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

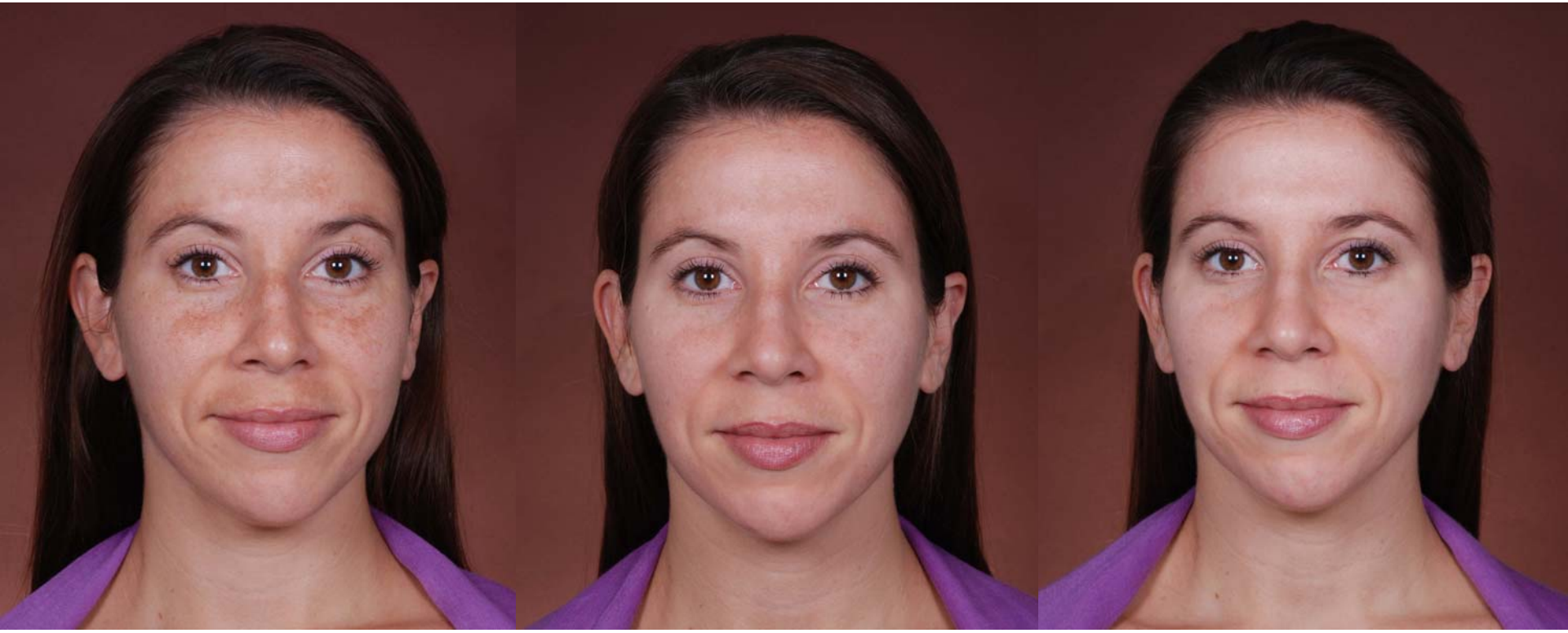
Results

- 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

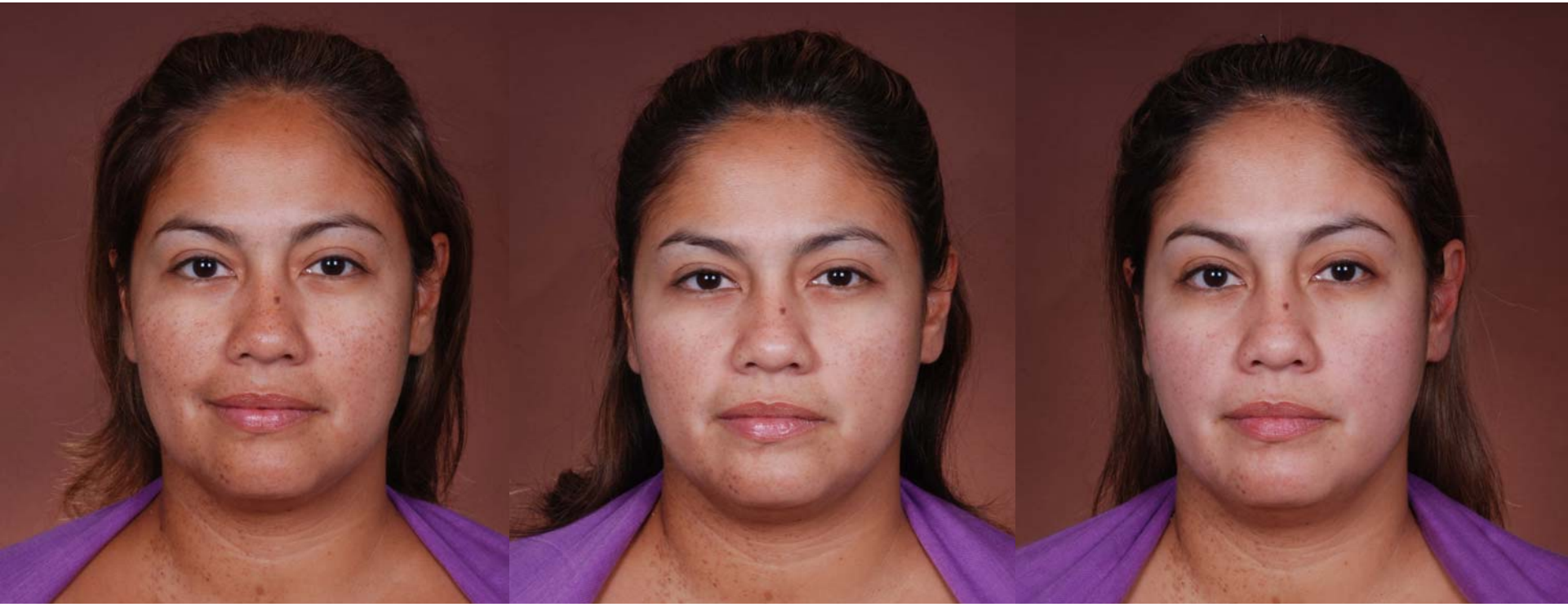


Baseline

Week 4

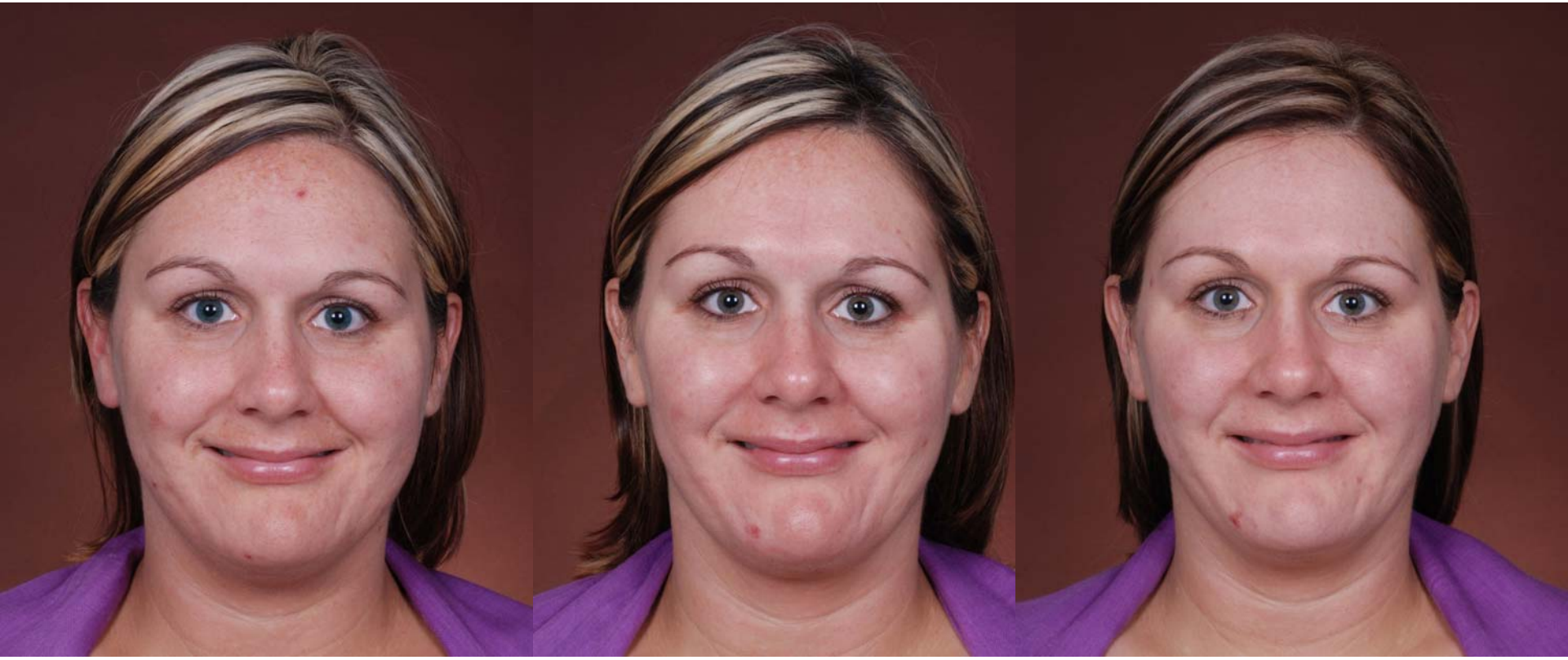
Week 12

Clinical Improvement



Baseline | Week 4 | Week 12

Clinical Improvement



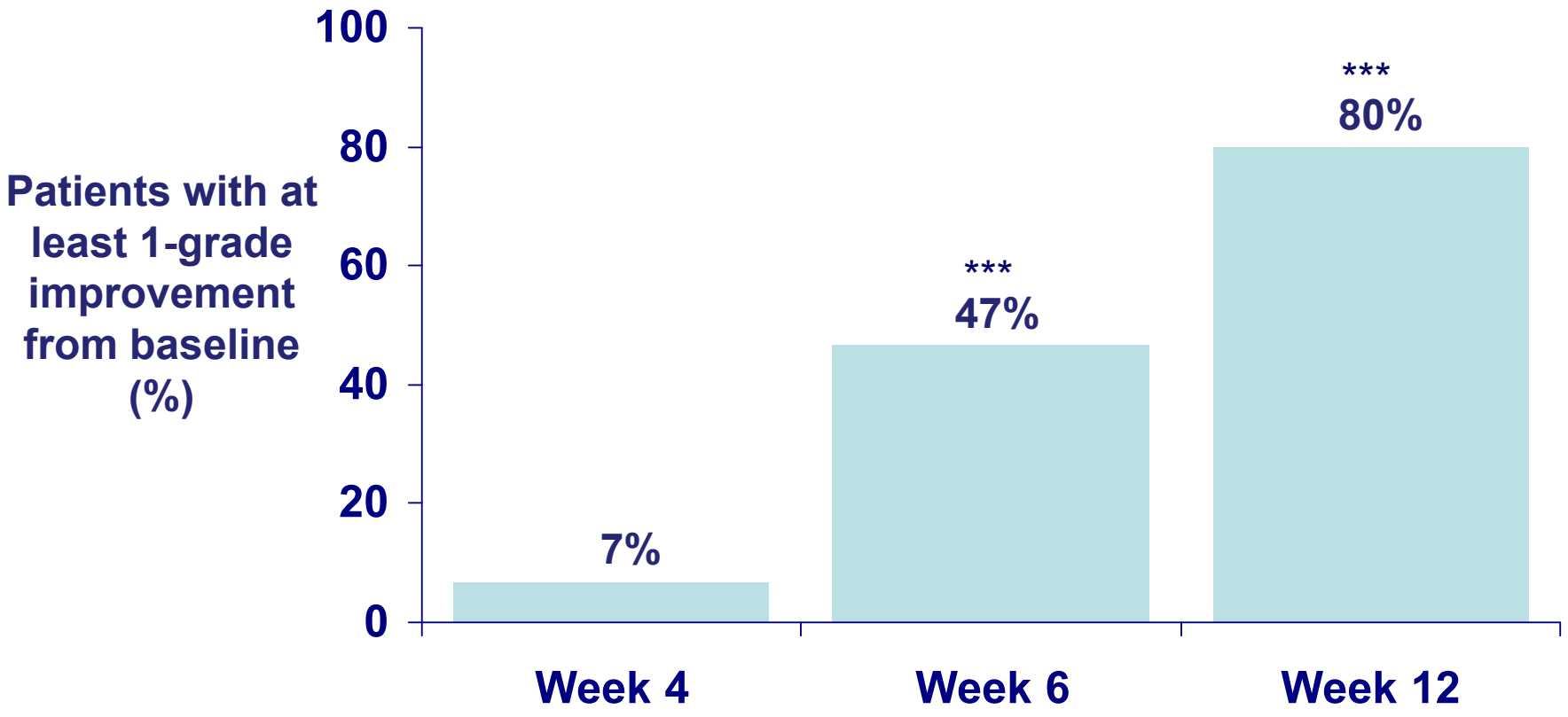
Baseline

Week 4

Week 12

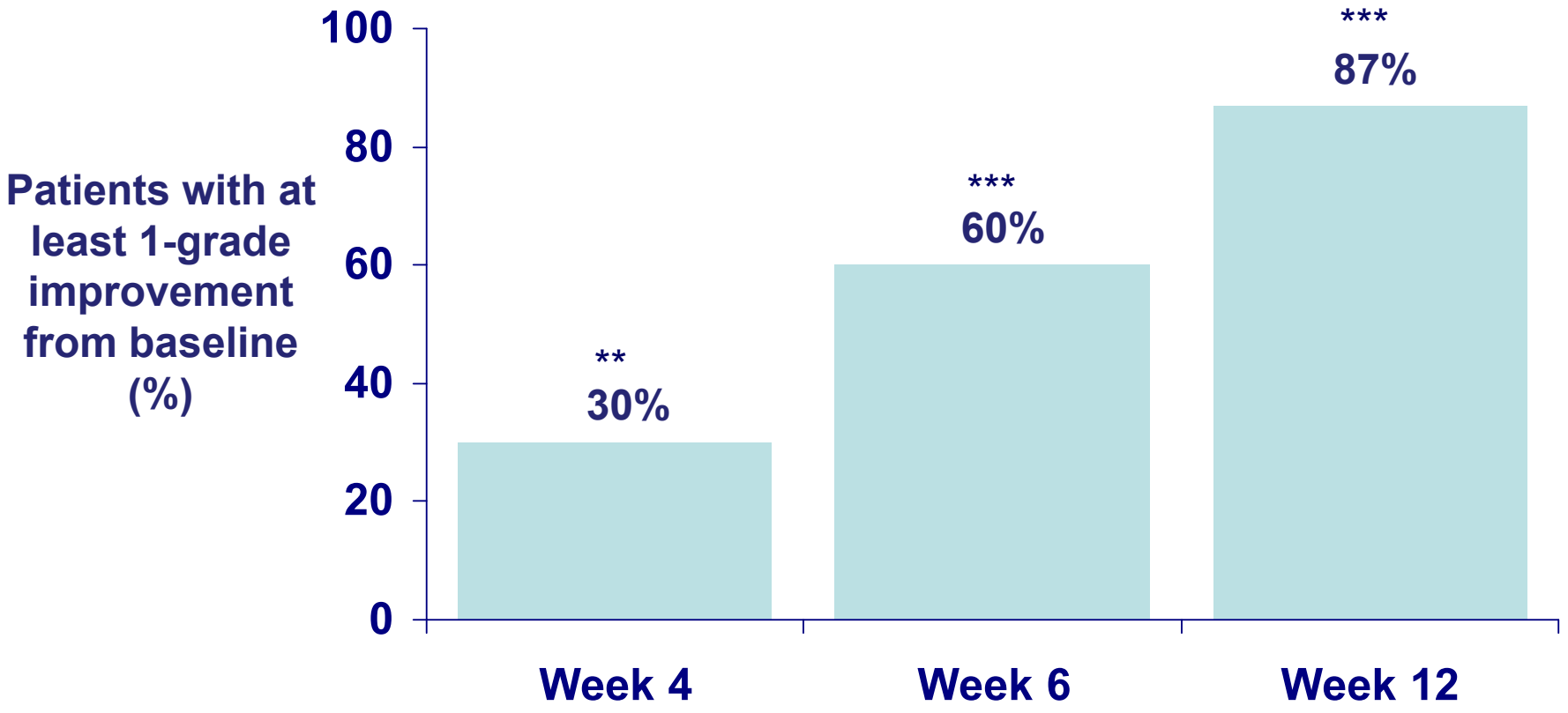
Investigator Evaluations

Overall Integrated Assessment of Photodamage



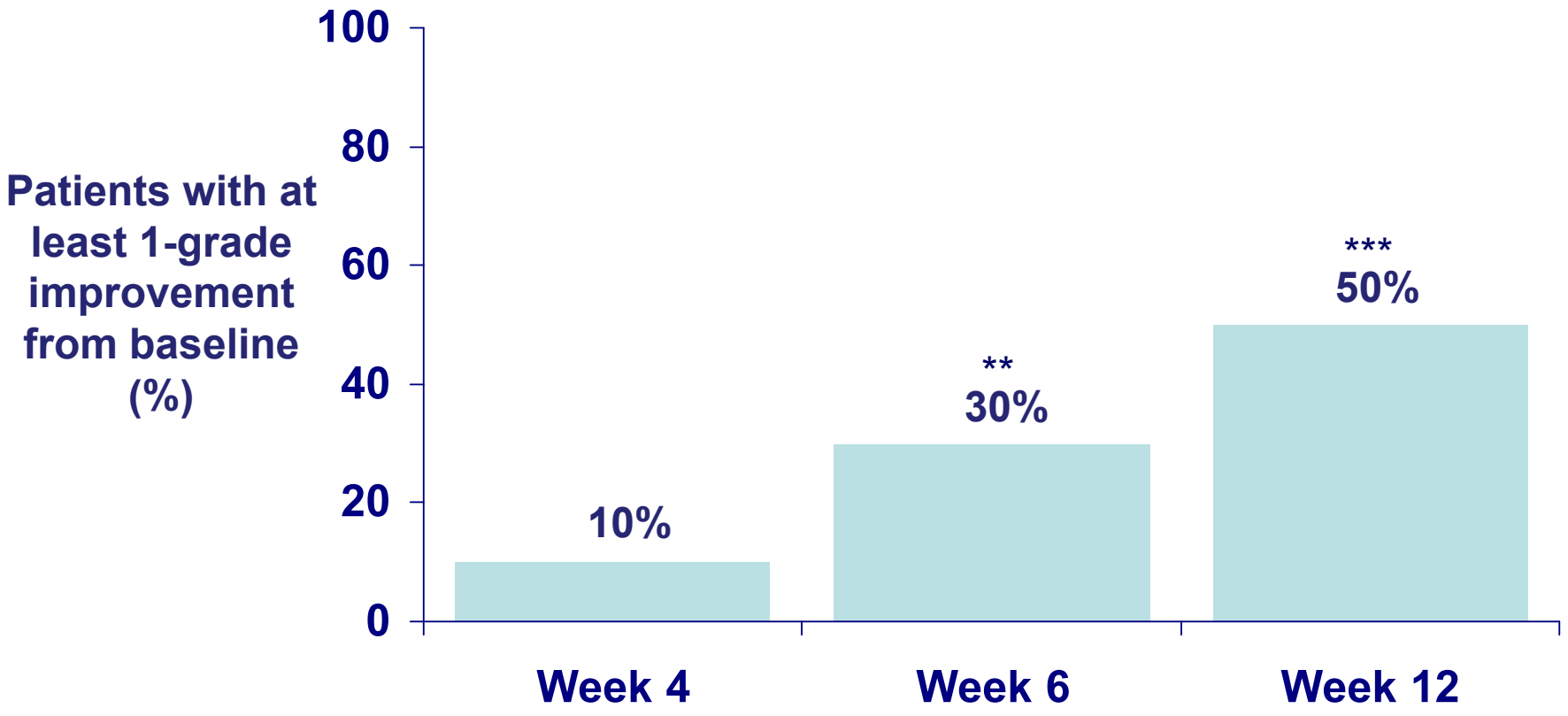
*** P≤.001 for median score versus baseline

Overall Intensity of Pigmentation



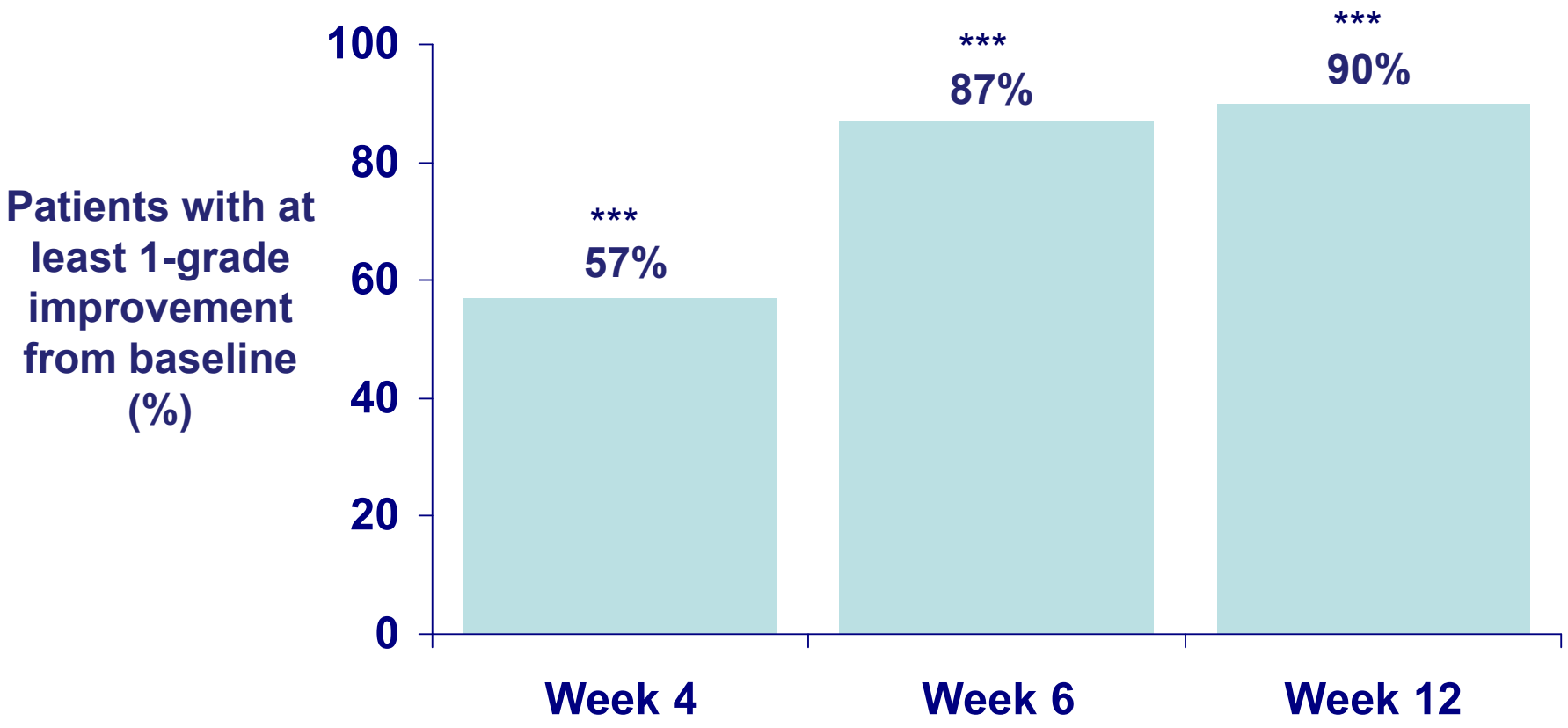
** P≤.01, *** P≤.001 for median score versus baseline

Fine Lines and Wrinkles



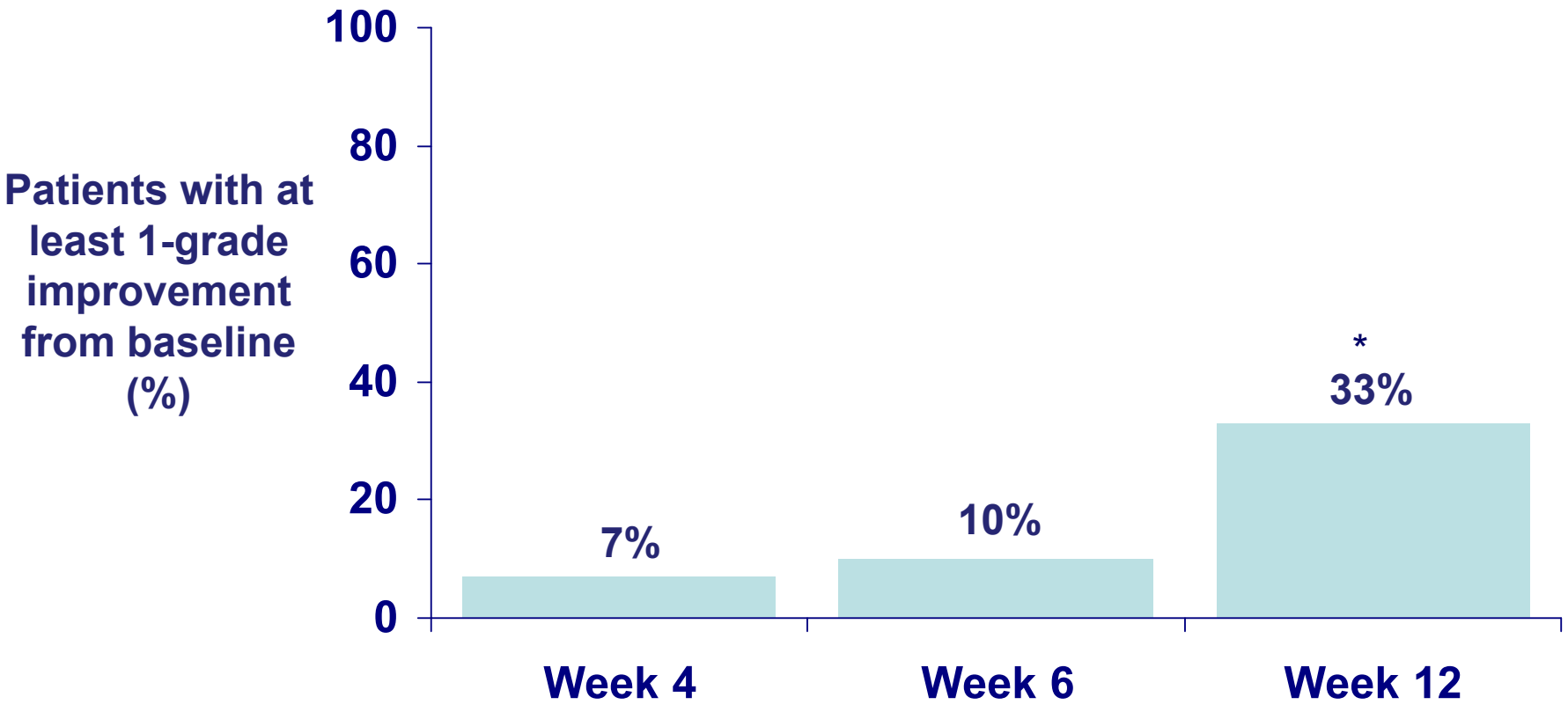
** P≤.01, *** P≤.001 for median score versus baseline

Tactile Roughness



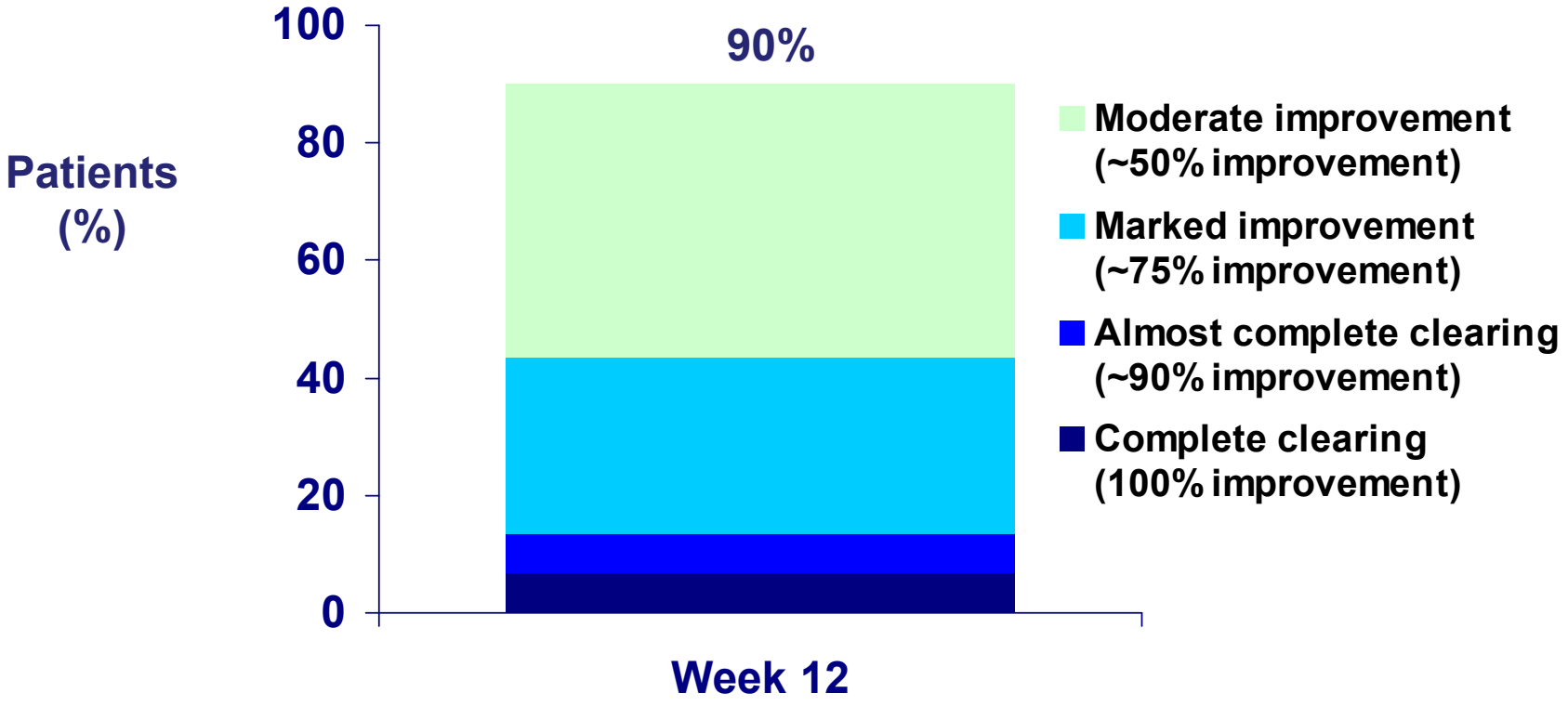
*** P≤.001 for median score versus baseline

Laxity

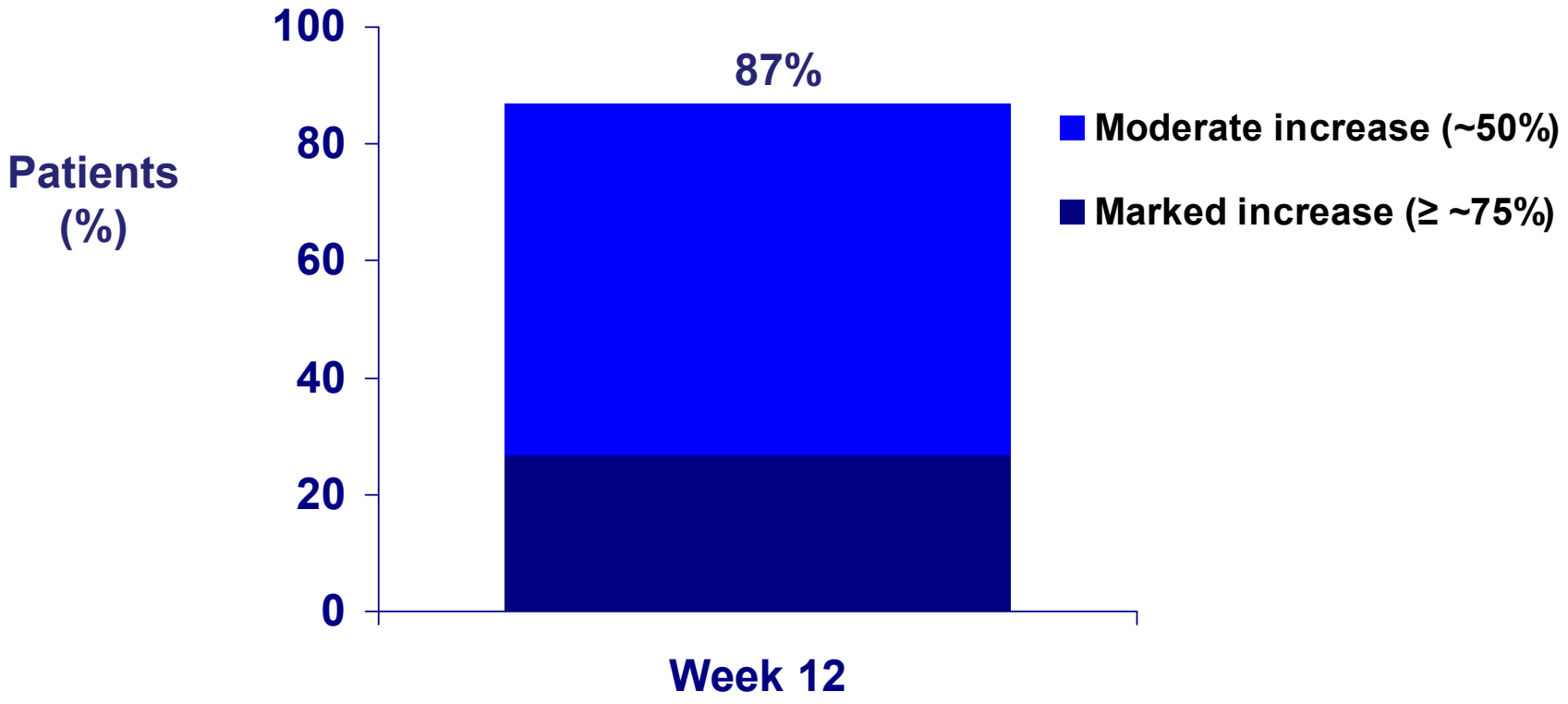


* P≤.05 for median score versus baseline

Incidence of ≥ 50% Global Improvement

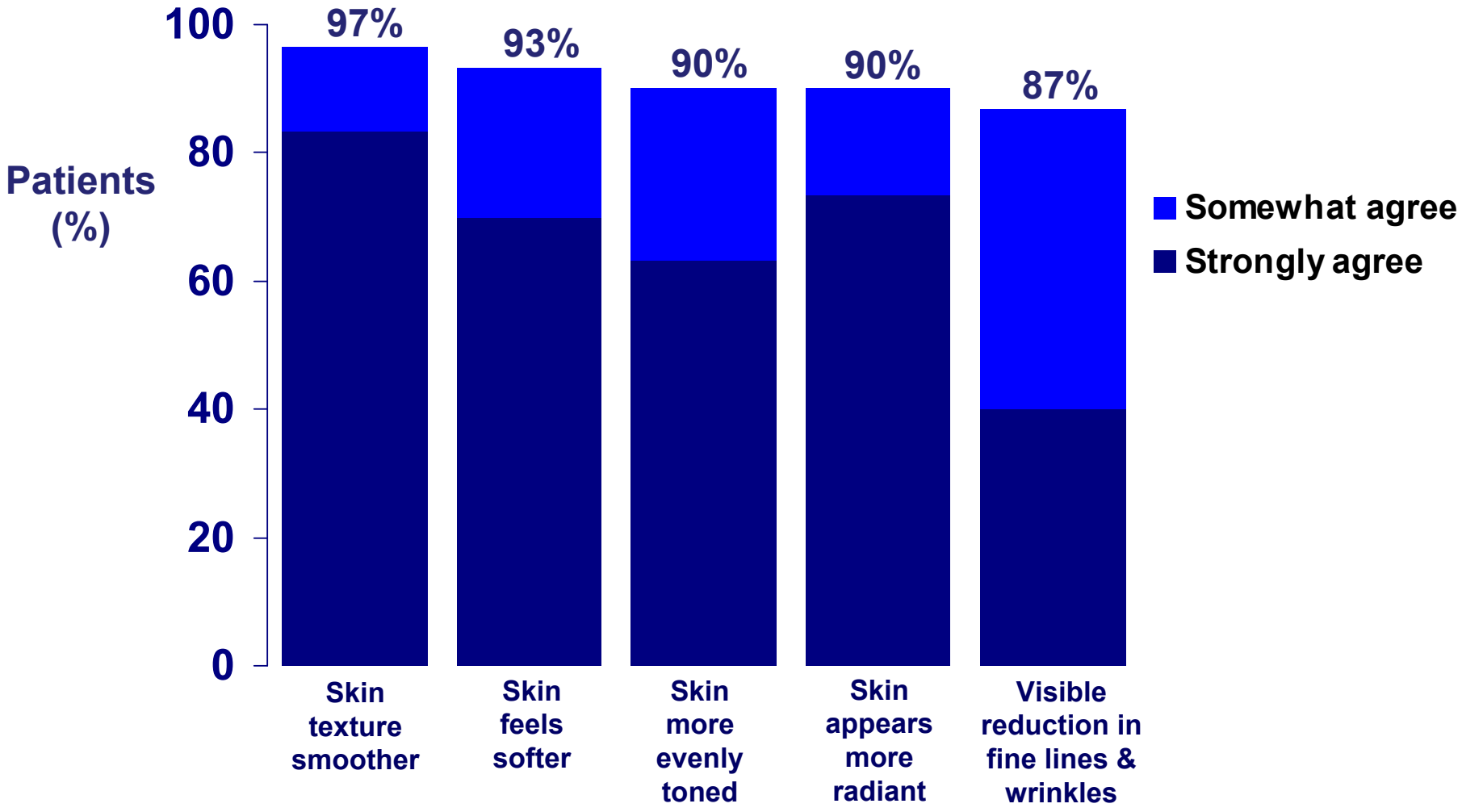


Incidence of ≥ 50% Increase in Lightness/Brightness of Facial Skin

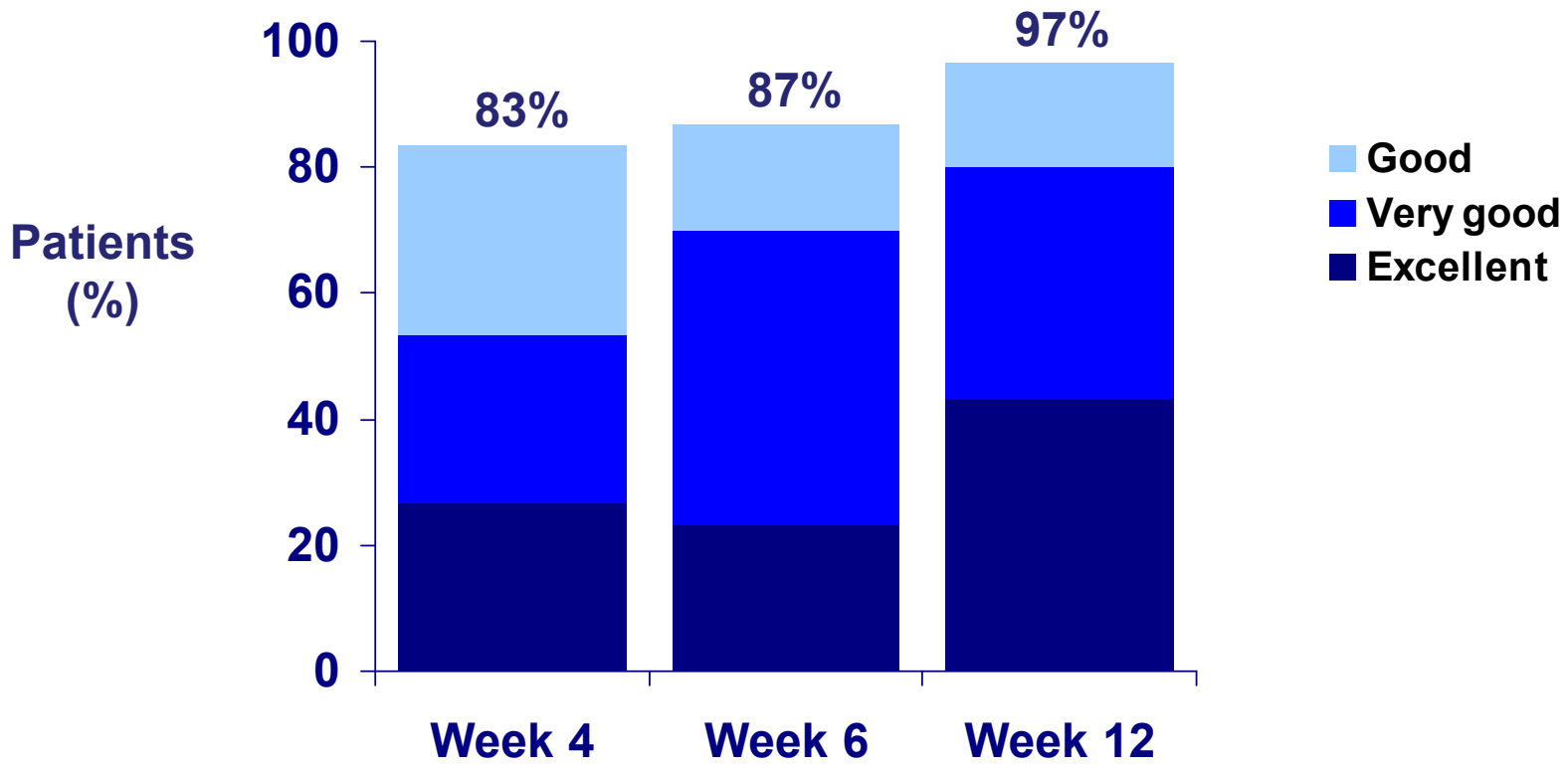


Patient Evaluations

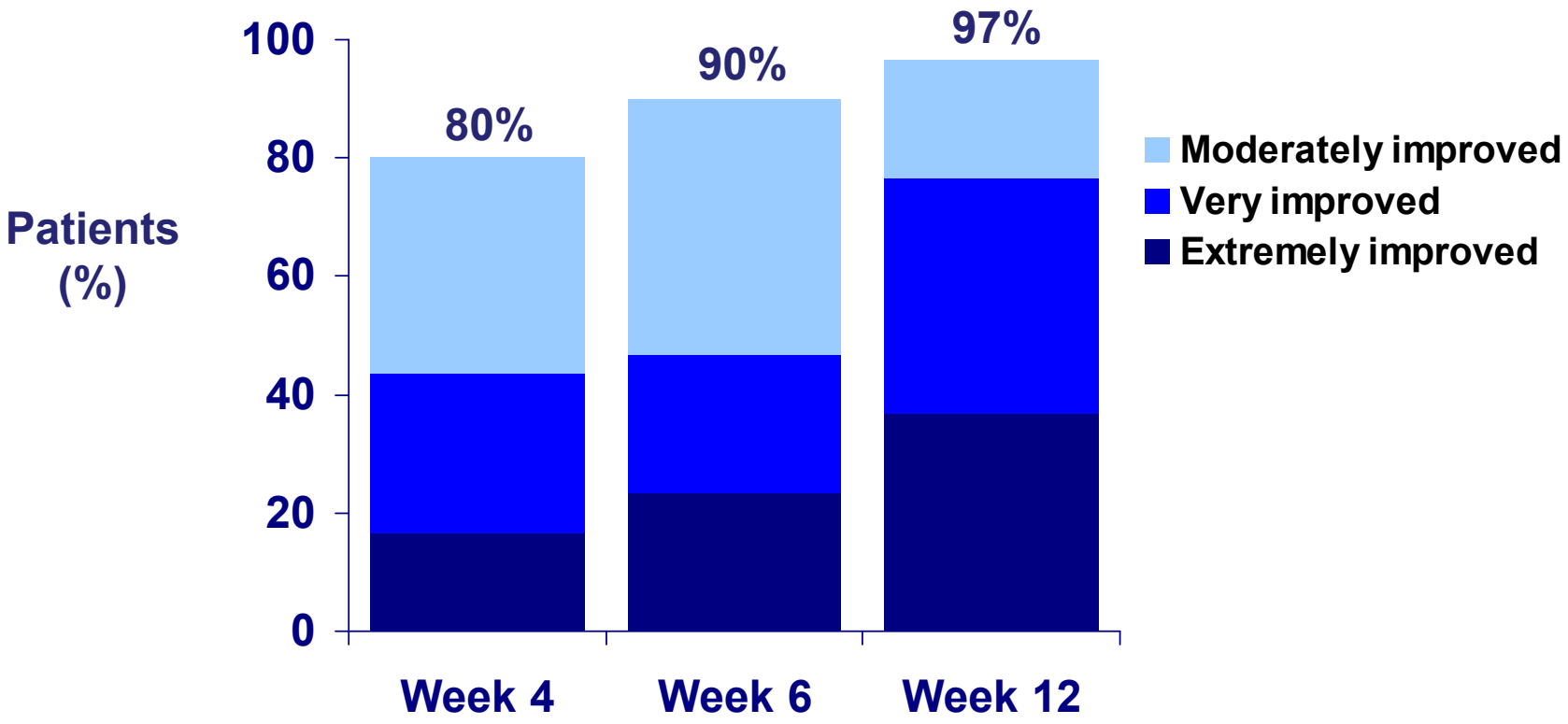
Patient Ratings of Improvement at Week 12



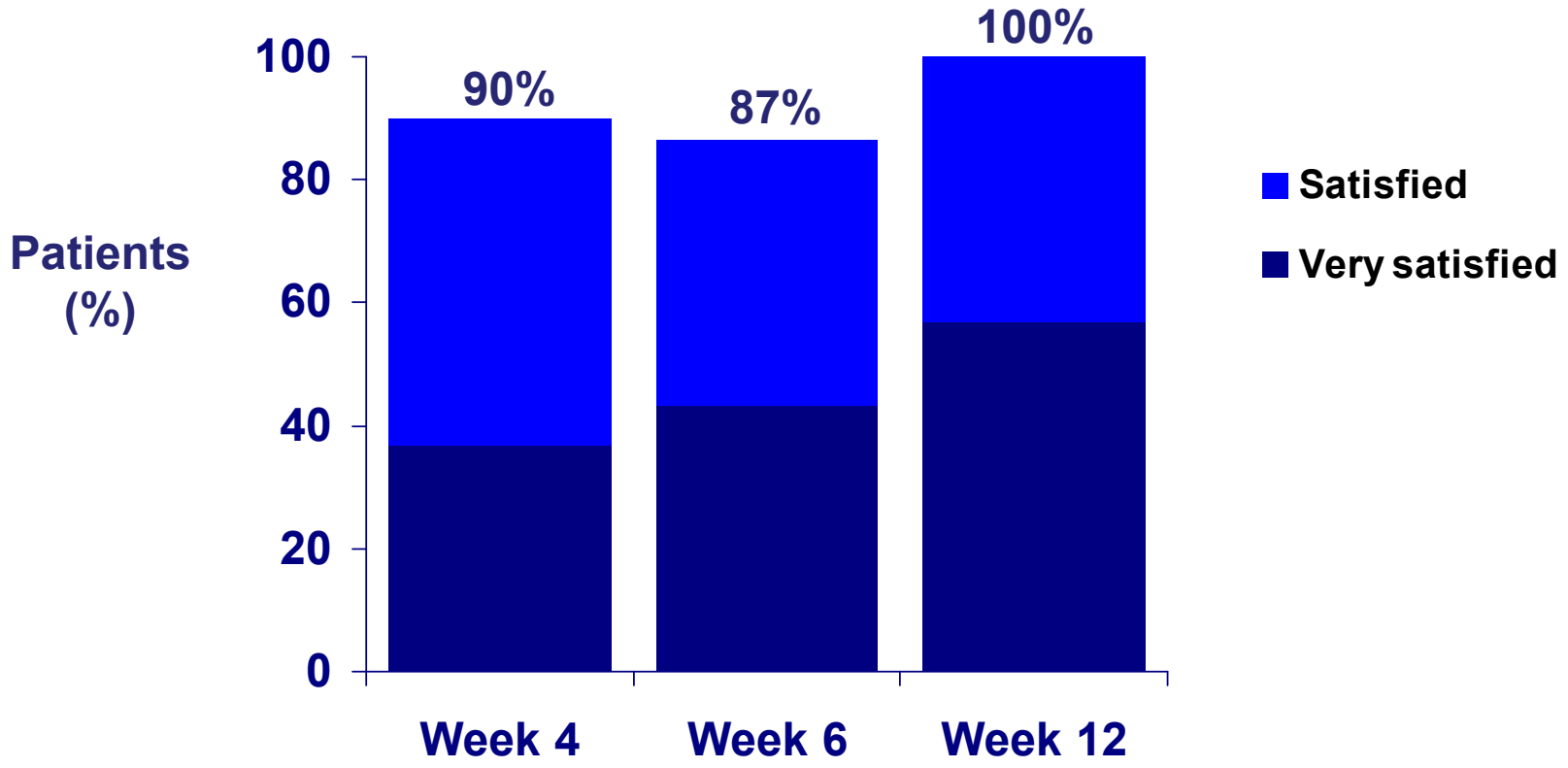
Efficacy of HQ/L-Ascorbic Acid Treatment System



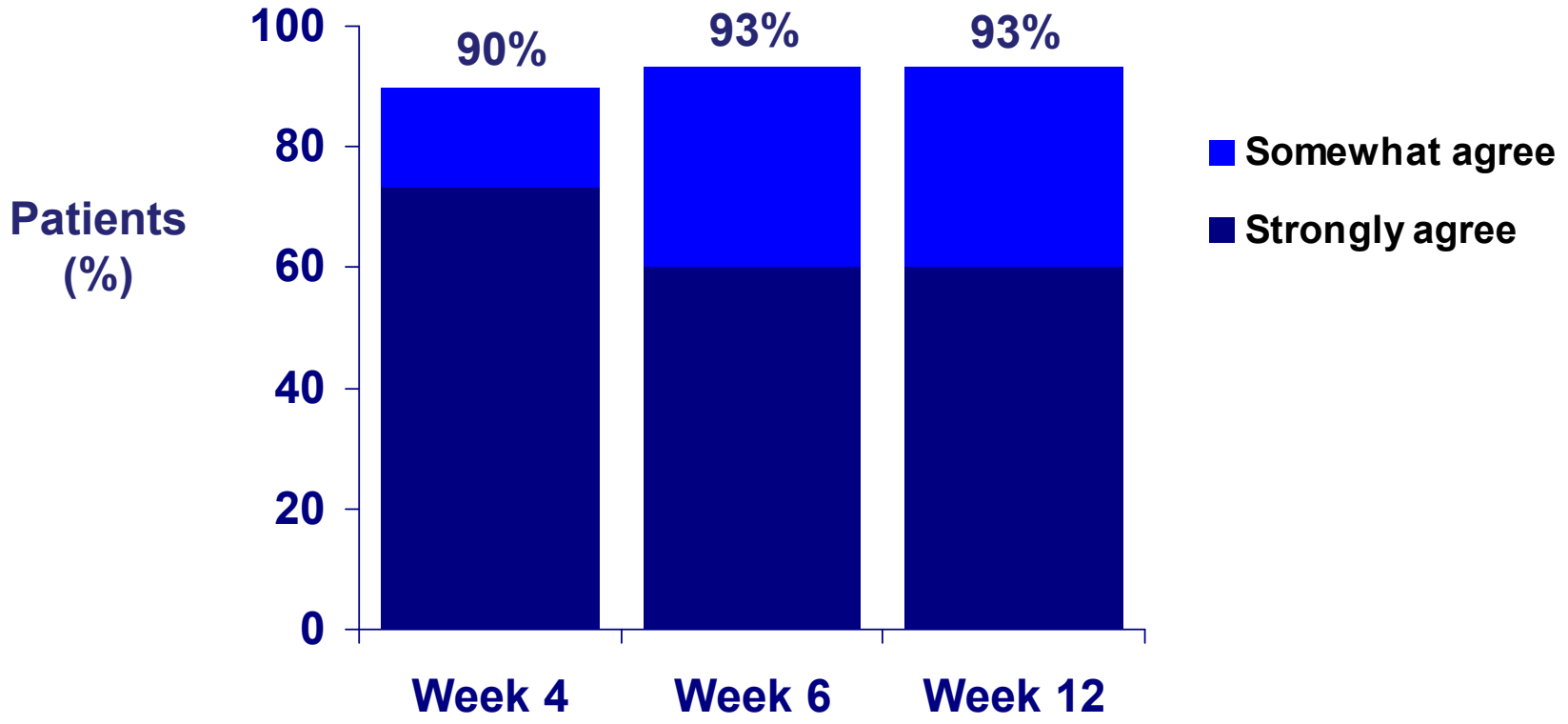
Improvement in Overall Appearance of Skin



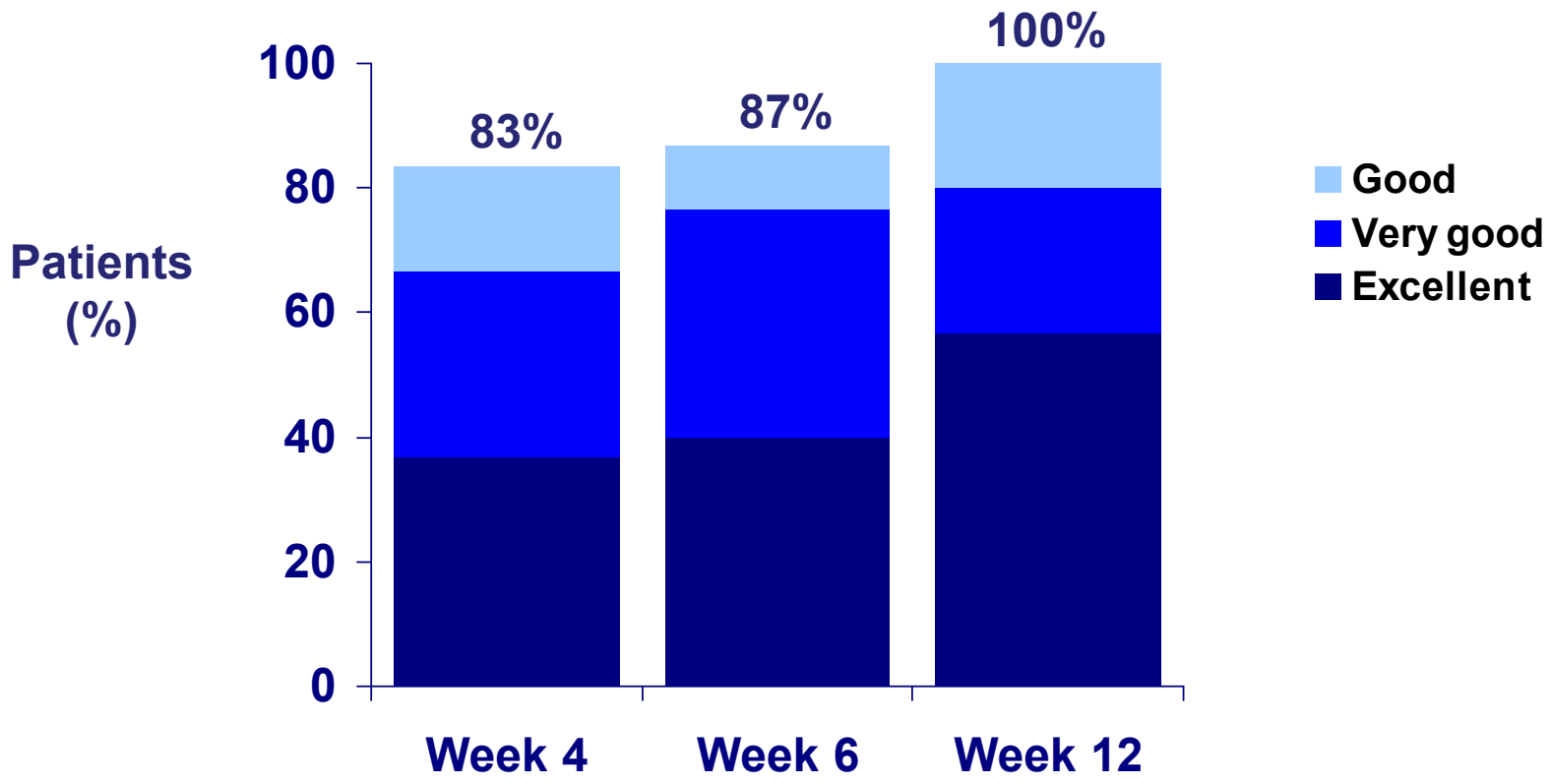
Satisfaction with Overall Appearance of Skin



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