An Evaluation of Efficacy and Tolerability of Novel Enzyme Exfoliation Versus Glycolic Acid in Photodamage Treatment

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Study Objective

Evaluate the safety and efficacy of hydrolyzed roe products vs. glycolic acid products during a 12 week period
Study Design

- 75 subjects
- 25 women in each cell
- Double-blinded
- Clinical photography and visual assessment, at baseline, 8 weeks, and 12 weeks
Test Materials

- Hydrolyzed Roe Cream
- 4% Glycolic Acid Cream
- 8% Glycolic Acid and 2% Citric Acid Cream
# Inclusion/Exclusion Criteria

<table>
<thead>
<tr>
<th><strong>Inclusion Criteria</strong></th>
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<tbody>
<tr>
<td>Age 30-70 years</td>
<td>Pregnancy or nursing</td>
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<tr>
<td>Exhibits facial hyperpigmentation, fine lines, and wrinkles</td>
<td>Allergy to cosmetics</td>
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<tr>
<td>Fitzpatrick skin type I-VI</td>
<td>Acute or chronic dermatological conditions</td>
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<td>Agrees to avoid prolonged UV/sun exposure</td>
<td>Participation in another study using the face within 2 weeks of start</td>
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<tr>
<td>Agrees to wear sunscreen</td>
<td>Using OTC or Rx medication to treat dermatological facial condition</td>
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<tr>
<td>Agrees to refrain from facial products other than test materials</td>
<td>Has used any retinol product within 3 months</td>
</tr>
<tr>
<td>Signs photography release and informed consent</td>
<td>Has taken Accutane within 1 year</td>
</tr>
<tr>
<td>Capable of compliance and following directions</td>
<td>Has used AHA, salicylic acid, lightening, or any anti-aging products within 60 days of study start</td>
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<td>In good health</td>
<td></td>
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</table>
Subject Questionnaire

☐ Scent
☐ Texture
☐ Age spots
☐ Improvement
☐ Feel and look younger
☐ Vibrancy
☐ Absorbency
☐ Hydration
☐ Overall impression
☐ Recommendation
Patient Characteristics

75 subjects enrolled. 52 completed. Ages 31-70.

Hydrolyzed Roe Cream (n=19)  4% Glycolic Acid Cream (n=17)  8% Glycolic Acid and 2% Citric Acid Cream (n=16)

The majority of subjects were dropped due to non-compliance of protocol
Statistical Methods

Analysis of variance consists of 2 factors

- TIME is fixed, consistent effect
- SUBJECT is random effect

Change from baseline to 8 and 12 week analysis is declared statistically significant if p-value is = or <0.05 at 95% significance level

Tolerance and Safety evaluation were tallied at 8 and 12 weeks
Statistical Methods

Subjective questionnaires were analyzed by Z-tests

Z-tests are used to determine statistically significant differences in patients responding positively or negatively to questions.

The proportion of subjects choosing neutral responses are split equally and added respectively to the positive and negative responses.

Z-scores greater than or equal to the absolute value of 1.96 at the 95% confidence level were considered statically significant.
Results: Clinical Photography-VISIA evaluation

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<th>4% Glycolic Acid Cream</th>
<th>8% Glycolic Acid and 2% Citric Acid Cream</th>
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<tbody>
<tr>
<td>• Statistically significant decreases in brown spots, redness, and general spots</td>
<td>• Statistically significant decreases in spot counts were seen in week 12</td>
<td>• No statistically significant changes in brown spots, pores, porphyrins, redness, texture, UV spots, or wrinkles…</td>
</tr>
</tbody>
</table>

Comparison Between Test Materials

• Decreases in brown spot counts were statistically greater for Hydrolyzed Roe than 4% Glycolic Acid Cream at Week 12. No other statistically significant differences were seen in brown spots, pores, porphyrins, redness, texture, UV spots, or wrinkles… at Week 8 or Week 12
Results: Clinical Photography: VISIA Evaluation

- **Subject 28, Hydrolyzed Roe**
  Greatest improvement in wrinkles (45th percentile to 70th percentile)

Before | After 12 Weeks
### Results: Visual Assessments

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<tr>
<td>• Evenness in skin tone improved statistically at Week 12</td>
<td>• Improvement based on Packman and Gans scores were seen in superficial facial lines and improvement based on visual analog scale was seen in facial hyperpigmentation</td>
<td>• Evenness in skin tone, tactile roughness, and skin laxity were shown to improve at week 12.</td>
</tr>
</tbody>
</table>

**Comparison Between Test Materials:**

• NO significant differences in Packman and Gans scores for superficial facial lines were seen or Visual Analog Scale scores for facial hyperpigmentation, evenness of skin tone, skin clarity, skin laxity and tactile roughness existed between the different treatments
Results: Visual Assessments

- **Subject 39** *Hydrolyzed Roe* showed most improvement in skin clarity and skin roughness with 100% improvement (a score of 25 to 50 out of 100)
Results: Tolerance Evaluation-Objective

<table>
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<th>Effect</th>
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<tr>
<td>Hydrolyzed Roe Cream:</td>
<td>Improvement in dryness</td>
</tr>
<tr>
<td>4% Glycolic Acid Cream:</td>
<td>Improvement in edema and redness</td>
</tr>
<tr>
<td>8% Glycolic Acid and 2% Citric Acid Cream:</td>
<td>No significant changes in erythema, edema, or dryness</td>
</tr>
</tbody>
</table>

Comparison Between the Test Materials:
No statistically significant differences in erythema, edema, or dryness
Results: Tolerance Evaluation-Subjective

Test of significance indicates that

• Hydrolyzed Roe Cream had significantly lower stinging and burning scores and 4% Glycolic Acid Cream had significantly lower stinging and burning scores than 8% Glycolic Acid/2% Citric Acid
Adverse Event

- Subject #29 using the 8% Glycolic Acid/2% Citric Acid Cream was discontinued due to an adverse event
- Pt treated with aloe at home and returned for follow up appointment
- Sensitive skin
Subject questionnaire

With the exception of product “heaviness” which was rated more favorably for 8% Glycolic Acid/2% Citric Acid, there were no significant differences in patient feedback.
Limitations

- This study compares commercially available products and could not control for differences in the vehicles.
- Subjects did not bring products to appointments and therefore did not assure myself that subjects were indeed using products.
Conclusions

Hydrolyzed Roe Cream improved skin tone and evenness with subjective and objective measures after 12 weeks of use.

The improvement in skin tone is likely due to the exfoliating effect of this product and not likely due to pigment production inhibition.

Hydrolyzed Roe Cream was better tolerated with less stinging and burning than 8% Glycolic Acid/2% citric acid.