

Cream-gel containing azeloglycine and Centella asiatica extract is effective in reducing erythema and inflammatory lesions in patients with rosacea

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Introduction

Rosacea is a chronic inflammatory disease that manifests mainly on face skin in form of erythema, telangiectasias, swelling and inflammatory papules or pustules. Moreover, episodes of flushing are very common. Effective rosacea treatment should be aimed to maximize the duration of remission.

The aim of this study was to examine the efficacy, safety and tolerability of the cream-gel no. 1449 containing azeloglycine, *Centella asiatica* extract (reduces telangiectasia), *Hamamelis Virginiana* Leaf Water (witch hazel water, anti-inflammatory agent) and *Agastache Mexicana* Flower/Leaf /Stem Extract (reduces inflammation due to psychological stress) in patients with rosacea.

Methods

In vivo: In this open-label study, we included adults aged 20-70 with diagnosis of rosacea regarding NRS classification. They were asked to apply the gel no. 1449 on the cleansed face skin twice daily for 4 weeks. Satisfaction and self-reported changes in skin appearance were measured on an analogue scale or assessed by a dermatologist (ongoing test). Instrumental skin evaluation was done at the baseline and after 4 weeks of product application. Severity of erythema (Mexamater), visibility of dilated blood vessels (Visioface) and amount of porfirins (Visia) were evaluated in the group of 18 volunteers. All testing was performed by experienced technicians, using a single device, in the same room and under the same environmental conditions. Additionally in dermatological trial, 15 patients with rosacea undergoing medical treatment (ivermectinum, isotretinoinum or clindamicin with tretinoin) were included.

Dermatological patch test: The skin of 40 healthy adults was exposed to tested formulation with Finn Chamber patches. The appearance of skin irritations was assessed after 48 and 72 hours.

Results

Forty two subjects with stages 1-3 of rosacea were included and completed the study. Twelve subjects were examined in the Dr Irena Eris Centre for Science and Research and thirty patients were included from an independent scientific laboratory. Instrumental skin analysis showed decrease in erythema and visibility of dilated blood vessel. We did not report any change in the number of porfirins, however 75% of the participants have noticed a decrease in the number of inflammatory spots (pustules, papules). The mean self-reported improvement in skin moisturization was 63%. Product was well tolerated even while used around the eye area. No allergy reaction was reported. Similarly, the patch test results showed that use of 1449 does not irritate the skin. In dermatological evaluation the product was calming the skin, had moisturization effect and in 50% cases reduced skin redness (data not shown).

Conclusion

The cream-gel no. 1449 was well-tolerated. It may be considered as an effective formulation to reduce erythema and number of papules and pustules in patients with rosacea. Further clinical studies with assessments by dermatologists displayed safety of the cream. Tested product can be used together with medications for rosacea as well as a continuation of treatment after completing medical treatment.

Results from the independent scientific laboratory

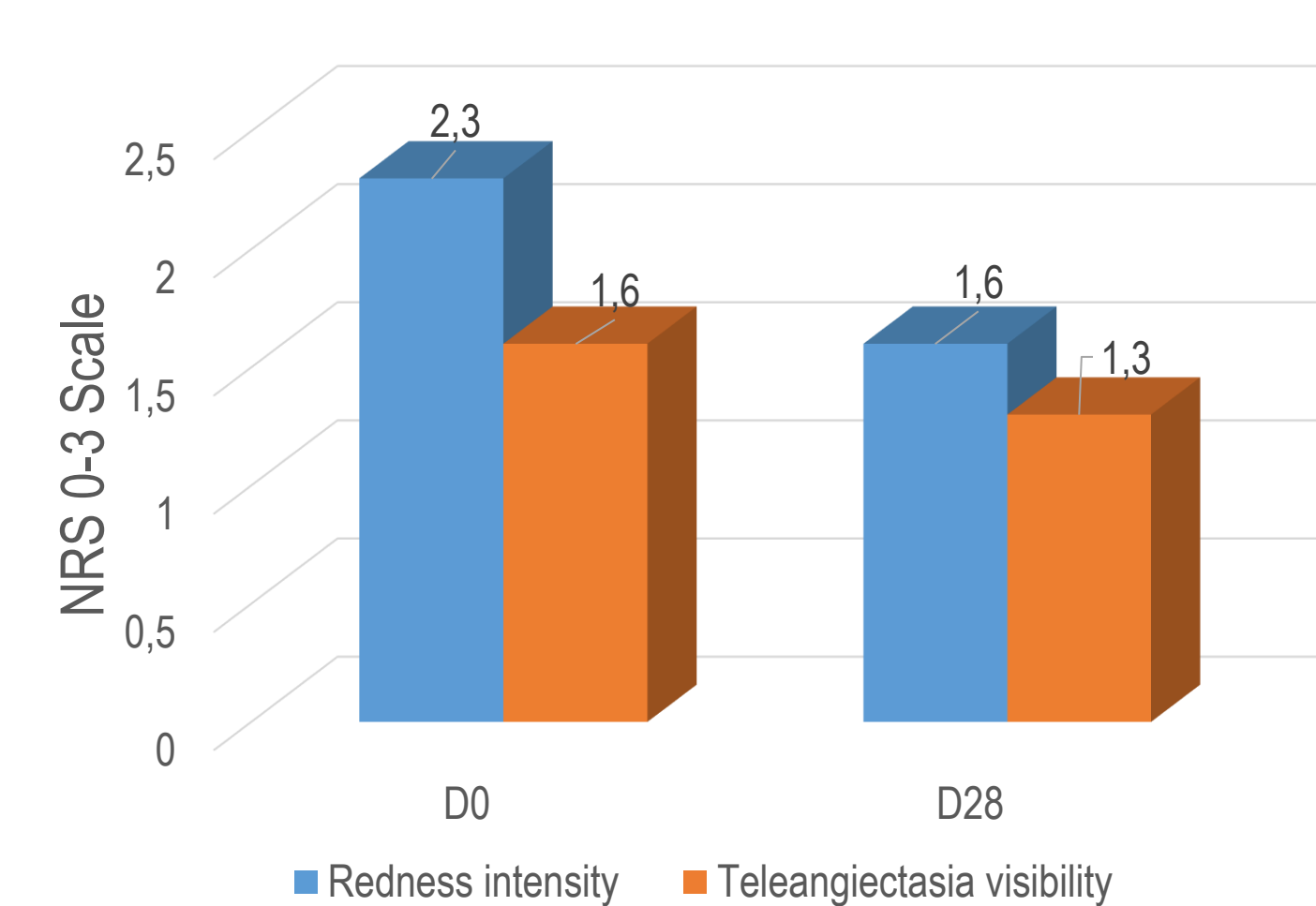


Figure 1. Clinical evaluation of skin condition in 3-point NRS scale (n=10). After 4 weeks the reduction of erythema by 30,43% and teleangiectasia visibility by 18,75% was evaluated.



Figure 2. Visioface photography of female patient (age 57, III stage of rosacea) before and after 4 weeks of product 1449 usage. The reduction of erythema and papules and pustules is visible.

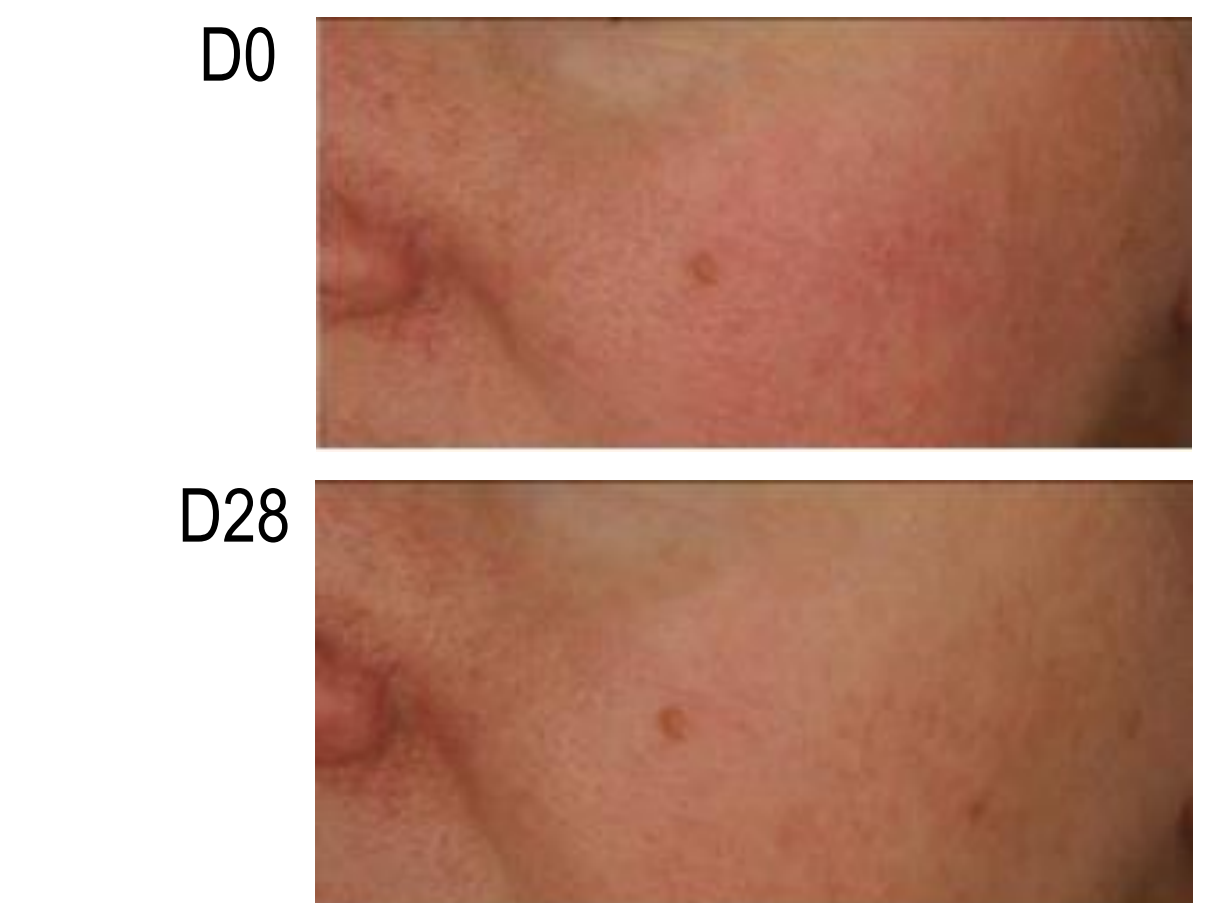


Figure 3. Visioface photography of female patient (age 36, II stage of rosacea) before and after 4 weeks of product 1449 usage. The reduction of erythema is visible.

Mexameter® MX18			
after 1 application			
(P1 – first measurement after controlled redness increase, P2 – measurement after 1 application of tested cream)	P1	P2	Reduction in %
	474	432	- 9%
after 4 weeks of product usage			
(P0 – first measurement before cream usage, P3 – final measurement)	P0	P3	Reduction in %
	414	364	- 12%

Table 1. Mexameter evaluation of erythema showed decrease in redness after 4 weeks of product usage, as well as decrease after just one application after controlled redness increase.

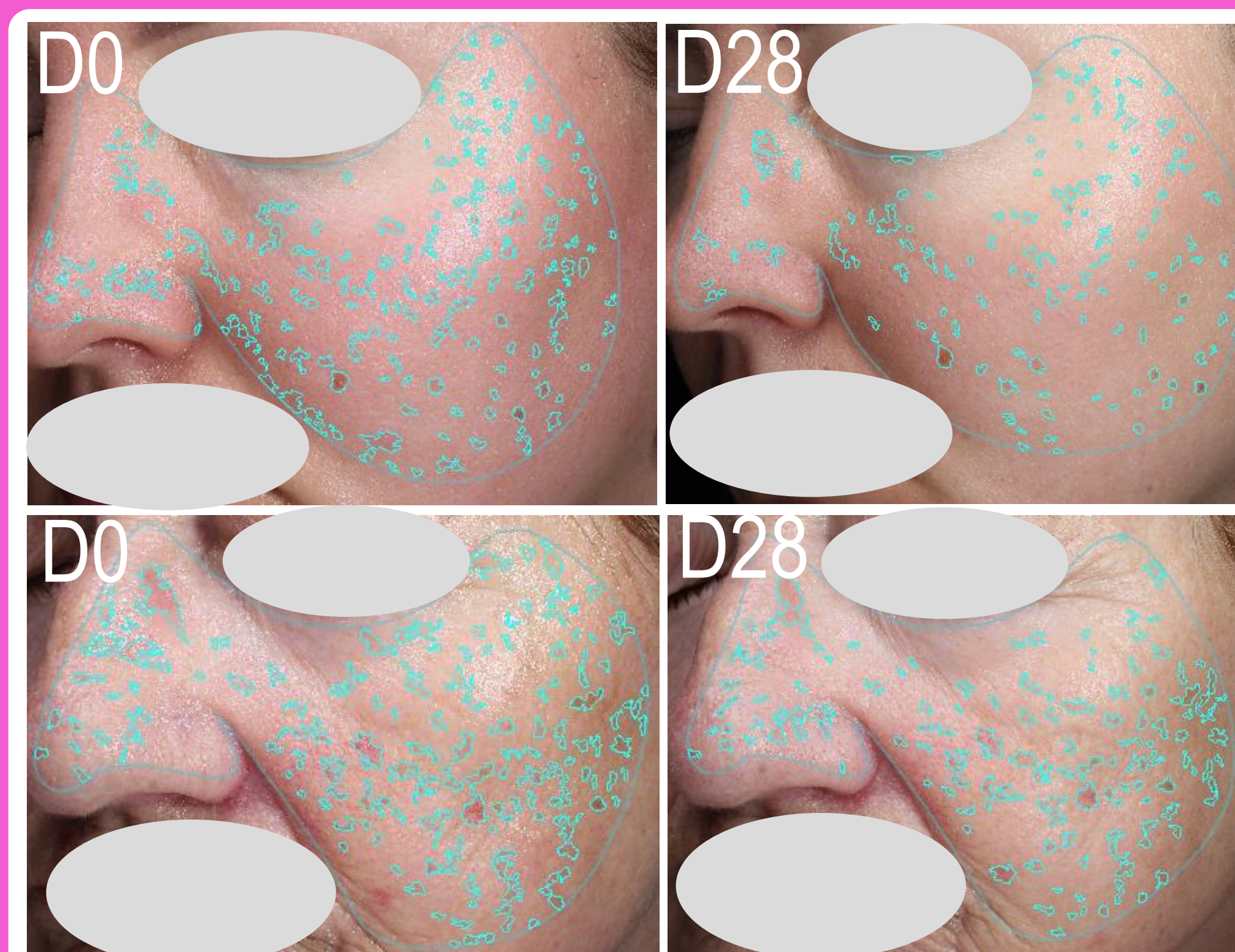


Figure 4. Visia photography of female patient (ID: EP, upper photo) before and after 4 weeks of product 1449 usage. The reduction of spots number by 24% and its size by 40%. Second female patient (ID: GP, lower photo), also the reduction of spots number by 14% and its size by 12% were measured.

Results from Centre for Science and Research

Parameter	5-point analogue scale (1 - lack of symptom, 5 – intensive symptom)		
	D0	D28	Change in %
moisturization (n=12)	2,5	4,08	+ 63%
erythema visibility and intensity (n=12)	3,42	2,25	- 34%
teleangiectasia visibility (n=8)	3,63	2,75	- 24%
papules and pustules number and size (n=12)	2,33	1,33	- 43%

Table 2. Self-evaluation of skin parameters according to 5-point analogue scale. The improvement in all cases was seen.

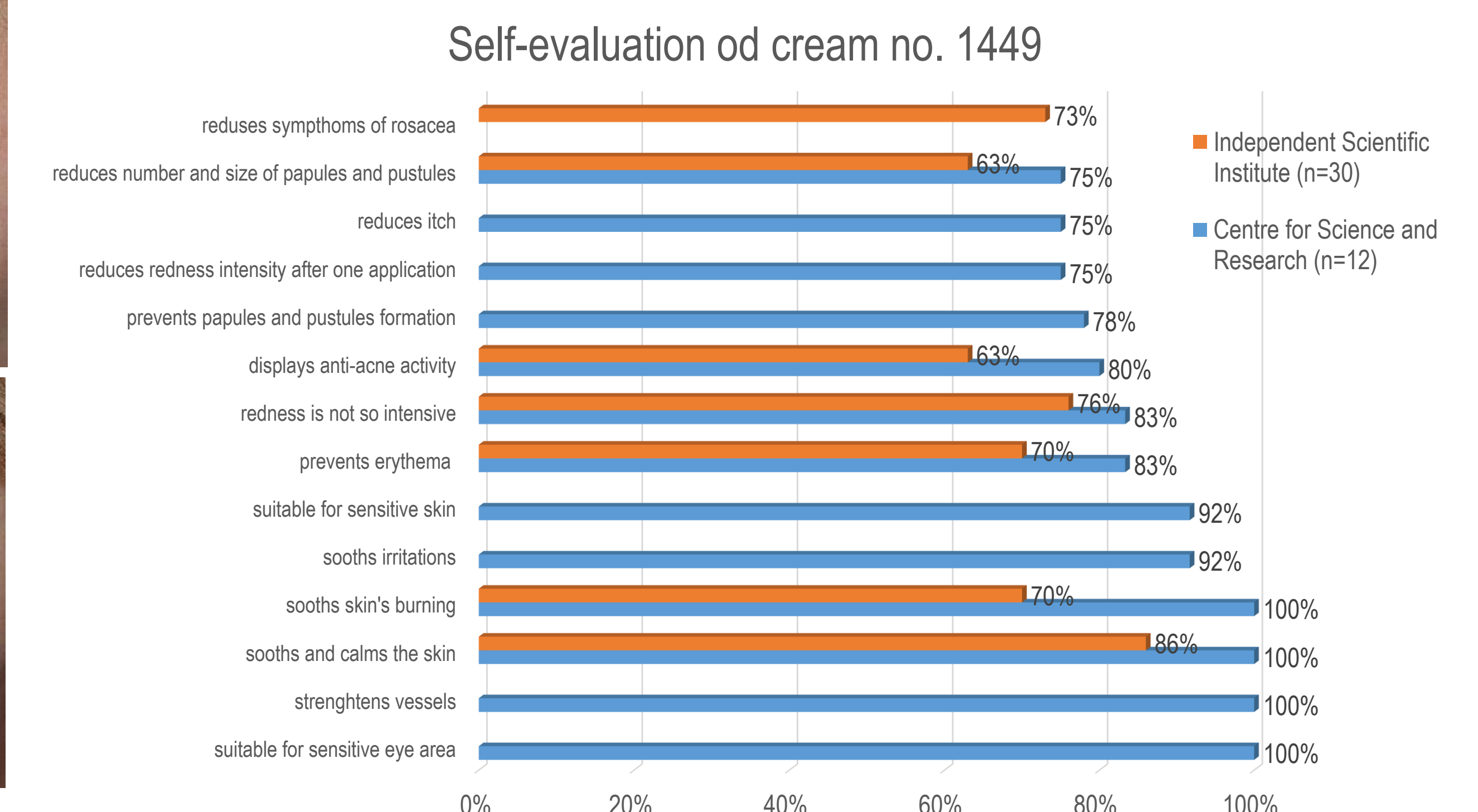


Figure 5. Self-evaluation of skin condition. Comparison of results from Independent Scientific Laboratory and Centre for Science and Research. After 4 weeks of product usage the reduction of rosacea symptoms was seen.