

EFFICACY OF A NEW BARRIER GLOVE IN THE TREATMENT OF CHRONIC HAND ECZEMA

INTRODUCTION

Chronic hand eczema is a common dermatologic problem of multifactorial etiology, varying severity and varying response or resistance to therapy. Treatment strategies include identification and avoidance of the causative agents, e.g. by wearing of gloves, therapy with topical steroids and emollients.

AIMS

The main aim of this study was the evaluation of a new glove made of Uretex (MICROAIR® IN-BETWEEN) in the treatment of mild to moderate severe hand eczema in comparison to standard therapy with the potent steroid ointment diflucortolone valerate (Nerisona® Ointment) planned as a non-inferiority study in a prospective, controlled, standardised, randomised, stratified and evaluator-blinded manner.

The second aim of the study in the glove group was to investigate whether a second silk glove coated with antibacterial, antifungal AEGIS™ AEM 7772/5 (Dermasilk®) worn under the barrier glove on one hand would result in additional improvement of the eczema.

Material & Methods

The material Uretex consists of three layers, the two external layers are made of knitted polyester microfibre, the central layer of a microporous film (maximum porosity = 3 microns). Thus, Uretex is a very lightweight, elastic, waterproof and breathable material that can withstand sterilisation at 115°C for 45 minutes.

During the study, all Patients used the same emollient (Locobase® Repair) as needed.

- Hand eczema was classified as toxic-irritative, atopic, contact-allergic or combination type according to the case history, clinical presentation and the following test results:
 - skin prick test and atopy patch test with inhalative allergens
 - patch testing with European Standard Series and depending on the occupation and hobbies with additional series for contact allergen identification
 - determination of total IgE- and specific IgE levels to prick test positive allergens.
- General severity assessment: modified SCORAD score (scoring atopic dermatitis)
- Comparative severity assessment between right and left hands: HECSI score (hand eczema severity index)
- Severity was assessed by both scores weekly over the study period of three weeks.
- Bacterial cultures were taken with cotton swabs at baseline and if positive at all clinical evaluations.
- QoL Questionnaire was filled in by the patients before and weekly during the study.

Study design

59 Patients were randomised in two treatment groups (planned number 66):

- standard therapy with diflucortolone valerate ointment or
- treatment with barrier gloves 8 hours a day and additionally the barrier glove group were randomised to wear a Dermasilk® glove under the barrier glove on one hand

Stratification criteria considered were: main type of hand eczema, gender, handedness and SCORAD severity (SCORAD between 21 and 50 = mild hand eczema, SCORAD between 51 and 80 = moderate hand eczema)

Results, Clinical Pictures

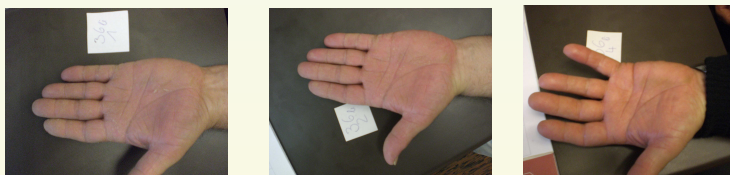


Fig. 1 a, b, c
Hand eczema treated with Uretex-gloves, a=baseline, b=visit 2, c= visit 4



Fig. 2 a, b, c
Hand eczema treated with diflucortolone valerate ointment, a=baseline, b=visit 3, c= visit 4

The additional use of Dermasilk® gloves resulted in some patients in a more pronounced improvement of the eczema on the used side and the general acceptance of the gloves as well as of the emollient Locobase® Repair by the patients was very high (data not shown).

DISCUSSION

We hypothesise that, due to its physical properties -skin protection from exogenic irritants, contact-allergens, extreme humidity by absorption of sweat and exudation as well as inhibition of exsiccation- MICROAIR® IN-BETWEEN barrier gloves create an environmental setting that allows a rapid skin regeneration and recovery of hand eczema.

CONCLUSION

Our study indicates that the investigated water- and allergen-proof, breathable barrier glove (MICROAIR® IN-BETWEEN) worn during daily activities is at least as efficient as standard therapy with the potent topical steroid diflucortolone valerate (Nerisona® Ointment) in the treatment of chronic hand eczema of mild to moderate severity. As mode of action varies completely, additional efficacy can be expected from the combination of this two treatment modalities.

References

RESULTS

		Treatment group	
		Nerisona® Ointment	Microair®-In-Between
		Count	Count
Gender	Male	14	14
	Female	16	15
Handedness	Left-handed	2	2
	Right hander	28	27
Type of hand eczema	Atopic	12	11
	Contact-allergic	4	3
	Irritative	10	8
	Atopic generalised	0	1
	Irritative.+ contact-allergic	1	4
	Irritative + atopic	3	2
	Contact-allergic + atopic	0	0
Severity	Mild HE	19	20
	Moderate HE	11	9

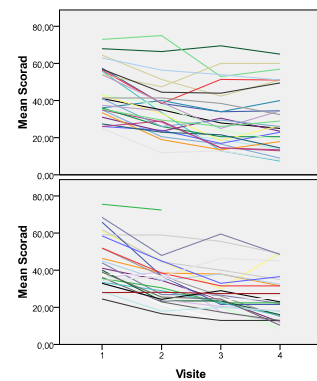


Table. 1
Equally distribution of patients in both treatment groups according to the stratification criteria

Fig. 3
SCORAD Score decreased in both treatment groups.

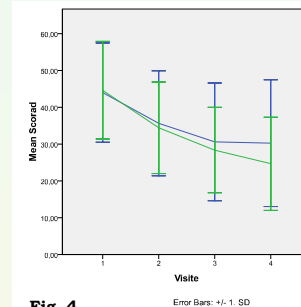


Fig. 4
The mean SCORAD Score decreased in Microair-In-Between group more pronounced than in the corticosteroid group. P= 0.174

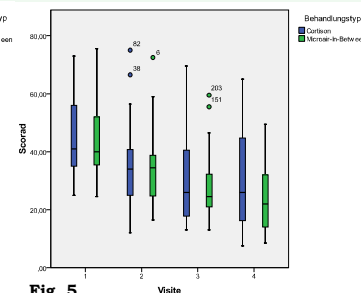


Fig. 5
The boxplot graphic illustrates also that baseline SCORADs were comparable in both treatment groups, with a similar decrease in SCORAD score after 1 week in both groups. At visit 3, there was further improvement in both groups, it was slightly higher for steroid therapy. At visit 4, the results were better for the Microair-In-Between group

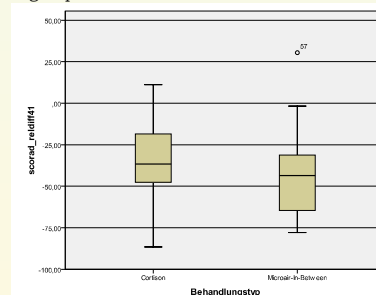


Fig. 6
mean relative difference in SCORAD between the study endpoint and baseline was for the barrier glove -43% and for the topical steroid group -34 %. This slightly higher decrease in severity scores in the glove group did not reach statistical significance.

		Relative difference in SCORAD			
		Mean	Standard Deviation	Minimum	Maximum
Treatment group	Cortison	-34,08 %	24,44 %	-86,61 %	11,11 %
	Microair®-In-Between	-43,24 %	24,43 %	-77,92 %	30,43 %