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CENTRE FOR SCIENCE AND RESEARCH

Safety and efficacy of product containing 20% of azelaic acid enriched with anti-inflammatory complex in patients with acne and hyperpigmentation

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INTRODUCTION & OBJECTIVES

Azelaic acid (AzA) is a well-known topical agent used to reduce the visibility of acne lesions, as well as post-inflammatory hyperpigmentation and melasma. It is observed to not only reduce the intensity of existing discolorations, but also prevent the formation of new ones.
The aim of the study was to evaluate the effectiveness of a topical cosmetic formulation (14017) containing 20% azelaic acid, enriched with a complex of polyphenols: magnolol and honokiol (MaHo) with antioxidant and anti-inflammatory properties, in a group of individuals with acne and different types of skin discolorations. The reference in the preliminary study was an emulsion containing only 20% azelaic acid, without additional active ingredients (20% AzA).

MATERIALS & METHODS

In vitro antioxidant activity to estimate the Radical Protection Factor (RPF) of the tested emulsion (14017) was determined using DPPH radical scavenging assay.
In a preliminary study *in vivo*, a comparison of both emulsions was conducted in split-face study in a group of 9 volunteers (11-36 y.o.) who applied emulsion 14017 with azelaic acid and MaHo on the right half of the face, and emulsion only with azelaic acid (20% AzA) on the left side. Skin instrumental evaluations of both sides were performed (melanin and erythema, sebum level, topography parameters, number of skin irregularities).
In another assay, a group of volunteers (11-50 y.o.) applied the product 4017 with azelaic acid and MaHo twice daily. The change in the number of pores, porphyrins, spots, UV spots, irregularities (Visia) was assessed. Additionally, the dermatological assessment of acne severity on a 4-point scale on D0, D10 and D28 was performed. At the end of each study, volunteers were asked to complete a self-evaluation and satisfaction questionnaire.

RESULTS

14017 exhibits antioxidant properties *in vitro*: DPPH assay value was 18,9 x 10^{17} DPPH/g of cream. In a split-face study, 14017 with azelaic acid and MaHo soothed the skin better (8% reduction in erythema in objective measurements) indicating higher skin calming properties. A stronger effect in lightening discolorations and evening out acne scars was observed for 14017 compared to 20% AzA as well. (**Fig 1**). According to respondents, emulsion with azelaic acid and MaHo was more effective in smoothing the skin surface where acne lesions were present (**Fig. 6**).
Dermatological evaluation has shown acne reduction by 40% after 3 weeks of using 14017. Moreover, instrumental analysis showed a significant reduction in the number of porphyrins and pores (**Fig. 5**). In the the group of volunteers with melasma, reduction in melanin by 10% was confirmed, as well as decrease in the number and size of spots after 4 weeks of product application (representative photograph in **Fig. 8**).

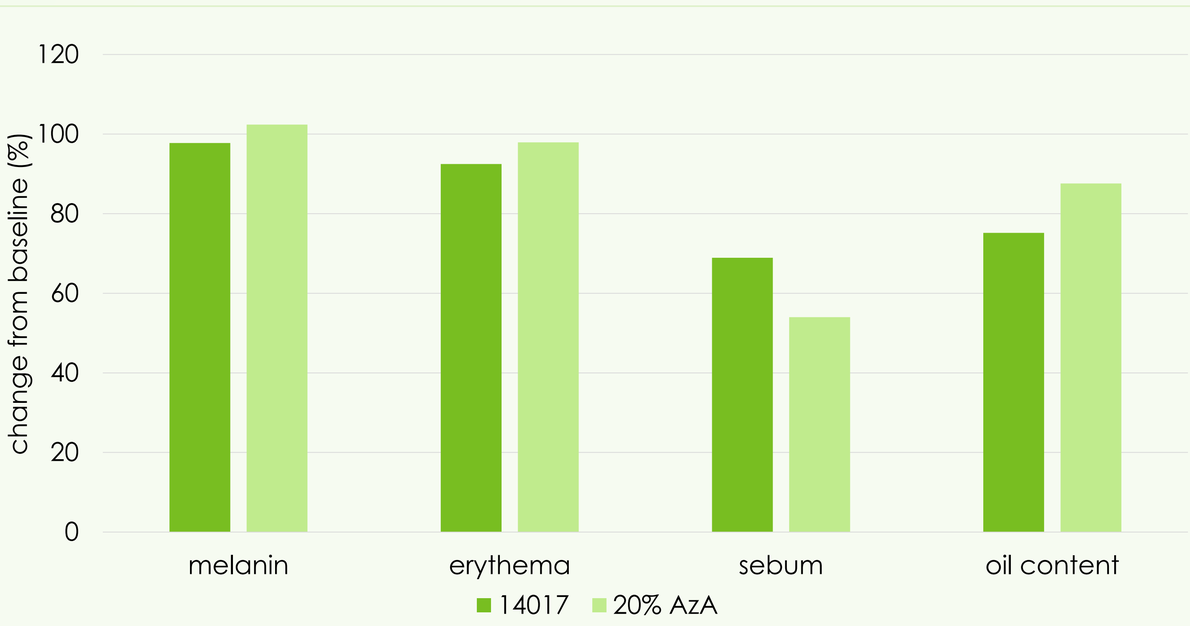

Figure 1. Preliminary study results, comparing the efficacy of 14017 (formulation with 20% AzA and MaHo) and a formulation devoid of MaHo (20% AzA). Results are presented as mean change from baseline (100%) after 20 days of using the products in a group of volunteers (n=9, age 11-36).

	Subjective evaluation of imperfection (papules, pustules) visibility % of volunteers					
	1 low visibility	2	3	4	5 high visibility	mean
Baseline	0	11	0	33	56	4.33
After 20 days	11	33	33	22	0	**2.67**
						37% decrease

Figure 2. Subjective evaluation of visibility of acne lesions (papules, pustules) at baseline and after 20 days of using 14017 (n=8).

	Subjective evaluation of hyperpigmentation visibility % of volunteers					
	1 no hyperpigmentation	2	3	4	5 very intensive	mean
Baseline	44	0	11	22	22	2.78
After 20 days	44	22	22	11	0	**2**
						28% decrease

Figure 3. Subjective evaluation of visibility of hyperpigmentation at baseline and after 20 days of using 14017 (n=8).

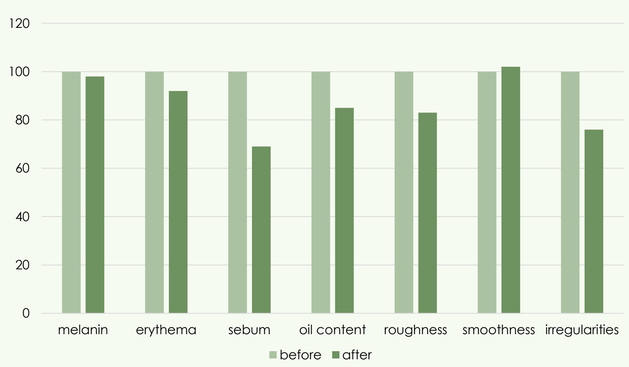

Figure 4. Efficacy of 14017 in improving skin condition after 20 days of product use in a group of volunteers (n=8). Notable reduction of sebum content, as well as skin roughness and irregularities (uneven skin structure) was observed. A slight increase in epidermal smoothness was reported as well.

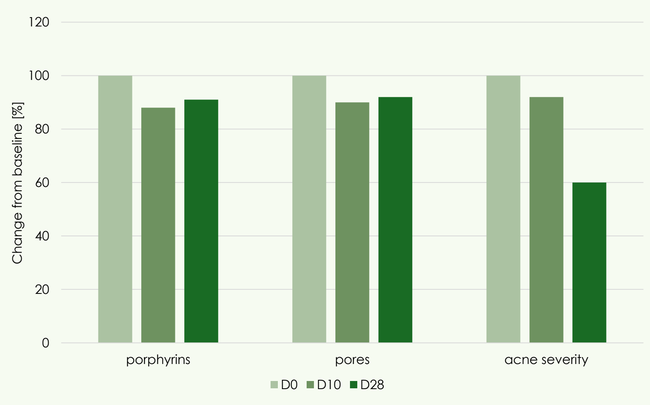

Figure 5. Reduction in acne-related skin characteristics (porphyrins, pores, acne severity) after 10 (D10) and 28 days (D28) of product usage (n=21; age 14-33 y.o.) Pores and porphyrins were evaluated using Visia skin analyzer, acne severity was evaluated in a 4-point analog scale by the dermatologist.

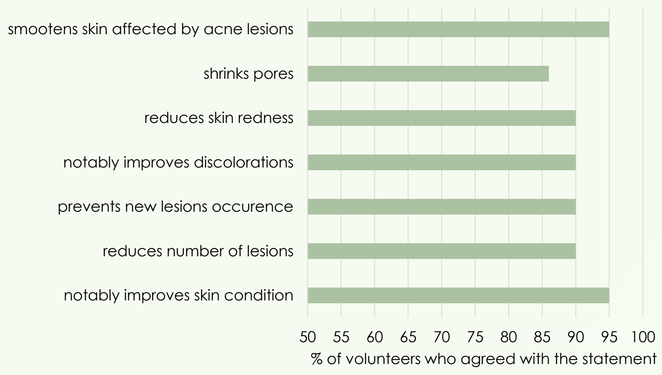

Figure 6. Subjective evaluation of the efficacy of 14017 in terms of improving skin condition after 28 days of product use (n=21; age 14-33 y.o.).

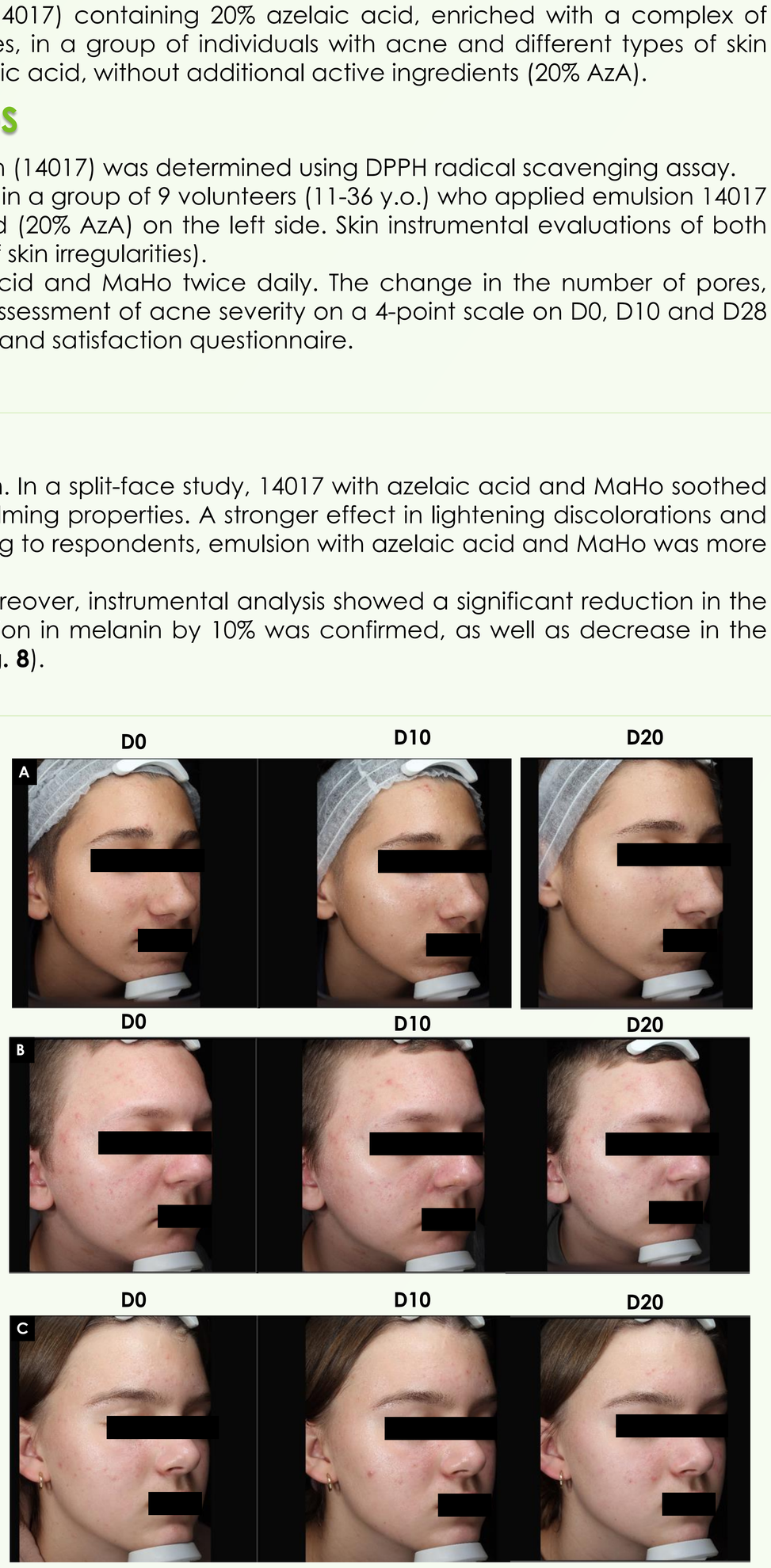

Figure 7. Efficacy of 14017 in reducing the visibility of acne lesions in volunteers (volunteer's age: **A** - 14, **B** - 13, **C** – 11). Volunteers's faces were photographed at baseline (**D0**), after 10 days (**D10**), and after 20 days (**D20**). Apart from changes in acne severity, notable reduction in the visibility of post-inflammation discolorations was observed

Figure 8. Skin lightening properties of 14017 observed in a volunteer with melasma. Effect was achieved after 4 weeks of daily use. Photographs were taken at baselin (left) and after 28 days (right).

CONCLUSIONS

Due to good soothing properties, the product with 20% of AzA enriched with MaHo can be recommended for the care of inflammed skin with mild and papulopustular acne as well as skin with melasma.