lentigines	19.4*	36.4
Tactile Roughness	18.8*	48.5
Laxity	11.4*	30.3
Fine Wrinkling	15.2*	42.4
Crepiness	12.7*	36.4

*Mean grading score, statistically significant ($p < 0.05$) improvement when compared to baseline. N=33

Note: Only attributes with significant changes at week 8 are shown. Other attributes evaluated include: Coarse Wrinkling.

Clinical Benefits - Week 12

	% Clinical Improvement (average change in condition)	% of Panel Improved
Melasma Disease Severity	17.5*	59.4
Melasma Pigmentation Intensity	29.1*	87.5
Melasma Area Severity Index (MASI)	41.8*	93.8
Overall Photodamage	24.0*	84.4
Mottled Hyperpigmentation	32.7*	87.5
Lentigines	30.3*	56.3
Tactile Roughness	28.0*	65.6
Laxity	22.1*	59.4
Fine Wrinkling	23.3*	59.4
Crepiness	25.0*	65.6

*Mean grading score, statistically significant ($p < 0.05$) improvement when compared to baseline. N=32

Note: Only attributes with significant changes at week 12 are shown. Other attributes evaluated include: Coarse Wrinkling.

Clinical Benefits - Week 18

	% Clinical Improvement (average change in condition)	% of Panel Improved
Melasma Disease Severity	24.1*	81.3
Melasma Pigmentation Intensity	36.1*	93.8
Melasma Area Severity Index (MASI)	53.5*	93.8
Overall Photodamage	33.1*	93.8
Mottled Hyperpigmentation	41.1*	87.5
Lentigines	47.0*	71.9
Tactile Roughness	35.4*	75.0
Laxity	30.2*	75.0
Fine Wrinkling	41.1*	78.1
Crepiness	32.9*	68.8
Coarse Wrinkling	13.9*	34.4

*Mean grading score, statistically significant ($p < 0.05$) improvement when compared to baseline. N=32

Clinical Benefits - Week 24

	% Clinical Improvement (average change in condition)	% of Panel Improved
Melasma Disease Severity	37.1*	83.9
Melasma Pigmentation Intensity	47.7*	93.5
Melasma Area Severity Index (MASI)	64.1*	96.8
Overall Photodamage	42.4*	96.8
Mottled Hyperpigmentation	46.2*	87.1
Lentigines	56.1*	77.4
Tactile Roughness	48.8*	83.9
Laxity	40.5*	90.3
Fine Wrinkling	43.7*	80.6
Crepiness	54.1*	83.9
Coarse Wrinkling	20.0*	48.4

*Mean grading score, statistically significant ($p < 0.05$) improvement when compared to baseline. N=31

Nu-Derm + Renova/Retinol Studies Clinical Improvement Comparison - Week 4

	% Clinical Improvement (average change in condition) Nu-Derm + Renova 2014 Study	% Clinical Improvement (average change in condition) Nu-Derm + <u>Retinol</u> 2014/2015 Study	% of Panel Improved Nu-Derm + Renova 2014 Study	% of Panel Improved Nu-Derm + <u>Retinol</u> 2014/2015 Study
Melasma Disease Severity	7*	1.4 (NS)	22.2	6.1
Melasma Pigmentation Intensity	23.7*	8.1*	63.9	39.4
Melasma Area Severity Index (MASI)	26*	8.5*	77.8	57.6
Overall Photo damage	13.7*	3.2*	44.4	12.1
Lentigines	8.9*	4.5 (NS)	22.2	9.1
Tactile Roughness	38.2*	7.1 (NS)	38.9	27.3
Mottled Hyperpigmentation	17.0*	10.9*	50	36.4

*Mean grading score, statistically significant ($p < 0.05$) improvement when compared to baseline
 Only attributes showing significant changes at week 4 for the Nu-Derm + Renova study are shown.
 NS – not statistically significant ($p > 0.05$) vs. baseline

Nu-Derm + Renova/Retinol Studies Clinical Improvement Comparison - Week 8

	% Clinical Improvement (average change in condition) Nu-Derm + Renova 2014 Study	% Clinical Improvement (average change in condition) Nu-Derm + <u>Retinol</u> 2014/2015 Study	% of Panel Improved Nu-Derm + Renova 2014 Study	% of Panel Improved Nu-Derm + <u>Retinol</u> 2014/2015 Study
Melasma Disease Severity	17.7*	11.3*	51.4	39.4
Melasma Pigmentation Intensity	35.3*	22.4*	80	78.8
Melasma Area Severity Index (MASI)	49.4*	28.4*	97.1	84.8
Overall Photo damage	17.4*	12.1*	54.3	39.4
Lentigines	19.1*	19.4*	48.6	36.4
Tactile Roughness	56.1*	18.8*	48.6	48.5
Mottled Hyperpigmentation	27.0*	24.5*	74.3	72.7
Laxity	0 (NS)	11.4*	0	30.3
Fine Wrinkling	2.2 (NS)	15.2*	5.7	42.4
Crepiness	4.3*	12.7*	11.4	36.4

*Mean grading score, statistically significant (p<0.05) improvement when compared to baseline

NS – not statistically significant (p>0.05) vs. baseline

Nu-Derm + Renova/Retinol Studies Clinical Improvement Comparison - Week 12

	% Clinical Improvement (average change in condition) Nu-Derm + Renova 2014 Study	% Clinical Improvement (average change in condition) Nu-Derm + <u>Retinol</u> 2014/2015 Study	% of Panel Improved Nu-Derm + Renova 2014 Study	% of Panel Improved Nu-Derm + <u>Retinol</u> 2014/2015 Study
Melasma Disease Severity	28.7*	17.5*	61.1	59.4
Melasma Pigmentation Intensity	48.3*	29.1*	88.9	87.5
Melasma Area Severity Index (MASI)	60.2*	41.8*	100	93.8
Overall Photo damage	26.5*	24.0*	63.9	84.4
Lentigines	28.9*	30.3*	55.6	56.3
Tactile Roughness	75.0*	28.0*	61.1	65.6
Mottled Hyperpigmentation	35.7*	32.7*	75.0	87.5
Laxity	0 (NS)	22.1*	0	59.4
Fine Wrinkling	8.4*	23.3*	22.2	59.4
Crepiness	6.2*	25.0*	16.7	65.6

*Mean grading score, statistically significant (p<0.05) improvement when compared to baseline

NS – not statistically significant (p>0.05) vs. baseline

Nu-Derm + Renova/Retinol Studies Clinical Improvement Comparison - Week 18

	% Clinical Improvement (average change in condition) Nu-Derm + Renova 2014 Study	% Clinical Improvement (average change in condition) Nu-Derm + <u>Retinol</u> 2014/2015 Study	% of Panel Improved Nu-Derm + Renova 2014 Study	% of Panel Improved Nu-Derm + <u>Retinol</u> 2014/2015 Study
Melasma Disease Severity	36.4*	24.1*	75.9	81.3
Melasma Pigmentation Intensity	54.5*	36.1*	89.7	93.8
Melasma Area Severity Index (MASI)	68.7*	53.5*	100	93.8
Overall Photo damage	32.6*	33.1*	72.4	93.8
Lentigines	38.4*	47.0*	69.0	71.9
Tactile Roughness	71.4*	35.4*	60.7	75.0
Mottled Hyperpigmentation	44.8*	41.1*	79.3	87.5
Laxity	0 (NS)	30.2*	0	75.0
Fine Wrinkling	11.5*	41.1*	31.0	78.1
Crepiness	8.9*	32.9*	24.1	68.8
Coarse Wrinkling	1.1 (NS)	13.9*	3.4	34.4

*Mean grading score, statistically significant (p<0.05) improvement when compared to baseline

NS – not statistically significant (p>0.05) vs. baseline

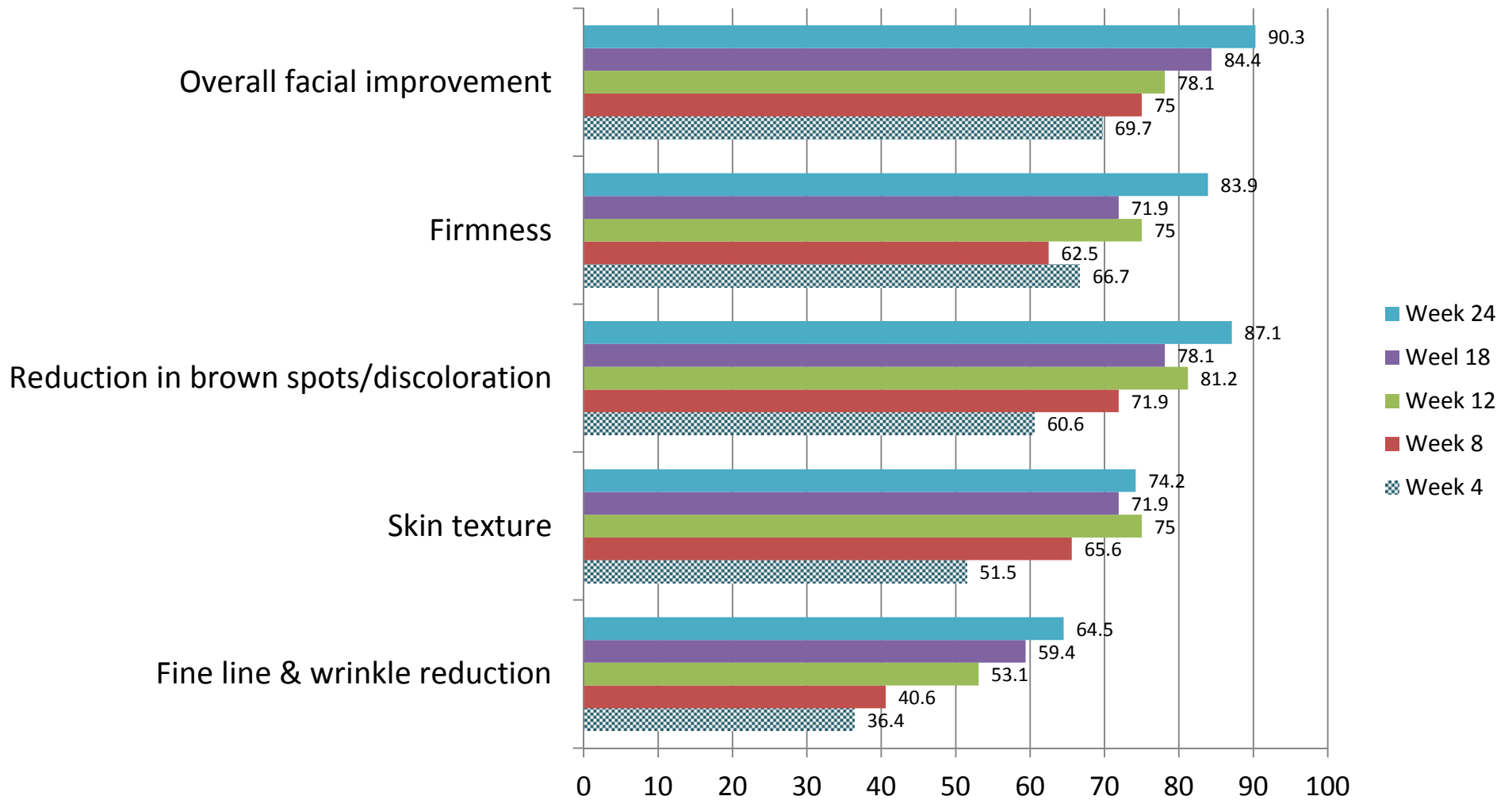
Nu-Derm + Renova/Retinol Studies Clinical Improvement Comparison - Week 24

	% Clinical Improvement (average change in condition) Nu-Derm + Renova 2014 Study	% Clinical Improvement (average change in condition) Nu-Derm + <u>Retinol</u> 2014/2015 Study	% of Panel Improved Nu-Derm + Renova 2014 Study	% of Panel Improved Nu-Derm + <u>Retinol</u> 2014/2015 Study
Melasma Disease Severity	37.1*	37.1*	78.8	83.9
Melasma Pigmentation Intensity	57.5*	47.7*	90.9	93.5
Melasma Area Severity Index (MASI)	70.9*	64.1*	100	96.8
Overall Photo damage	33.6*	42.4*	75.8	96.8
Lentigines	39.5*	56.1*	66.7	77.4
Tactile Roughness	76.7*	48.8*	64.5	83.9
Mottled Hyperpigmentation	50.5*	46.2*	87.9	87.1
Laxity	5.1 (NS)	40.5*	9.1	90.3
Fine Wrinkling	12.4*	43.7*	33.3	80.6
Crepiness	6.7*	54.1*	21.2	83.9
Coarse Wrinkling	2.0 (NS)	20.0*	6.1	48.4

*Mean grading score, statistically significant (p<0.05) improvement when compared to baseline

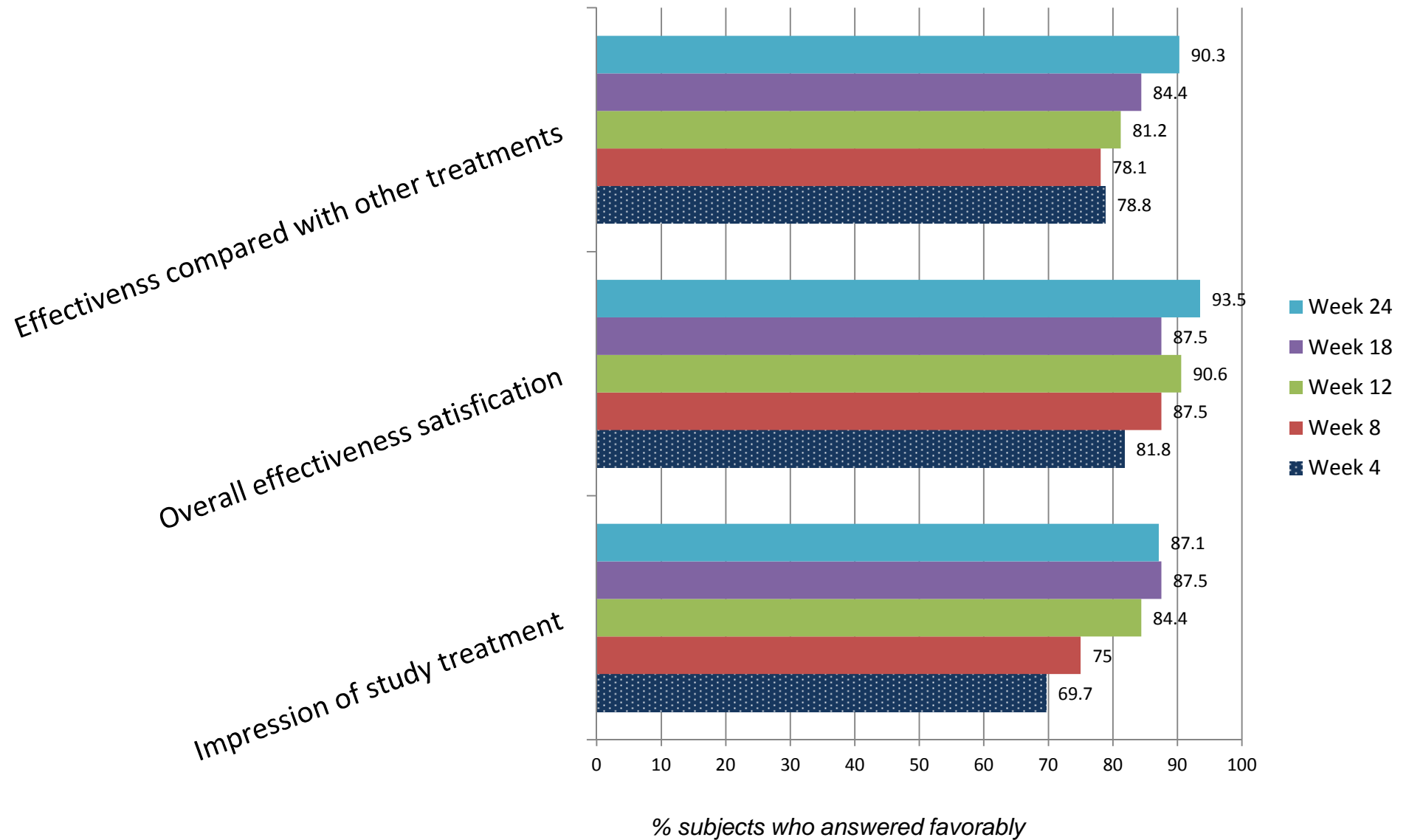
NS – not statistically significant (p>0.05) vs. baseline

Consumer-Perceivable Benefits

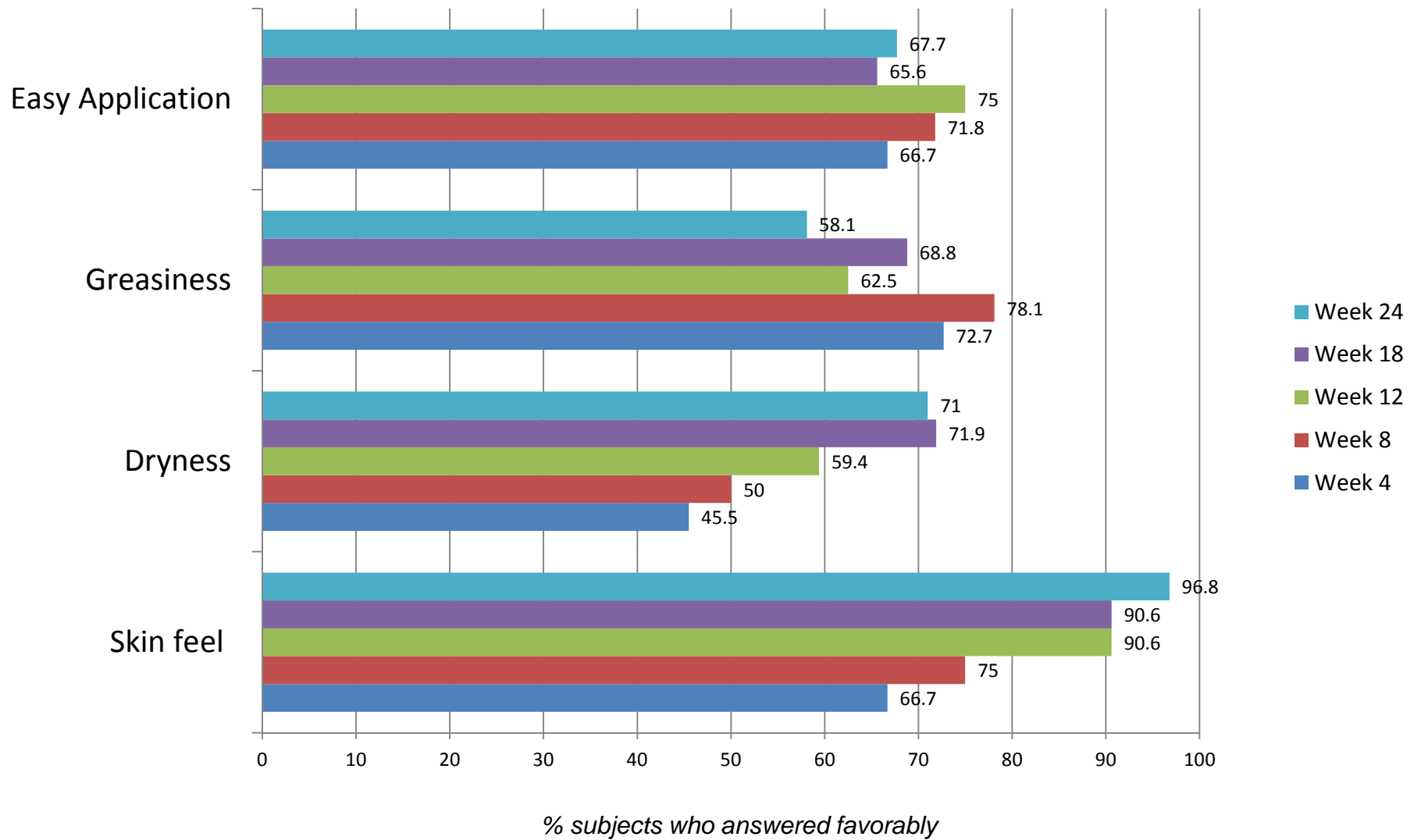


% subjects who answered "Excellent" or "Very Good" and "Good"

Positive Overall Impression



High Subject Acceptance



Quality of Life – Treatment Relevancy

