A NEW BARRIER GLOVE SHOWS COMPARABLE EFFICACY TO A POTENT STEROID IN THE TREATMENT OF MILD TO MODERATE SEVERE

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CHRONIC HAND ECZEMA

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INTRODUCTION

Chronic hand eczema (HE) 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

- Evaluation of a new glove made of **Uretex (MICROAIR BARRIER FABRIC®)** in the treatment of **mild to moderate severe** HE in comparison to standard therapy with the potent steroid ointment **diflucortolone valerate (Nerisona® Ointment)**.
- In the glove group: Evaluation of the benefit due to additionally worn silk glove coated with antibacterial, antifungal AEGISTM AEM 7772/5(Dermasilk®) under the barrier glove on one hand in the improvement of the eczema.
- Evaluation of Dermatology QoL (data not shown), comfort of and problems with the barrier glove.

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 mainly as toxic-irritative, atopic or contact-allergic (ACD) type according to the case history, clinical presentation and allergologic work-up.
- 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 al clinical evaluations.
- · QoL Questionnaire was filled in by the patients before and weekly during the study.

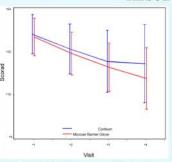
STUDY DESIGN

It was planned as a non-inferiority study in a prospective, controlled, standardised, randomised, stratified and evaluater-blinded manner.

Patients (n= 67) were randomised in steroid ointment group vs Microair Barrier® glove wearing (8 hours a day) group. The glove group was additionally randomised to wear Dermasilk® glove under the barrier glove on one hand.

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

RESULTS 1



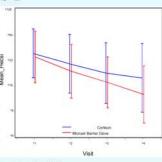


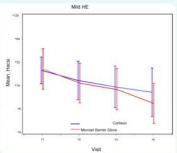
Fig. 1 A: SCORAD scores in both groups at all visits.

Steroid n=33, Microair Barrier® Glove n=32. Two drop-outs.

Mean rel. difference in SCORAD baseline vs visit 4 in the Steroid-group: minus 34,08 %, in the glove-group: minus 43,24 %, p= 0.255

B: HECSI scores in both groups at all visits show a similar result.

SCORAD and HECSI (mean of both hands) scores show a highly significant correlation rate (data not shown): $r = 0.83 \, p < 0.001$.



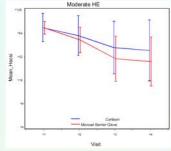
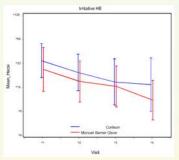
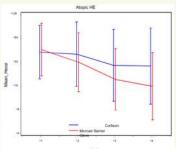


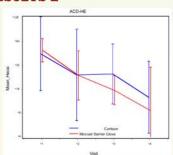
Fig. 2: Results according to the severity of HE: mild ← → moderate

- **2 A:** mild HE: n total = 43, steroid n = 20, barrier glove n = 23. Comparable improvement in weeks 1 and 2 in both groups. In week 3 glove-group shows further improvement of HE while steroid-group stagnates.
- **2 B:** moderate HE: n total = 22, steroid n = 13, barrier glove n = 9. Here, the glove-group shows better results during all 3 weeks of treatment.

RESULTS 2







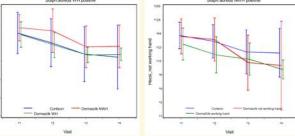


- 3 A: Irritative HE: n total= 34, steroid n= 17, barrier glove n= 17. In week 3, the glove group has further improvement of HE whereas the steroid group stagnates.
- **3 B: Atopic HE:** n total = 26, steroid n= 13, barrier glove n = 13. Barrier glove is definitely superior to the steroid group.
- 3 C: Contact-allergic HE: n total = 7, steroid n= 4 barrier glove n = 3. Although the total numbers are very low, a much better result is found in the glove group in the treatment of chronic HE.

Ds=Dermasilk WH=working hand NWH=not working hand SA= Staphylococcus aureus								nd
	Total pat.	Both H SA +	One H SA+	All SA + hands	All Ds WH	All Ds NWH	Ds WH SA+	Ds NWH SA+
Nerisona® Ointment	33	8	3	19	n.r.	n.r.	n.r.	n.r.
Microair Barrier® G	32	7	3	17	19	14	10	7

Table 1: Shows the SA results of the cotton swab bacterial culture tests. From all Microair® and Dermasilk wearing WH (n=19), 10 hands and from all Microair® and Dermasilk wearing NWH (14), 7 hands are SA positive.

Visit	Comfort				Problems Visit				
	2	3	4	Total		2	3	4	Total
1 & 2	26	26	25	77	no	20	23	27	70
3 & 4	5	5	6	16	yes	11	8	4	23
Total	31	31	31	93		31	31	31	93



in Ds-SA (+) hands
Ds-WH-SA (+) = 10
Ds-NWH-SA (+) = 7

4 A: WH: All Ds-WH = 19

4 B: NWH: All Ds-NWH=14
Additional use of
Dermasilk® gloves
resulted in higher

improvement of HE

if worn in NWH.

Fig. 4: WH ← → NWH

Table 2: From 31 answers, in 26 cases patients felt very comfortable (1 & 2) with the gloves and only 5 persons less comfortable(3 & 4). 20/31 patients had no problems with the glove after 1 week of treatment. After 2 and 3 weeks of treatment problems with the glove decreased. At visit 4 only 4/31 declared having some problems with the gloves in daily life.

CONCLUSION

- Microair® Barrier glove is at least as effective as Nerisona® Ointment in the treatment of mild to moderate chronic HE.
- Microair® Barrier glove is effective in all 3 types of HE. The effect is best for ACD type > atopic > irritative HE.
- Additional wearing of Dermasilk® gloves fastens the recovery of HE in SA positive cases: in SA (+) NWH >> in SA (+) WH.
- In 80% of the patients, barrier glove was well accepted. Problems with the glove decreased with study duration.
- Microair® Barrier glove might be combined with steroid ointment for additive effects.
 The emollient Locobase® Repair was also well accepted by the patients.