

# In-Vivo Assessment of the Efficacy and Tolerability of a Topical Omega-6-Fatty Acid Treatment in Children with Atopic Dermatitis

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## Abstract

The pathogenesis of atopic dermatitis involves an epidermal lack of omega-6-fatty acids, which correlates positively with disease severity. In the present study the efficacy and tolerability of a topical omega-6-fatty acid treatment with Eucerin® 12% Omega Cream or Eucerin® 12% Omega Lotion has been investigated in children with atopic dermatitis. 28 (cream group) respectively 30 children (lotion group) in the age of 2-18 years with atopic dermatitis were enrolled in this open, controlled clinical study. The cream, respectively the lotion was applied 2 times daily to the face (cream) respectively to the body (lotion). Concomitant pharmaceutical medication was allowed if necessary. Evaluation of the treatment areas in comparison to baseline was performed and compatibility of the products with concomitant medication was assessed by physicians after 3 weeks of treatment. At the end of the study patients or their mother/father filled out a questionnaire regarding the product properties, especially regarding the tolerability of the cream around the eyes. During the studies Eucerin® Lipid Shower Oil was used for standardized cleansing. The results showed a substantial improvement of the skin condition in 42.9% and an improvement in another 42.9% of patients treated with the cream. In the lotion group the skin condition had substantially improved in 44.8 % of patients and improved in 41.4% after 3 weeks of treatment. The patients stated the product properties generally as very good with the best values for general tolerability and tolerability around the eyes especially for the cream.

## Introduction

Atopic dermatitis is one of the most common diseases in children. In this disease a deficiency in the essential omega-6 fatty acids linoleic and gamma-linolenic acid is often detectable that shows a positive correlation with the severity of the skin symptoms (1). These symptoms can improve or normalize, however, after topical application of these fatty acids (2). Previously, different vegetable oils were studied for their efficacy in atopic dermatitis (3-5). Unlike other vegetable oils, evening primrose oil with its high content of linoleic and gamma-linolenic acids and low content of oleic acid showed a very good efficacy and tolerability especially in a water-in-oil emulsion (6-8). The aim of this work was therefore to obtain further information on the efficacy and tolerability of a topical therapy with omega fatty acids in children with atopic dermatitis.

## Patients and Methods

28 (cream = C) and 30 (lotion = L) children aged 2 to 18 with dry skin and a history of and clinically diagnosed atopic dermatitis were included in these open, pediatrically controlled studies after written and oral instruction and consent of the parents (Tab.1). The gender ratio was nearly 1:1. The mean ages were 5.3 (C) (STD 3.0) and 5.1 (L) (STD 2.8) years. The face was treated with Eucerin® 12% Omega Cream and the body with Eucerin® 12% Omega Lotion at least twice daily. The duration of treatment was 3 weeks.

At the beginning and end of the study the skin condition on the face and body was evaluated clinically for the symptoms dryness, reddening, scaling, rhagades, lichenification, itching, tightness, burning and oozing and the results recorded. Additionally, the investigating physician assessed the tolerability. At the end of the study the product properties spreadability, absorbency, odour, skin compatibility, long-lasting skincare effect, packaging, ease of removal, and use in the eye area were ranked by the patients or their parents on a scale of 1 (poor) to 7 (excellent). 4 (C) and 9 (L) children received additional topical treatment for their atopic dermatitis.

In both studies only Eucerin® Lipid Shower Oil was used for standardized cleansing. Biometric analysis of both studies was performed with SAS Version 8.0 on an IBM-compatible computer under MS-Windows.

## Results

### Study with 12% Omega Cream

Overall comparison of the skin condition on the face at the start and end of the study showed a very good efficacy of this cream. The skin condition was substantially improved in 42.9% of the patients, improved in another 42.9% and unchanged in 14.3% (Fig.1a). The improvement in four symptoms (dryness, reddening, scaling and itching) was statistically significant at the 5% level ( $p \leq 0.001$ ) with the greatest effect observed for the symptoms dryness and scaling (Fig.1b). The skin tolerability of the cream was assessed as very good in 60.7% of the patients and good in 39.3% (Fig.1c).

The patients or their parents assessed the product properties overall as very good with the best values obtained for the skin compatibility (mean 6.0 of 7) and ease of removal (mean 5.9 of 7) as well as tolerability in the eye area (mean 5.7 of 7) (Fig.1d).

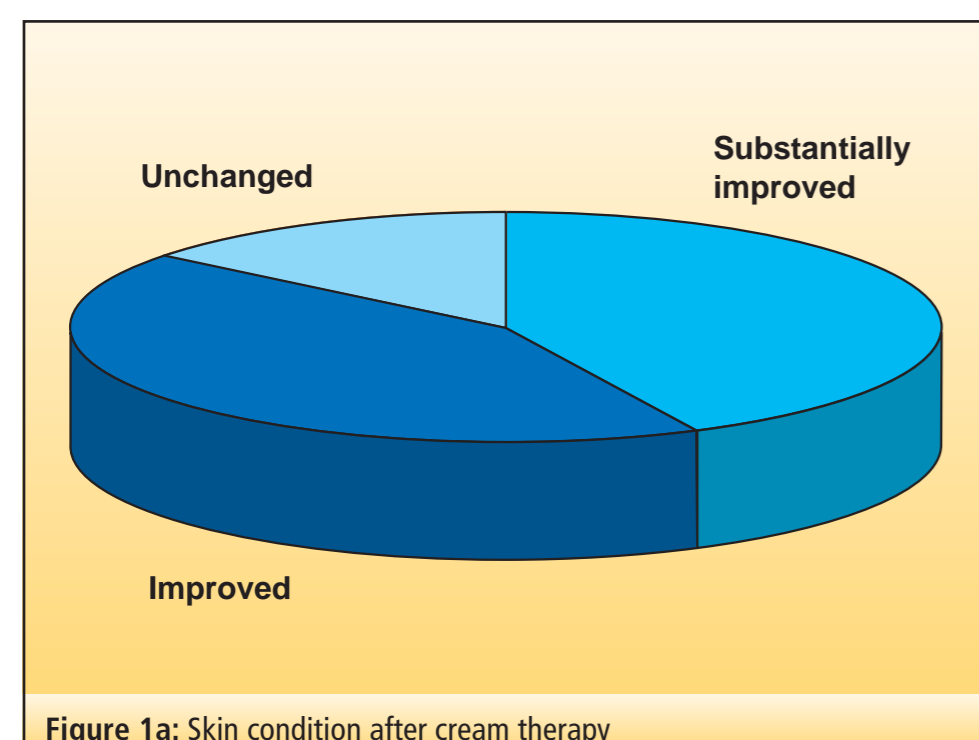


Figure 1a: Skin condition after cream therapy

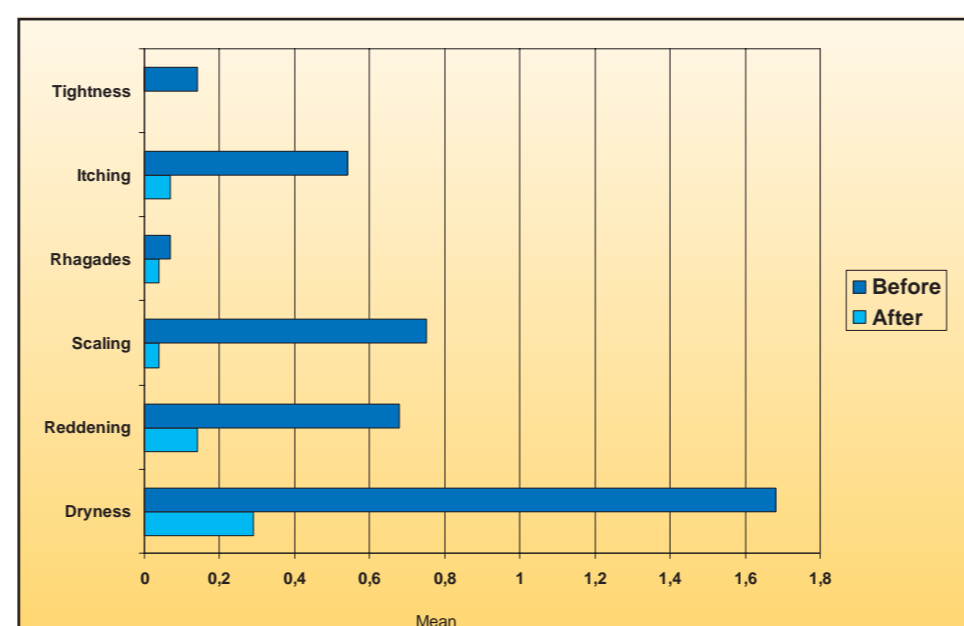


Figure 1b: Symptoms before and after cream therapy

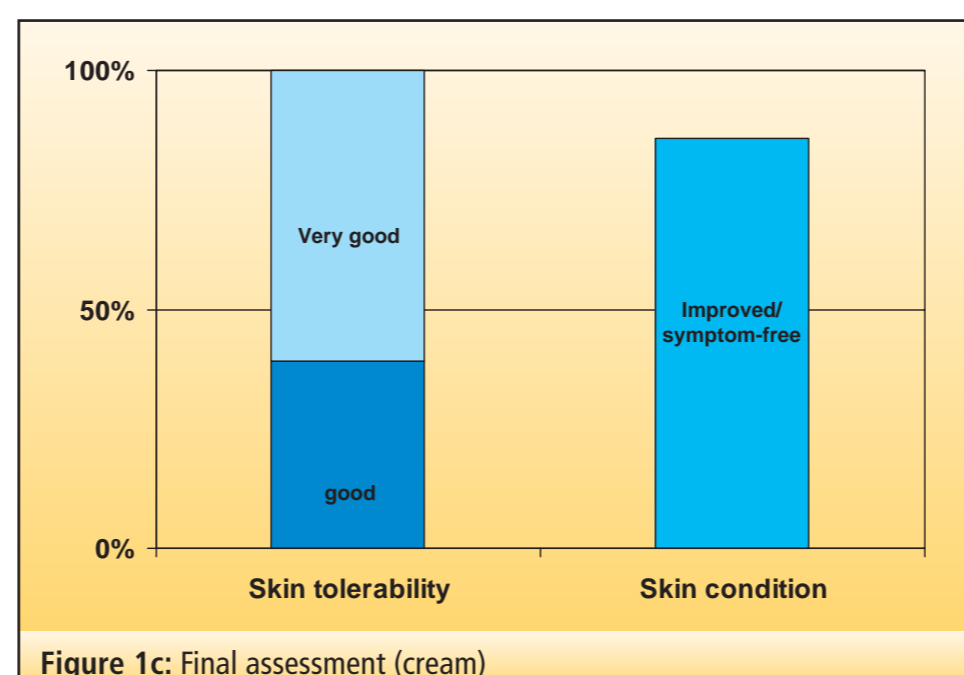


Figure 1c: Final assessment (cream)

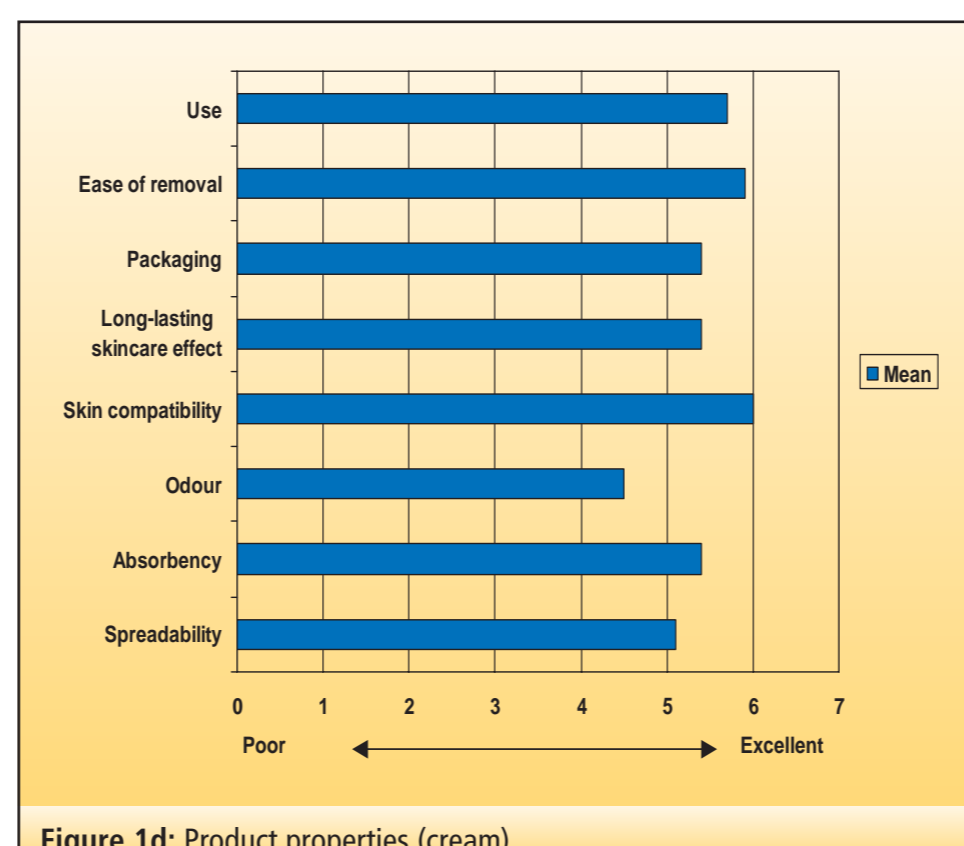


Figure 1d: Product properties (cream)

### Study with 12% Omega Lotion

The overall comparison of the skin condition at the beginning and end of this study also showed a very beneficial effect of application of this lotion. There was a substantial improvement in the skin condition of 44.8% of the children (Fig.2a). Another 41.4% showed an improved skin condition, whereas it was unchanged in 13.8%.

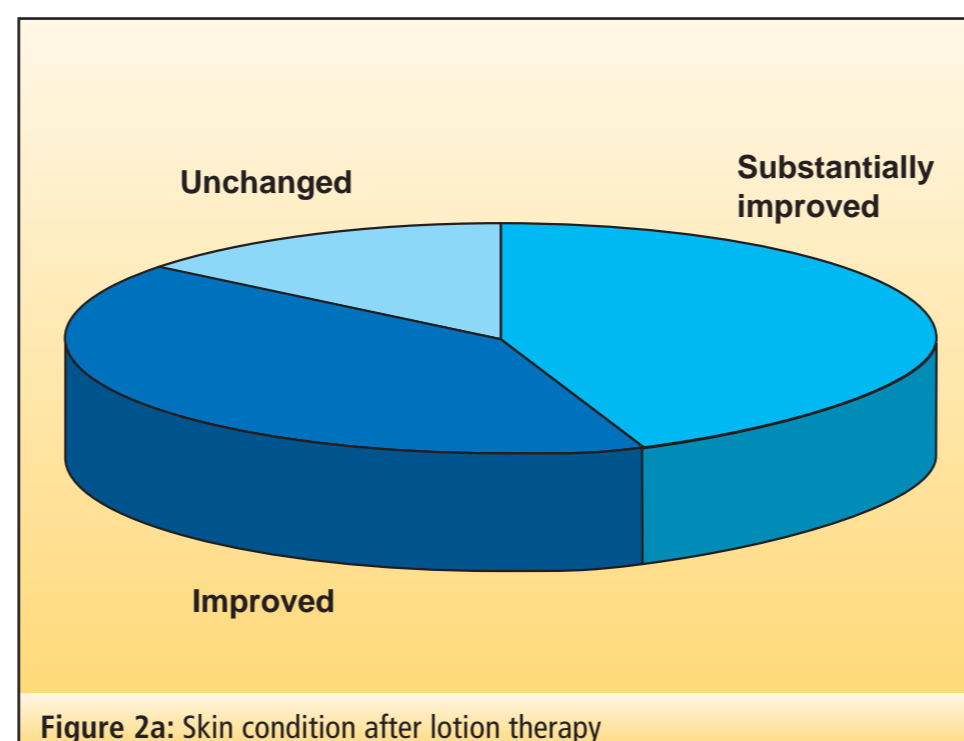


Figure 2a: Skin condition after lotion therapy

5 of the 9 symptoms (dryness, reddening, scaling, lichenification and itching) showed a statistically significant improvement at the 5% level with the largest differences observed for dryness and scaling (Fig.2b).

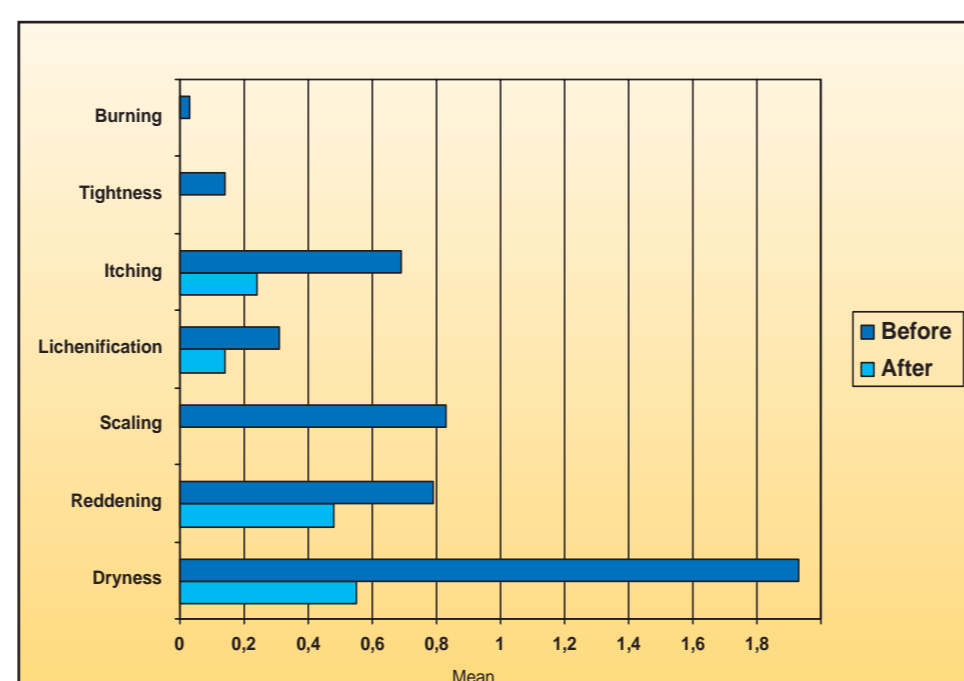


Figure 2b: Symptoms before and after lotion therapy

The skin tolerability was assessed as very good in 48.3% of the patients and as good in 51.7%. One patient dropped out of the study because of papular efflorescences with itching. According to the assessment of the investigating physician, there was no causal relationship with the test product (Fig. 2c).

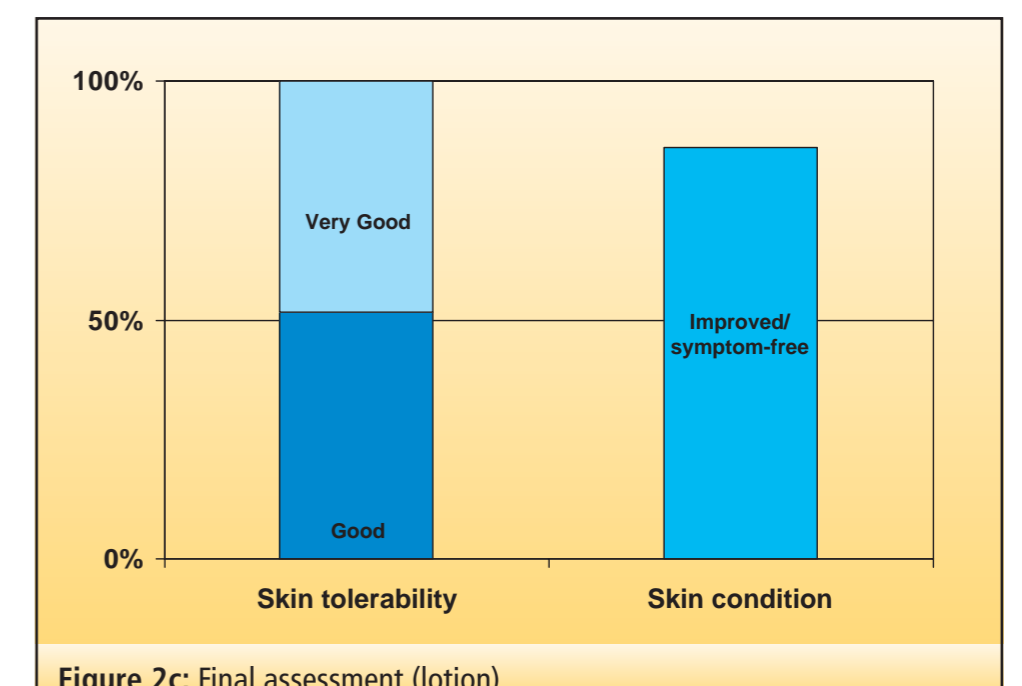


Figure 2c: Final assessment (lotion)

The product properties were assessed overall as very good with the skin compatibility (mean 6.3 of 7) and ease of spreading (mean 6.2 of 7) receiving the best scores (Fig.2d).

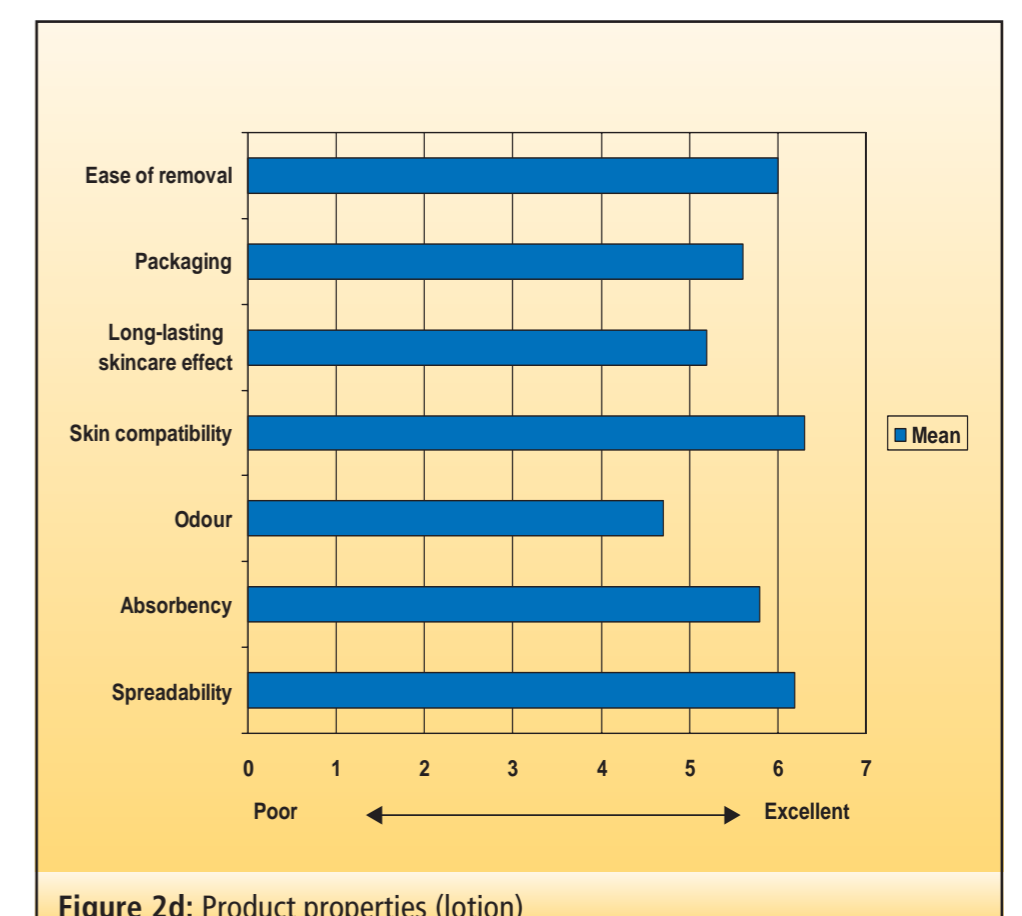


Figure 2d: Product properties (lotion)

## Discussion and Conclusion

Skin care plays an especially important role in the prevention and treatment of atopic dermatitis in children. The increased transcutaneous absorption of active substances and increased irritability of the skin especially in sensitive areas like the face are factors that need to be considered.

In atopic dermatitis there is often a deficiency in essential omega-6 fatty acids in the epidermis that shows a positive correlation with the severity of symptoms. Omega-6 fatty acids were already shown to be effective in earlier studies. This study confirms the very good efficacy and tolerability of topically applied evening primrose oil in water-in-oil emulsions for this indication in children.

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