PRO-HEAL® SERUM ADVANCE+ STUDY

induced inflammation study

PREVENTION OF INFLAMMATION

STUDY OBJECTIVE The ability of PRO-HEAL® SERUM ADVANCE+ to prevent or decrease skin inflammation was investigated.

STUDY DESIGN Inflammation was induced by a detergent applied to human skin. On the control side, only the detergent was applied. On the treated side, PRO-HEAL® SERUM ADVANCE+ was applied before the detergent.

Both sides were visually evaluated using the following parameters — erythema, roughness, scaling, edema and fissures. Both the control side and treated side were biopsied. A full-thickness biopsy was performed and sent to a dermatopathologist for histologic examination. Photomicrographs were taken.

SIGNIFICANCE OF STUDY Many pathologic processes (such as sunburn, insect bites, rosacea, acne, etc.) involve inflammation. A certain amount of inflammation is necessary for healing and normal immune processes. However, excess inflammation is associated with increased oxidative stress and free radical damage. Excess inflammation causes negative effects on skin and is associated with photoaging, intrinsic aging, scarring, thickening and other chronic inflammatory events. Products that control excess inflammation have potential wide application.

RESULTS AND CONCLUSIONS The side treated with PRO-HEAL® SERUM ADVANCE+ exhibited minimal visual changes due to induced inflammation compared to the control. Histology demonstrated preservation of normal skin architecture on the treated side. The control side demonstrated marked cellular edema, influx of inflammatory cells and destruction of normal skin architecture.

A cumulative inflammation score was given by an examiner and included the parameters of erythema, roughness, scaling, edema and fissure formation. The highest possible score of inflammation was +20. On the side treated with PRO-HEAL® SERUM ADVANCE+, the cumulative inflammation score was +1 after 48 hours. On the untreated control side, the cumulative inflammation score after 48 hours was +11. Application of PRO-HEAL® SERUM ADVANCE+ provided near-complete protection against inflammatory damage caused by an applied strong detergent. A table of the cumulative inflammation score is shown below:

PRO-HEAL® ADVANCE+ CLINICIAN'S INFLAMMATION SCORE TABLE

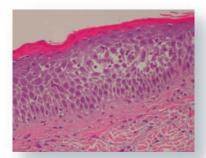
PARAMETER	CONTROL (no PRO-HEAL® SERUM ADVANCE+)	TREATED (with PRO-HEAL® SERUM ADVANCE+)
Erythema (0 - +4)	+3	+1
Roughness (0 -+4)	+2	0
Scaling (0 - +4)	+3	0
Edema (0 - ⁺ 4)	+1	0
Fissure Formation (0 -+4)	+2	0
Cumulative Score (0 - +20)	±11	.1

PRO-HEAL® SERUM ADVANCE+ STUDY

induced inflammation study

Biopsies were performed on the same subject in the experiment above. Photomicrographs of the control side and side pretreated with PRO-HEAL® SERUM ADVANCE+ are shown below. These are both H and E stains of full-thickness skin biopsies. The control side shows marked inflammation with migration of lymphocytes and Langerhans cells into the area, edema and destruction of normal skin architecture. On the side treated with PRO-HEAL® SERUM ADVANCE+, inflammatory cells are conspicuously absent and normal skin architecture is preserved.

EFFECTS ON INFLAMMATION



High power: Time: 48hrs - H & E stain control

High power: Time: 48hrs - H & E stain with PRO-HEAL® SERUM ADVANCE+

Note the marked inflammation with migration of lymphocytes and Langerhans cells into the area. Edema occurs and normal skin architecture is lost.

Note the absence of inflammatory cells and preservation of normal skin architecture.

Dermatopathology independently performed by PAML/InCyte