

A Placebo-Controlled Study of an Oral Supplement in Improving the Appearance of Photo Aged Skin

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Introduction

A novel oral supplement, Imedeem Time Perfection™, was tested for effects on photo aged skin.

Imedeem Time Perfection™ contained per day:

Biomarine Complex™	210 mg
Lycophence GS™ providing:	200 mg
• Tomato extract (incl. Lycopene)	29 mg
• Grape Seed Extract (incl. Oligomeric procyanidins)	28 mg
Acerola Extract (Natural Vitamin C)	60 mg

Materials and methods

12 weeks Randomized Double-Blind, Placebo-Controlled trial
74 female subjects (Age 35-60).

- 36 subjects: Imedeem Time Perfection™
- 38 subjects: Placebo Tablet Control
- 2 tablets / day

Individuals who presented with the following features were qualified for study participation:

- Fitzpatrick Skin Classification of I to III
- Modified Glogau score of II or III
- Mild to moderate fine lines and wrinkles

All subjects were provided with the same cleanser and moisturizer (with sunscreen) to use throughout the study to assure standardized conditions for topical skin treatment. Study outline is shown in Table 1.

Visit	Inclusion and Exclusion	
Visit 1 Screening		
Visit 2 Baseline	Clinical Grading TEWL NOVA	Self-Assessment Questionnaires Cutometer Ultrasound
Visit 3 4 weeks	Compliance Evaluation	Self-Assessment Questionnaires
Visit 4 8 weeks	Compliance Evaluation	Self-Assessment Questionnaires
Visit 5 12 weeks	Compliance Evaluation Clinical Grading TEWL NOVA	Self-Assessment Questionnaires Cutometer Ultrasound

Table 1

Clinical grading - Facial photo aging

Facial photo aging parameters shown in table 2 were assessed with a scale, where 0 < 3 = mild, 3.5 < 6 = moderate and 6 < 9 = severe.

Clinical Grading	Baseline		Week 12		ANOVA* p-value	
	Mean	SD	Mean	SD		
Imedeem Time Perfection™ (n=36)	Mottled Hyperpigmentation	4.97	1.34	4.54	1.48	0.0161
	Tactile Laxity/Sagging	4.00	1.26	3.38	1.19	0.0500
	Dull/Matte/Sallow Appearance	4.47	1.28	3.32	1.16	0.0126
	Tactile Roughness/Texture	2.81	1.56	1.28	1.07	0.0320
	Global Assessment	5.58	0.94	4.40	1.22	0.0017
	Average of all Parameters	3.96	0.61	3.03	0.68	0.0038
Placebo Tablet Control (n=38)	Mottled Hyperpigmentation	4.74	1.42	4.55	1.47	
	Tactile Laxity/Sagging	3.83	1.14	3.43	1.01	
	Dull/Matte/Sallow Appearance	4.26	1.14	3.58	1.22	
	Tactile Roughness/Texture	2.49	1.93	1.58	1.46	
	Global Assessment	5.64	1.08	4.99	1.30	
	Average of all Parameters	3.89	0.72	3.25	0.72	

Table 2

* Statistical comparisons between groups.

Improvement for pore size, visual laxity, visual roughness and under eye dark circles for Imedeem Time Perfection™ were borderline significant (p<0.10). All other facial clinical grading variables were in favour of Imedeem Time Perfection™, but not significant.

TEWL - Barrier function Cutometer - Skin elasticity

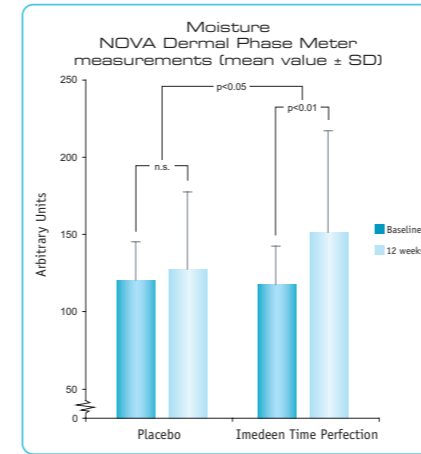
The mean scores of TEWL at both visits for Imedeem Time Perfection™ and Placebo groups were within a normal physiological range, not significantly different between groups.

The change in Cutometer measurements from baseline to 12 weeks were minimal and not significantly different between the groups.

Results

Nova DPM - Moisture

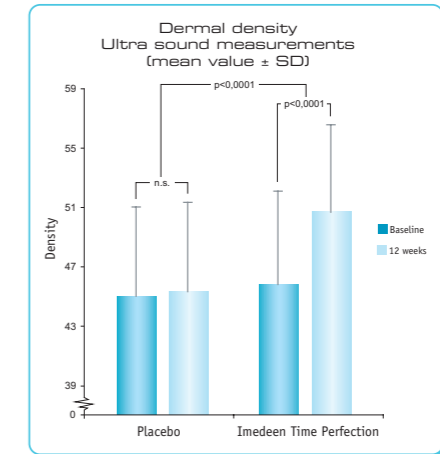
NOVA Dermal Phase Meter (DPM) 9003 measurements were taken to assess skin moisturization. Duplicate measurements were taken on the center of the cheek.



There was a significantly greater increase (improvement +30%) (p<0.05) for the Imedeem Time Perfection™ test group compared to the Placebo Tablet Control group for NOVA DPM values on the cheek.

Ultrasound - Skin density

A DUB 20 (Taberna, Pro Medicum, AG) Ultrasound unit was used to take a B scan of each subject's left periorbital area.



There was a significantly greater increase (improvement) (p<0.0001) for the Imedeem Time Perfection™ test group compared to the Placebo Tablet Control group for skin density.

Self-assessment Questionnaires

Self assessment	% Favorable response for ITP group
Week 4 Facial Skin: - Dilated capillaries	67%
Week 8 Facial Skin: - Dilated capillaries - Dryness	67%
Week 12 Facial Skin: - Texture - Dryness - Softness Body Skin: - Texture - Overall dryness	72%
	78%

Table 3

At each visit, a significantly greater proportion of subjects who used Imedeem Time Perfection™ supplements, but not Placebo Tablet Control, responded positively for attributes as shown in Table 3:

All other variables were also in favour of Imedeem Time Perfection™, but did not reach significance

Conclusion

This 12 week double-blinded, placebo-controlled study shows that Imedeem Time Perfection™ proved to be effective in improving the appearance of photo aged skin, and clearly indicates that individuals with photo aged skin may benefit from daily use of this supplement.

Ferrosan

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