

ABSTRACT

Objective: To evaluate a hydrolyzed roe cream in the reduction of facial erythema following a chemical peel treatment. Edema was also assessed. **Design:** The facial cream was applied to one side of the face of 30 healthy female subjects (average age = 54.9 years, range 33–65 years) immediately following 4 to 15 minutes peel treatment. The opposite side remained untreated. Visia-CR digital photographs were taken at baseline and 8 and 24 hours post-facial peel. Objective dermal irritation assessments were done by a blinded investigator, graded on severity of facial erythema and edema on a 5-point scoring scale; 0=none, 1=slight, 2=mild, 3=moderate, 4=severe. Subjects completed a perception questionnaire. **Results:** Reduction in erythema was greater ($P \leq 0.05$) for the treated side of the face compared to the untreated side at both 8 and 24 hours post-peel. Both sides showed reduction in erythema compared to immediate post-peel. No edema was observed. At eight hours, more than 50 percent of subjects agreed on the five attributes, and at 24 hours, 57 percent (17/30) of subjects agreed. At eight hours, ≥ 80 percent of subjects strongly agreed or agreed that the treated skin feels hydrated and moisturized immediately after application. At 24 hours, more than 90 percent of subjects strongly agreed or

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A Split-Face Evaluation to Assess the Efficacy of a Hydrolyzed Roe Cream in the Reduction of Erythema Following Chemical Peel

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FACIAL CHEMICAL PEELING agents, such as alpha hydroxy acids, glycolic acid, lactic acid, malic acid, and pyruvic acid, are among the most widely used superficial peeling agents.^{1–5} Numerous formulations containing hydroxy acids have been used in clinical practice for decades to treat a variety of skin conditions and are incorporated into a variety of cosmetic preparations.^{6,7} The most widely used chemical peeling agent is glycolic acid, which has the smallest molecular weight of the alpha hydroxy acids (AHA). Despite the wide use and patient acceptance of glycolic acid as a facial peel, there have been reports of skin irritation, especially at concentrations $\geq 10\%$.^{2,5} Proper patient selection, peel timing, and on-time neutralization assures good results. Depth of the glycolic acid peel depends on the concentration of the acid used, the number of coats applied, and the time for which it is applied. Hence, it can be used as a very superficial peel or even as a medium depth peel.⁵ The peel is generally neutralized within 3 to 5 minutes or when uniform erythema is seen.⁸ Recovery from chemical peeling can include extended periods of erythema, scaling, and irritation.^{9,10}

A product containing hydrolyzed roe cream has been studied for facial rejuvenation.¹¹ This same active ingredient has now been formulated into a lotion, Restorsea Rebalancing Lotion™ (Restorsea Inc., New York, New York).¹² The authors report their findings of accelerating the reduction in post-peel recovery with this unique ingredient.

PATIENTS AND METHODS

The objective of this study was to evaluate the potential of hydrolyzed roe cream to reduce facial erythema following a chemical peel treatment. Edema was also assessed.

The test material, hydrolyzed roe cream, study number, and subject numbers were identified by Clinical Research Laboratories (CRL). The identity of the hydrolyzed roe cream was Rebalancing Lotion, CRL71815, which is a mixture of hydrolyzed roe (proprietary enzyme extracted from post-hatching salmon fluid); *Alaria esculenta* (brown algae); and ascorbic acid 2-glucoside (AA2G), a stable form of vitamin C, squalane, and shea butter.

Facial peel kits (30% glycolic acid) were supplied by CRL. The chemical peel used was glycolic acid in a commercially available product, Peter

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agreed that treated skin feels perfectly hydrated and moisturized. When asked about their overall impression of the product, 60 percent (18 subjects) of subjects responded "I love it." All subjects completed the study. No adverse events were reported. **Conclusion:** Applying the facial lotion directly on post-procedure skin reduces redness after 8 and 24 hours significantly better compared to no treatment.

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Thomas Roth Glycolic Acid 30% Gel (alpha hydroxy acid, pH 3.14). Neutrogena® Sensitive Skin Sunscreen SPF 60+ was provided by Restorsea for distribution to subjects.¹³

From the pool of potentially eligible patients, 30 female patients were selected for the study and followed the institutional review board (IRB) protocol. The hydrolyzed roe cream was applied to one side of the face and the opposite side remained untreated. The side of the face to be treated was in accordance with a computer-generated randomization schedule. Evaluations consisted of objective dermal irritation assessments and Visia-CR™ (Canfield Scientific, Inc., Parsippany, New Jersey) digital photographs at designated study intervals.¹⁴ Photographs were taken at baseline, and at 8 and 24 hours post facial peel.

Eligible subjects had to be women between 30 and 65 years of age; have Fitzpatrick skin type I, II, or III; be in generally good health; and have a current Panelist Profile/Medical History Form on file. The subject had to be free of any skin disorders that might influence test results or preclude peel/test material application. In addition, the subject could not exhibit facial erythema or edema at the baseline evaluation, had to be willing to receive a peel treatment on the face at the CRL facility, and exhibit slight-to-moderate (level 1 to level 3) erythema following the facial peel.

The subject had to demonstrate dependability and intelligence in following directions, agree to make a reasonable effort to avoid prolonged

sun exposure and tanning salons during the course of this study, and to refrain from using any facial treatment products, other than the provided test material and soap for the duration of the study. All subjects signed an informed consent form in conformance with 21CFR Part 50: "Protection of Human Subjects"; completed a Health Insurance Portability and Accountability Act (HIPAA) Authorization Form in conformance with 45 CFR Parts 160 and 164, and signed a photography release form, providing consent for the capture of facial digital images for use in relation to this clinical study.

Exclusion criteria were pregnancy; planning a pregnancy; nursing; allergies to soap, cosmetic or toiletry products, topical medications, or alpha hydroxy acids; and subject self-perceived sensitive skin. Any subject who exhibited and/or reported a history of acute or chronic dermatologic or medical condition, which would preclude application of the peel/test material and/or could influence the outcome of the study (for example, uncontrolled disease, such as diabetes, hyperthyroidism, or hypothyroidism; history of hepatitis, immune deficiency, or autoimmune disease; participation in a study utilizing the face within two weeks of study initiation; and taking any systemic oral medications, including, but not limited to, sympathomimetics, antihistamines, vasoconstrictors, nonsteroidal anti-inflammatory agents, and/or systemic and/or topical corticosteroids within two weeks prior to initiation of the study) was



TABLE 1. Post-peel frequencies of erythema and edema

ASSESSMENT	TIME POINT	REBALANCING LOTION							p-VALUES	
		FREQUENCY					MEAN ± STD	MEAN CHANGE		p-VALUE†
		0*	1	2	3					
ERYTHEMA	Baseline Pre-Peel	30	0	0	0	0.0 ± 0.0				
	Baseline Post-Peel	0	3	19	8	2.2 ± 0.6				
	Baseline Post-Application	0	5	23	2	1.9 ± 0.5	-0.3 ± 0.5	0.0156	0.5000	
	8 Hours	0	21	8	1	1.3 ± 0.5	-0.8 ± 0.6	<0.0001	<0.0001	
	24 Hours	6	23	1	0	0.8 ± 0.5	-1.3 ± 0.7	<0.0001	<0.0001	
EDEMA	Baseline Pre-Peel	30	0	0	0	0.0 ± 0.0				
	Baseline Post-Peel	30	0	0	0	0.0 ± 0.0				
	Baseline Post-Application	30	0	0	0	0.0 ± 0.0	0.0 ± 0.0	NA	NA	
	8 Hours	30	0	0	0	0.0 ± 0.0	0.0 ± 0.0	NA	NA	
	24 Hours	30	0	0	0	0.0 ± 0.0	0.0 ± 0.0	NA	NA	

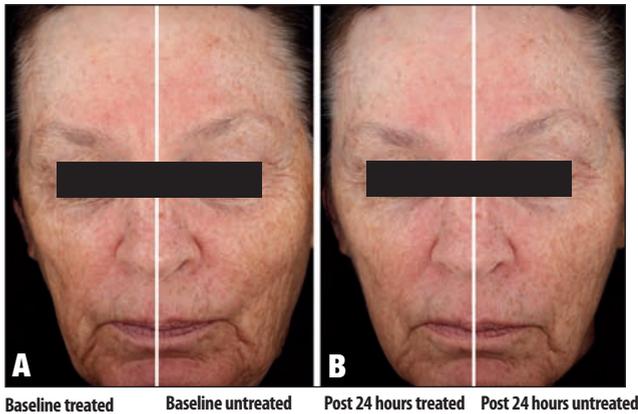
TABLE 1 continued. Post-peel frequencies of erythema and edema

ASSESSMENT	TIME POINT	UNTREATED							p-VALUES	
		FREQUENCY					MEAN ± STD	MEAN CHANGE		P-VALUE†
		0	1	2	3					
ERYTHEMA	Baseline Pre-Peel	30	0	0	0	0.0 ± 0.0				
	Baseline Post-Peel	0	3	19	8	2.2 ± 0.6				
	Baseline Post-Application	0	3	25	2	2.0 ± 0.4	-0.2 ± 0.4	0.0313	0.5000	
	8 Hours	0	6	23	1	1.8 ± 0.5	-0.3 ± 0.5	0.002	<0.0001	
	24 Hours	0	17	13	0	1.4 ± 0.5	-0.7 ± 0.6	<0.0001	<0.0001	
EDEMA	Baseline Pre-Peel	30	0	0	0	0.0 ± 0.0				
	Baseline Post-Peel	30	0	0	0	0.0 ± 0.0				
	Baseline Post-Application	30	0	0	0	0.0 ± 0.0	0.0 ± 0.0	NA	NA	
	8 Hours	30	0	0	0	0.0 ± 0.0	0.0 ± 0.0	NA	NA	
	24 Hours	30	0	0	0	0.0 ± 0.0	0.0 ± 0.0	NA	NA	

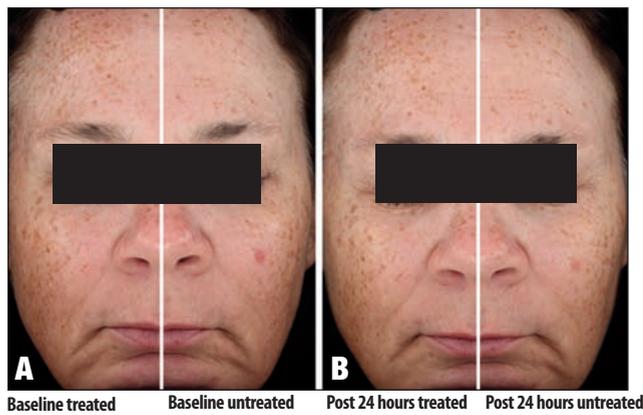
STD = standard deviation
 *Severity score: 0=none, 1=slight, 2=mild, 3=moderate, 4=severe (no subject met this criterion therefore no column with this score appears in the Table)
 Bold/italics indicate statistical significance. NA=not applicable. All edema scores were zero. Therefore, it is neither possible nor necessary to compare identical zero scores.
 †Comparison of post-peel and each post-treatment evaluation
 ‡Comparison of differences in change from baseline post-peel at each evaluation between the treated and untreated sides of the face



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Figures 1A–1B. A 65-year-old woman at baseline post-peel and at 24 hours. (A) Baseline post-peel; erythema scores: treated = 3.0, untreated = 3.0. (B) 24 hours post-peel; erythema scores: treated = 1.0, untreated = 2.0. Changes from baseline post-peel: treated = -2.0, untreated = -1.0



Figures 3A–3B. A 47-year-old woman at baseline post-peel and at 24 hours. (A) Baseline post-peel; erythema scores: treated = 2.0, untreated = 2.0. (B) 24 hours post-peel; erythema scores: treated = 1.0, untreated = 1.0. Changes from baseline post-peel: treated = -1.0, untreated = -1.0

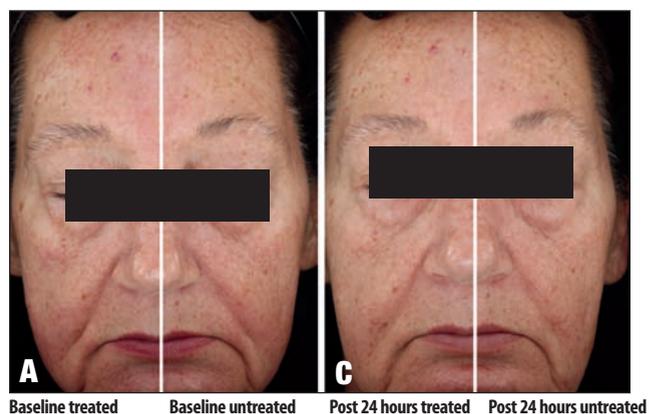
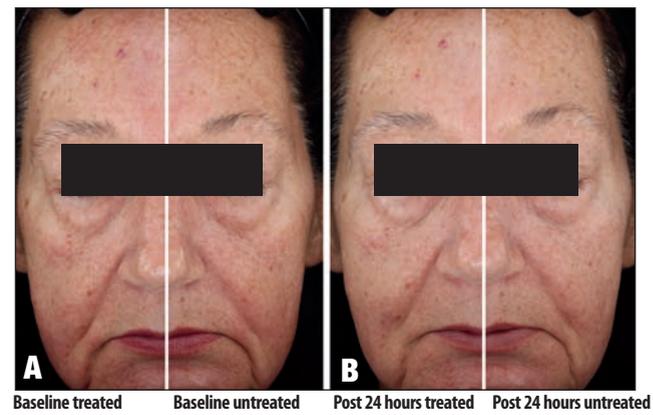
ineligible. Any subject who exhibited an adverse reaction to previous peels was excluded.

After admission to the study, the subject could withdraw at any time for any reason, but the reason must be reported fairly and accurately. Unless otherwise designated by Restorsea, subjects were not provided with information regarding the identity of the test material(s). The grader was blinded to treatment assignment to the left or right side of the face. Test materials were labeled with unique CRL study identification and panel codes and subject numbers upon test material receipt by CRL.

Digital clinical photography—Visia-CR facial imaging. The efficacy of skin treatment products was



Figures 2A–2B. A 57-year-old woman at baseline post-peel and at 24 hours. (A) Baseline post-peel; erythema scores: treated = 2.0, untreated = 2.0. (B) 24 hours post-peel; erythema scores: treated = 1.0, untreated = 1.0. Changes from baseline post-peel: treated = -1.0, untreated = -1.0



Figures 4A–4C. A 57-year-old woman at baseline post-peel and at and 24 hours. (A) Baseline post-peel; erythema scores: treated = 3.0, untreated = 3.0. (B) 24 hours post-peel; erythema scores: treated = 2.0, untreated = 2.0. Changes from baseline post-peel: treated = -1.0, untreated = -1.0. (C) 24 hours post-peel; erythema scores: treated = 1.0, untreated = 2.0. Changes from baseline post-peel: treated = -2.0, untreated = -1.0

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assessed by means of Canfield's Visia-CR photo imaging equipment (Canon EOS-1Ds Mark III camera). Visia-CR has multiple built in lighting modes and can acquire up to seven images in one sitting from a user-definable shooting template. Subjects can be photographed using standard light, ultraviolet (UV), cross-polarization, and parallel-polarization techniques, which produce high-quality, reproducible facial images. Canfield's RBX Technology for subsurface red/brown analysis provides visualization of melanin and vascular conditions.

Features include an adjustable forehead rest, a stationary chin cup with multiple settings, three positioning mirrors, and image preview tools to assure proper repositioning of the panelist from baseline to endpoint without obscuring the area of interest. Video preview and display overlay tools further facilitate consistent positioning of each subject. This ensures that any observed changes are attributable to the use of the test material.

One set of images (front, left, and right views) was captured using standard lighting, and cross-polarized lighting remained consistent from visit to visit to ensure photographs can be compared. Special attention was placed on the subject positioning. All subjects were photographed with eyes closed and hair pulled off the forehead and away from the cheeks using a hair band. No makeup was worn during the photographs including foundation, blush, eye shadow, lipstick, and mascara. Subjects were required to

remove all jewelry in the test area prior to having photographs taken.

Dermal procedures and evaluations. A blinded investigator assessed and graded the severity of facial erythema and edema on each side of the face at baseline, 8 hours, and 24 hours after chemical peel. For each parameter, erythema and edema, a 5-point scoring scale was used; 0=none, 1=slight, 2=mild, 3=moderate, 4=severe.

At the baseline visit, subjects arrived at the laboratory with a clean face, free of makeup. Inclusion/exclusion criteria were verified and informed consent/photography release forms were read and signed by each subject. Subjects who met all of the study requirements continued participation.

Prior to treatment, one set of images (front, left and right views) was captured using Canfield's Visia-CR photo imaging equipment. Chemical peel treatment procedures were performed on the full face by a licensed cosmetologist in accordance with package instructions. The peel remained on the skin for 4 to 15 minutes. The exact time for each subject was determined by the cosmetologist and documented in the study file. An expert grader assessed facial skin erythema and edema according to a 5-point scoring scale; 0=none, 1=slight, 2=mild, 3=moderate; 4=severe. Subjects exhibiting slight-to-moderate erythema (grades 1–3) were enrolled for study participation. Post-peel digital images were obtained, and subjects completed a consumer perception questionnaire.

The hydrolyzed roe cream lotion was applied immediately after the facial peel treatment in accordance with a computer-generated randomization schedule. A CRL technician applied the lotion to the designated side of the face only. Fifteen minutes following the initial application, digital images were obtained and an expert grader assessed facial skin erythema and edema. Subjects were instructed to return to the laboratory eight hours (± 30 minutes) following the facial peel. Sunscreen with SPF 60 was applied to the entire face prior to leaving the laboratory and given to subjects to use as needed. Subjects were instructed to refrain from applying any skin treatment products/cosmetics to the face and to avoid sun exposure for the duration of the study.

At eight hours (± 30 minutes) following the facial peel, subjects returned to the CRL facility. One set of images (front, left, and right views) was captured using photo imaging equipment. An expert grader assessed facial skin erythema and edema. Afterwards, a CRL technician applied the test material to the designated side of the face in accordance with the computer-generated randomization schedule. Subjects were given nonmoisturizing soap and detailed study instructions.

Subjects returned for their second evaluation at 24 hours (± 30 minutes) following the facial peel. As before, one set of images (front, left, and right views) was captured using photo imaging equipment, and an expert grader assessed facial skin erythema and edema. Subjects completed the consumer perception

TABLE 2. Subjects' agreement ($\geq 50\%$) with hydrolyzed roe cream attributes

TIME POINT	ATTRIBUTE
8 HOURS	<ul style="list-style-type: none"> Reduced post-peel redness Reduced post-peel swelling Reduced post-peel irritation Skin feels hydrated/moisturized immediately after application Skin feels hydrated/moisturized
24 HOURS	<ul style="list-style-type: none"> Like the scent of the product Like the texture of this product Saw an overall improvement to skin's appearance Skin feels softer and smoother Reduced post-peel redness Reduced post-peel swelling Reduced post-peel irritation Absorbs just right, not too long, not too fast Skin feels hydrated/moisturized Fulfills needs for post-peel application Not too heavy for the subject's skin type Gentle/non-irritating to skin Love the product Would purchase this product Would recommend this product to a friend Prefer this product over my usual product Would use this product depending on skincare needs

questionnaire. Subjects exhibiting any irritation were followed until resolution.

All adverse events were to be documented in the subject's source documentation and reported to Restorsea promptly. Expected reactions from the peel, such as mild-to-moderate tingling, itching, heat/burning sensation, peeling, and redness, were not considered adverse events. Occurrences of severe erythema were to be reported as adverse events and followed to resolution.

Subjects were required to take a two-part consumer perception questionnaire post-peel. The first section of the questionnaire contained five questions and was given at the 8-hour timepoint. The second section contained 18 questions and was given at the 24-

hour timepoint. One of the 18 questions was open-ended but not scored, and the possible responses for another question were "I love it," "It's OK," or "I didn't like it." The possible responses to the remaining 16 of the 18 questions were strongly agree, agree, neither agree nor disagree, disagree, strongly disagree.

RESULTS

A total of 30 female subjects, ranging in age from 33 to 65 years with an average age of 54.9 years and in generally good health, were selected for the study. Subjects who met all of the inclusion/exclusion criteria were enrolled for participation.

The peel remained on the face for 10 minutes for subject numbers 1 through 23 and 15 minutes for subject numbers 24 through 30.

Statistically significant reductions in erythema were observed for both treated and untreated sides of the face at each post-treatment interval compared to the immediate post-peel evaluation. Importantly, the reduction in erythema was statistically greater for the side of the face treated with hydrolyzed roe cream compared to the untreated side of the face at 8 hours and at 24 hours post-peel. No edema was observed during the study (Table 1).

Four typical subjects with reduced post-peel erythema are presented (Figures 1–4). Each pair of photographs shows the treated side on the left (right side of the face) and the untreated side on the right (left side of the face). Figures 1 to 4 show results at baseline post-peel and at 24 hours. Figure 4 also shows the patient's results at eight hours post-peel. Under the conditions of this study and in this test population, the hydrolyzed roe cream demonstrated a potential to reduce facial redness following a chemical peel treatment. All subjects completed the study. No adverse events were reported during the study.

All subjects completed questionnaires at 8 hours and 24 hours after peel procedures followed by hydrolyzed roe cream application. The majority of subjects ($>50\%$) agreed on the five attributes at 8 hours and 17 at 24 hours (Table 2).

More than 90 percent of subjects strongly agreed or agreed that the hydrolyzed roe cream reduced skin redness and irritation from the peel within 24 hours, and after 24 hours strongly agreed or agreed that skin feels perfectly hydrated and moisturized. At eight hours, ≥ 80



TABLE 3. Subject responses to questionnaire

QUESTION	STRONGLY AGREE		AGREE		NEITHER AGREE NOR DISAGREE		DISAGREE		STRONGLY DISAGREE	
	#	%	#	%	#	%	#	%	#	%
8 HOURS POST-PEEL										
1. This product reduced the redness in my skin from the peel in 8 hours.	10	33.30%	10	33.30%	8	26.70%	2	6.70%	0	0.00%
2. This product reduced the swelling in my skin from the peel in 8 hours.	10	33.30%	8	26.70%	11	36.70%	1	3.30%	0	0.00%
3. This product reduced the irritation from the peel in 8 hours.	11	36.70%	11	36.70%	6	20.00%	2	6.70%	0	0.00%
4. After application of the product, my skin instantly feels perfectly hydrated/ moisturized immediately after application.	11	36.70%	13	43.30%	3	10.00%	3	10.00%	0	0.00%
5. After 8 hours, my skin feels perfectly hydrated/moisturized.	14	46.70%	11	36.70%	1	3.30%	4	13.30%	0	0.00%
24 HOURS POST-PEEL										
1. I like the scent of this product.	12	40.00%	14	46.70%	4	13.30%	0	0.00%	0	0.00%
2. I like the texture of this product.	14	46.70%	12	40.00%	3	10.00%	1	3.30%	0	0.00%
3. I saw an overall improvement to my skin's appearance.	13	43.30%	10	33.30%	4	13.30%	3	10.00%	0	0.00%
4. My skin feels softer and smoother.	14	46.70%	11	36.70%	3	10.00%	2	6.70%	0	0.00%
5. This product reduced the redness in my skin from the peel in 24 hours.	12	40.00%	16	53.30%	2	6.70%	0	0.00%	0	0.00%
6. This product reduced the swelling in my skin from the peel in 24 hours.	11	36.70%	14	46.70%	5	16.70%	0	0.00%	0	0.00%
7. This product reduced the irritation from the peel in 24 hours.	15	50.00%	13	43.30%	2	6.70%	0	0.00%	0	0.00%
8. This product absorbs just right, not too long, not too fast.	13	43.30%	13	43.30%	3	10.00%	1	3.30%	0	0.00%
9. After 24 hours, my skin feels perfectly hydrated/moisturized.	11	36.70%	17	56.70%	1	3.30%	1	3.30%	0	0.00%
10. This product is the answer to my skin's needs for post-peel application.	9	30.00%	12	40.00%	8	26.70%	1	3.30%	0	0.00%
11. This product was too heavy for my skin type.	3	10.00%	4	13.30%	6	20.00%	11	36.70%	6	20.00%
12. This product was gentle/non-irritating to my skin.	15	50.00%	11	36.70%	2	6.70%	2	6.70%	0	0.00%
14. I would purchase this product.	12	40.00%	11	36.70%	4	13.30%	1	3.30%	2	6.70%
15. I would recommend this product to a friend.	12	40.00%	12	40.00%	3	10.00%	2	6.70%	1	3.30%
16. I prefer this product over my usual product.	11	36.70%	6	20.00%	9	30.00%	2	6.70%	2	6.70%
18. I would use this product depending on my skincare needs.	12	40.00%	14	46.70%	2	6.70%	1	3.30%	1	3.30%



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percent of subjects strongly agreed or agreed that hydrolyzed roe cream treated skin feels perfectly hydrated and moisturized immediately after application and after eight hours (Table 3).

When subjects were asked “What is your overall impression of this product?” 60 percent (18 patients) responded “I love it”, 36.7 percent (11 patients), “It’s OK,” and 3.3 percent (1 patient) did not like the product.

DISCUSSION

Glycolic acid facial peels are frequently associated with irritation and need to be properly neutralized in order to stop acidification of the skin since excess acid must be neutralized to avoid burning.¹⁵ Alpha-hydroxy acid peels can be neutralized with water or with basic solutions, such as ammonium salts, sodium bicarbonate, or sodium hydroxide.⁵ Various commercial products are available to restore the pH of the skin after peeling.¹⁶

The lotion used in this study is anchored by hydrolyzed roe (proprietary enzyme extracted from post-hatching salmon fluid that allows for continuous exfoliation without any inflammation); brown algae extract that helps soothe, calm, and moisturize skin; and AA2G, a natural vitamin C stabilized with glucose that acts as an antioxidant to help protect the skin from the harmful effects of free radicals. Other ingredients are squalane to help prevent moisture loss and restore suppleness and flexibility to skin and shea butter to help soothe, calm, and moisturize skin.

Hydrolyzed roe cream lotion was

found to reduce the appearance of redness and inflamed skin and to calm and soothe stressed skin. Subjects mostly agreed that skin felt smoother, softer, and firmer.

CONCLUSION

Hydrolyzed roe cream alleviates side effects of chemical peels. When applied directly on post-procedure skin, it reduces redness after 8 and 24 hours significantly better compared to no treatment.

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