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. **Foaming gel cleanser** (contains aloe barbadensis leaf juice)  
2. **Toner** (contains aloe barbadensis leaf juice and witch hazel)  
3. **4% hydroquinone**  
4. **Exfoliation enhancer** (contains glycolic acid and lactic acid)  
5. **Sunscreen SPF 35**  

**PLUS**

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

*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\(^1\)
- May enhance compliance\(^1\)
- 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)

\(^1\) Bowe et al. Semin Cutan Med Surg 2008
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 ≤ 0.01, *** P ≤ 0.001 versus baseline

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

Median grade for pigmentation intensity

Week

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)

Median MASI score

*** P≤.001 versus baseline
Improvement in Melasma

At least 1-grade improvement in melasma severity:
- Week 4: 47%
- Week 8: 70%
- Week 12: 80%

At least 1-grade improvement in melasma pigmentation intensity:
- Week 4: 74%
- Week 8: 75%
- Week 12: 85%

Marked (≥ 51%) improvement in melasma:
- Week 4: 16%
- Week 8: 40%
- Week 12: 60%
Patient Ratings at Week 12

- **Study treatment easy to apply**: 90%
  - Very easy: 90%
  - Easy: 0%

- **Satisfied with overall effectiveness of treatment**: 85%
  - Very satisfied: 40%
  - Satisfied: 45%

- **Study treatment more effective than other medications**: 90%
  - Much more effective: 50%
  - More effective: 40%
Improvements in Photodamage-Related Parameters at Week 12

- **Patient ratings of good, very good, or excellent improvements (%)**
  - Skin texture/roughness: 85%
  - Fine lines and wrinkles: 70%
  - Skin firmness: 70%
  - Brown spots/discholoration: 68%
Improvements in Melasma
Improvements in Melasma
Improvement in Quality of Life Parameters

Patients rating parameter as “very much” or “a lot” (%)

- Embarrassed/self-conscious due to skin: Baseline 80%, Week 12 20%
- Feeling unattractive due to skin: Baseline 80%, Week 12 35%
- Effort put into hiding skin discoloration: Baseline 90%, Week 12 37%
- Focus on skin discoloration by others: Baseline 55%, Week 12 15%
- Social/leisure activities affected: Baseline 50%, Week 12 20%
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/discholoration
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.