

NDFX-001 Nu-Derm Fx™ Regimen with Tretinoin Cream USP 0.1%

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24 WEEK FINAL ANALYSIS

Intent to Treat Population

May 2011

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MAIN INCLUSION CRITERIA

- Female Asian or non Asian subject, 25-65 years old, inclusive
- Diagnosis of photodamage and moderate mottled hyperpigmentation of the face
- Glogau Photodamage Classification Type II or Type III
- Mottled Hyperpigmentation Severity of 4 to 7 inclusive
- Overall Facial Hyperpigmentation Intensity of 2 to 7 inclusive
- Fitzpatrick Skin Type III and IV
- Subject may have minimal or mild melasma, as long as melasma is epidermal, unchanged, stable for continuous period 3 months prior to Baseline; and also has diagnosis of photodamage and moderate to severe mottled hyperpigmentation of the face

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STUDY TREATMENT REGIMEN

	AM	PM (evening prior to bedtime)
Nu-Derm Fx™ Treatment Regimen with Tretinoin Cream USP 0.1%	<ul style="list-style-type: none">• Nu-Derm® Foaming Gel• Nu-Derm® Skin Balancing Toner Tonique• Nu-Derm® ClearFx™ (with Arbutin) (1 gram)• Nu-Derm® Exfoderm® Forte (1/2 gram)• Nu-Derm® Healthy Skin Protection SPF 35	<ul style="list-style-type: none">• Nu-Derm® Foaming Gel• Nu-Derm® Skin Balancing Toner Tonique• Nu-Derm® ClearFx™ (with Arbutin) (1 gram)• Tretinoin Cream USP 0.1% (1/2 gram) mixed with Nu-Derm® BlendFx™ (with Arbutin) (1/2 gram)

All subjects were provided Nu-Derm® Action® moisturizer and instructed to use as needed for dryness.

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DEMOGRAPHICS

N (Total Number Subjects Enrolled)	28
Gender Female (%)	100%
Age (Mean)	48
Asian Subjects (%)	32%
White/Caucasian Subjects (%)	68%
Fitzpatrick Skin Type III (%)	54%
Fitzpatrick Skin Type IV (%)	46%
Glogau Photodamage II (%)	61%
Glogau Photodamage III (%)	39%

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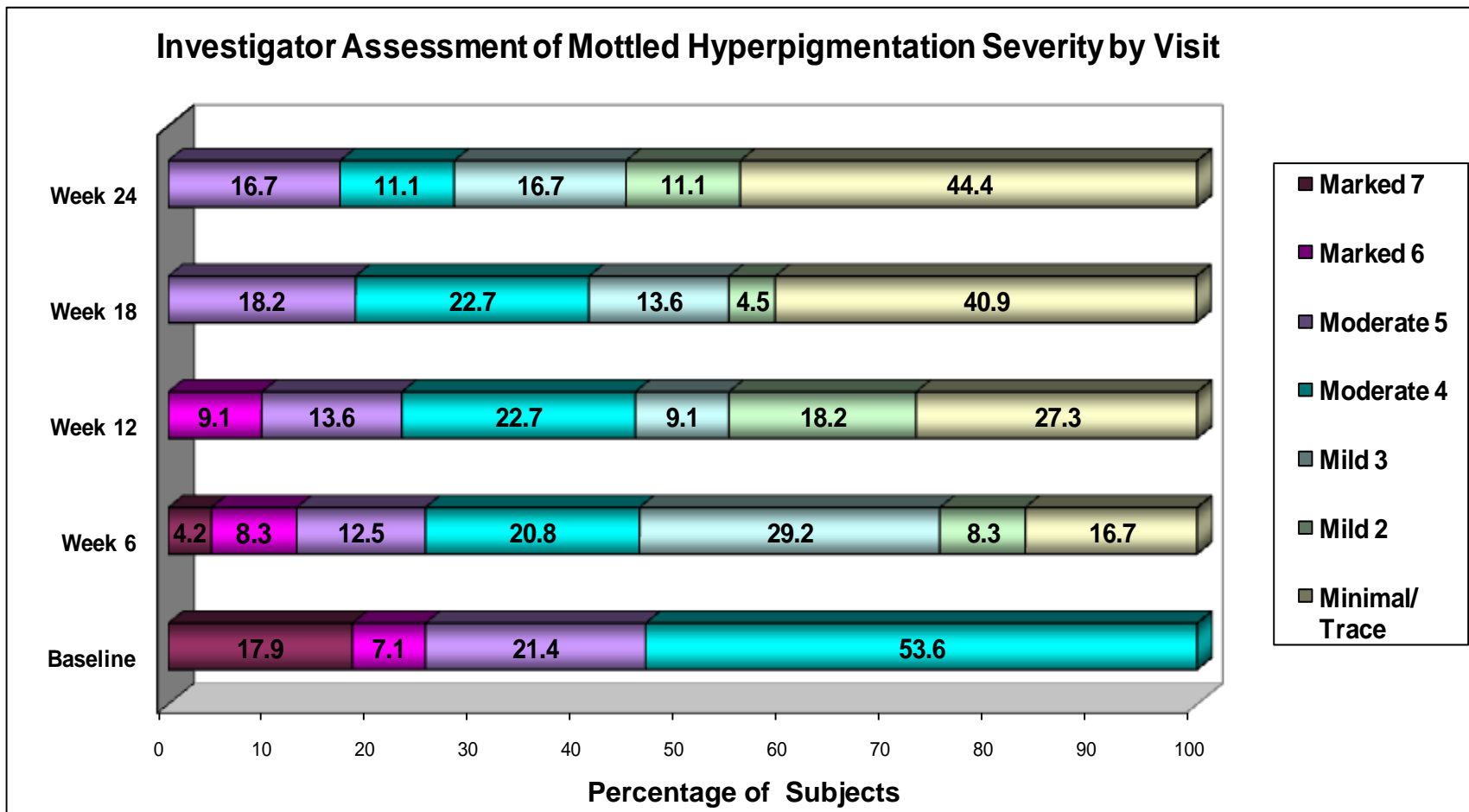
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STATISTICAL ANALYSIS GRAPHS INVESTIGATOR ASSESSMENTS

BASELINE THROUGH WEEK 24 VISIT

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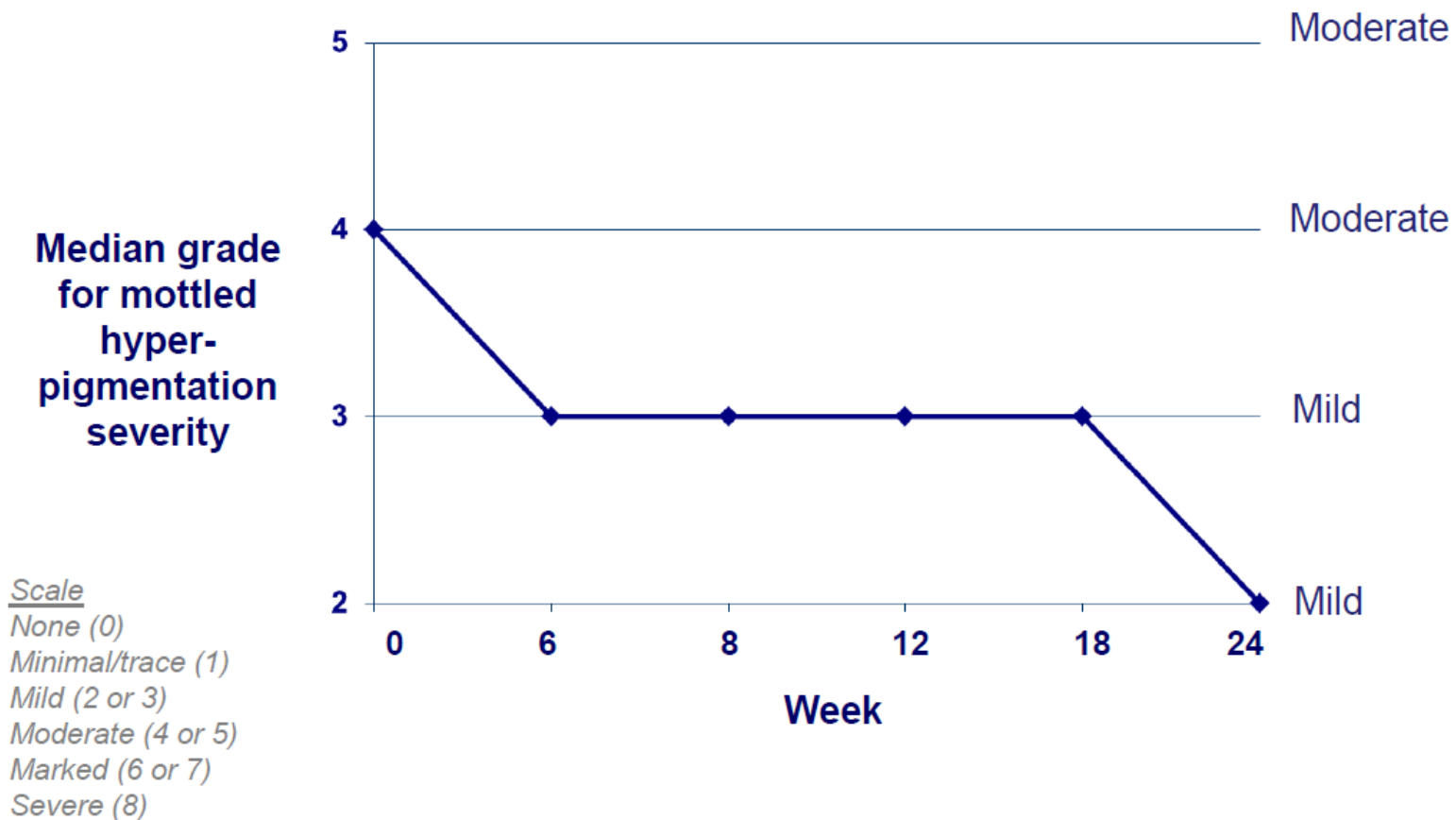
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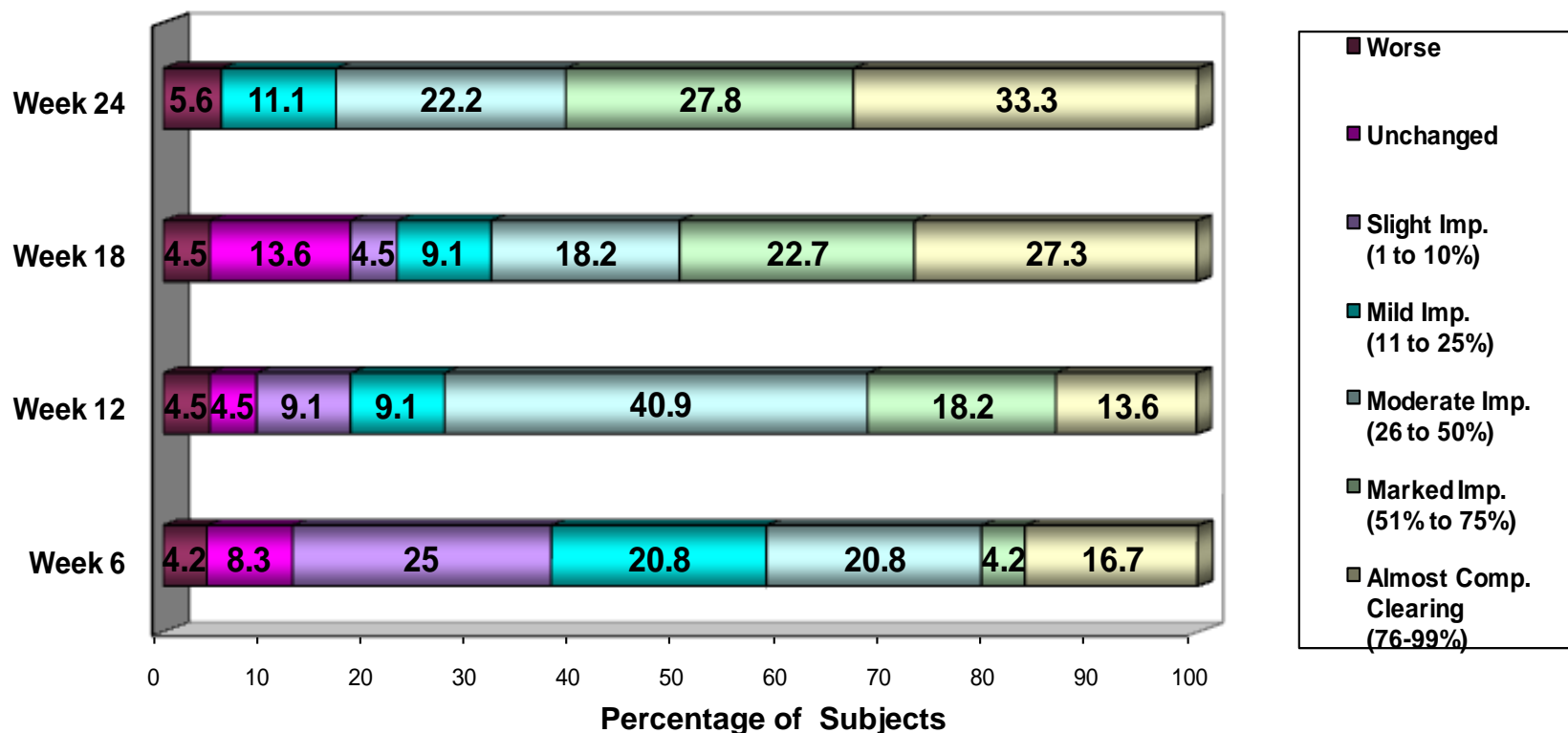
MOTTLED HYPERPIGMENTATION SEVERITY



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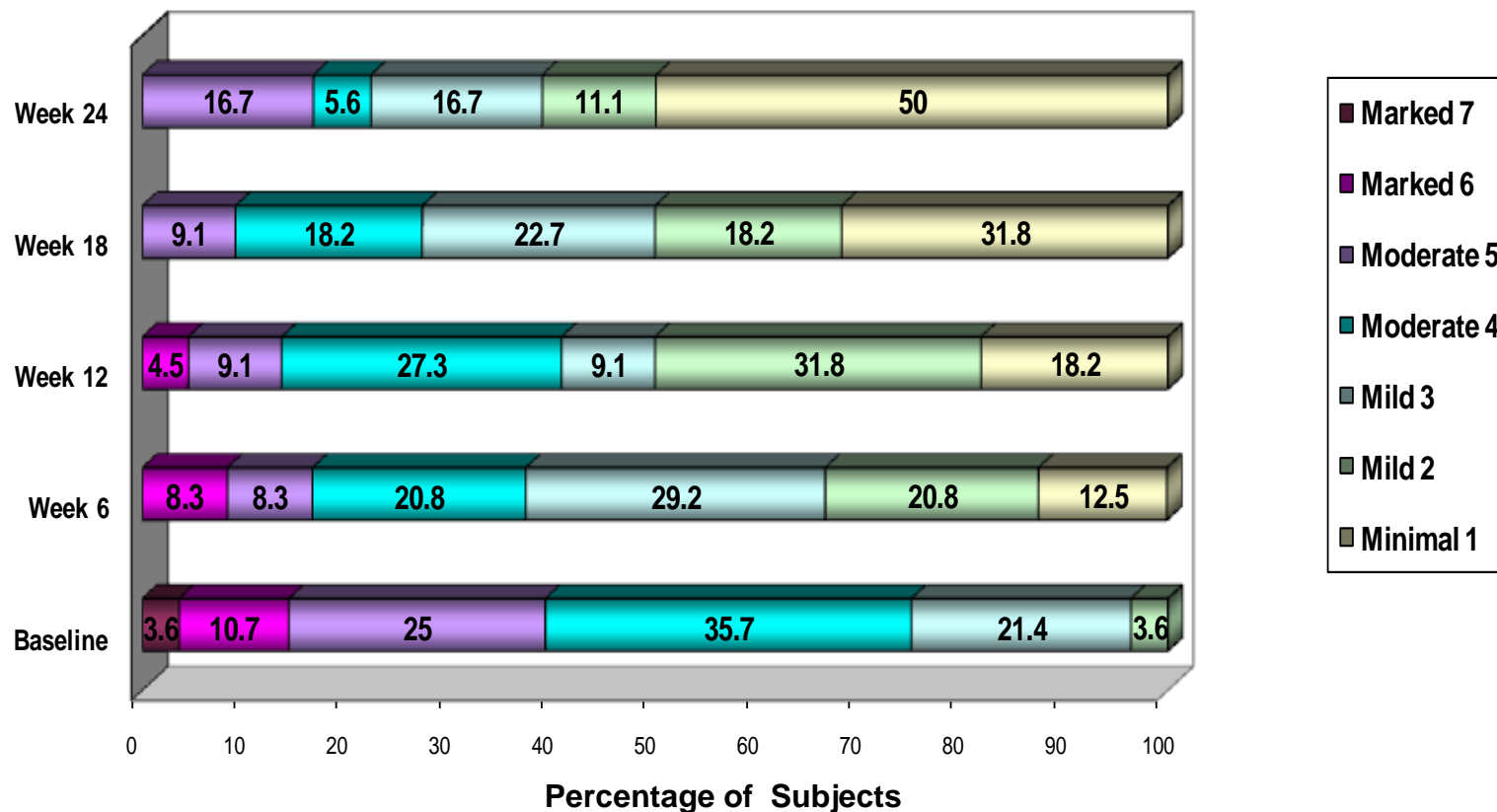
Investigator Assessment of Mottled Hyperpigmentation Improvement by Visit



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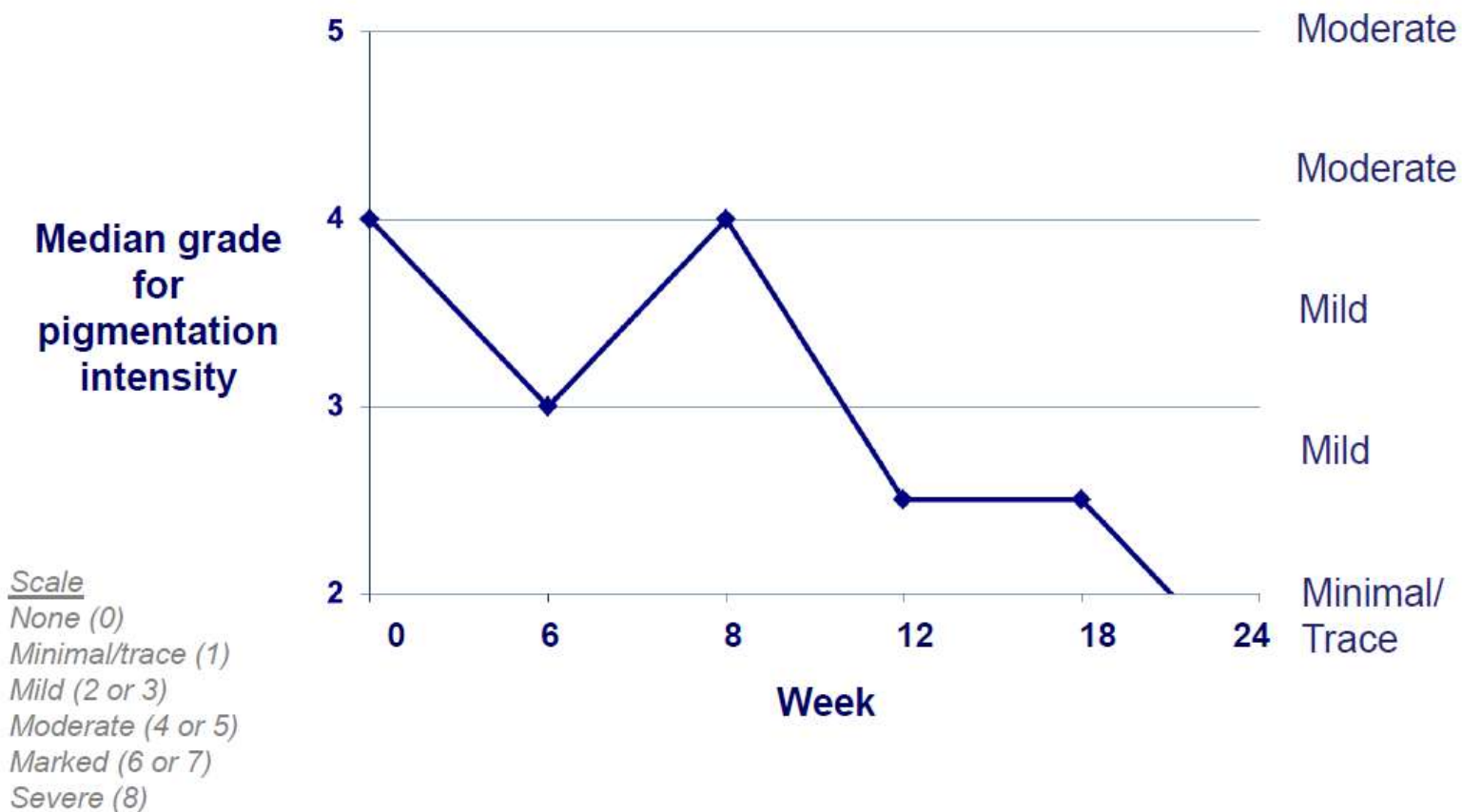
Investigator Assessment of Overall Hyperpigmentation Intensity by Visit



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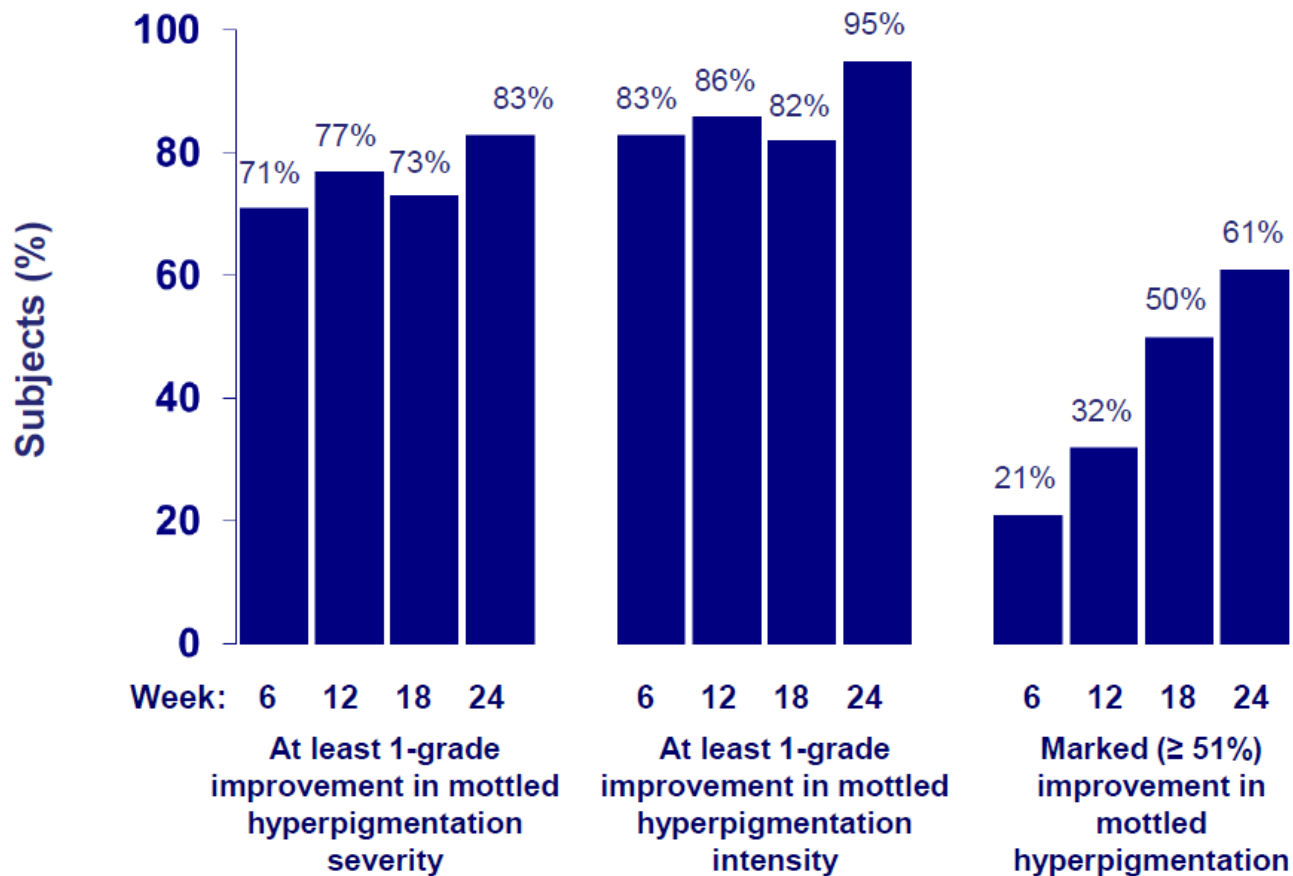
MOTTLED HYPERPIGMENTATION INTENSITY



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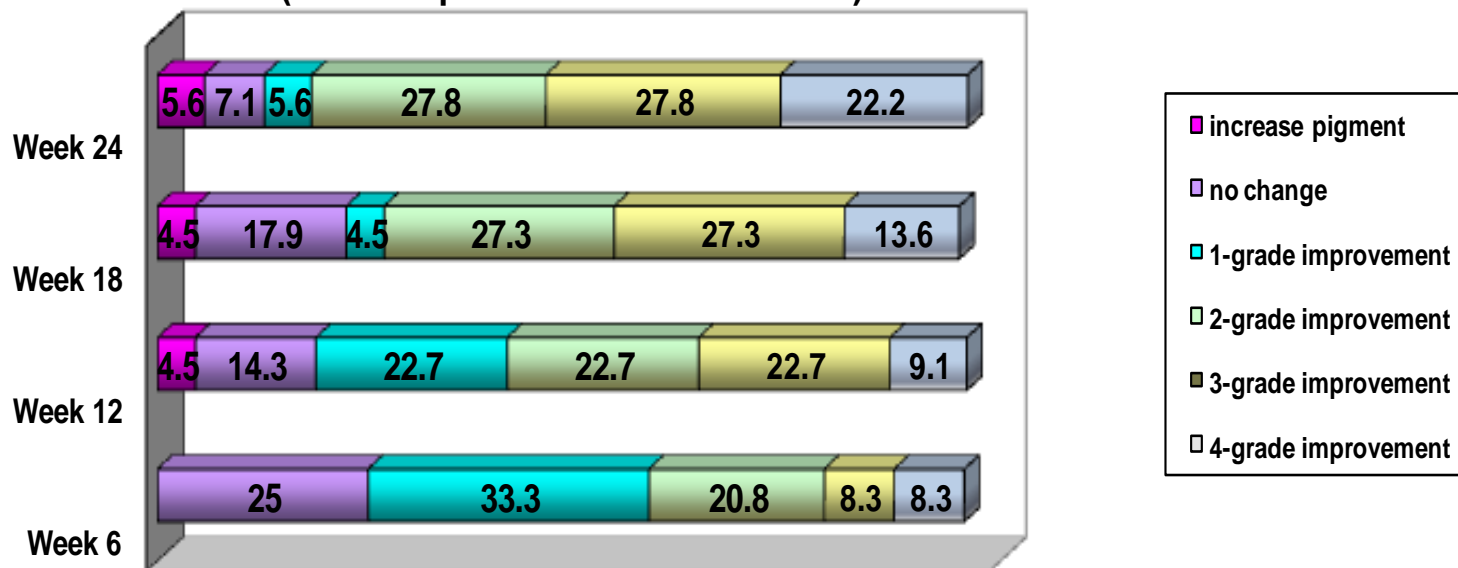
IMPROVEMENT IN MOTTLED HYPERPIGMENTATION



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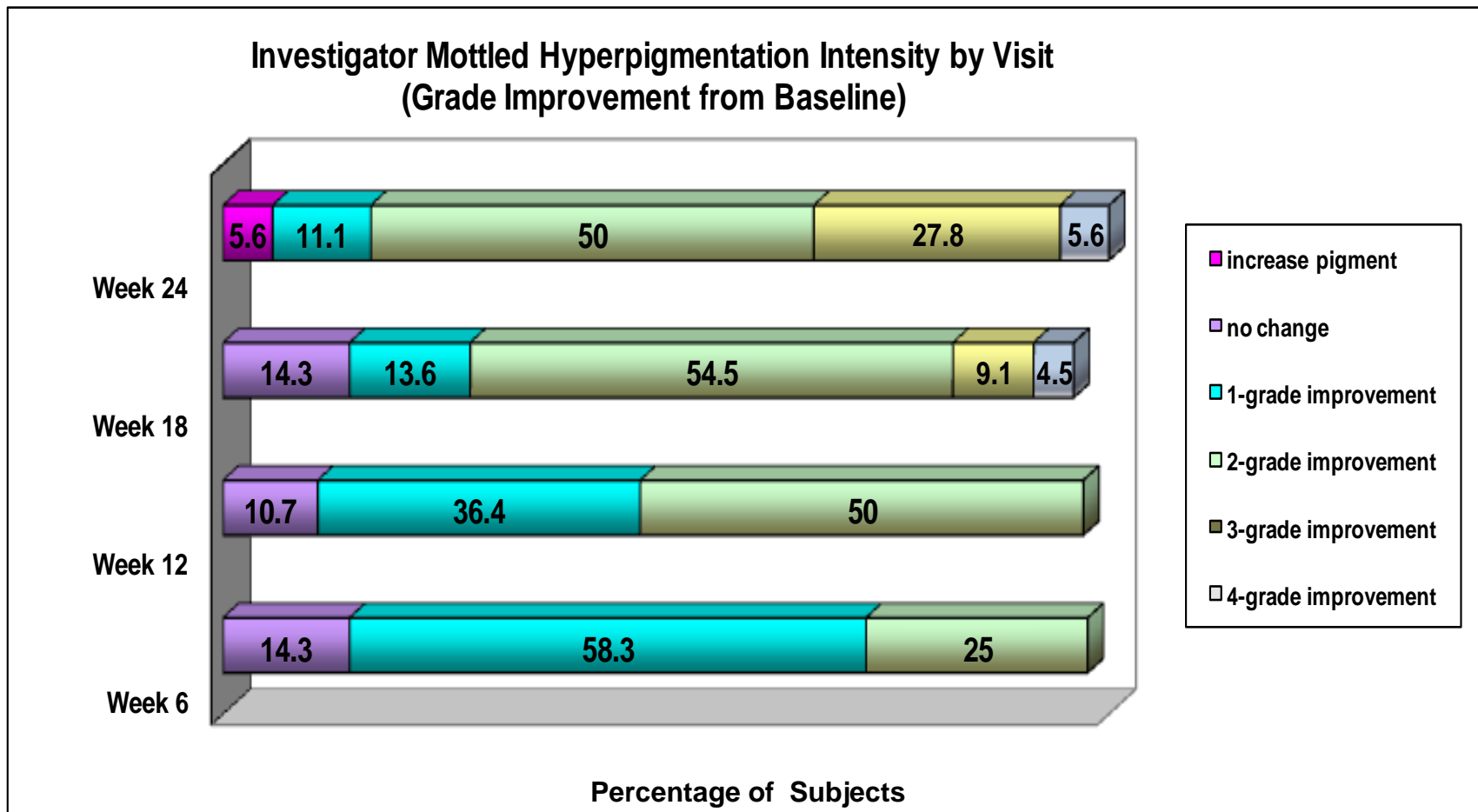
Investigator Mottled Hyperpigmentation Severity by Visit
(Grade Improvement from Baseline)



Percentage of Subjects

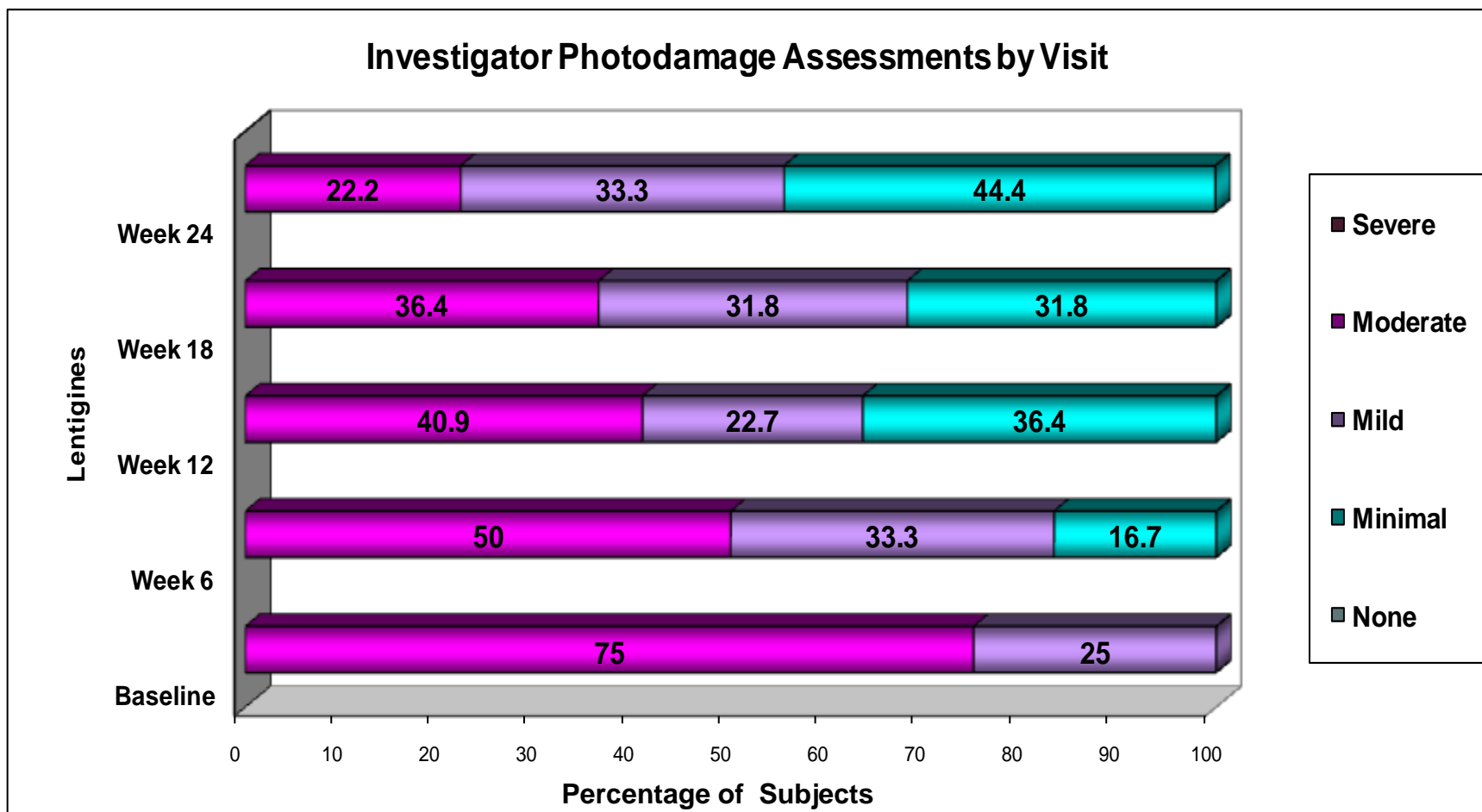
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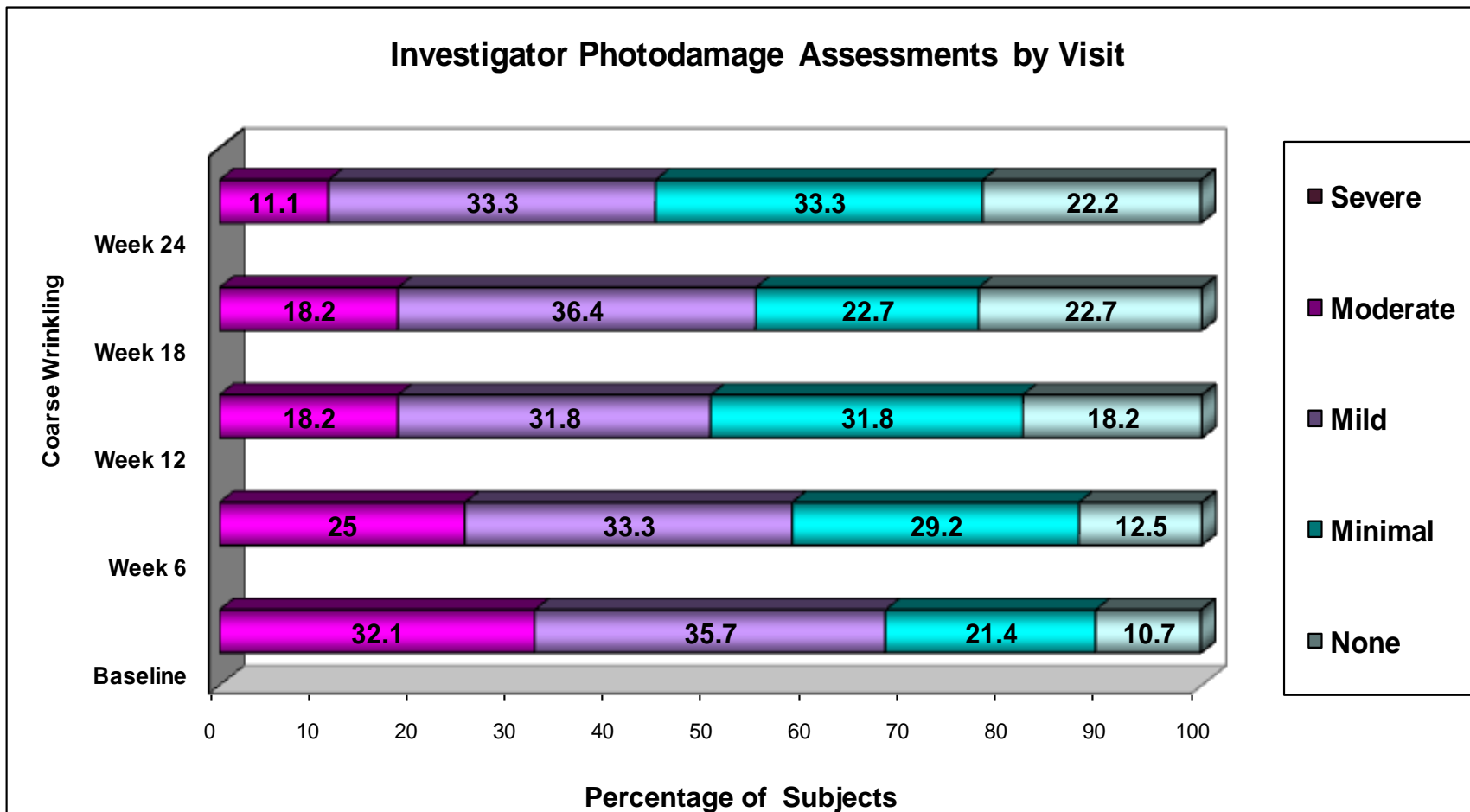
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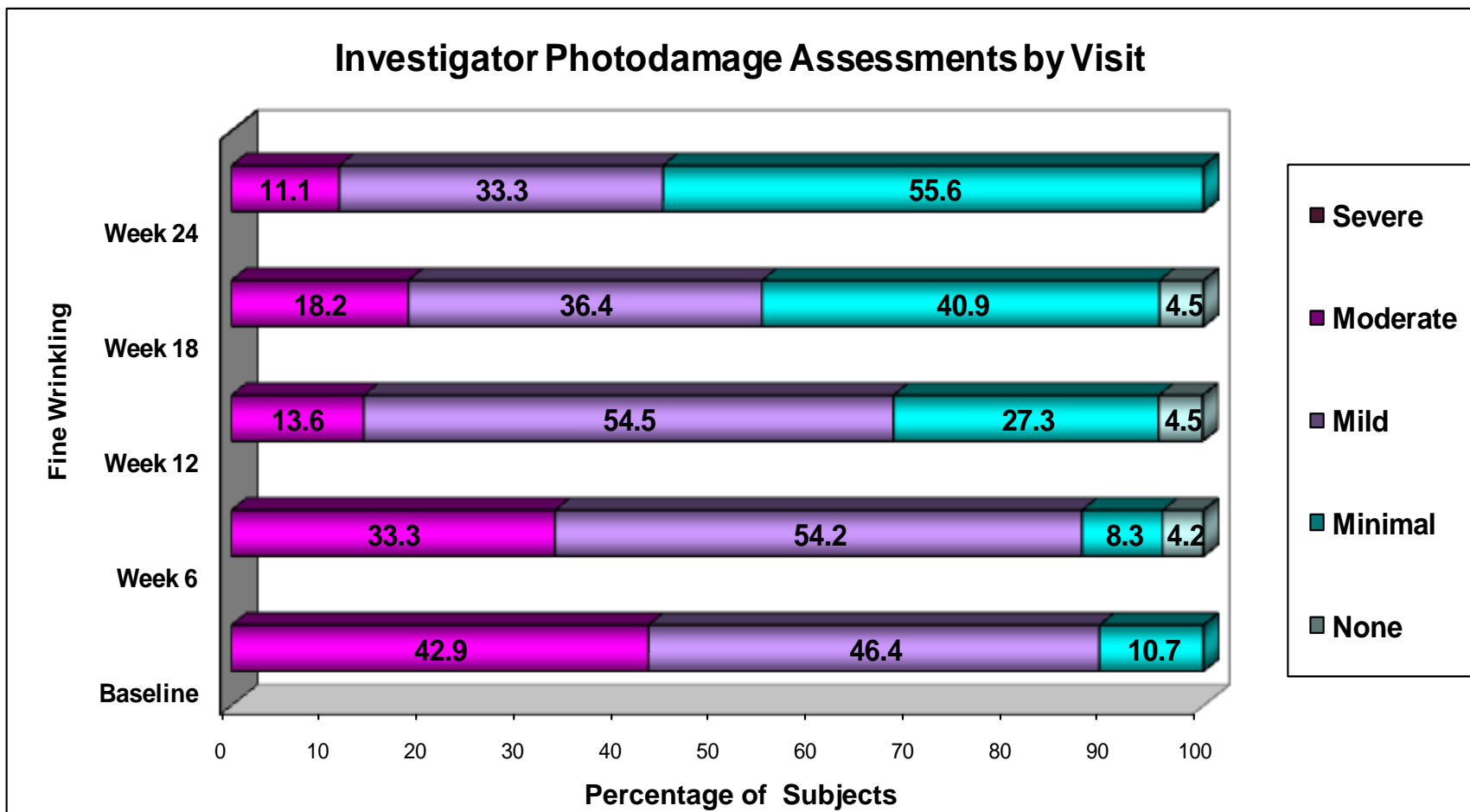
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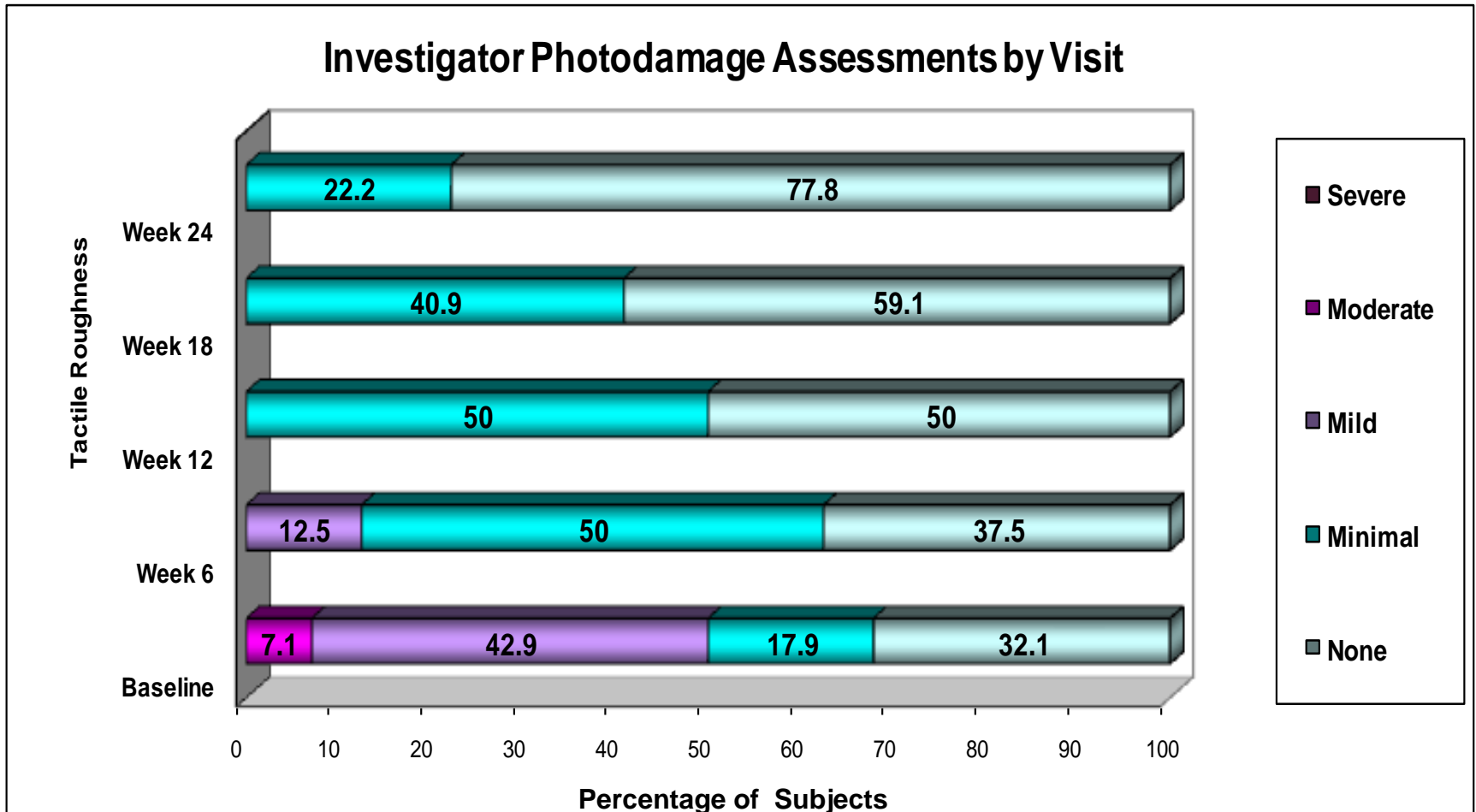
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TREATMENT RELATED ADVERSE EVENTS

ADVERSE EVENT DESCRIPTION	AE INTENSITY	TOTAL # SUBJECTS
Burning, Face *	Mild	1
Burning/Stinging (Face)	Moderate	1
Dermatitis Left Chin	Moderate	1

*Subject discontinued at Week 1

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EARLY DISCONTINUATIONS (10 Subjects)

- One Subject Early Terminated at Week 1 visit due to adverse event of mild facial burning.
- Two Subjects Early Terminated for non-compliance
- Four Subjects Early Terminated – Voluntary Withdrawal
- Three Subjects Early Terminated lost to follow-up.

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SUBJECT QUESTIONNAIRE RESPONSES BASELINE AND WEEK 24 VISIT

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Subject Quality of Life Questionnaire Responses

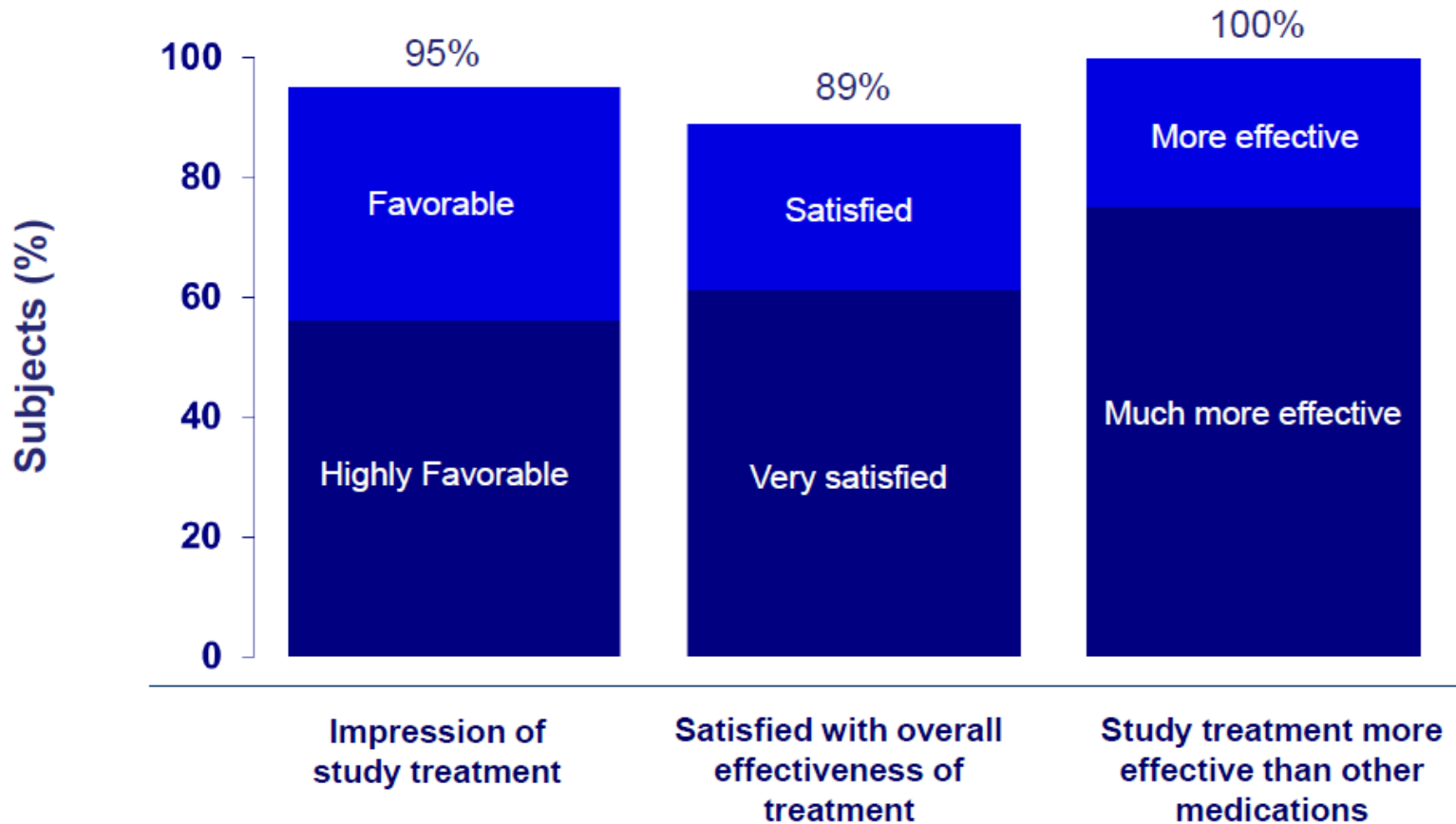
QUESTION ASKED	<u>BASELINE</u> Percent (%) Of The Subjects Who Stated They *				<u>WEEK 12</u> Percent (%) Of The Subjects Who Stated They *				<u>WEEK 24</u> Percent (%) Of The Subjects Who Stated They *			
	Very Much	A Lot	A Little	Not At All	Very Much	A Lot	A Little	Not At All	Very Much	A Lot	A Little	Not At All
How embarrassed or self conscious have you been because of your skin?	13	33	29	25		5	55	41		17	33	50
How much have people focused on your skin discoloration rather than on what you are saying or doing?	4	17	50	29		14	50	36		33	17	50
How much has your skin discoloration made you feel unattractive to others?	8	46	25	21		27	50	23		12	41	47
How much effort have you put into hiding your skin discoloration from others?	13	35	35	17		14	59	27		18	41	41
How much has your skin affected any of your social or leisure activities?	4	8	42	46		9	46	46		17	39	44

Balkrishnan R, , et al. Improved Quality of Life With Effective Treatment of Facial Melasma: The Pigment Trial. *Journal of Drugs in Dermatology* 2004; 3(4): 377-381.

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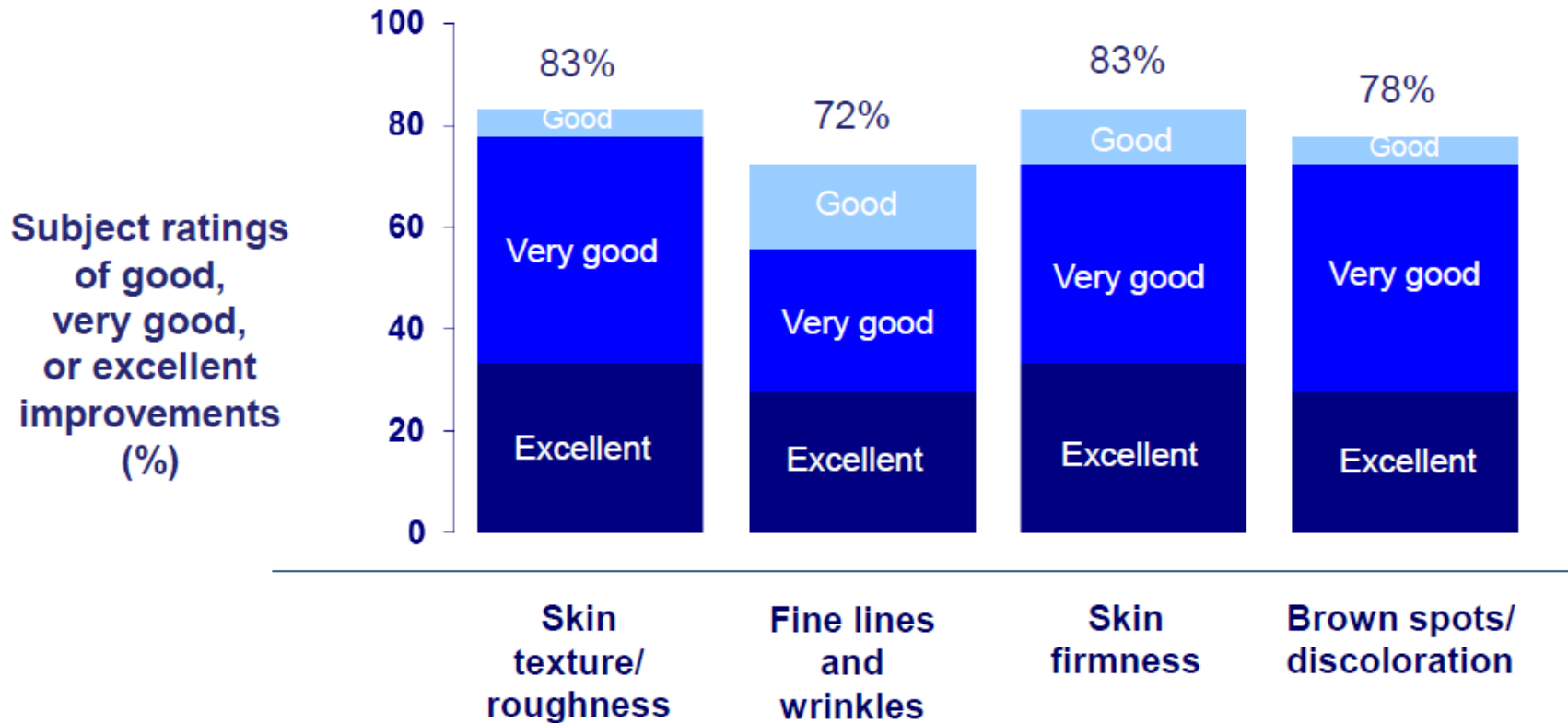
SUBJECT RATINGS AT WEEK 24



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IMPROVEMENTS IN PHOTODAMAGE-RELATED PARAMETERS AT WEEK 24



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SAMPLE SUBJECT PHOTOGRAPHS



Protocol NDFX-001

Subject # 001 LKL



Protocol NDFX-001

Subject # LKL - 001

SUBJECT 001
BASELINE



SUBJECT 001
WEEK 12



SUBJECT 001
BASELINE



SUBJECT 001
WEEK 24





Protocol NDFX-001

Subject # 011 JRS



Protocol NDFX-001

Subject # JRS - 011

SUBJECT 011
BASELINE



SUBJECT 011
WEEK 12



SUBJECT 011
BASELINE



SUBJECT 011
WEEK 24





Protocol NDFX-001

Subject # 012 YCH



Protocol NDFX-001

Subject # 012 YCH

SUBJECT 012
BASELINE



SUBJECT 012
WEEK 12



SUBJECT 012
BASELINE



SUBJECT 012
WEEK 24





Protocol NDFX-001

Subject # 019



Protocol NDFX-001

Subject # 019



Protocol NDFX-001



Subject # 021



Protocol NDFX-001



Subject # 021

SUBJECT 021
BASELINE



SUBJECT 021
WEEK 12



SUBJECT 021
BASELINE



SUBJECT 021
WEEK 24





Protocol NDFX-001



Subject # 022



Protocol NDFX-001



Subject # 022



Protocol NDFX-001



Subject # 022



Protocol NDFX-001



Subject # 022





Protocol NDFX-001

Subject # 022



Protocol NDFX-001



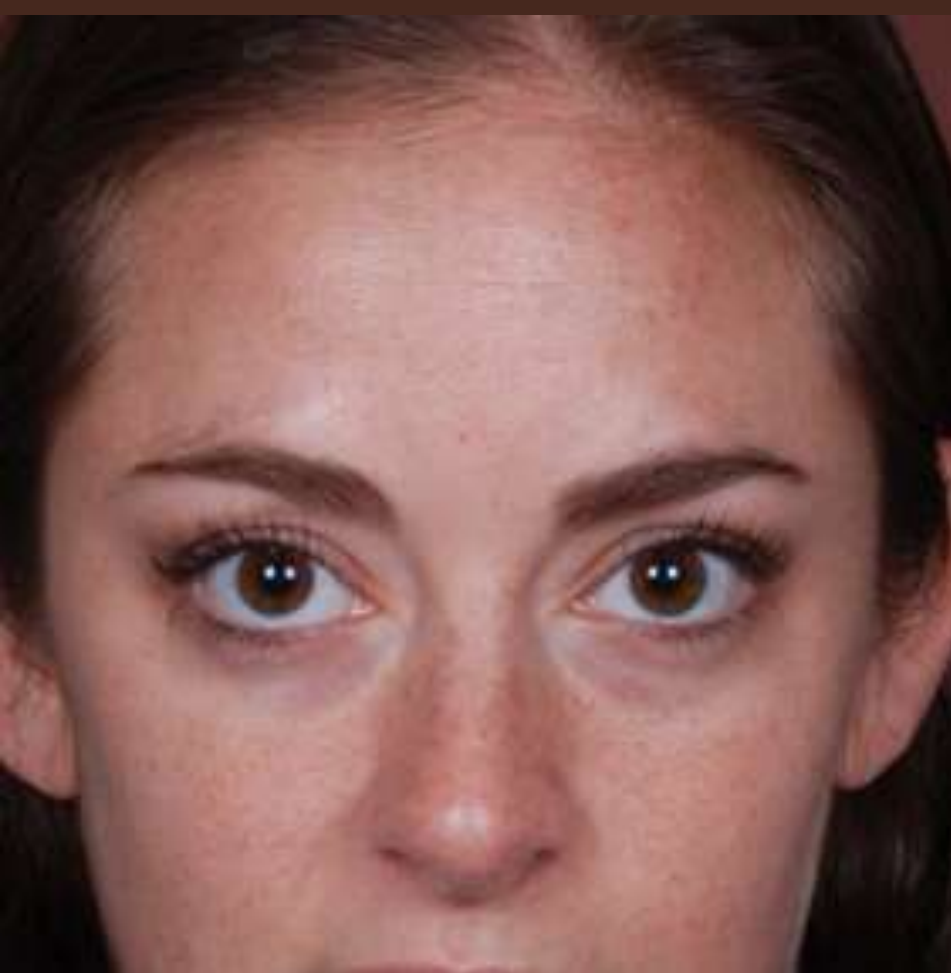
Subject # 023



Protocol NDFX-001



Subject # 023





Protocol NDFX-001

Subject # 026



Protocol NDFX-001

Subject # 026



Protocol NDFX-001

Subject # 026



Protocol NDFX-001

Subject # 026



Protocol NDFX-001

Subject # 026

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CONCLUSIONS

- Improvement was seen in efficacy assessments from Baseline to Week 24. 83% subjects mottled hyperpigmentation severity decreased and 94% subjects pigmentation intensity decreased.
- Overall compliance with the treatment regimen was less than 60%.
- Treatment compliance impacted clinical efficacy.
- Number of products in regimen and dosage may need to be taken into consideration for future Marketing strategy.
- 89% of the Subjects were satisfied or very satisfied with the results of their treatment. 88% of Subjects wanted to continue with the regimen after the study.

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CONCLUSIONS (CONTINUED)

- Efficacy is seen with NuDerm Fx (Arbutin) System, but more gradual and not as pronounced as with NuDerm Rx (HQ)
- NuDerm Fx System use as possible maintenance regimen once desired effect is achieved with NuDerm Rx System
- NuDerm Fx System for International or Domestic Market where NuDerm Rx is not available