

# Treatment of Melasma with a Hydroquinone Skin Care System Plus Tretinoin

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# Purpose

- To evaluate the efficacy and tolerability of treating melasma in darker skin using a 4% hydroquinone skin care system plus 0.025% tretinoin cream  
[This regimen treats melasma and provides a complete skin care routine]

# Rationale for Study

- Melasma can cause great distress with significant negative effects on a patient's:
  - Emotional well being
  - Social life
  - Quality of life
- It is NOT merely a cosmetic nuisance – such misperceptions have resulted in underdiagnosis and undertreatment
- Hydroquinone and tretinoin are both effective in treating melasma and their use:
  - In combination facilitates faster improvements
  - As part of a comprehensive skin care system may offer additional advantages in terms of convenience, efficacy, and tolerability
- Optimal tolerability is especially important in darker skin to minimize the potential for other pigmentary problems

# Patients

- 25- to 65-year old females with:
  - Mild or moderate epidermal melasma (confirmed by Wood's lamp examination)
  - Minimal to marked intensity of melasma pigmentation
  - Cutaneous melanosis stable over preceding 3 months
  - Fitzpatrick skin type III-VI

# Treatment Regimen

**4% hydroquinone skin care system**, consisting of 5 proprietary products:

- |   |   |              |
|---|---|--------------|
| 1. <b>Foaming gel cleanser</b> (contains aloe barbadensis leaf juice)   | } | Twice daily  |
| 2. <b>Toner</b> (contains aloe barbadensis leaf juice and witch hazel)  |   |              |
| 3. <b>4% hydroquinone</b>   |   |              |
| 4. <b>Exfoliation enhancer</b> (contains glycolic acid and lactic acid) | } | Each morning |
| 5. <b>Sunscreen SPF 35</b>  |   |              |

**PLUS**

**0.025% tretinoin cream + 4% hydroquinone (mixed 1:1)** Each evening

*Plus, as needed:*

*Moisturizer for dryness*

*0.5% hydrocortisone for other tolerability issues*

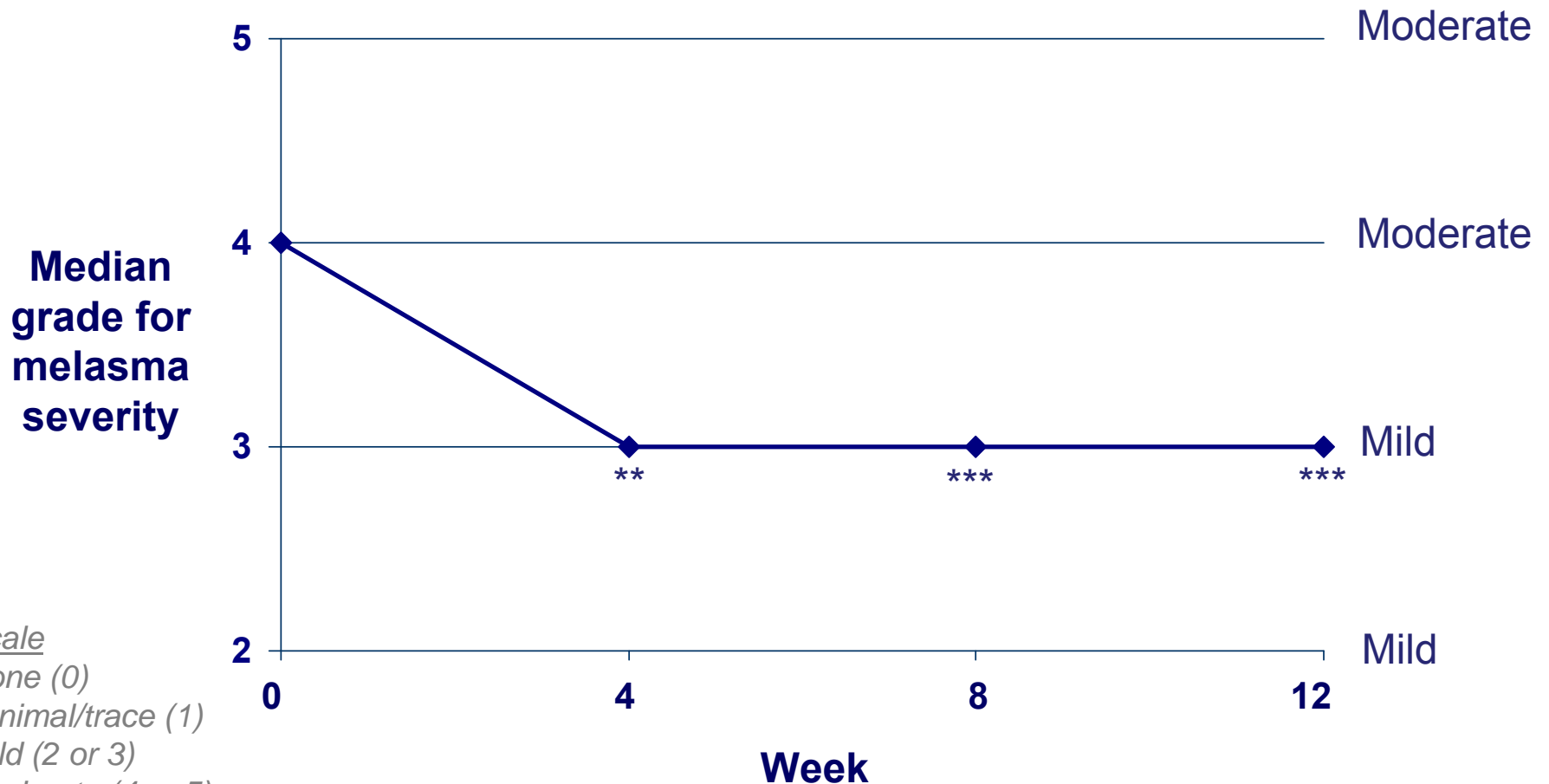
# Potential Advantages of Treatment Systems

- Convenient
  - Provide medical treatment and overall skin care in one regimen, saving confusion juggling different regimens
- Popular with patients<sup>1</sup>
- May enhance compliance<sup>1</sup>
- May enhance efficacy:
  - Cleansing and exfoliating may help penetration of other ingredients into skin
  - Sunscreen may help maintain efficacy of treatment
- May enhance tolerability:
  - May contain agents with soothing and anti-inflammatory properties (eg, aloe barbadensis leaf juice and witch hazel)

# Results

- 20 females enrolled, 100% completed
- Mean of 50 years old
- 65% black/African American + 35% white/Caucasian
- Fitzpatrick skin type:
  - IV (40%)
  - V (40%)
  - VI (20%)
- Melasma was:
  - Malar in 65%
  - Centrofacial in 35%

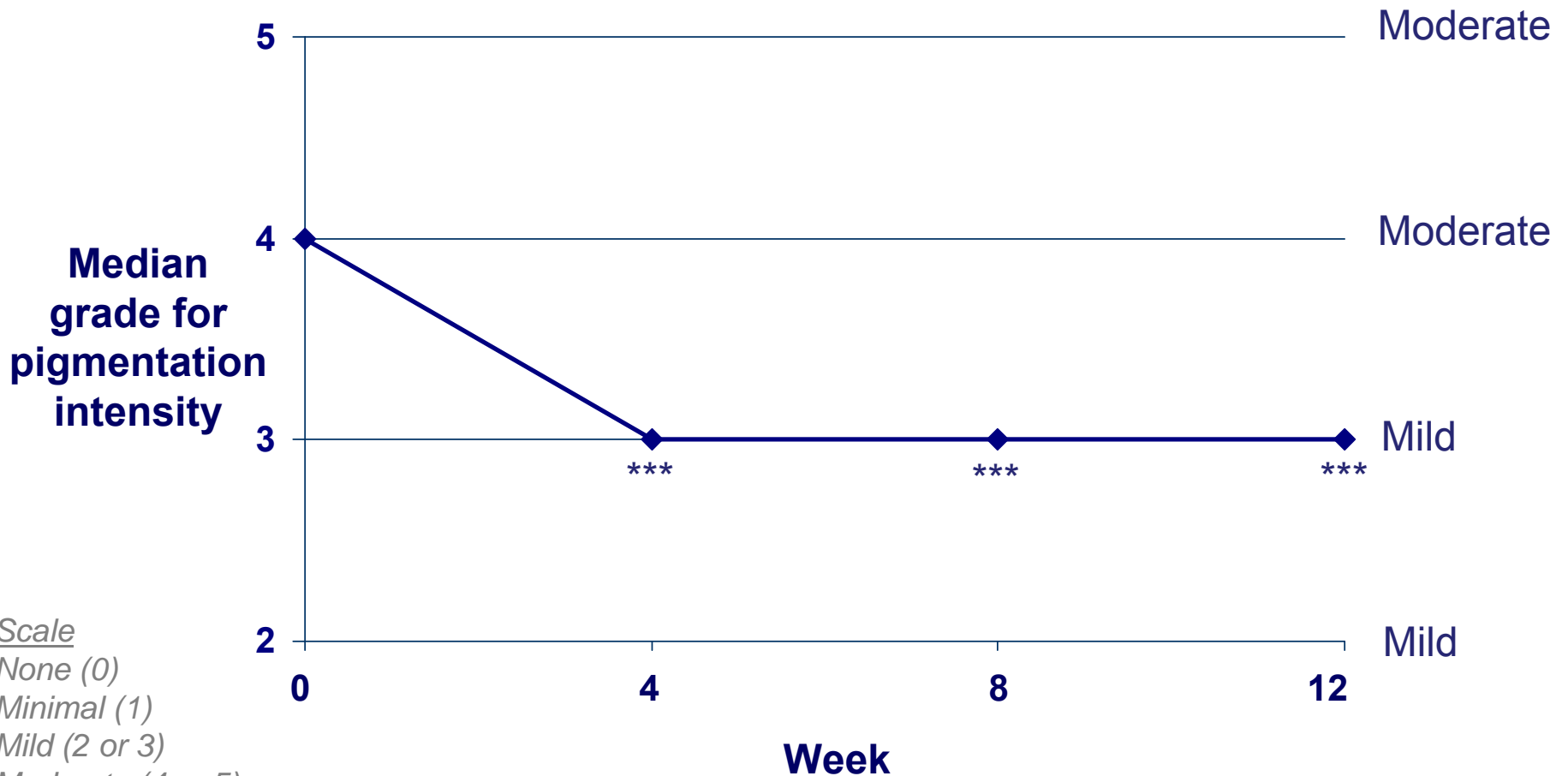
# Melasma Severity



\*\* P≤.01, \*\*\* P≤.001 versus baseline



# Pigmentation Intensity

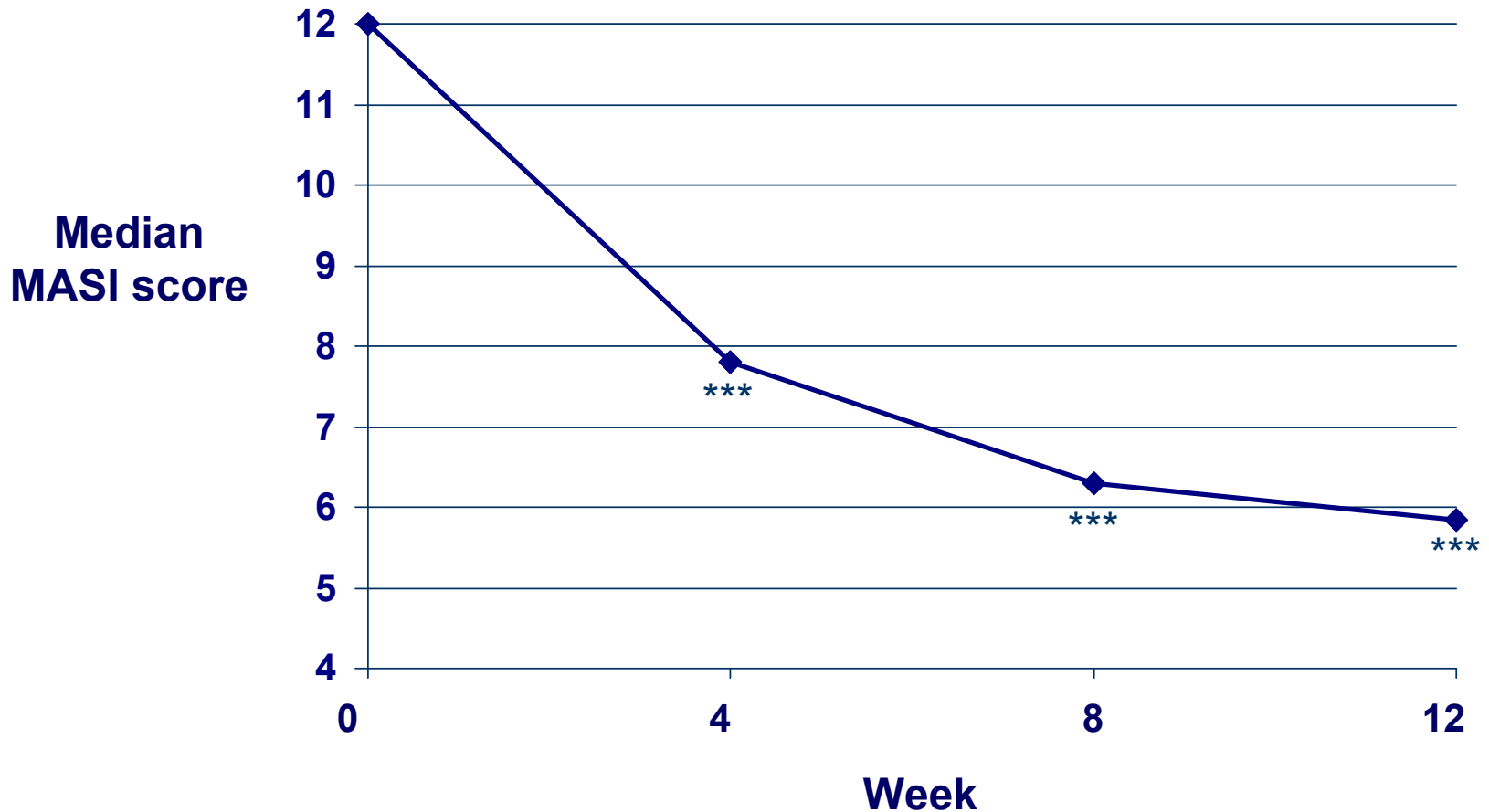


Scale  
None (0)  
Minimal (1)  
Mild (2 or 3)  
Moderate (4 or 5)  
Marked (6 or 7)  
Severe (8)

\*\*\* P≤.001 versus baseline

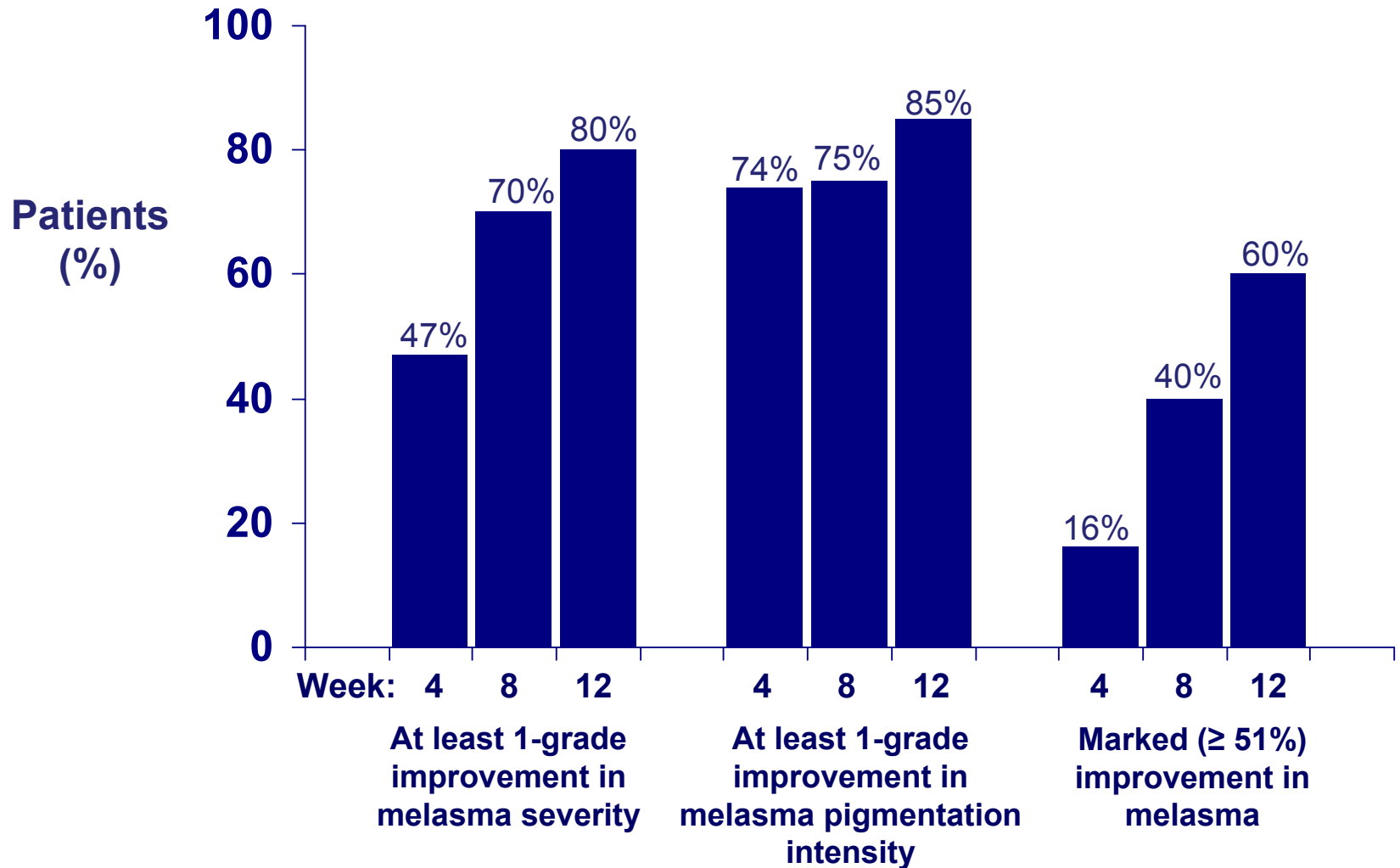
# MASI Score

## (Melasma Area and Severity Index)

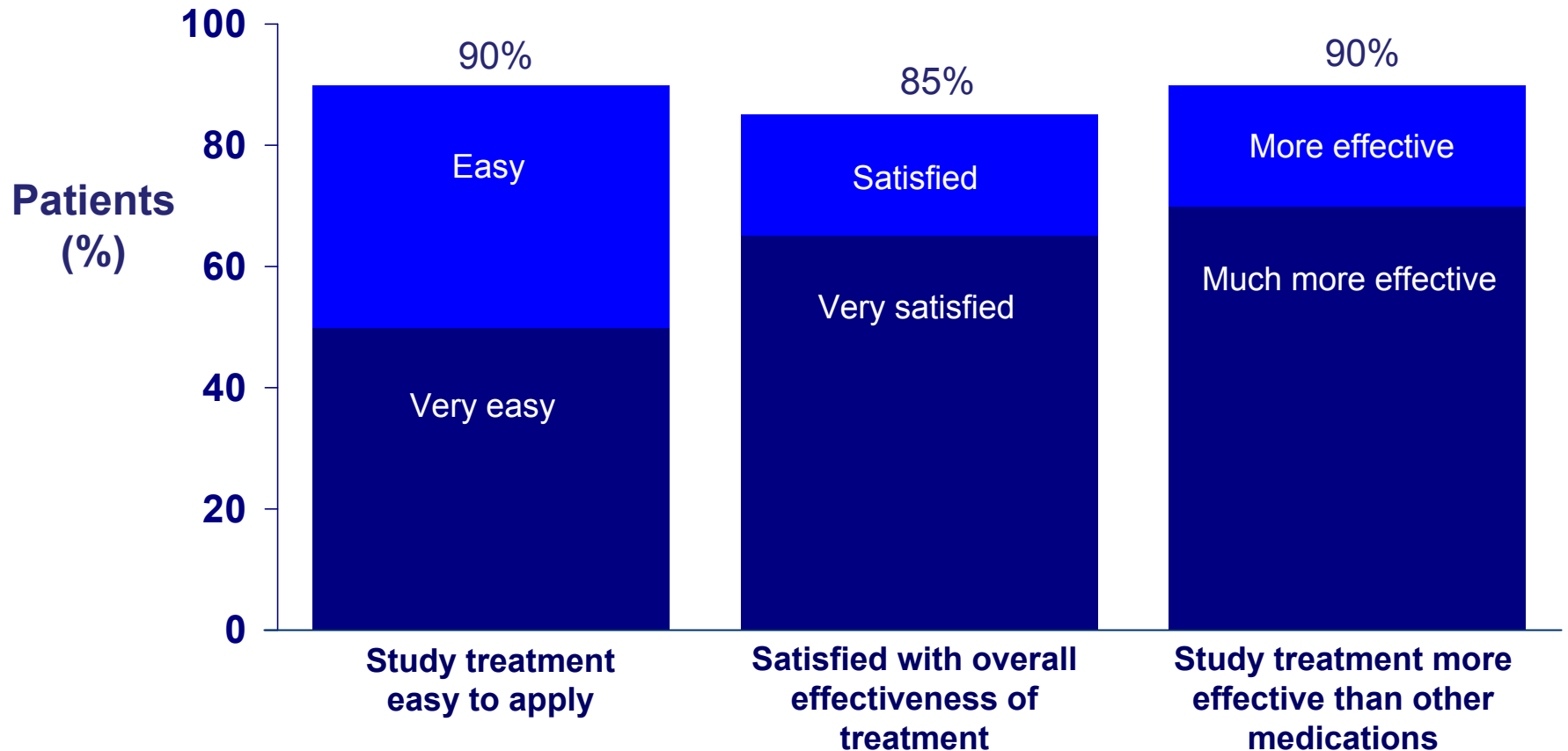


\*\*\* P ≤ .001 versus baseline

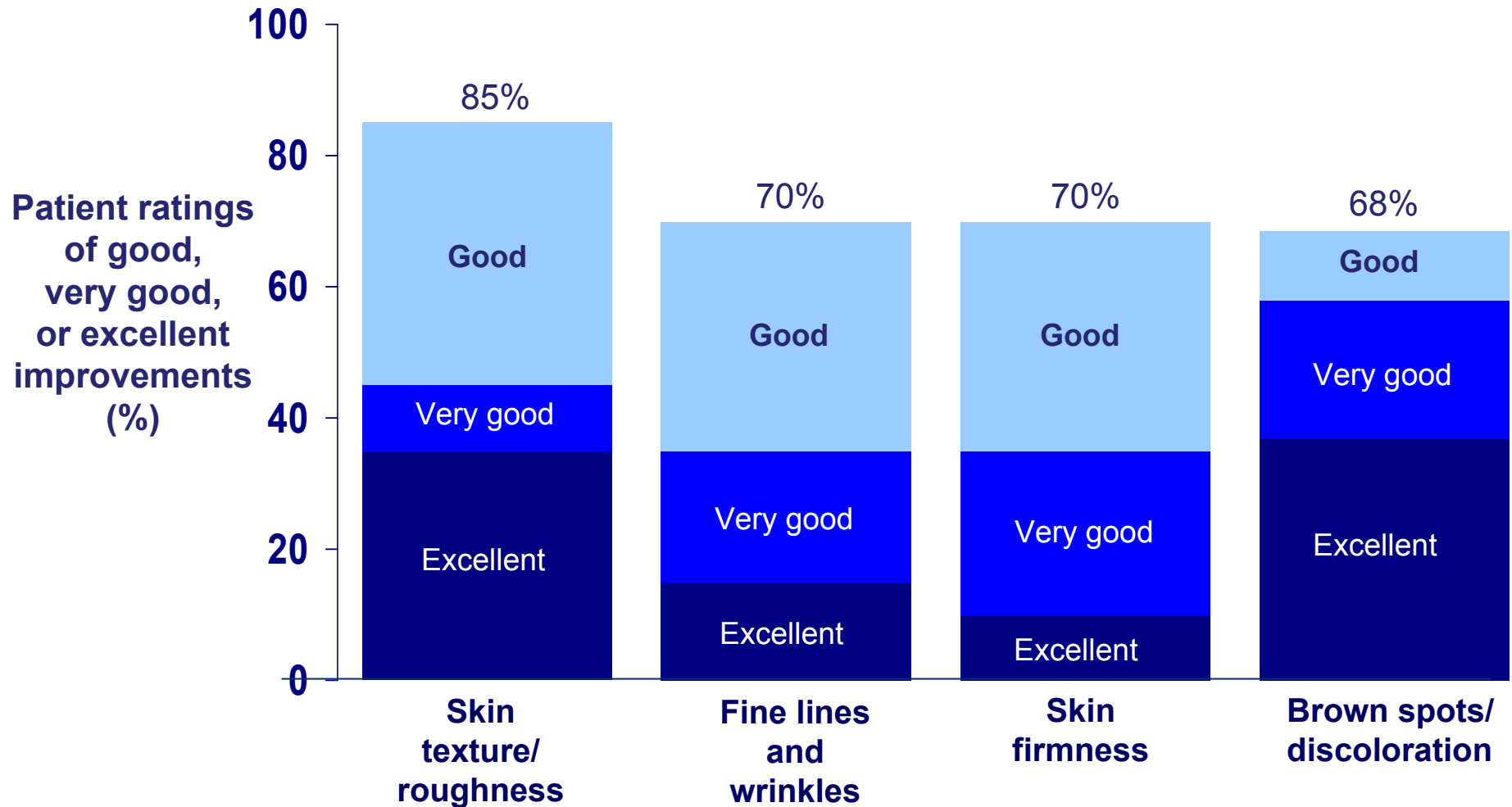
# Improvement in Melasma



# Patient Ratings at Week 12



# Improvements in Photodamage-Related Parameters at Week 12



# Improvements in Melasma



BASELINE

WEEK 12



BASELINE

WEEK 12



BASELINE

WEEK 12

# Improvements in Melasma

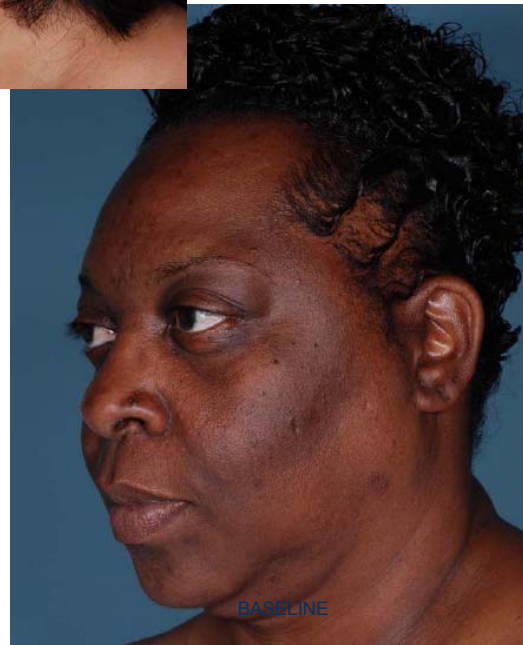


BASELINE

WEEK 12

BASELINE

WEEK 12

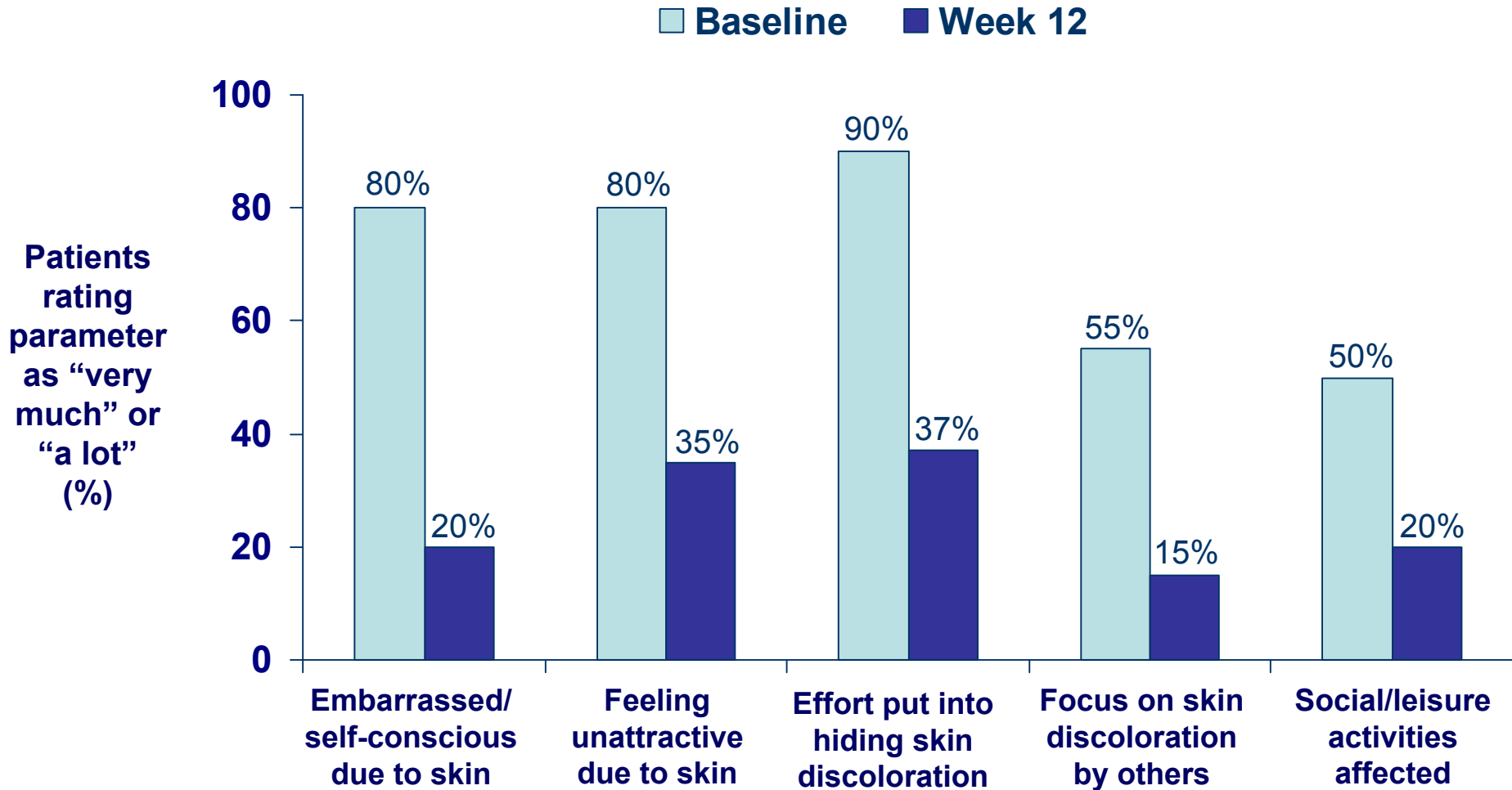


BASELINE



WEEK 12

# Improvement in Quality of Life Parameters





# Efficacy Summary

- Treating melasma with the 4% hydroquinone skin care system + 0.025% tretinoin was associated with:
  - Significant improvements in melasma
    - Less severe melasma
    - Less intense pigmentation
    - Lower MASI score
  - High levels of patient satisfaction
  - Considerable improvements in quality of life
    - Less embarrassment/self-consciousness
    - Less feeling of being unattractive
    - Less effort hiding skin discoloration
    - Less focus from other people on the melasma
    - Less effect on social and leisure activities
  - Good improvements in photodamage-related parameters:
    - Improvements in skin texture
    - Improvements in fine lines and wrinkles
    - Improvements in skin firmness
    - Improvements in brown spots/dyschromia

# Tolerability

- Erythema, dryness, peeling, and burning/stinging:
  - Mean grades between “none” and “trace” at all timepoints
  - Median grades “none” at all timepoints
  - Only significant change from baseline was ↑ erythema at week 12
- 3 patients had adverse events probably related to treatment:
  - Erythema/dryness
  - Dryness/peeling
  - Erythema/dryness/stinging sensation
  - All mild except one case of erythema was moderate
- 16/20 patients used the study moisturizer as a preventive measure against dryness
- 3/20 patients used hydrocortisone:
  - 2 as preventive measure
  - 1 for erythema/stinging sensation

# Conclusion

- Using the 4% hydroquinone skin care system + 0.025% tretinoin cream to treat epidermal melasma in darker skin can achieve significant reductions in:
  - Melasma severity
  - Melasma pigmentation intensity
  - Melasma area and severity index
- Importantly, treatment is also associated with considerable improvements in:
  - Quality of life
  - Signs of photodamage (eg, skin roughness, fine lines/wrinkles)
- Treatment is well tolerated and associated with a high level of patient satisfaction

# Conflicts of Interest

- Study supported by OMP, Inc.
- Dr Grimes has been an investigator, consultant, and speaker for Allergan and an investigator and consultant for OMP, Inc. and P & G. She has also been an investigator and speaker for Galderma and an investigator for Cutera, Skin Medica, Clinuvel, and Merz Pharmaceuticals.
- Dr Watson is an employee of, and holds stock and stock options in, OMP, Inc.