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## INTRODUCTION

Topical application of hydroquinone (HQ) produces a reversible depigmentation of the skin, primarily by inhibition of the enzymatic oxidation of tyrosine to 3,4-dihydroxyphenylalanine (dopa) and the conversion of tyrosine to melanin. However, use of HQ may have a number of irritation-related side effects. In China, 2% HQ cream is the only marketed prescription product used to treat melasma and pigmented spots. A cosmetic tone regimen (CTR) containing niacinamide and Sepiwhite® has been developed to improve the appearance of hyperpigmentation without the negative skin reactions associated with hydroquinone.

## OBJECTIVE

This study compared treatment with the CTR versus treatment with 2% Hydroquinone cream to determine:

- ❖ Relative efficacy at improving the appearance of hyperpigmentation (spot area; lightness of spots and basal skin).
- ❖ Subject tolerance of treatment

The effect of treatments on skin barrier integrity was also evaluated.

## STUDY DESIGN

- ❖ Randomized, double-blind, full-face study in 160 Chinese female subjects 25-55 yrs old with qualified melasma or hyperpigmented spots.
- ❖ After 1 wk pre-conditioning, subjects treated themselves for 12 wks with either:
  - A - HQ cream (each evening on facial hyperpigmented area) + Daytime SPF30
  - B - Cosmetic Tone Regimen (morning/evening)
    - Daytime SPF30 with 5% Niacinamide, 3ppm Pal-KITKS, 5.5ppm Pal-KT, 0.2% Carnosine
    - Cream containing 5% Niacinamide, 2% NAG (N-Acetyl glucosamine), 0.1% Hexamidine
    - Concentrated cream containing 1% Niacinamide, 1% Sepiwhite®, 3% NAG
- ❖ Computer analysis of digital images was used to measure changes in facial spot area (color and melanin-specific) and overall tone (L\*a\*b\*, evenness) after 2, 4, 8 and 12 wks of treatment.
- ❖ Facial skin barrier integrity was assessed by TEWL (Vapometer®) after 2, 4, 8 and 12 wks treatment. Irritation was graded at the same times using a 0-3 scale.
- ❖ Changes from baseline were analyzed using analysis of covariance.

## IMAGE ANALYSIS METHOD

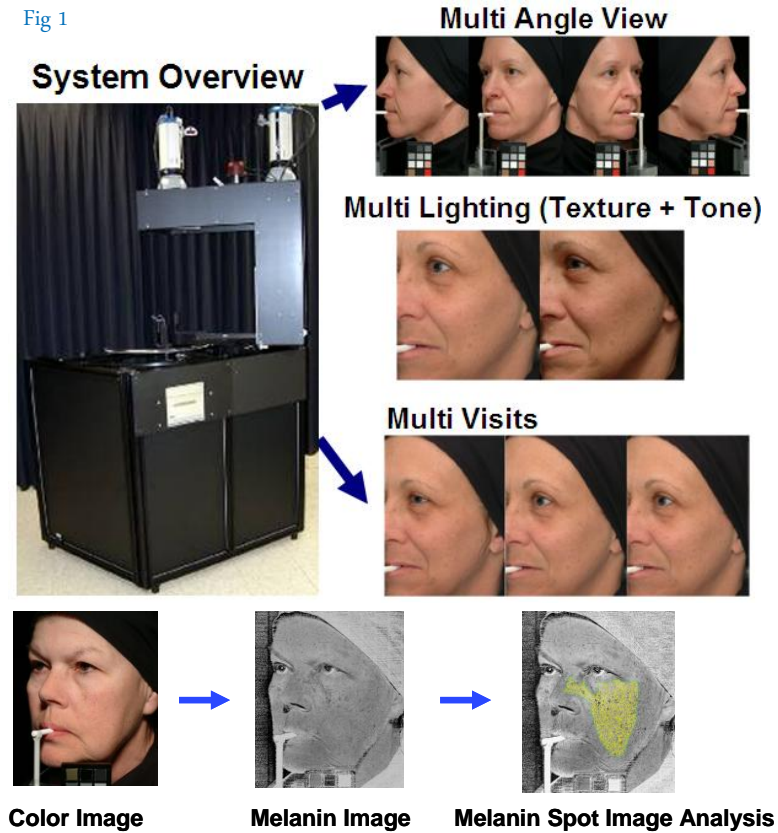


Fig 2. Examples of strong responses to treatment

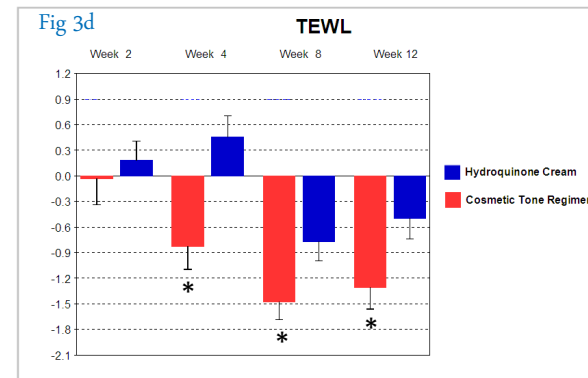
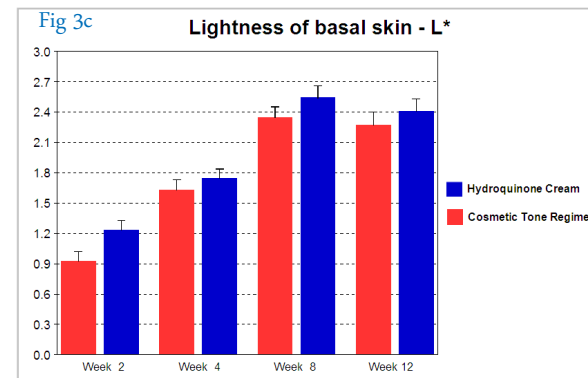
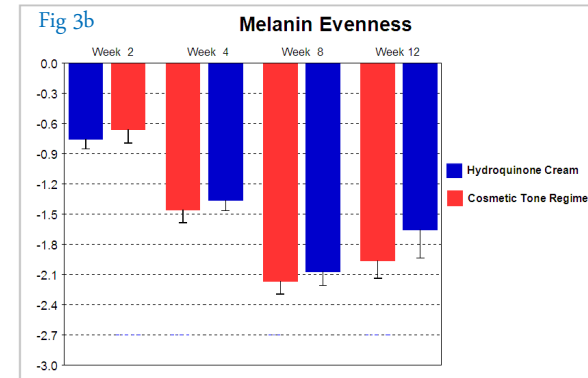
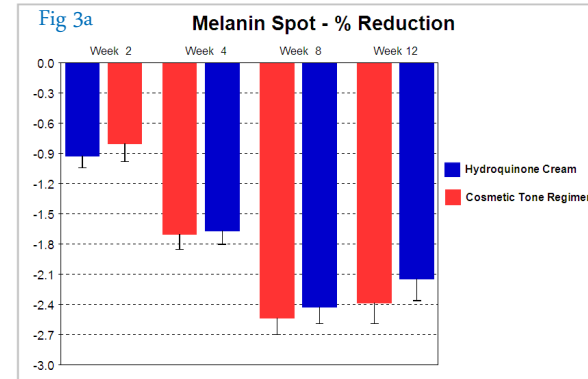
### By Hydroquinone cream (Subject# 96)



### By Tone regimen (Subject# 84)



## STUDY RESULTS



\* Statistically significant vs. HQ treatment at p<0.05

## CONCLUSIONS

- ❖ As expected, 2% HQ cream (available by prescription in China) lightened skin and reduced hyperpigmentation (Figs 3a-3c)
- ❖ The CTR showed comparable improvements to 2% HQ in appearance related pigmentation parameters (melanin spot area, melanin evenness and skin L\*-value; Figs 3a-3c).
- ❖ Neither treatment was irritating in this study (overall mean irritation scores of 0.49 for HQ and 0.41 for CTR).
- ❖ Treatment with the CTR improved skin barrier function significantly better than the 2% HQ treatment (Fig 3d).

## ACKNOWLEDGEMENT

The authors thank Dr. Wei Liu (China Air Force General Hospital), Dr. James Chan (Taiwan Cathay General Hospital), Dr. Wenyuan Zhu (Nanjing Medical University) and Dr. Xuejun Zhu (Peking University) for their collaboration on this study.