

# AN INVESTIGATION OF THE SKIN BARRIER RESTORING EFFECTS OF A CREAM CONTAINING CERAMIDES IN A MULTI VESICULAR EMULSION IN PEOPLE WITH DRY, ECZEMA-PRONE, SKIN: THE RESTORE STUDY PHASE 2

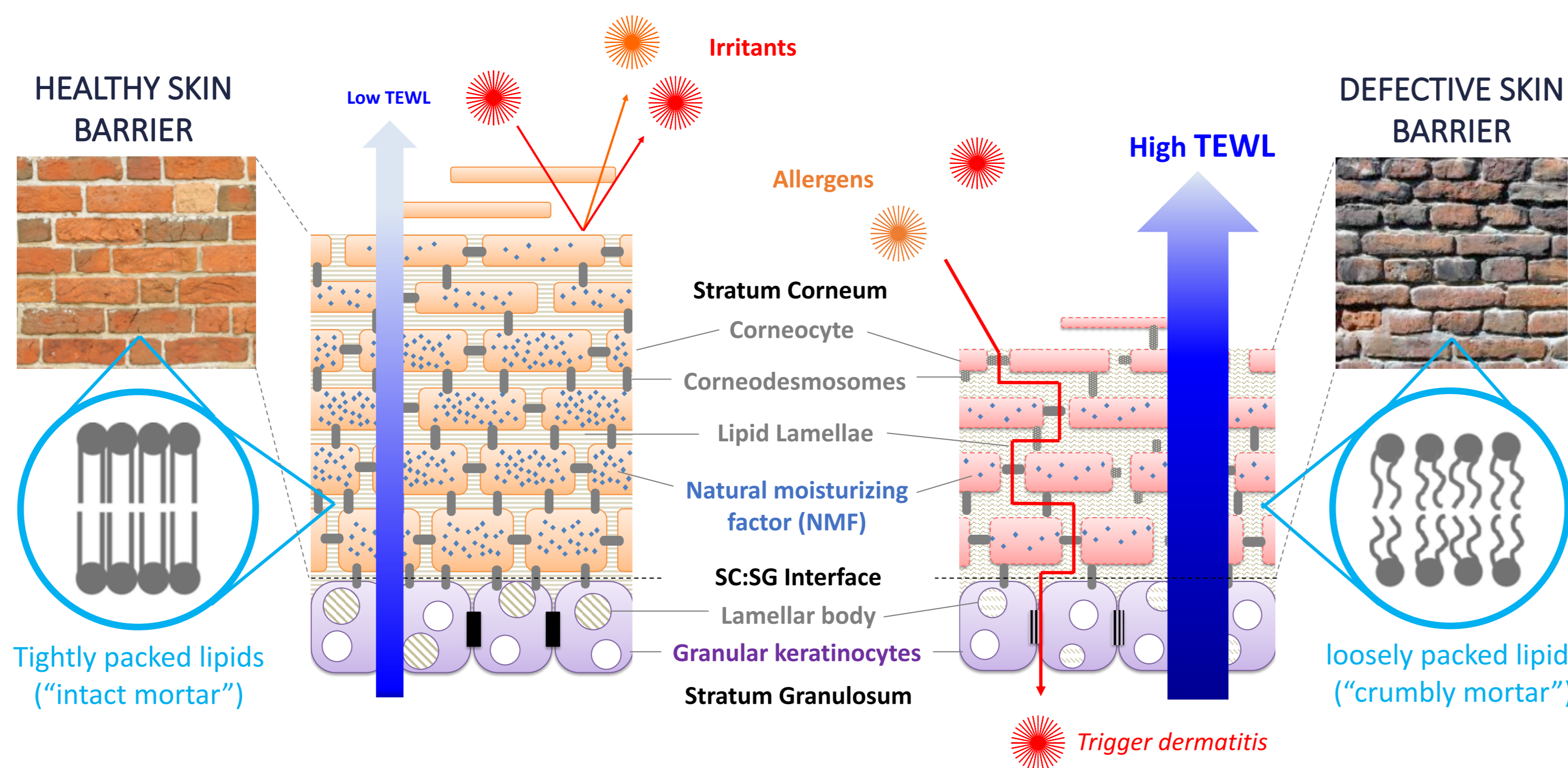
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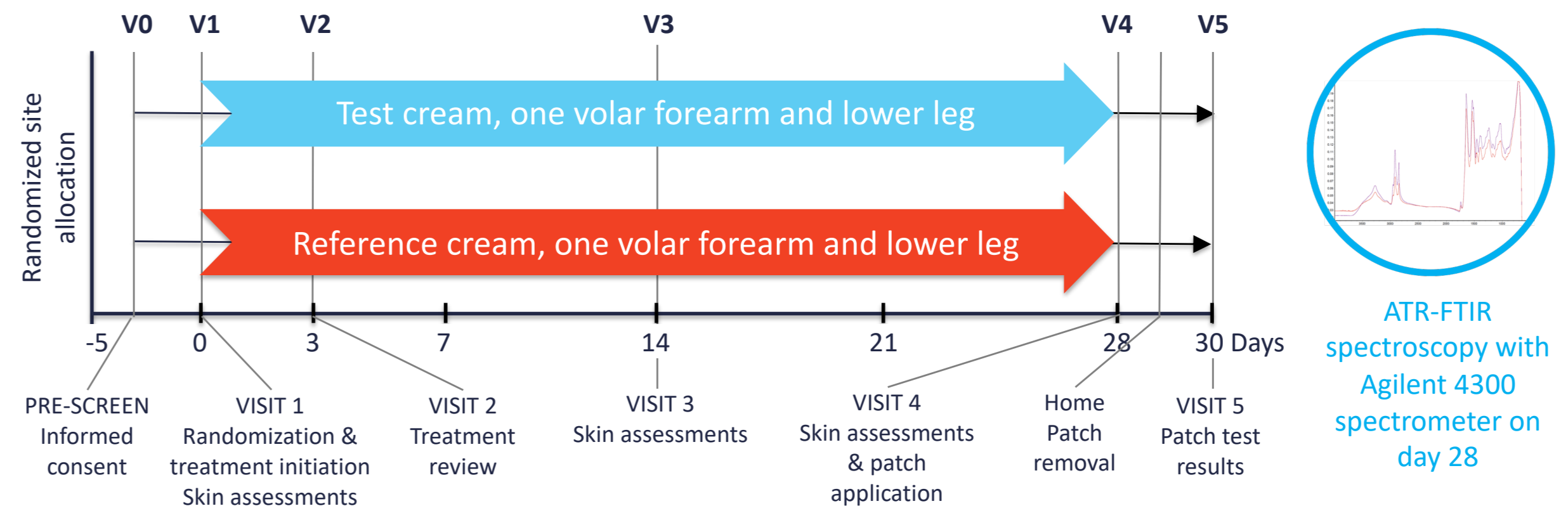
## INTRODUCTION

- The skin of atopic dermatitis (AD) patients is characterized by abnormal stratum corneum (SC) lipid levels [1,2,3].
- Consequently, the lamellar matrices are disrupted and skin barrier function is diminished, increasing skin sensitivity to irritants and allergens.

**OBJECTIVE:** To investigate whether a cream containing skin lipids (ceramides, triglycerides & cholesterol) in a multi-vesicular emulsion [4] (the test cream) can reinforce the skin barrier.



## METHODS

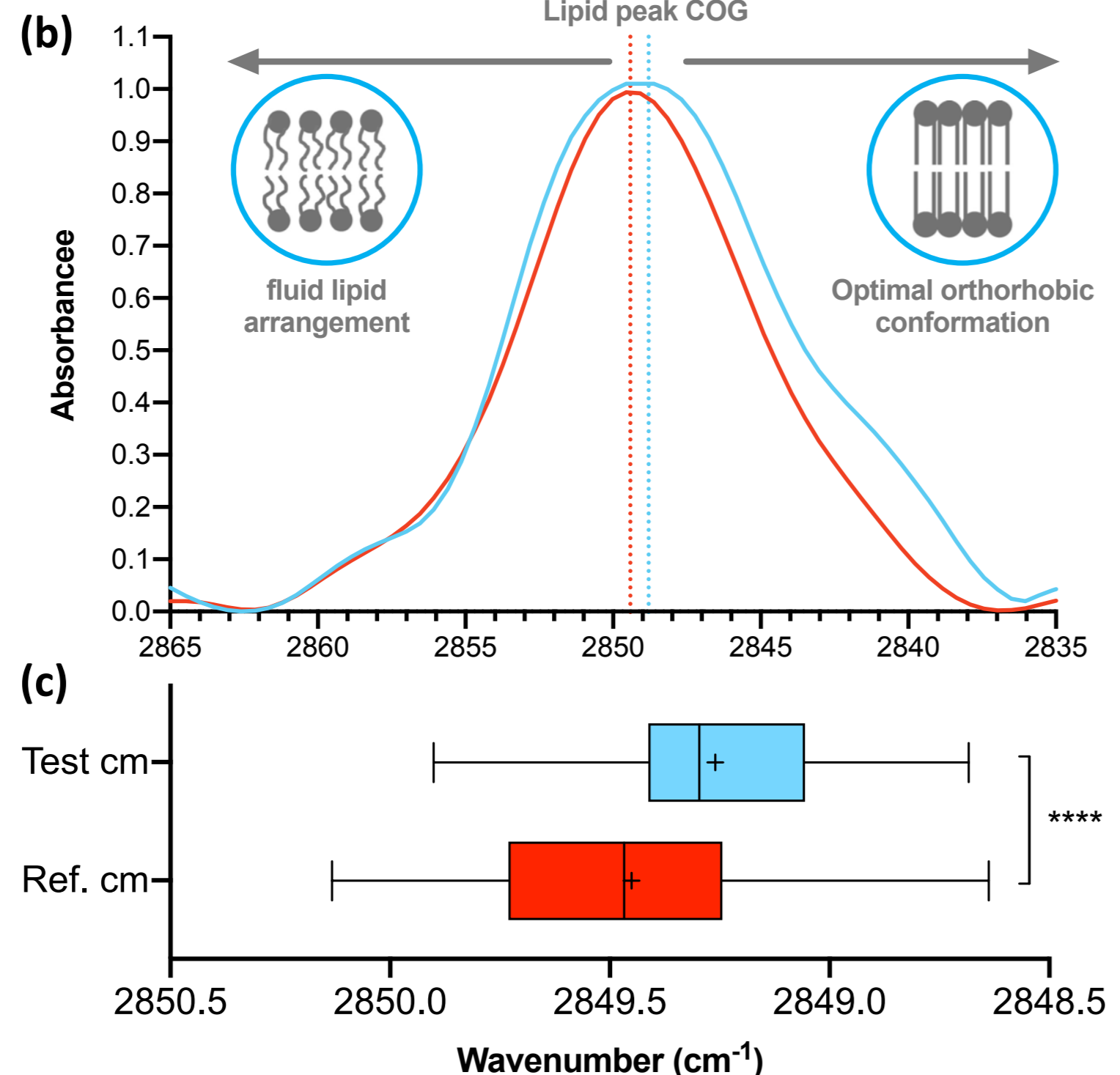
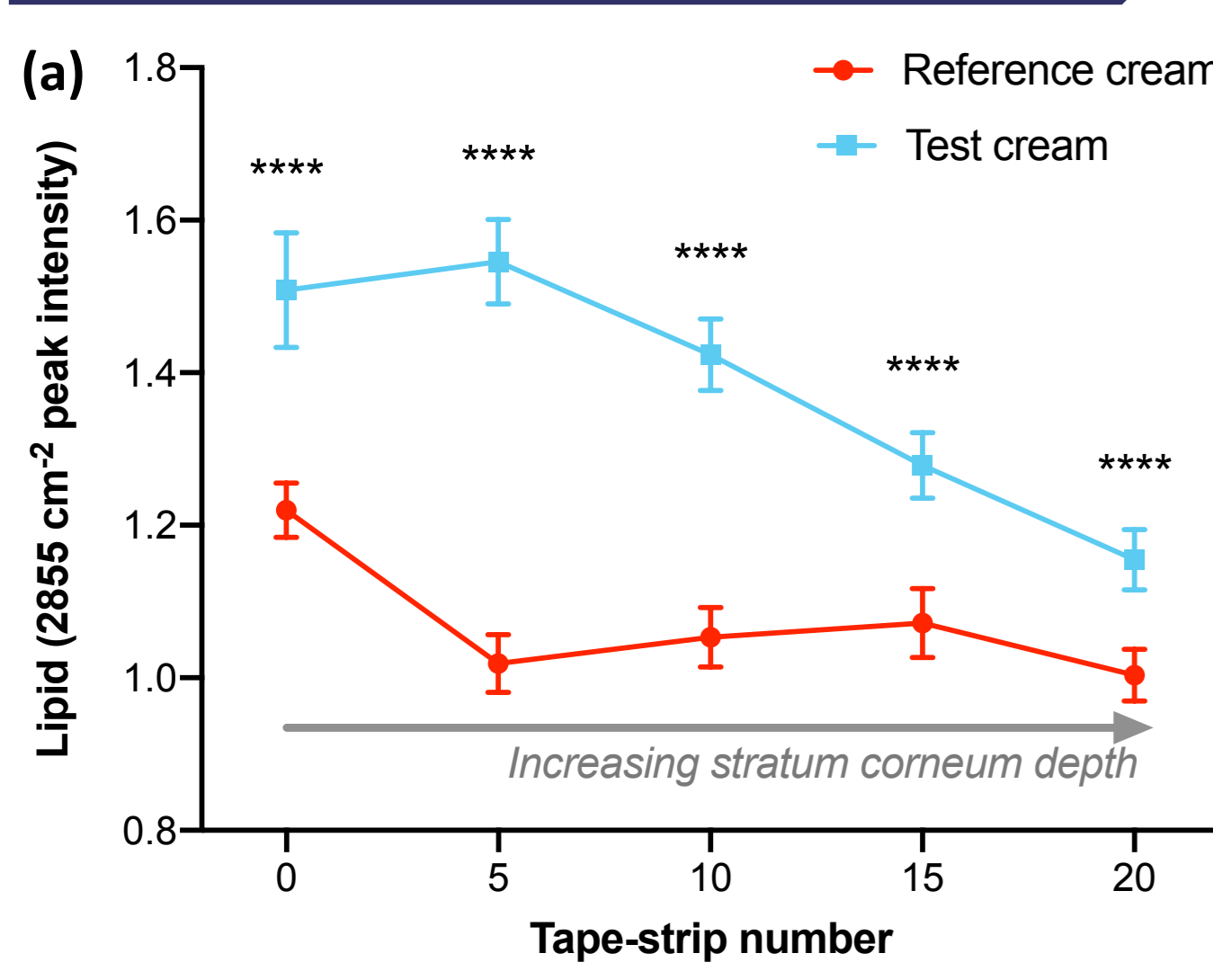


- A double-blind intra-subject-controlled study involving 34 participants aged 20-89 with dry eczema-prone skin
- 4 weeks twice-daily treatment of the right or left forearms and lower legs
- Randomized allocation of the test cream or the reference cream (a basic SLS-free emollient commonly prescribed by National Health Service (UK) [5])

## CONCLUSIONS

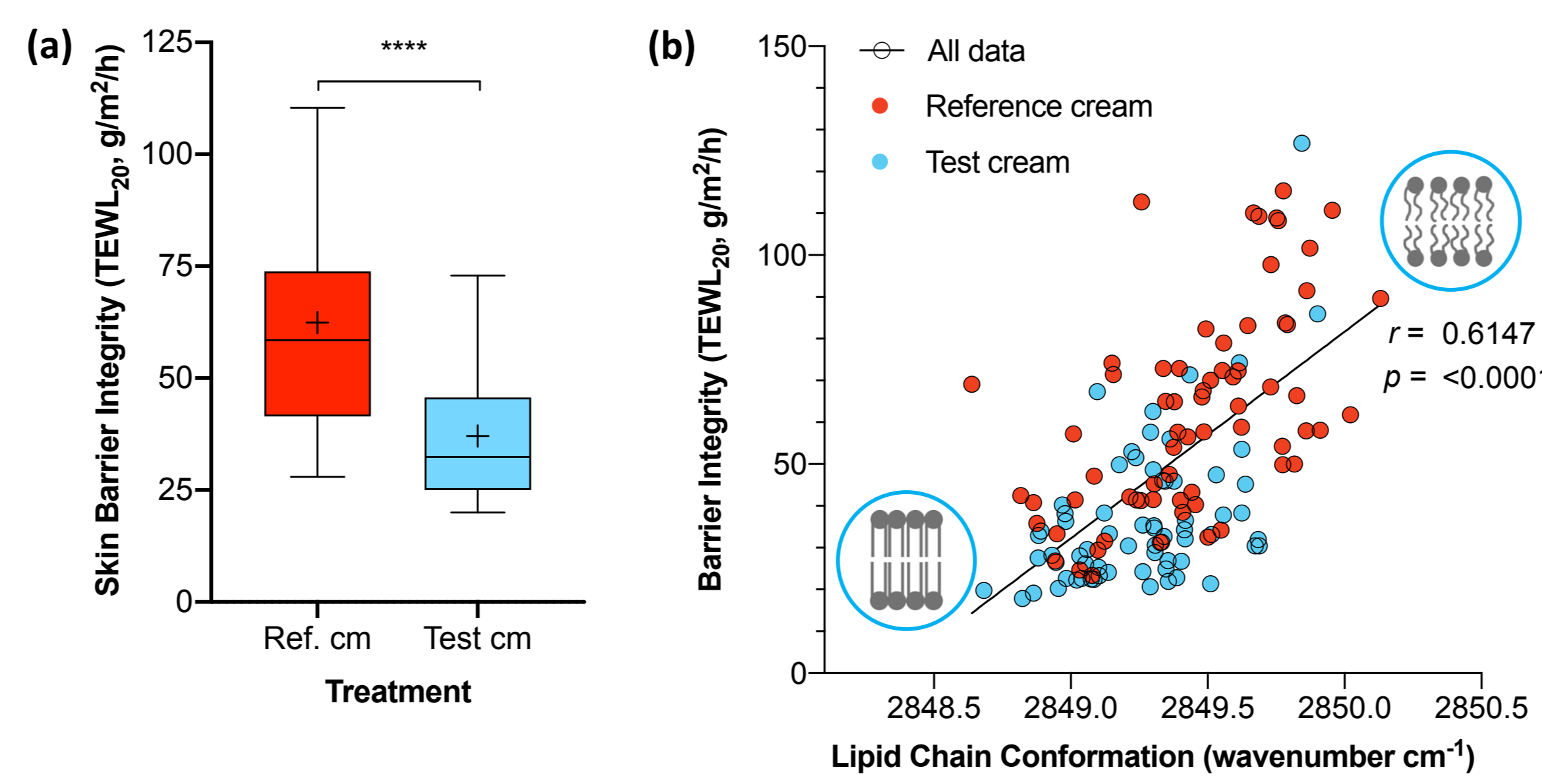
- The test cream delivers essential skin lipids deep within the SC where they reinforce the skin barrier and protect the skin from dryness and irritation.
- Compared to the reference emollient cream, commonly prescribed in the UK, the test cream is highly suited to the management of dry, sensitive, skin.

### The test cream increased lipid levels deep within the stratum corneum and enhanced lipid structure



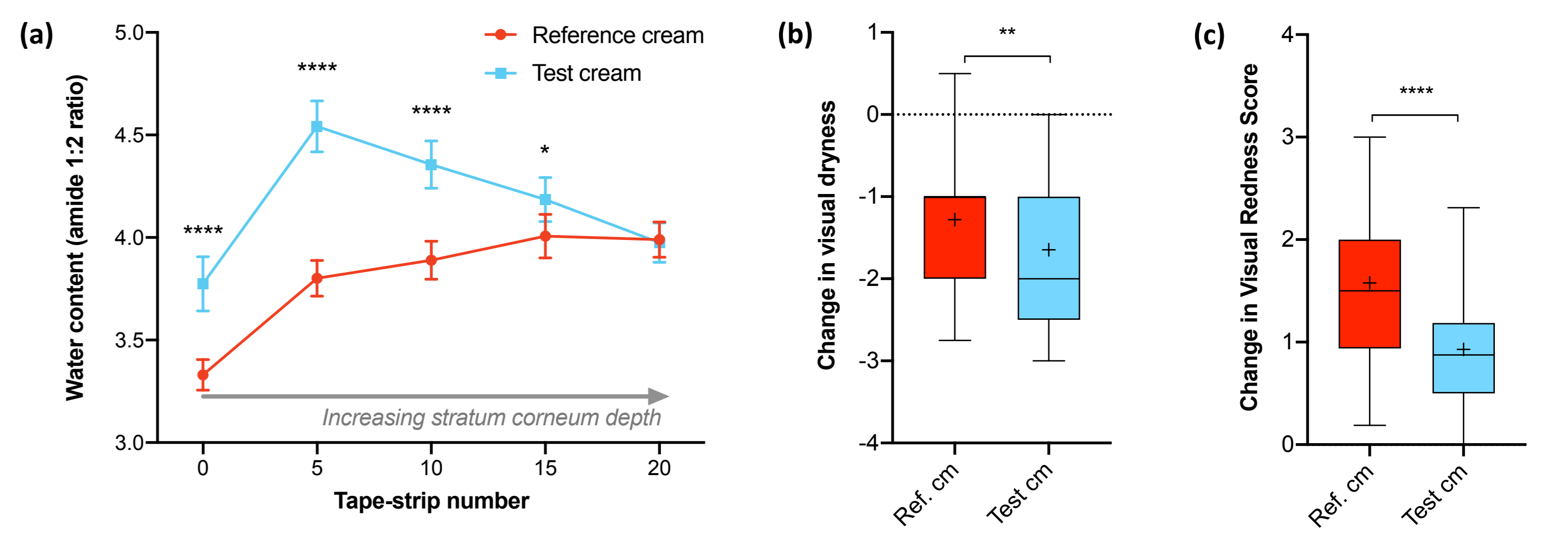
(a) LIPID CONCENTRATION (relative to amide II) within the stratum corneum (forearm) measured by FTIR spectroscopy after 28 days of treatment (b) LIPID CHAIN ORDER is indicated by the centre of gravity (COG) of the FTIR spectrum lipid band at 2850 cm<sup>-1</sup>[6]. (c) MEAN LIPID CHAIN ORDERING across the stratum corneum. Asterisk indicate results of pairwise comparison (\*\*\*\*p<0.0001)

### Enhanced lipid structure was significantly associated with improved skin barrier integrity



(a) SKIN BARRIER INTEGRITY on the forearm after 28 days treatment. TEWL<sub>20</sub>, trans-epidermal water loss measured after 20 consecutive tape-strips to experimentally disrupt the skin. (b) CORRELATION between skin barrier integrity and lipid chain conformation. \*\*\*\*results of a pairwise comparison (p<0.0001)

### Improved skin barrier structure was accompanied by increased hydration, decreased dryness and reduced sensitivity to irritants



(a) SKIN HYDRATION on the forearms after 28-days treatment, measured as surface stratum corneum water content by FTIR spectroscopy during tape-stripping [7]. (b) VISUAL DRYNESS scored (0-4) on the lower legs after 28 days treatment. (c) SKIN SENSITIVITY after 28-days treatment. Change (Day 30-day 29) in visual redness/erythema after 1% sodium lauryl sulphate (SLS) patch (applied for 24h). Boxes indicate the median, 25<sup>th</sup>/75<sup>th</sup> percentiles, with '+' for the mean and whiskers for the 5-95<sup>th</sup> percentiles. Asterisks indicate the results of pairwise comparison (\*p<0.05, \*\*p<0.01, \*\*\*\*p<0.0001).