

# P3202 - Private Practice Evaluation of Topical 10% L-ascorbic Acid and 0.15% Retinol

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## Abstract

**Introduction** - Vitamins C and A have been shown to be effective in the treatment of photoaging. These compounds have also shown effectiveness in the treatment of pigmentation disorders and inflammatory dermatoses.

**Objective** - The objective of this study was to determine the safety and efficacy of topical vitamin C and A formulations using a microsphere delivery system supplied in unit-dose capsules.

**Materials & Methods** - 5 female subjects (2 Caucasian and 3 African-American) in a private practice setting between the ages of 30 and 60 completed the study. Subjects applied the vitamin C capsules to the full face daily in the morning and the vitamin A capsules in the same area daily at night. Subject evaluations were collected before treatment and at the end of 12 weeks of application. High resolution standardized digital photographs were performed pretreatment and after 12 weeks of treatment.

**Results** - Four out of five patients assessed excellent clinical results as early as 4 weeks. The remaining one patient experienced fair results at 12 weeks. Improvement in skin clarity and even texture/tone were noted as best improvements by all patients. Two patients experienced some acne breakouts over the 12 week study period, however the breakouts were considered acceptable. The most commonly reported adverse event was a slight drying effect.

**Conclusions** - Topical vitamin C and A in unit-dosing capsules applied for 12 weeks resulted in improvement in skin clarity, texture and tone. This observation was most easily seen in the African-American subjects. For inflammatory dermatoses, one Caucasian patient experienced impressive results, presumably due to the use of vitamin C. The unit-dose delivery method was well-tolerated and considered easy to use by all patients. All five patients elected to continue treatment after the study.

## Results



## Methods & Materials

### ELIGIBILITY CRITERIA

- Female subjects aged 30-60
- Darker skin type III-VI
- Evidence of photodamage, hyperpigmentation or inflammation
- No concurrent use of alpha hydroxy acids, salicylic acids, other retinoids, or medicated topicals during the study or within 30 days of study start
- Avoid sun exposure, artificial tanning devices and direct heat sources during the study
- No concurrent use of botulinum toxin, facial fillers, chemical peel or facial resurfacing or within 6 months of study start

### STUDY DESIGN

- Open-label single-center study for 12 weeks
- Morning routine: subjects applied L-ascorbic acid 10% capsules to clean, dry skin, followed by a 40 SPF sunscreen
- Evening Routine: subjects applied retinol 0.15% capsules to clean, dry skin, followed by a moisturizer if desired
- Baseline and 12-week visits
  - Patient pre-treatment assessment
  - Patient post-treatment assessment
  - Standardized clinical photographs using the Profect Digital Photography system

### ASSESSMENTS

- Subject Self-Assessment
  - Subjects rated their skin pigmentation, wrinkles, texture/tone and clarity on four or five point scales at baseline and at 12 weeks
  - Subjects rated the conditions they experienced during treatment, how long it took to see improvement, and the ease of use of the products at 12 weeks
- Investigator Assessment of Standardized

## Summary

### STUDY PARAMETERS

- Patients: 6 total (female)
- Average Age of Patients: mid 40s
- Time frame: 12 weeks
- Skin Type: III-V, irregular texture, sun damage and inflammation.

### PATIENT SURVEY

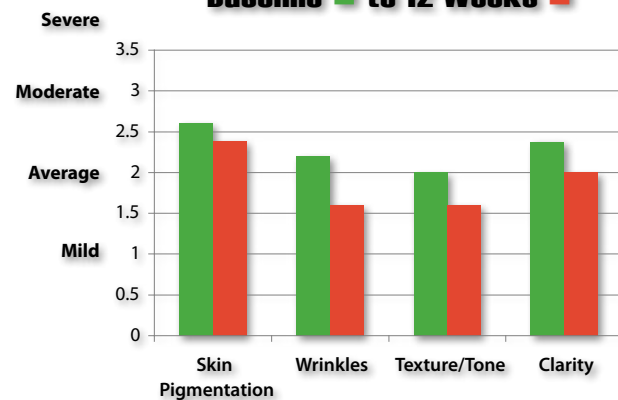
- Total of 5 patients (1 patient discontinued)
  - 4 out of 5 patients assessed excellent clinical results. Results experienced as early as 4 weeks.
  - Remaining 1 patient had fair results; experienced results at 12 weeks.
- Improvement in skin clarity & even texture/tone were noted as best improvements

### PATIENT EVALUATION

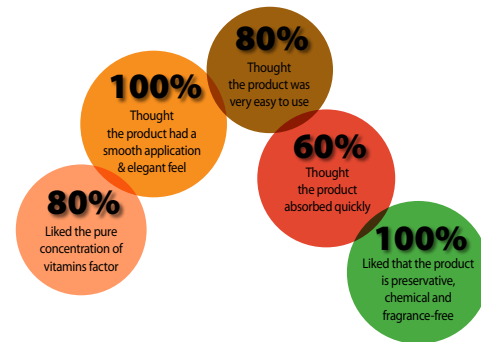
- Smooth application/elegant feel:
  - 100% of patients had a favorable experience
- Preservative, chemical & fragrance-free:
  - 100% of patients had a favorable experience
- Biodegradable unit dose vegi-caps:
  - 90% of patients had a favorable experience
- Pure ingredients:
  - 90% of patients had a favorable experience
- Fast absorption:
  - 80% of patients had a favorable experience

### Patient Assessment Ratings

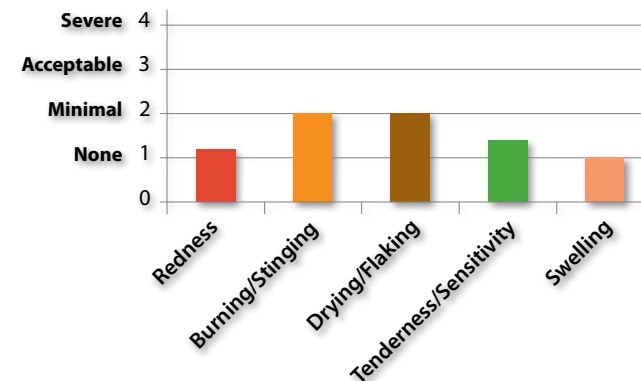
Baseline ■ to 12 Weeks ■



### Product Use Assessment



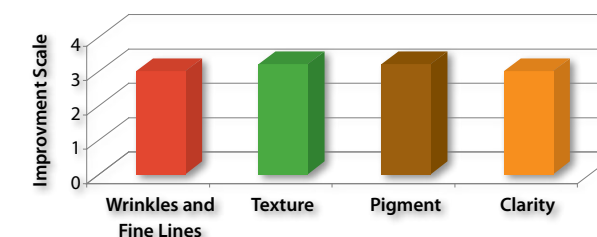
### Conditions Experienced



### Overall Physician Rating of Patients at 12 Weeks



### Physician Skin Condition Rating at 12 Weeks



### Bibliography

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