P802

# Evaluation of a Prescription Strength Hydroquinone/L-Ascorbic Acid Treatment System for Normal to Oily Skin

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**Supported by OMP, Inc.**

# Background

- With photodamaged skin, early intervention is important for:
  - Improving the appearance of the skin
  - Minimizing the need for future treatment by encouraging skin care and protection at a young age
- Mild photodamage can be improved by:
  - Hydroquinone (reduces hyperpigmentation)
  - L-ascorbic acid (has antioxidant activity, is essential for collagen synthesis, and reduces melanin synthesis)
- 4% hydroquinone (prescription strength) is quicker and more effective than over-the-counter concentrations (up to 2%)

# Introduction

- A 4% hydroquinone (HQ)/10% L-ascorbic acid treatment system has been developed to:
  - Treat early signs of photodamage in youthful looking skin
  - Help prevent further photodamage
- Two versions, for:
  - Normal to dry skin (original version)
  - Normal to oily skin (newly available)

# Objective

- To evaluate the 4% HQ/10% L-ascorbic acid treatment system for normal to oily skin in individuals with minimal or mild facial photodamage and hyperpigmentation

# Main Inclusion Criteria

- 18-40 years old
- Normal to oily facial skin with:
  - Photodamage (minimal or mild)
  - Hyperpigmentation (minimal or mild intensity)
- Glogau photodamage type I or II

# Treatment Regimen

- Prescription strength HQ/L-ascorbic acid treatment system for normal to oily skin used for 12 weeks
- System composed of:
    1. Cleansing gel (twice daily)
    2. Balancing toner (twice daily)
    3. Clarifying serum (each morning)
    4. Sunscreen SPF 30 (each morning and as needed)
    5. Night cream (each evening)

# Ingredients in Treatment System

- 4% hydroquinone
- 10% L-ascorbic acid
- Vitamin E
- Witch hazel
- Aloe barbadensis leaf juice
- Proprietary penetrating ingredients
- Micronized zinc oxide
- Octinoxate

# Investigator Evaluations

- Overall integrated assessment, fine lines and wrinkles, tactile roughness, laxity
  - None, minimal, mild, mild up to moderate, moderate, severe
- Overall intensity of pigmentation
  - None, minimal, mild 2, mild 3, moderate, marked, severe
- Global improvement
  - 0%, ~10%, ~25%, ~50%, ~75%, ~90%, ~100% improvement
- Lightness/brightness of skin
  - 0%, ~10%, ~25%, ~50%, ≥ ~75% increase

# Patient Evaluations

- Smoothness of skin
- Softness of skin
- Evenness of skin tone
- Radiance of skin
- Visible reduction in fine lines and wrinkles
- Efficacy of HQ/L-ascorbic acid system
- Improvement in overall appearance of skin
- Satisfaction with overall appearance of skin
- Ease of application of HQ/L-ascorbic acid system
- Comparison with previous skin care treatments

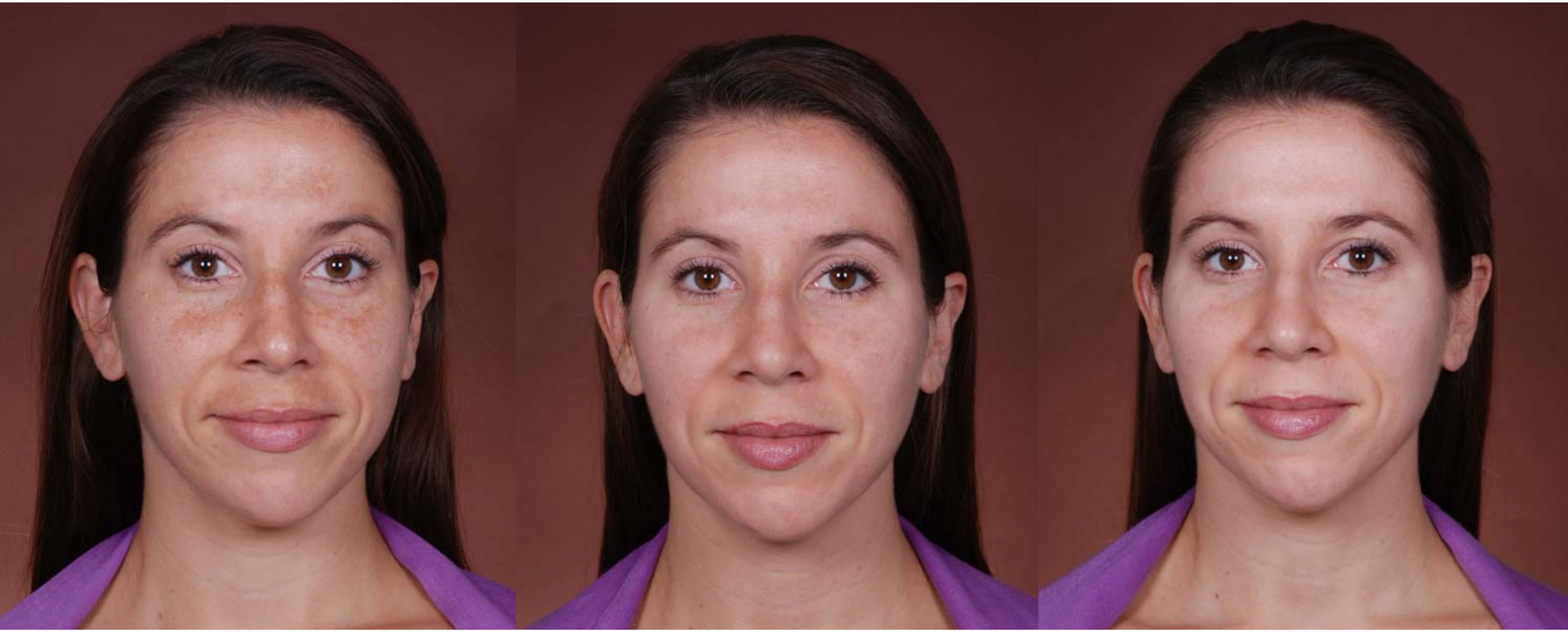
# Results

- 34 patients enrolled:
  - 30 (88%) completed
  - 4 discontinued (3 due to mild adverse events, 1 due to voluntary withdrawal)
- Mean age of 32 years
- 82% Caucasian, 12% Asian, 6% black
- Majority (88%) were Fitzpatrick skin type II-IV
- Glogau photodamage classification:
  - 27% type I
  - 74% type II

# Clinical Improvement

Baseline | Week 4 | Week 12

# Clinical Improvement

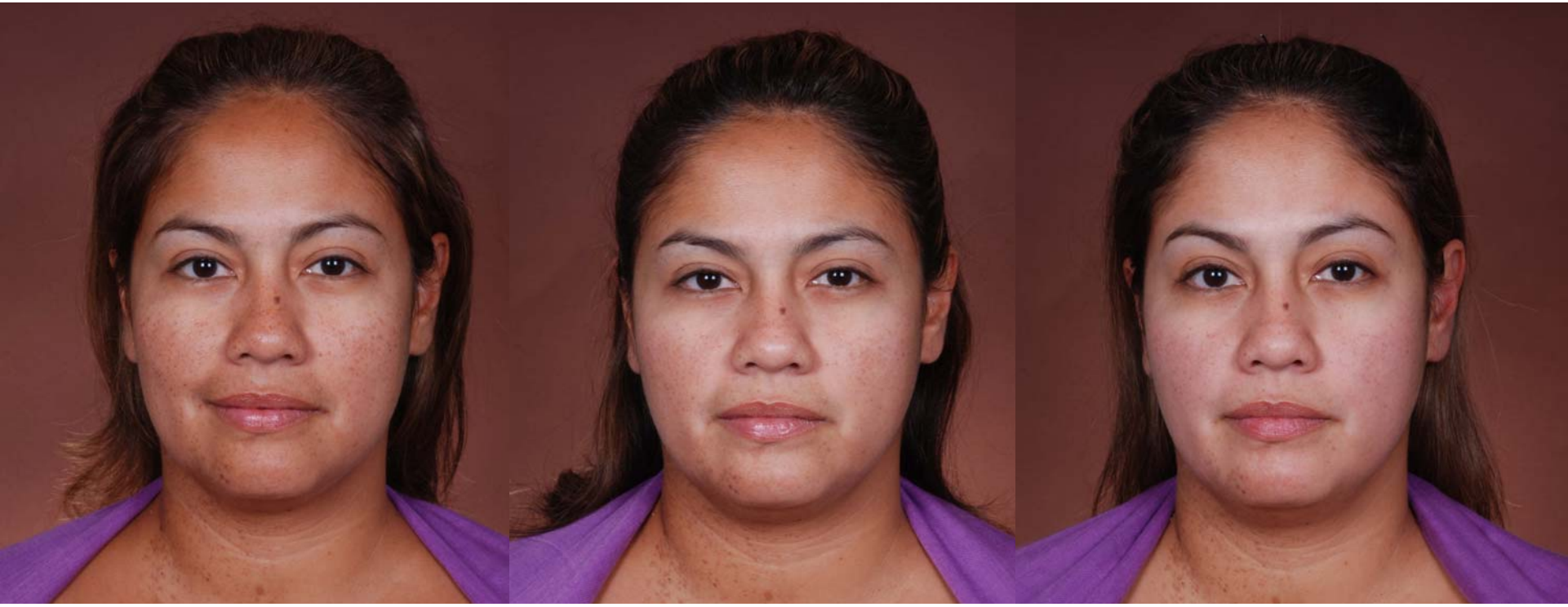


Baseline

Week 4

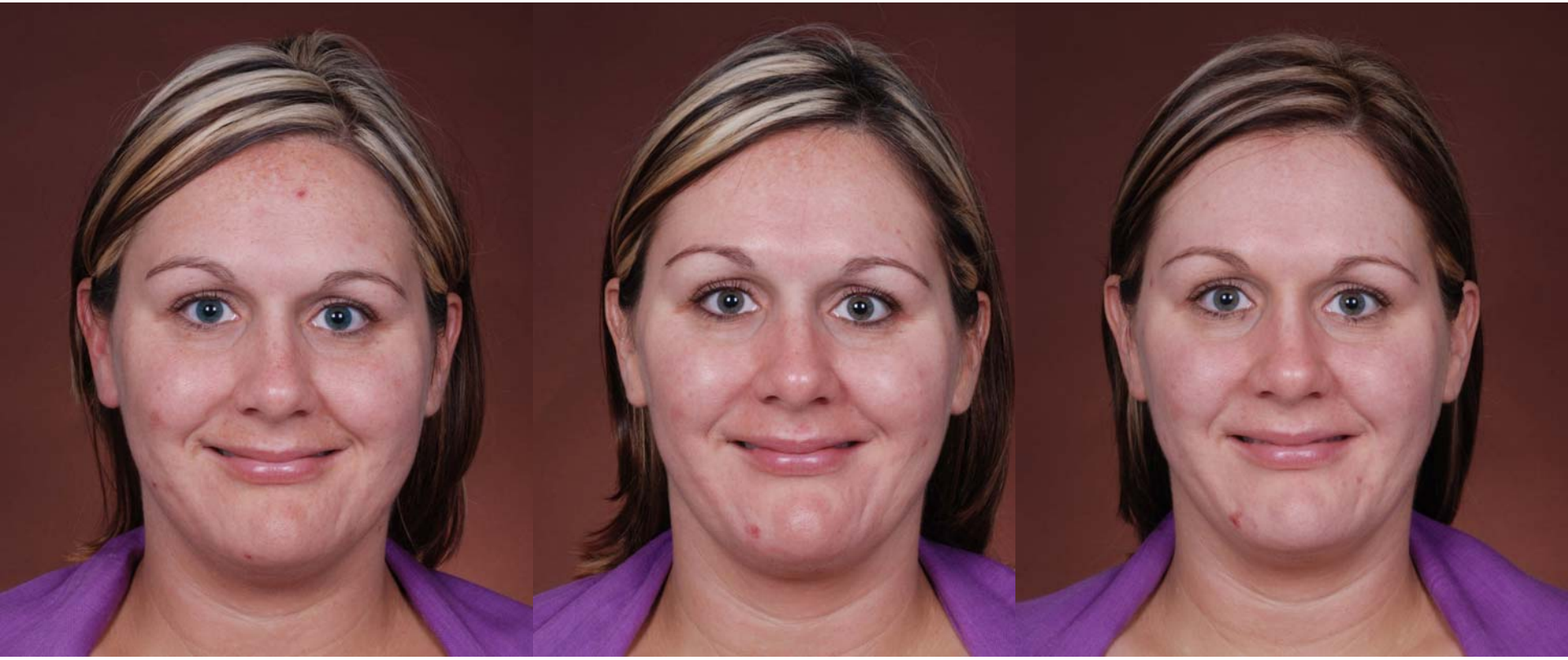
Week 12

# Clinical Improvement



Baseline | Week 4 | Week 12

# Clinical Improvement



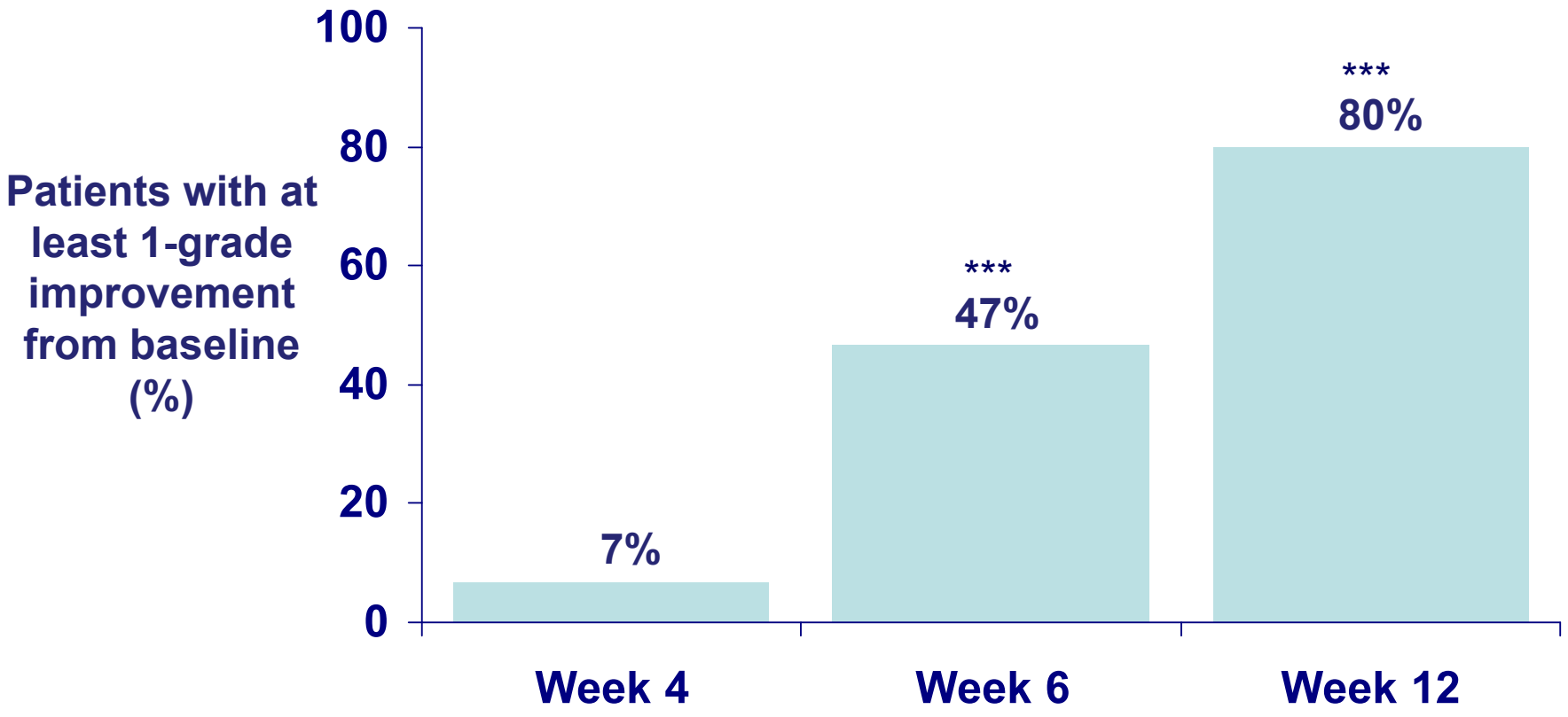
Baseline

Week 4

Week 12

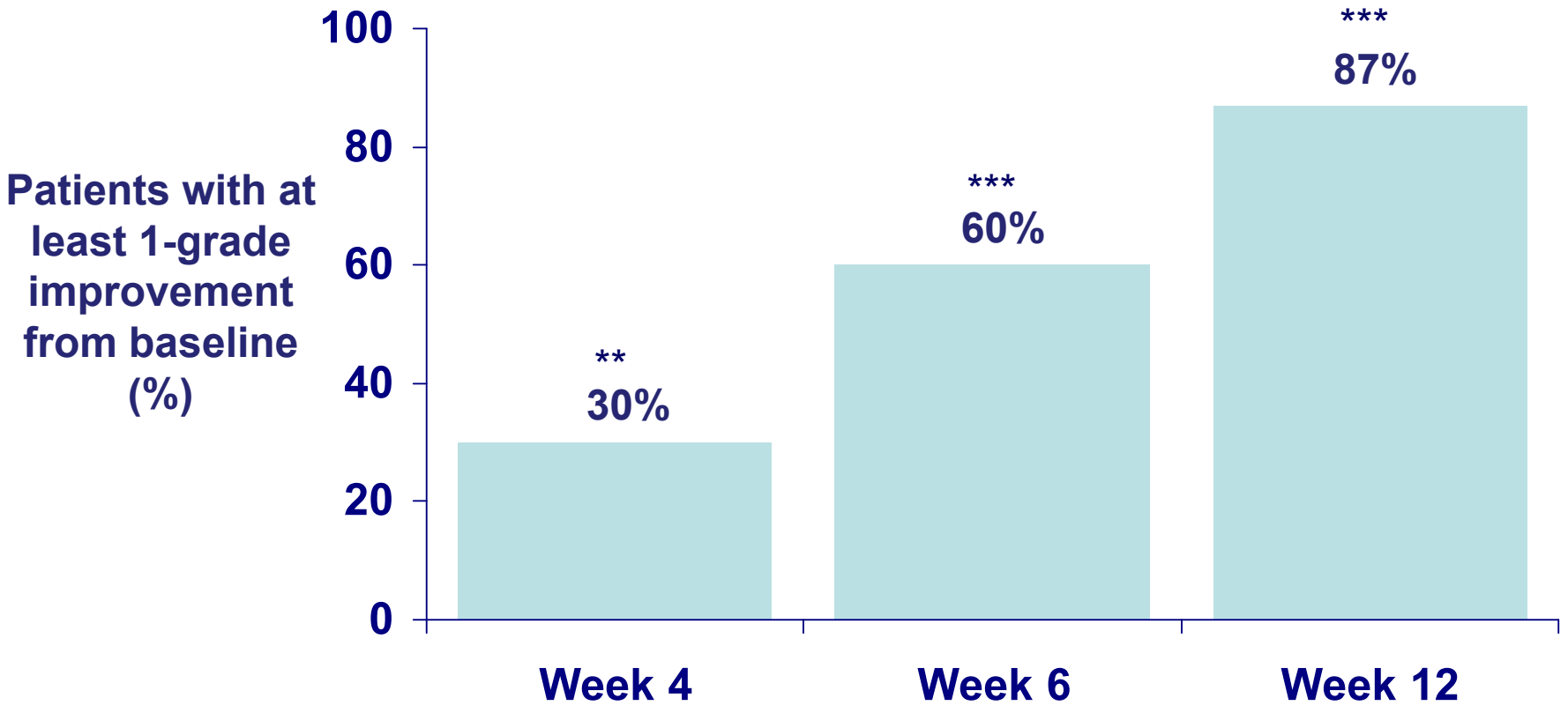
# Investigator Evaluations

# Overall Integrated Assessment of Photodamage



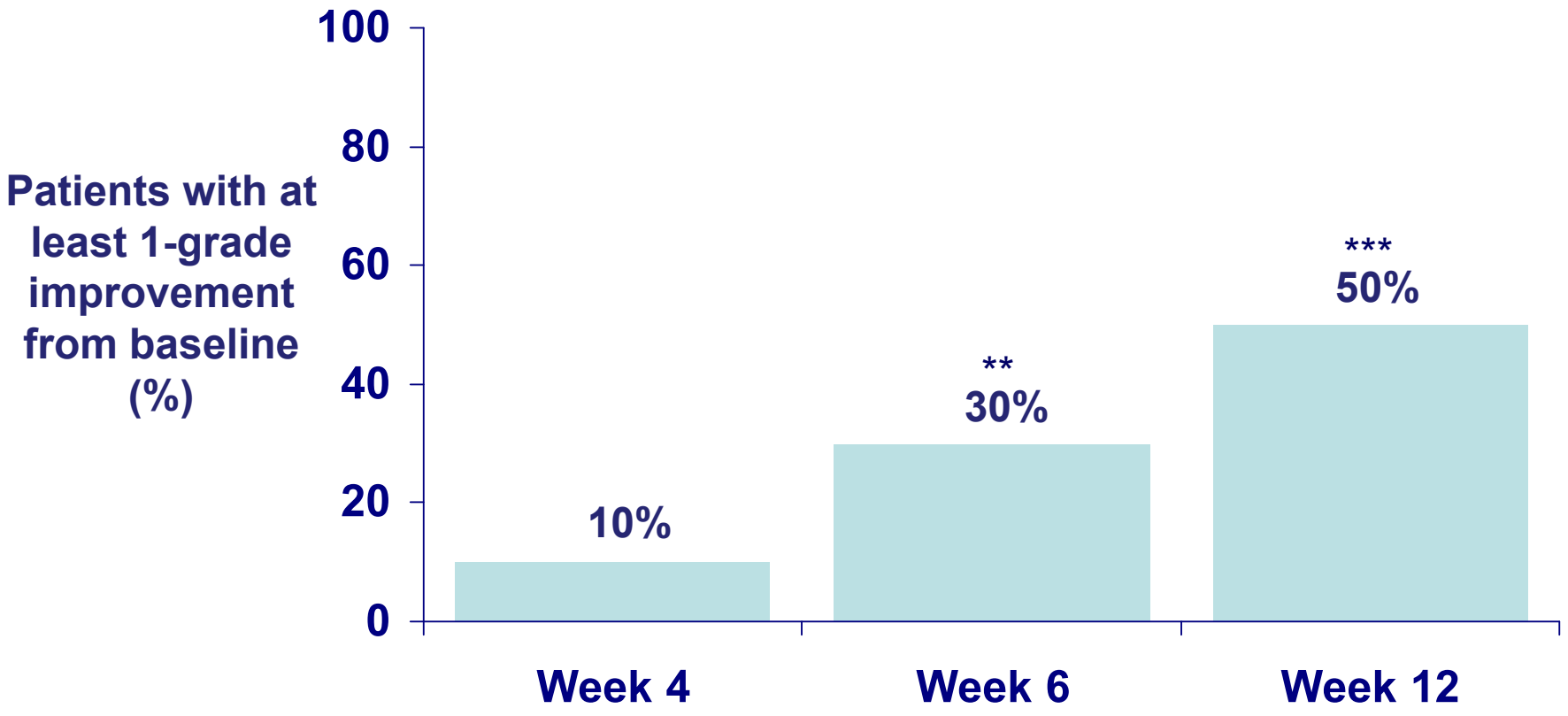

*** P≤.001 for median score versus baseline

# Overall Intensity of Pigmentation



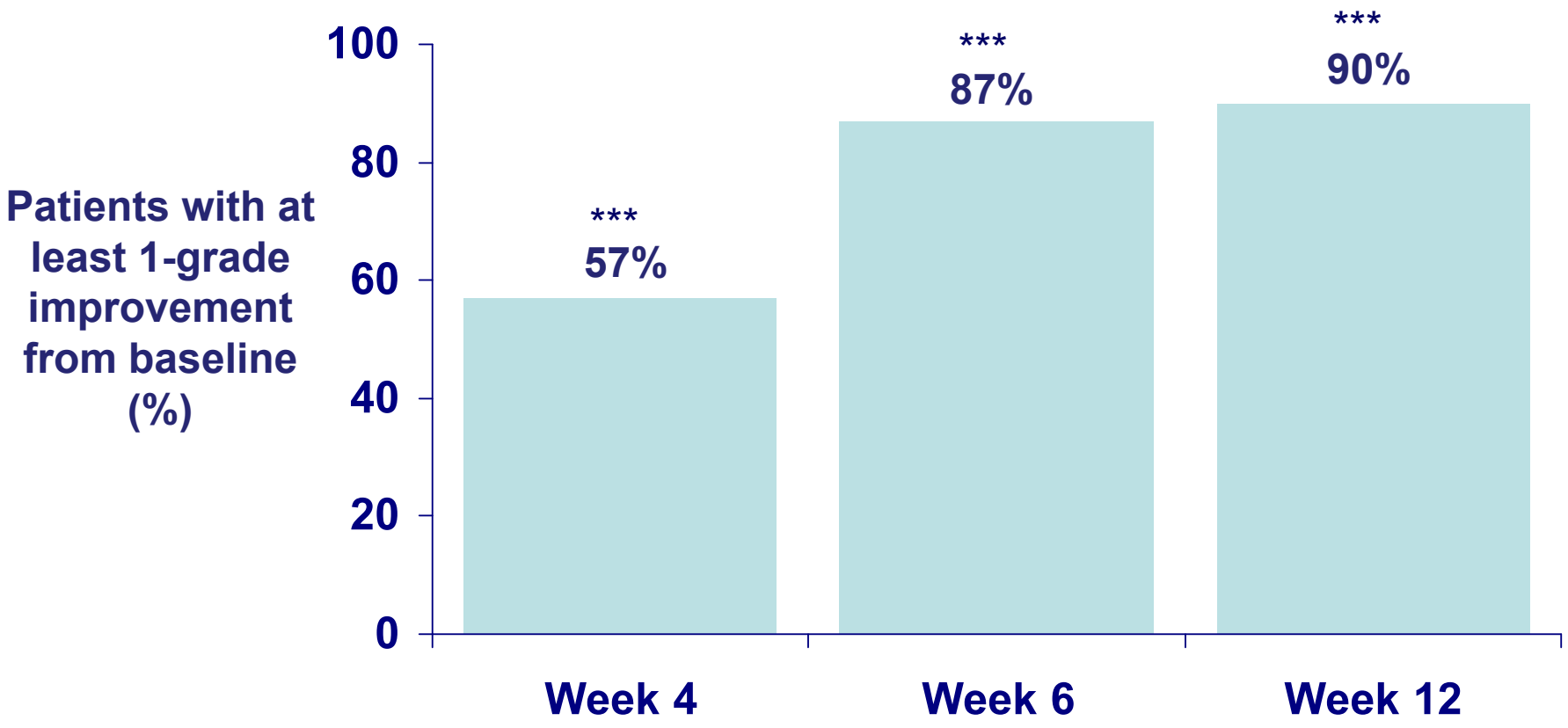

** P≤.01, *** P≤.001 for median score versus baseline

# Fine Lines and Wrinkles



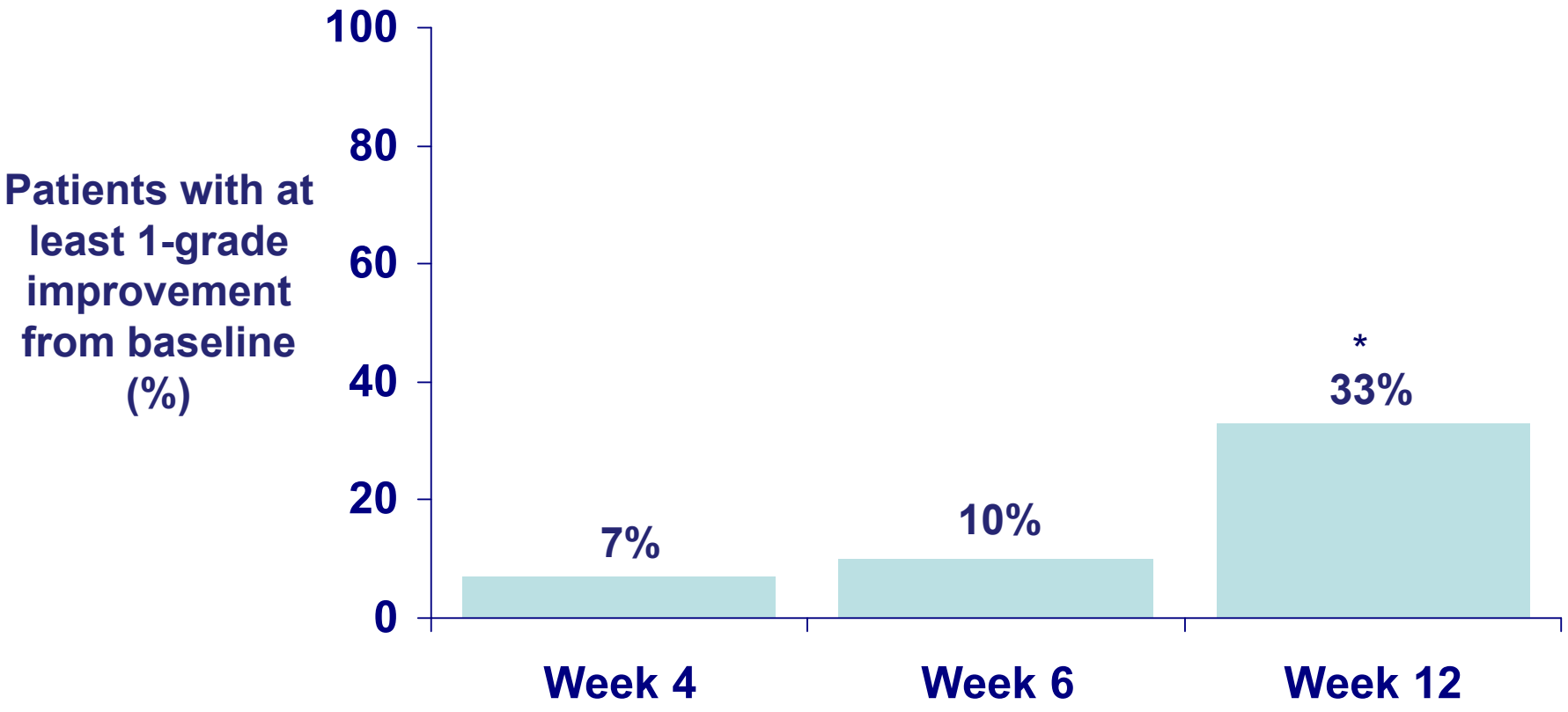

** P≤.01, *** P≤.001 for median score versus baseline

# Tactile Roughness



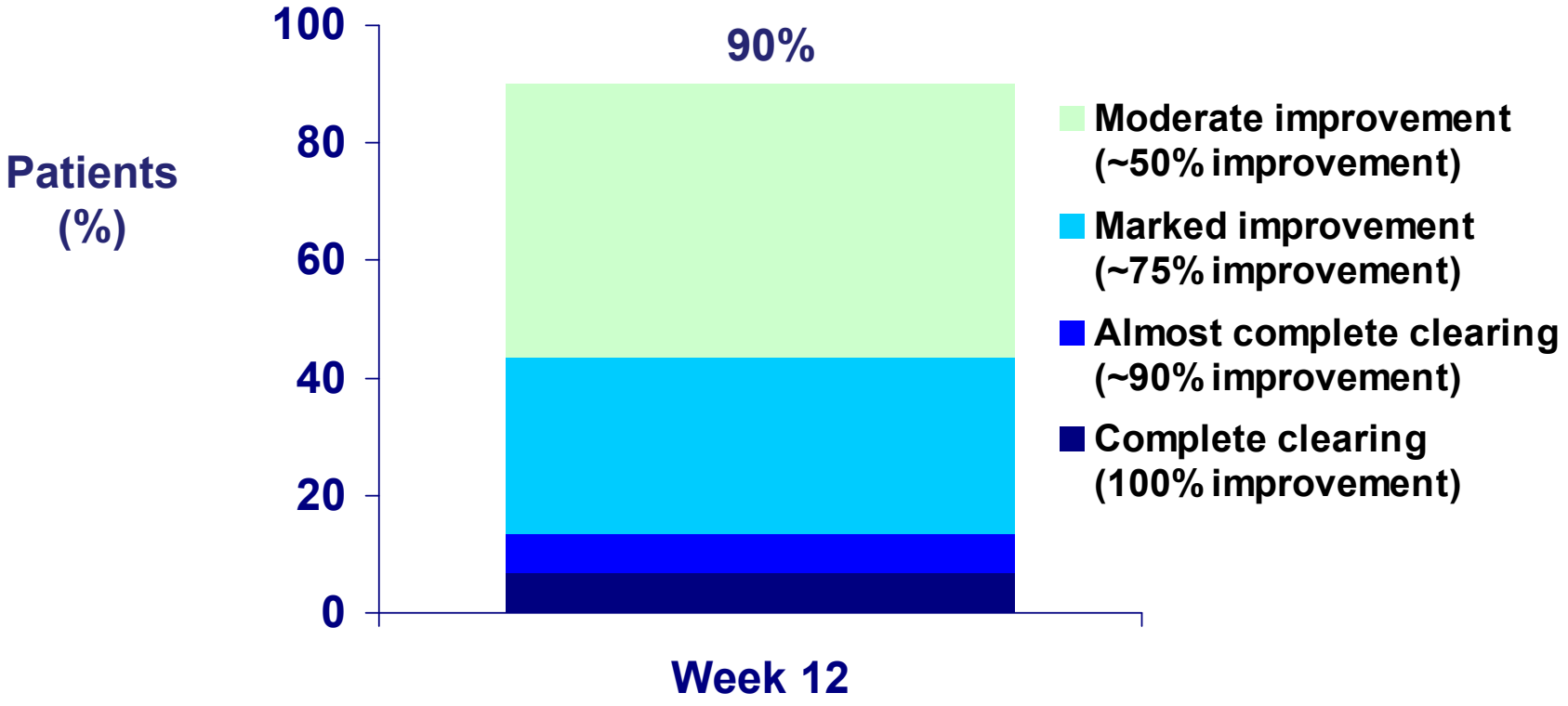

*** P≤.001 for median score versus baseline

# Laxity

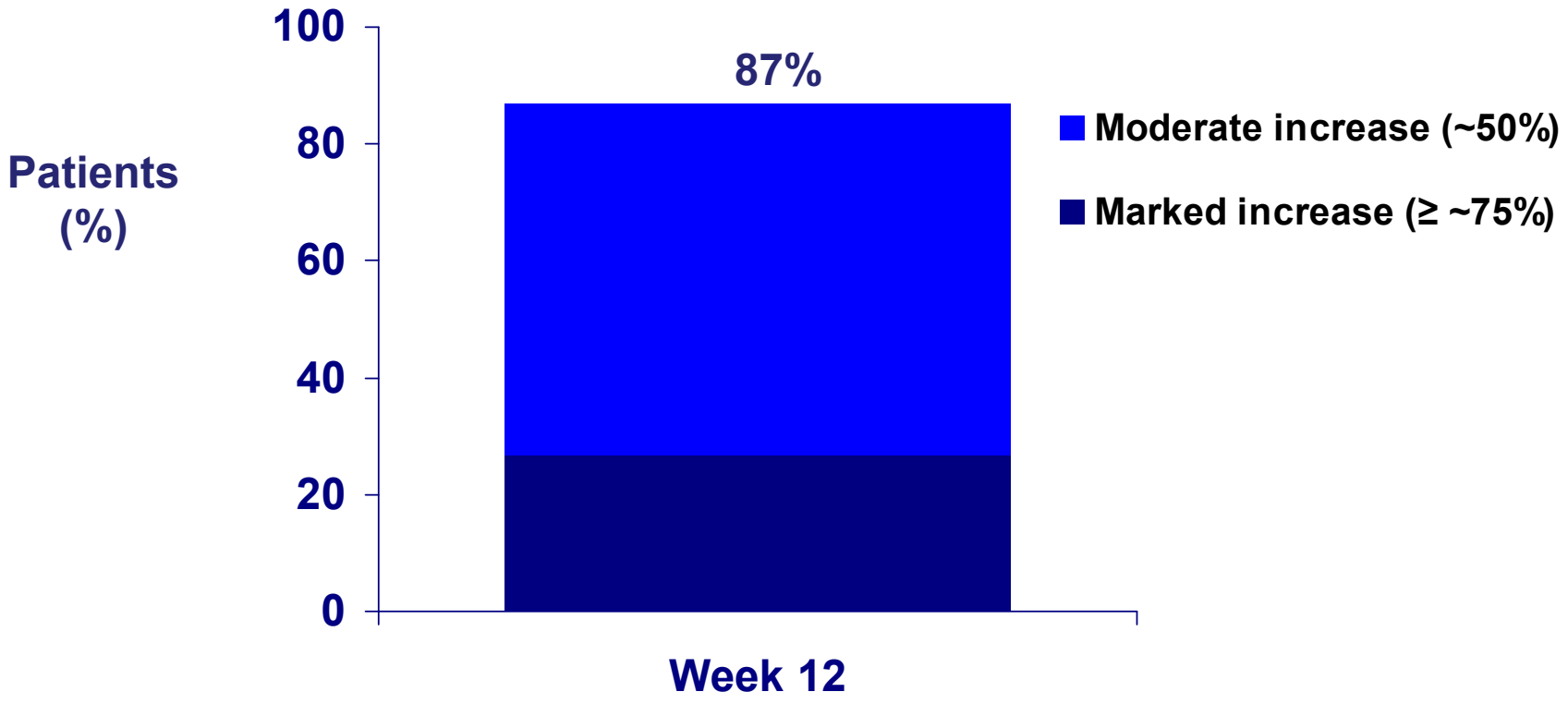



* P≤.05 for median score versus baseline

# Incidence of ≥ 50% Global Improvement

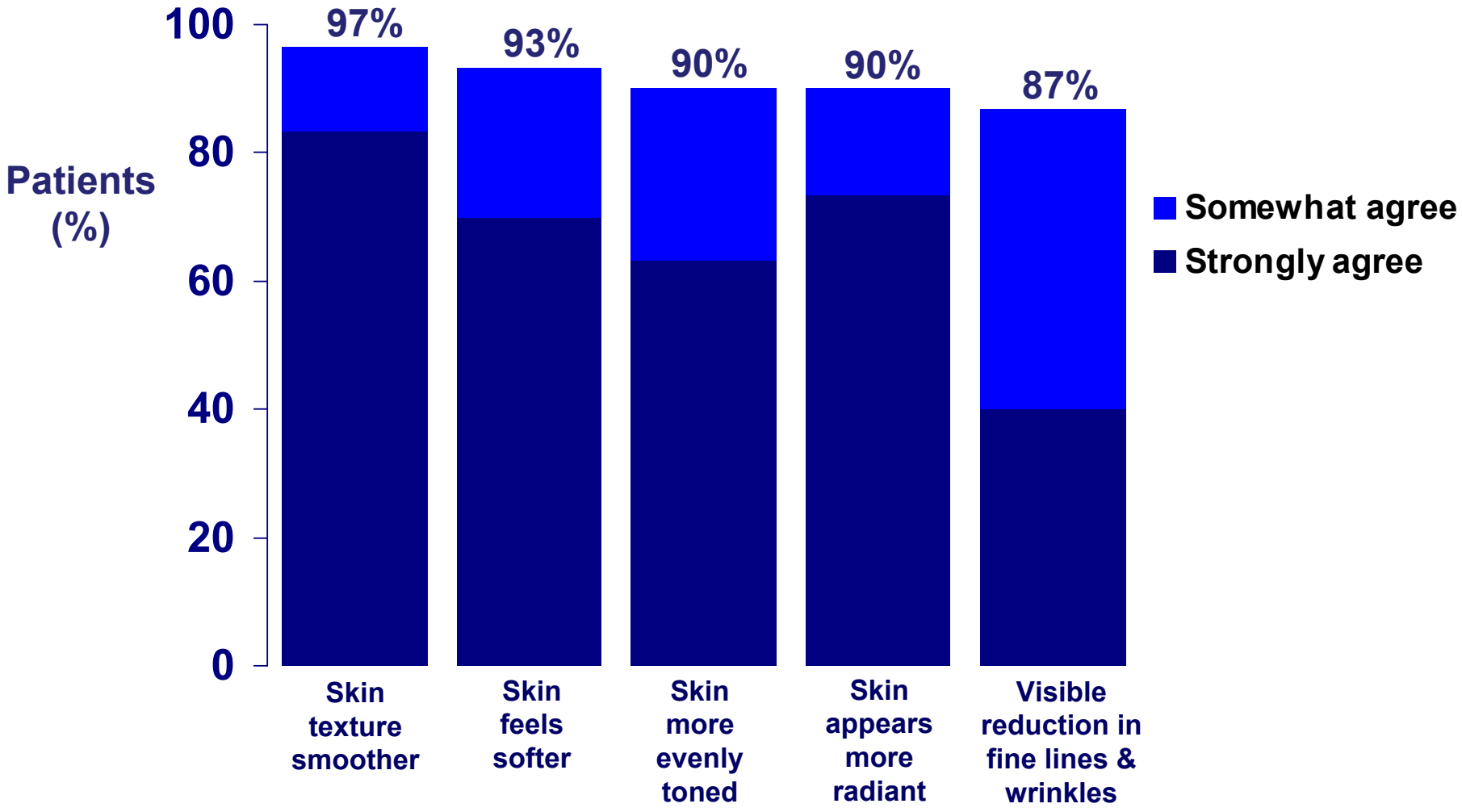


# Incidence of ≥ 50% Increase in Lightness/Brightness of Facial Skin

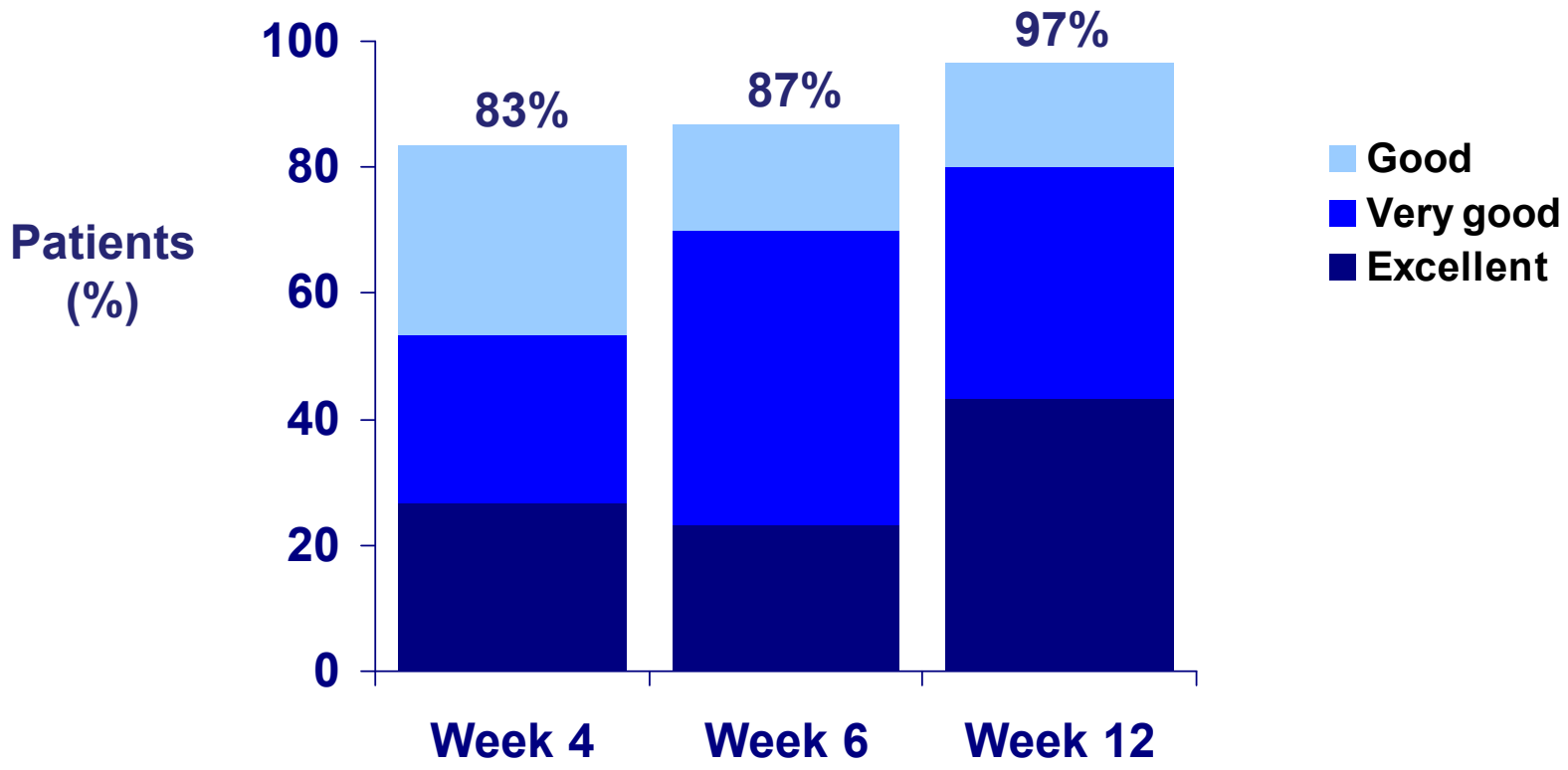


# Patient Evaluations

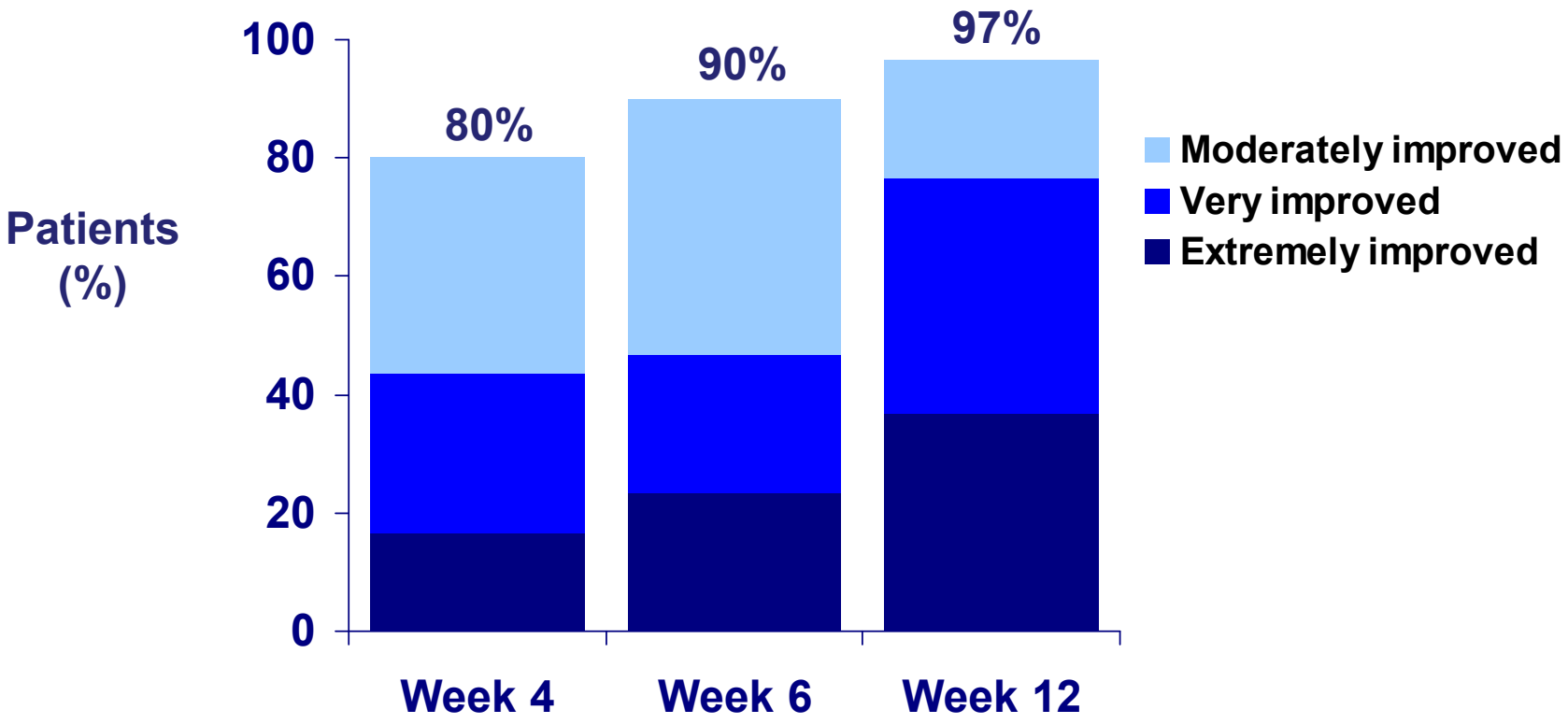
# Patient Ratings of Improvement at Week 12



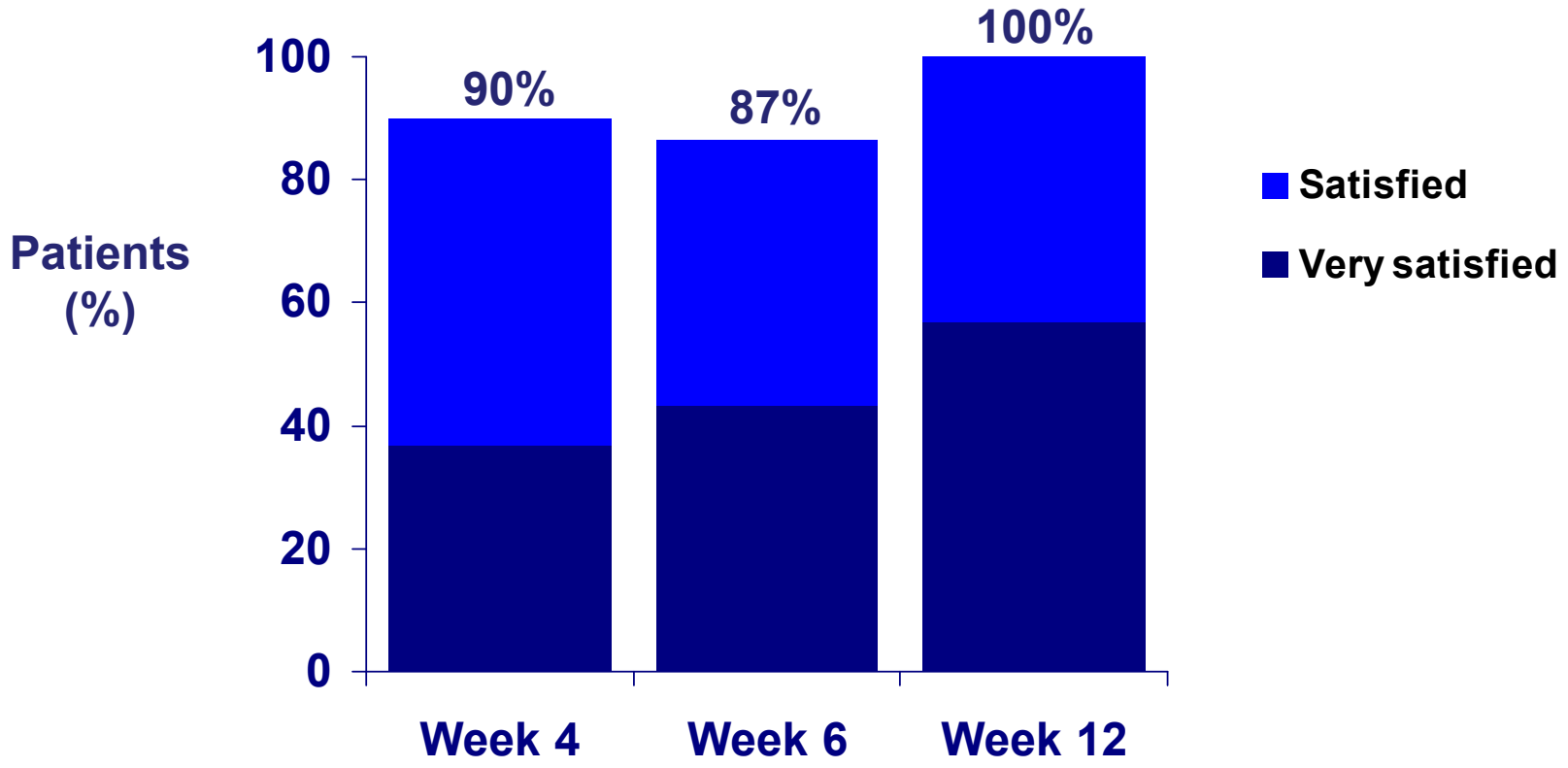
# Efficacy of HQ/L-Ascorbic Acid Treatment System



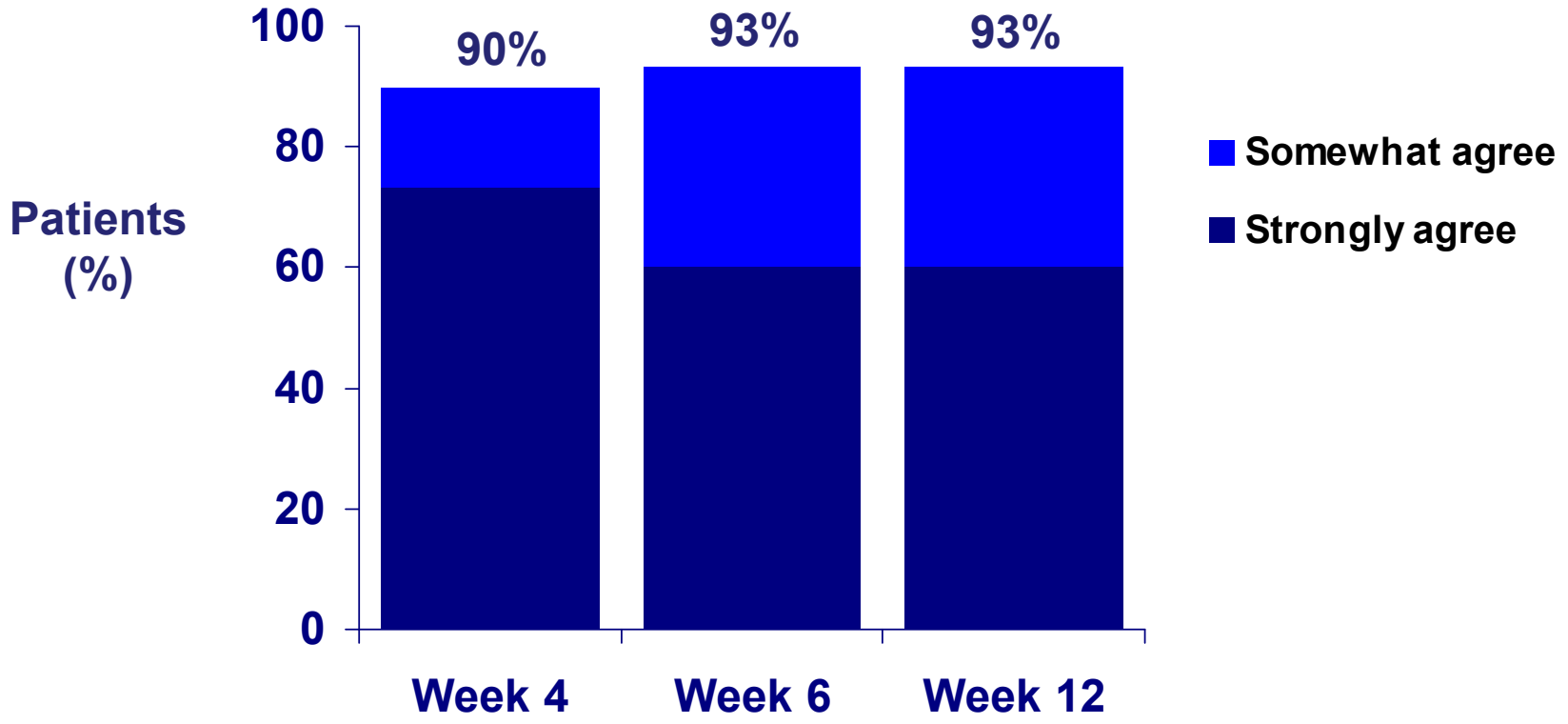
# Improvement in Overall Appearance of Skin



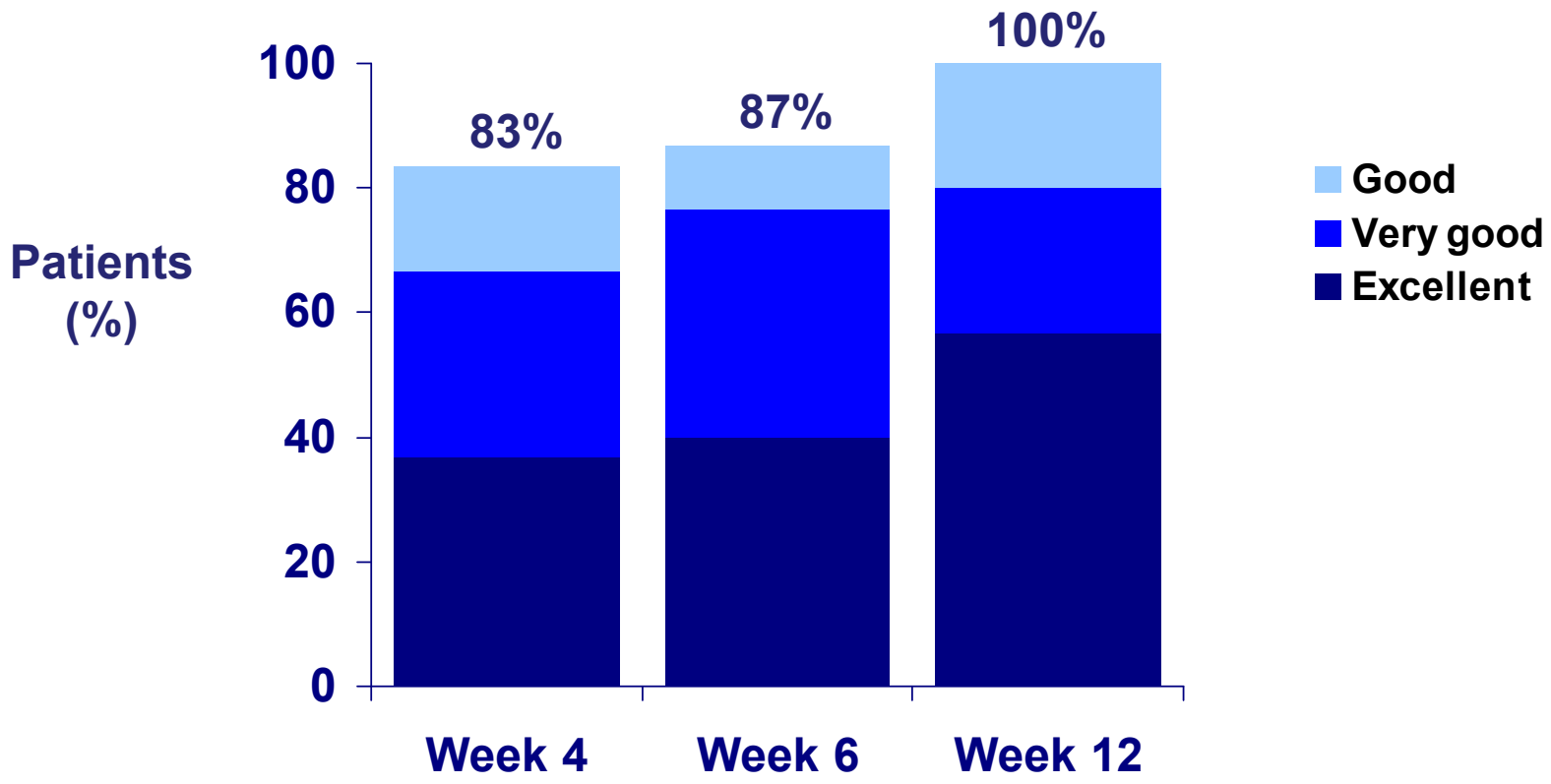
# Satisfaction with Overall Appearance of Skin



# HQ/L-Ascorbic Acid Treatment System is Easy to Apply



# Comparison of Study System with Other Skin Care Treatments Used Previously



# Efficacy Summary

- The HQ/L-ascorbic acid system was associated with improvements in:
  - Fine lines and wrinkles
  - Tactile roughness
  - Laxity
  - Intensity of pigmentation
  - Evenness of skin tone
  - Lightness/brightness of the skin
  - Smoothness of the skin
  - Softness of the skin
  - Radiance of the skin
  - Overall appearance of the skin
- 93% patients reported the HQ/L-ascorbic acid system was easy to apply
- 100% patients were satisfied with the overall appearance of their skin
- 100% patients reported the system was good, very good, or excellent compared with other skin treatments they had used before

# Tolerability

- Adverse events at least probably related to treatment:
  - Dryness (32%)
  - Erythema (9%)
  - Peeling (9%)
  - Pruritus (6%)
  - Milia (6%)
  - Rash (3%)
  - Burning sensation (3%)
  - Contact dermatitis (3%)
  - Acne (3%)
- 3 discontinuations due to mild facial adverse events:
  - Dryness
  - Erythema, pruritus, dryness, rash
  - Contact dermatitis

# Conclusion

- The prescription strength HQ/L-ascorbic acid treatment system can help to ameliorate early signs of photodamage in normal to oily skin including:
  - Fine lines and wrinkles
  - Tactile roughness
  - Laxity
  - Hyperpigmentation and unevenness of skin tone
- At week 12, 100% of patients were satisfied or very satisfied with the overall appearance of their skin
- The system is easy to apply and compares favorably with other skin treatments patients have used previously