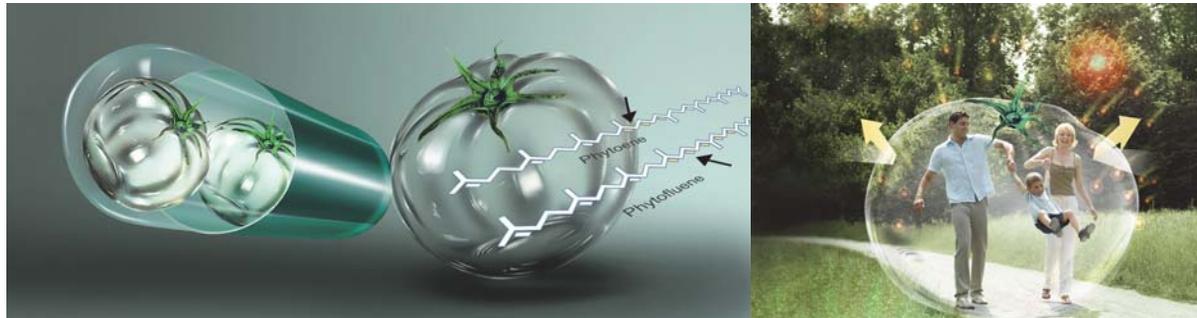


Abstract:

Carotenoids are one natural way of protecting against excessive irradiation, as seen in carotenogenic organisms. Humans do not produce carotenoids, but may accumulate them from their diet. Carotenoids are widely used in dietary supplements, but the use of strongly colored carotenoids may result in coloration of the skin. Phytoene and phytofluene are the first carotenoids in the biosynthesis of all other carotenoids in nature. These carotenoids absorb light in the UV range only, and are thus devoid of visible color. Phytoene and phytofluene have been reported to be bioavailable and accumulate in several tissues, including the skin.



Protection from UV exposure and natural safe skin lightening are two ongoing needs of the personal care industry, commonly achieved through external means such as sun avoidance, shading, or sunscreen application. To assess the photoprotective and skin lightening effects of phytoene and phytofluene by oral intake in humans, two clinical studies were conducted, results of which are presented here: a photoprotection study (tracking the evolution of MED) and a skin lightening study (tracking the evolution of skin tone by colorimetry), with dietary consumption of a tomato powder food supplement rich in phytoene and phytofluene. The results showed, respectively: a significant increase in MED, i.e. a photoprotective effect; and, a significant skin lightening effect. Both studies demonstrate the capacity of phytoene and phytofluene to provide the skin with photoprotective power, and to lighten and even out the skin tone, through dietary consumption in the form of a proprietary tomato powder rich in these colorless carotenoids.

Studies Aims:

- To evaluate skin photo-protection and skin tone lightening with dietary consumption of a tomato powder rich in phytoene and phytofluene (PhytofORAL®) and their effect on skin qualities.
- In both studies, an additional assessment of skin quality parameters on subjects' face, was performed separately by an expert clinician and by the study participants (self-evaluation) for characteristics such as: dryness, roughness, suppleness, evenness of the complexion and skin texture.

The studies were open and intra-individual studies, each with n=22, average age 24±1 years old (between 20 and 40). Skin phototype was II and IV for the photoprotection and lightening study respectively.

Results:

Skin Lightening Effect

Skin Lightening: Skin color was measured using a spectroradiometer and skin lightening was evaluated as a change in colorimetric parameters L*, b* and ITA°.

L* (from dark to light) Change from baseline D0					
Timepoint	Delta	SEM	95% CI	% subjects improved	p-value
D42 vs D0	0.62	0.17	[0.29;0.95]	73	0.001
D84 vs D0	0.61	0.24	[0.13;1.08]	73	0.02

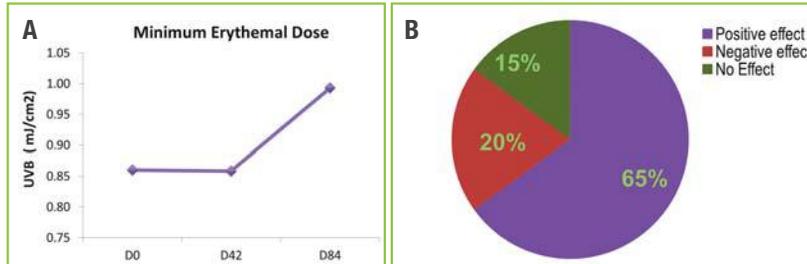
L* - (from dark to light). This is the lightness parameter. An increase in this parameter characterizes a **lightening of the skin**.

Individual Typological Angle (ITA°) Change from baseline D0					
Timepoint	Delta	SEM	95% CI	% subjects improved	p-value
D42 vs D0	1.08	0.39	[0.35;1.82]	77	0.009
D84 vs D0	1.43	0.57	[0.36;2.50]	82	0.02

ITA° - (Individual Typological Angle). This parameter shows the skin pigmentation degree of a subject using the lightness (L*) and cutaneous melanin parameters (b*). An increase in the ITA° parameter characterizes a **decrease in skin pigmentation**.

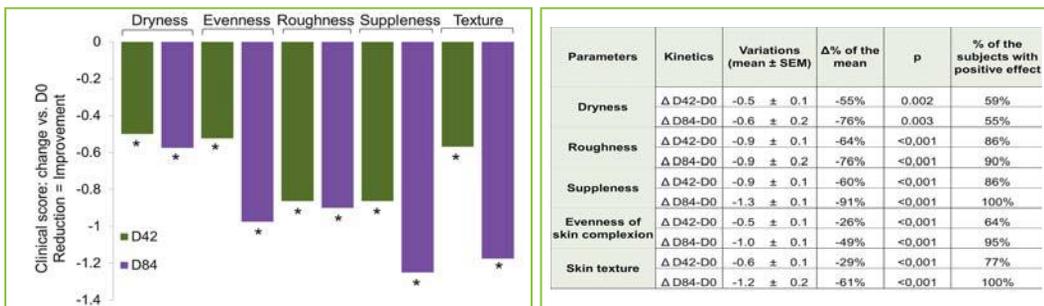
Results:

Photo-Protective Effect



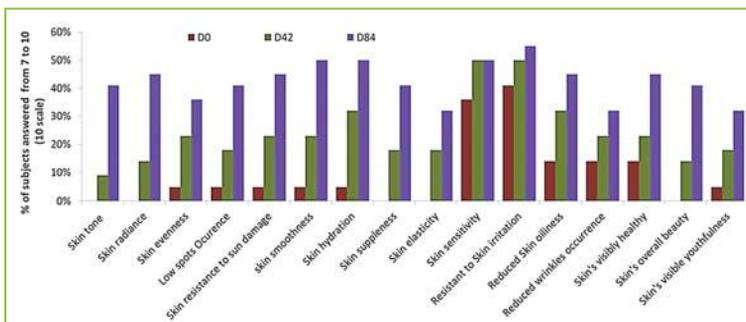
Photoprotection: (A) Minimum Erythral Dose (MED), corresponding to the minimum irradiation dose inducing a clearly contoured erythral filling. Subjects were evaluated for MED at day zero and the following indicated days. A photoprotective effect is described as an increase in MED value. (B) Photoprotective distribution among the tested subjects.

Clinical Scoring of Skin Parameters



Clinical Scoring: The tested subjects were assessed for skin quality parameters by an expert clinician. Each parameter was evaluated separately and was characterized with descriptive score and statistics.

Subjective Evaluation



Subjective evaluation: Self assessment of the study participants skin quality as evaluated by a detailed questionnaire. Skin quality estimation was scored by the subjects in a scale ranging from 1-10 (1=low quality, 10=high quality). Results are presented as percent of subjects that indicated high quality skin by scoring between 7 to 10 for the above parameters.

Conclusions:

Under the study conditions, PhytoFLOREAL®, a tomato powder rich in Phytoene and Phytofluene, provided:

- ✓ a significant photoprotective effect
- ✓ a significant skin lightening effect
- ✓ a significant improvement in several key skin quality parameters resulting in overall anti aging effect.

These results provide evidence that dietary supplements containing phytoene and phytofluene may help protect the skin against photo-damage, as well as deliver safe and natural skin lightening from within. They may also confirm indirectly literature evidence for high skin bioavailability of ingested phytoene and phytofluene. Additional studies with PhytoFLOREAL® are required to confirm. PhytoFLOREAL® provides a natural and unique product to maintain beautiful, healthy, radiant and younger looking skin from within

Future Plans:

IBR is actively looking for partners for future studies with oral and topical phytoene and phytofluene.