



SUPERIOR DERMATOLOGICAL  
AND OPHTHALMOLOGICAL TESTING

# Future Directions in Personal Care and Medical Device Topical Product Testing: How to ensure they are safe and deliver benefits for consumers

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# About us



- The longest established continually active CRO in this field in the UK and one of the longest established globally. Our continued success is built on our heritage.
- Founded by Professor of Dermatology, Ronnie Marks, we continue to operate to the original principles
- Many of the techniques used widely today were developed at Cutest
- Focus on innovation and new measurement techniques



# Outline of talk

- The beauty market
- Overview of upcoming claims
- Measuring consumer experience
- Ensuring products are safe



# Is the beauty market important?

The Global Beauty and Personal Care Market was valued **at \$422.72 billion** in 2020 and is expected to reach **\$558.12 billion**, growing with the CAGR of 4.82% by 2026.

**UK market contributes £30bn to UK GDP and employs over half a million people**

*Based on global estimated figures. Source: Euromonitor International  
and Oxford Economics*

# Complexity is increasing in the market

- The market is global but
- Northern European/ U.S. consumer demands have traditionally driven claims:
  - Moisturisation
  - Wrinkle reduction
  - Skin firming
- Emerging global science on pollution, microbiome, health and others, impacts consumer demands
- Lifestyle and technology trends, such as personal health monitoring, clean living, experiential spending starting to impact the future direction of beauty care



To meet these future needs, we need to think about how these will impact skin appearance and develop appropriate tests



# Which of these might be classified as a cosmetic claim?

- The product and or ingredient actions.
- The product or ingredient benefits.
- What it contains (or not?).
- Instructions for use.
- Its comparative benefits.
- Who should use it.
- How its been tested.
- Trademark.
- Patent.
- Product name.
- Who uses it.
- Who recommends it.
- Photograph of the pack
- Photograph of someone using the product

# The regulations

- ASA, Clearcast and Trading Standards are the major upholders of the regulations
  - Companies self regulate (except for TV advertising)
- CAP code of practice:
  - Broadcast and non-broadcast advertising (including websites, social media)
  - Legal, Decent, Honest, Truthful
  - Requires **adequate** and **appropriate** evidence to support claims
- EU Cosmetics Regulation
  - Article 11(2)(d) ....proof of the effect claimed...
  - Article 20(1)...not imply the products have characteristics or functions they do not have.
  - Must follow **the Common Criteria for Claims**



# Who are our target audience for claims?

- The consumer
  - Safety
  - Delivers the promised benefits
- Regulatory authorities
  - Safety
  - Delivers the promised benefits



# The good old days!

**WASH AWAY FAT  
AND YEARS OF AGE**

**With La-Mar  
Reducing Soap**



**REDUCTION!**

The new discovery. Results quick and amazing—nothing internal to take. Reduce any part of body desired without affecting other parts. No dieting or exercising. Be as slim as you wish. Acts like magic in reducing double chin, abdomen, ungainly ankles, unbecoming wrists, arms and shoulders, large busts, or any superfluous fat on body. Sold direct to you by mail, post paid, on a money-back guarantee. Price 2/- a cake or three cakes for 4/-; one to three cakes usually accomplish the purpose. Send postal or money order to-day. Surprising results. **LA-MAR LABORATORIES, Ltd., 48, Rupert Street (110L), London. W.1.**

ALPHONSO & IMOGENE  
AN IDYL OF  
HENRY'S CARBOLIC SALVE.



ALPHONSO THIS REMEDY TRIES — AND AGAIN POSES THE QUESTION — NOR DOES SO IN VAIN HENRY'S CARBOLIC SALVE HAS SWEEPED HIS FACE CLEAN OF EVERY UNSIGHTLY SPOT THAT WAS SEEN AS A COMPOUND FOR HEALING ITS SPEEDY AND SURE AND FOR BURNS, CUTS AND BRUISES, READIEST CURE.

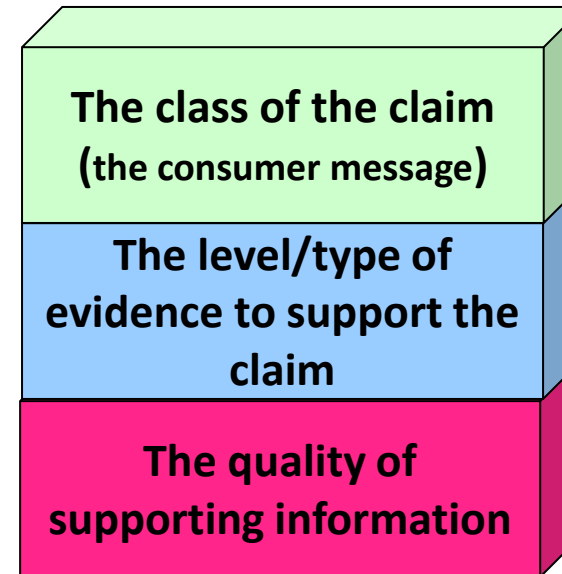
“ . . .Henry's carbolic salve has swept his face clean of every unsightly spot that was seen. . ”

# What do you want to claim?

## How will you justify the claims?

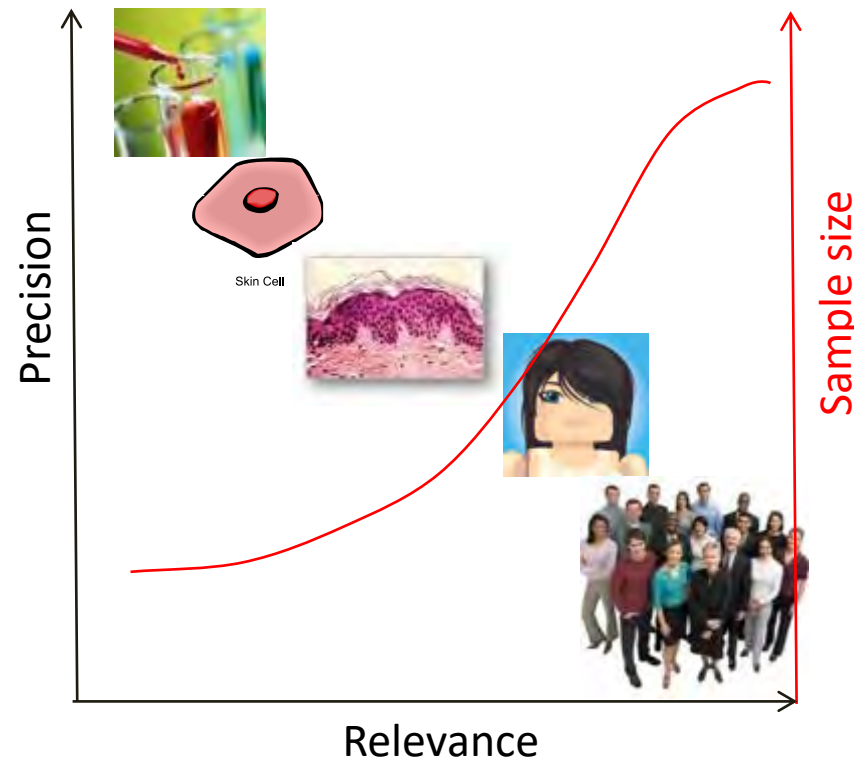
- What is the claim?
- Which product attributes will affect claims?
- What sources of evidence are permitted/enough?
- How will you know your claims have been achieved?
- Where is the consumer in this process?
- Can you put a value on your claims?

### CTPA BUILDING BLOCKS APPROACH



# Gathering & Evaluating evidence

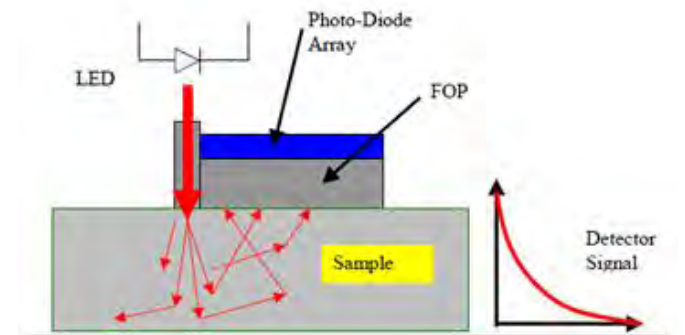
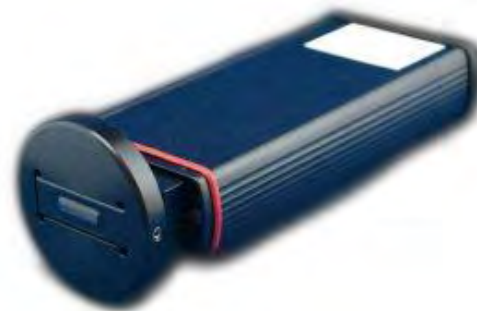
## Source & Design Factors



- In-tubo
  - Model; Concentration; End point
- In-vitro
  - Single cell; colonies; mixed cell types
- Ex-vivo
  - Longevity; donor number and tissue type
- In-vivo
  - Clinical; instrumental; sensory; observational.
- Consumer/volunteer study
  - Demographic; Numbers; exclusion/inclusion; randomisation

# How do we make this consumer relevant?

- How does the consumer experience the benefit?
- Why would the consumer keep buying if only a technical claim?
- Skin is infinitely more complex than invitro models can be
- Is the testing ethical?
  - E.g. pollution
- Should we not focus on how products protect natural skin systems to improve skin appearance?
  - **Focus on the consumer experience**
    - Skin radiance and translucency
    - Texture
    - Skin colour



# A more holistic approach to skin appearance measurement

- We need to be able to visualise consumer relevant end points for a very broad global demographic
  - Wrinkles and moisturisation are not relevant for many consumers
- We need methodologies that apply to emerging trends:
  - Pollution
  - Microbiome
  - Sleep
  - Healthy lifestyle
- The claim should relate to the consumer experience, not just be technical

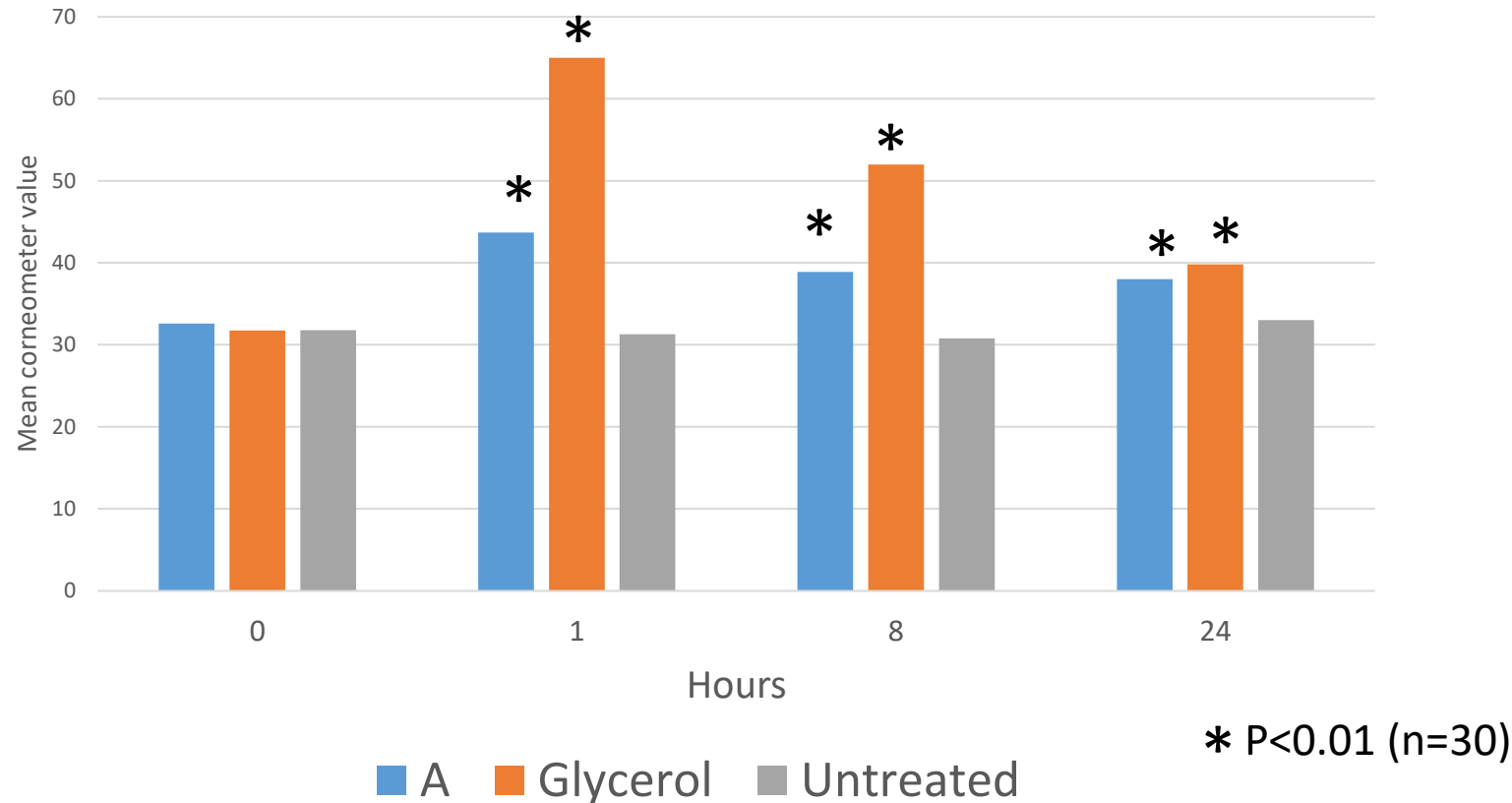


# Our approach to skin appearance measurement

- Skin appearance is not a single measurement:
  - Colour
  - Evenness of skin tone
  - Surface texture
  - Blind assessment of images
  - Translucency and Radiance



# Example: 24 Hour Moisturisation supported by Corneometer measurements



- Product 'A' was statistically significantly different from baseline at 24 hours supporting '24 hour moisturisation' claim
- No consumer perception data was collected for this study



# Blind assessment of images

- Randomised pairs presented to trained assessor or consumer panel
- Blind score visual differences
- Able to demonstrate 'visibly improved' claims
- Correlate to instrumental measurements and show **consumer perceivable** change
- Can be made more sophisticated e.g. 'younger looking', 'X years younger looking'

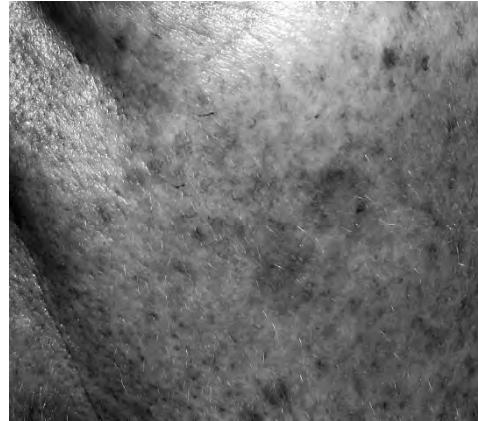
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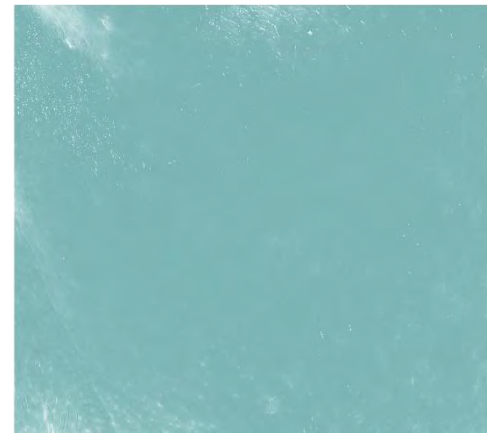
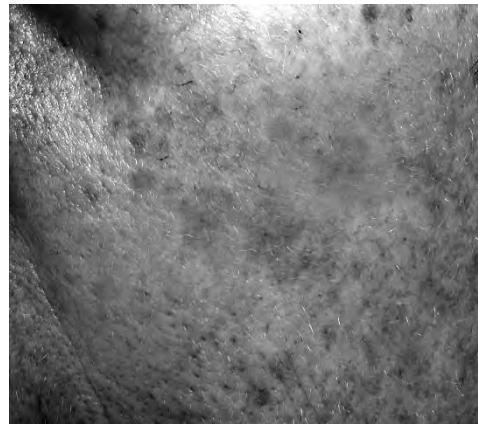
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# Evenness of skin tone



Mean grey level  $127 \pm 45$

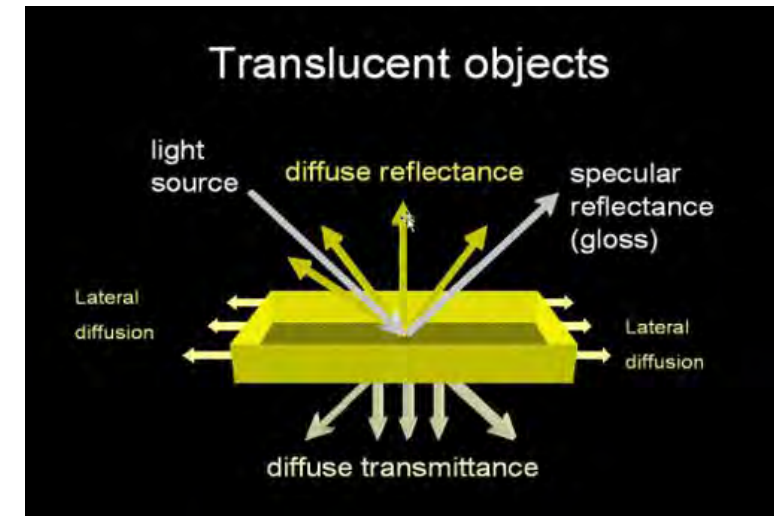


Mean grey level  $120 \pm 18$

**We can measure tonal variation and variation per colour to determine evenness of skin tone**

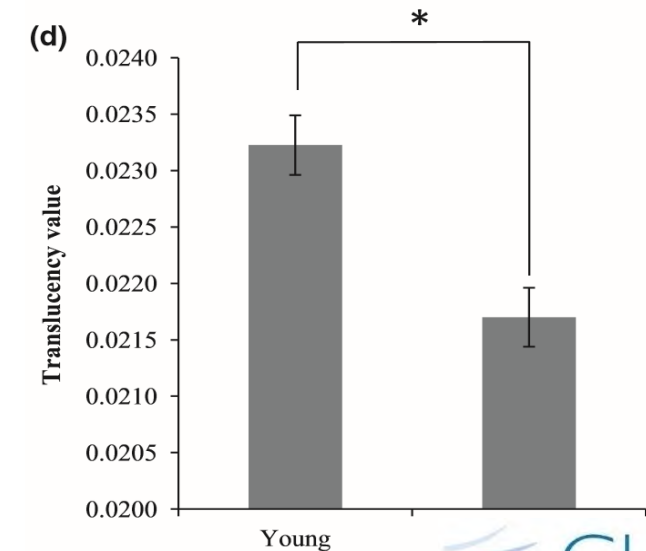
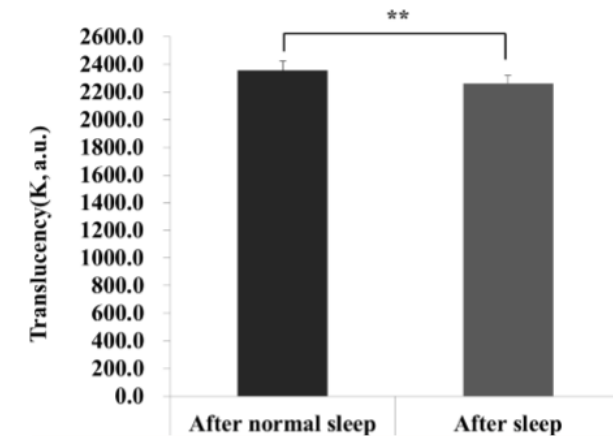
# Translucency and Radiance

- The missing element in skin appearance characterisation
- Skin translucency and radiance are not related to the surface
- Translucency and radiance are impacted by the underlying structure of the skin
  - Melanin
  - Blood flow
  - Ageing processes
  - Health status



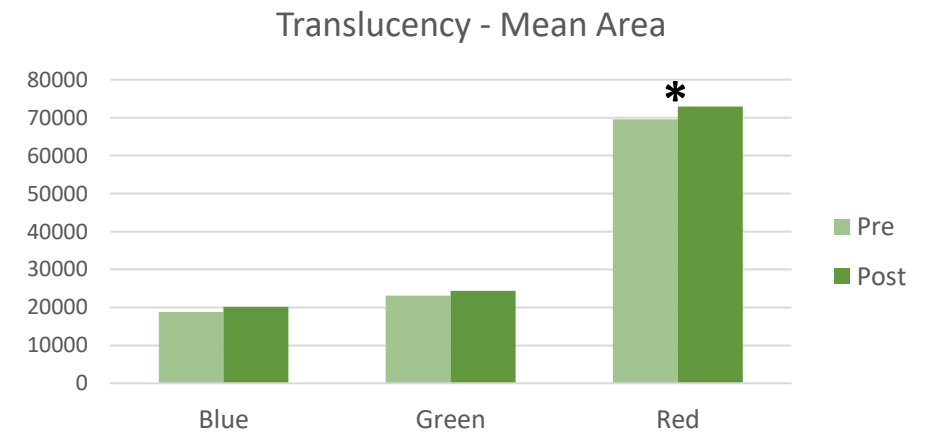
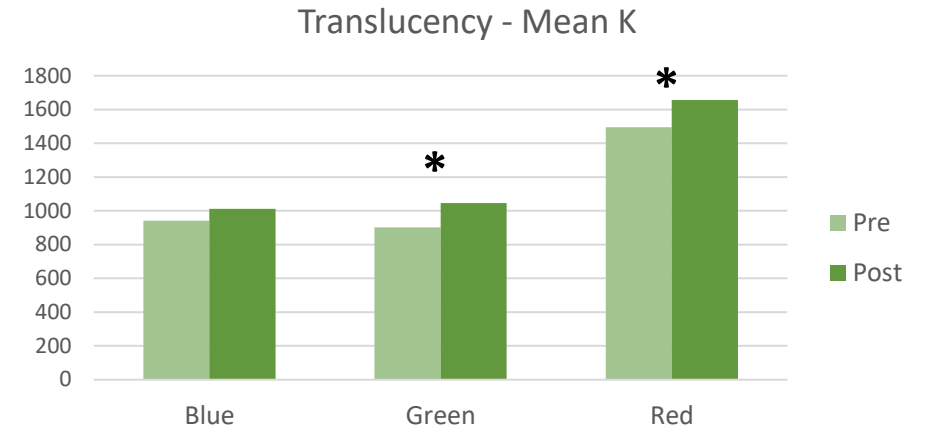
# Translucency associates to visual skin health

- Kim et al. 2017 showed perception of skin appearance after sleep deprivation relates to translucency
- Smaller change in skin tone
- Perceptible by observers
- Also showed significant age related differences



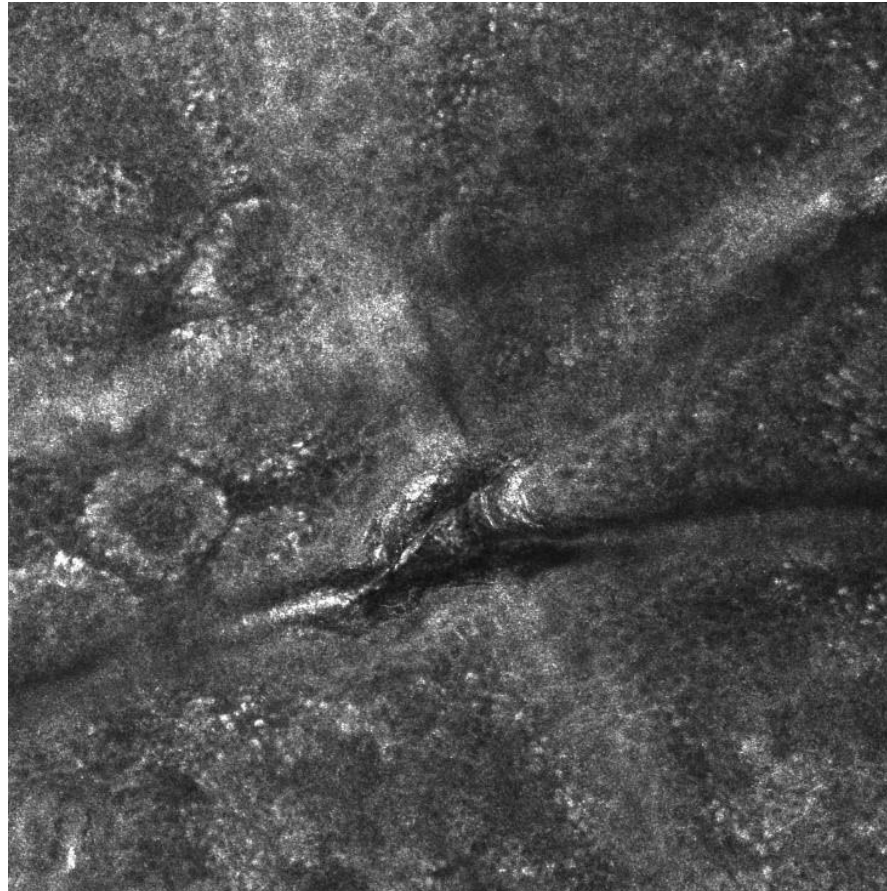
# We intuitively know radiance, now we can quantitate it

- Blue light is absorbed by melanin in skin
- Red light is least absorbed and most scattered within skin
- Each component of the measurements ( $\alpha$ , K and area) provide different information



\* p<0.05

# In vivo confocal imaging of skin- Vivascope



Non-invasive optical imaging through the epidermis:

- Melanocytes
- Melanin granules
- Dermal papillae
- Individual keratinocytes
- Collagen bundles

# Visia and Primos 3D skin profile imaging



# Example: Instrumental and self-perception data: ‘Reduces the visibility of stretch marks’

- Will require a body of evidence as no single test will adequately substantiate the claims
  - Ingredient benefits important
  - Measurable change to the skin to support ingredients benefits
  - Consumer relevant end points
- Approach: 12 week study with the following measures:
  - Clinical photography
  - Moisturisation
  - Elasticity
  - Clinical grading by nurses
  - Blind assessment of randomised before and after images
  - User perception questionnaires

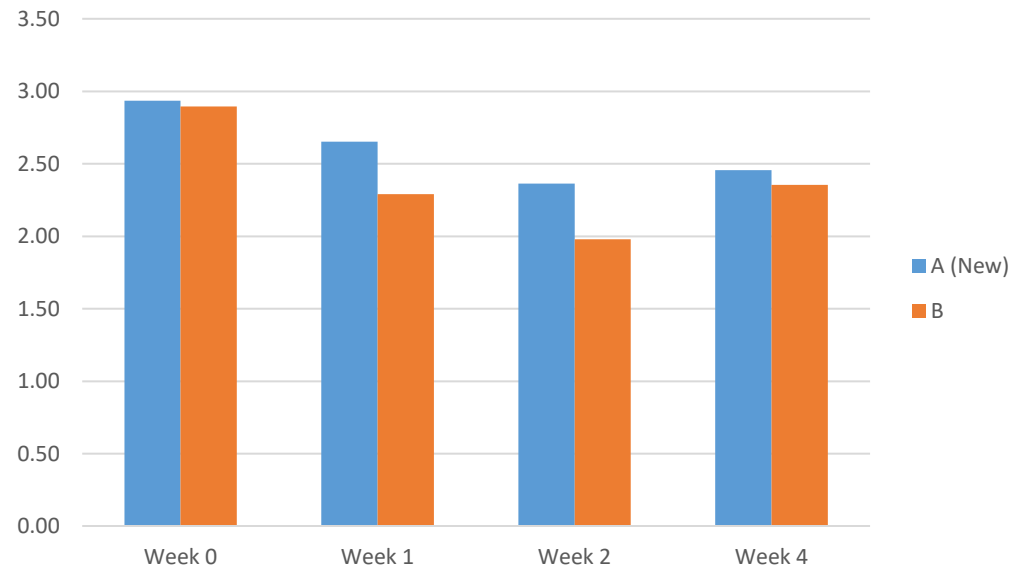




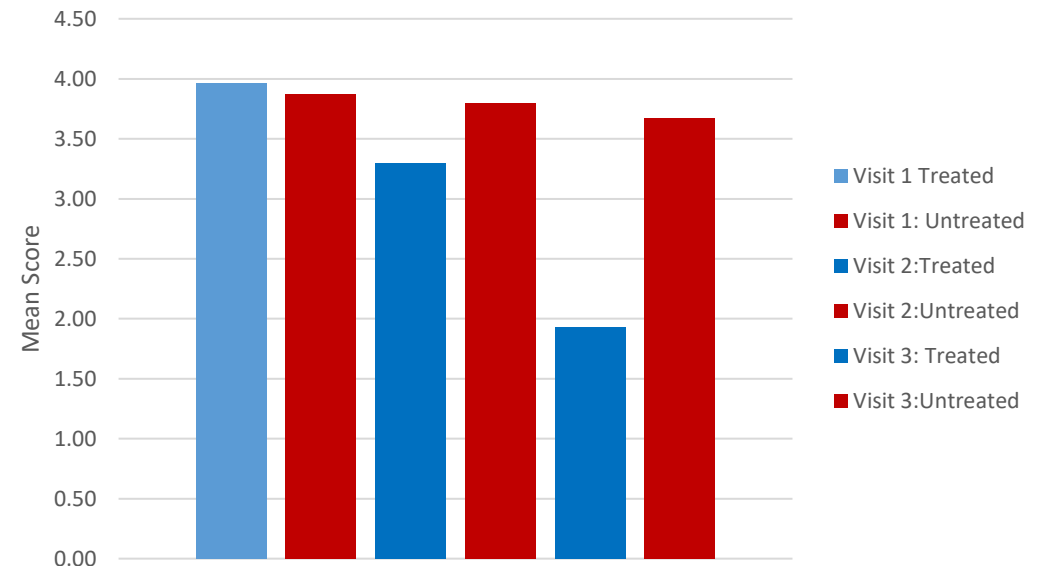
# Example: expert clinical grading

- Two different study examples below:
  - Facial serum
  - Foot product
- Calibrated and validated scoring scales and expert assessors can quantitate clinical changes

Clinical Grading: Crows Feet



Anhydrosis Score



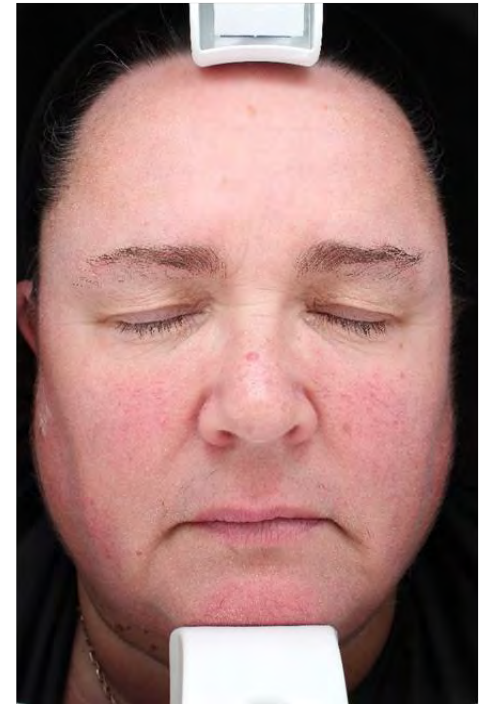
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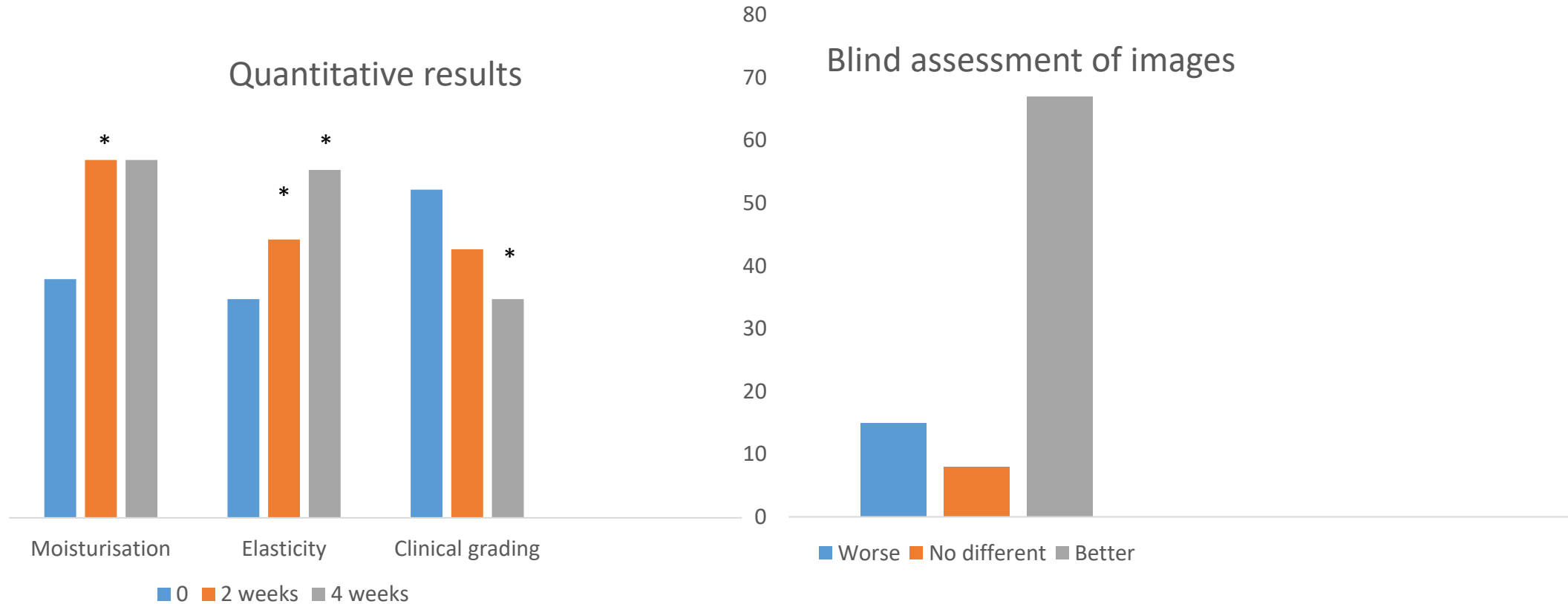
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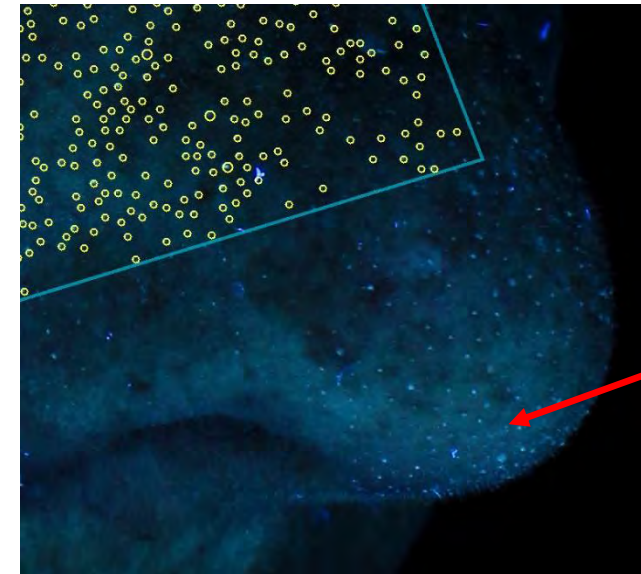
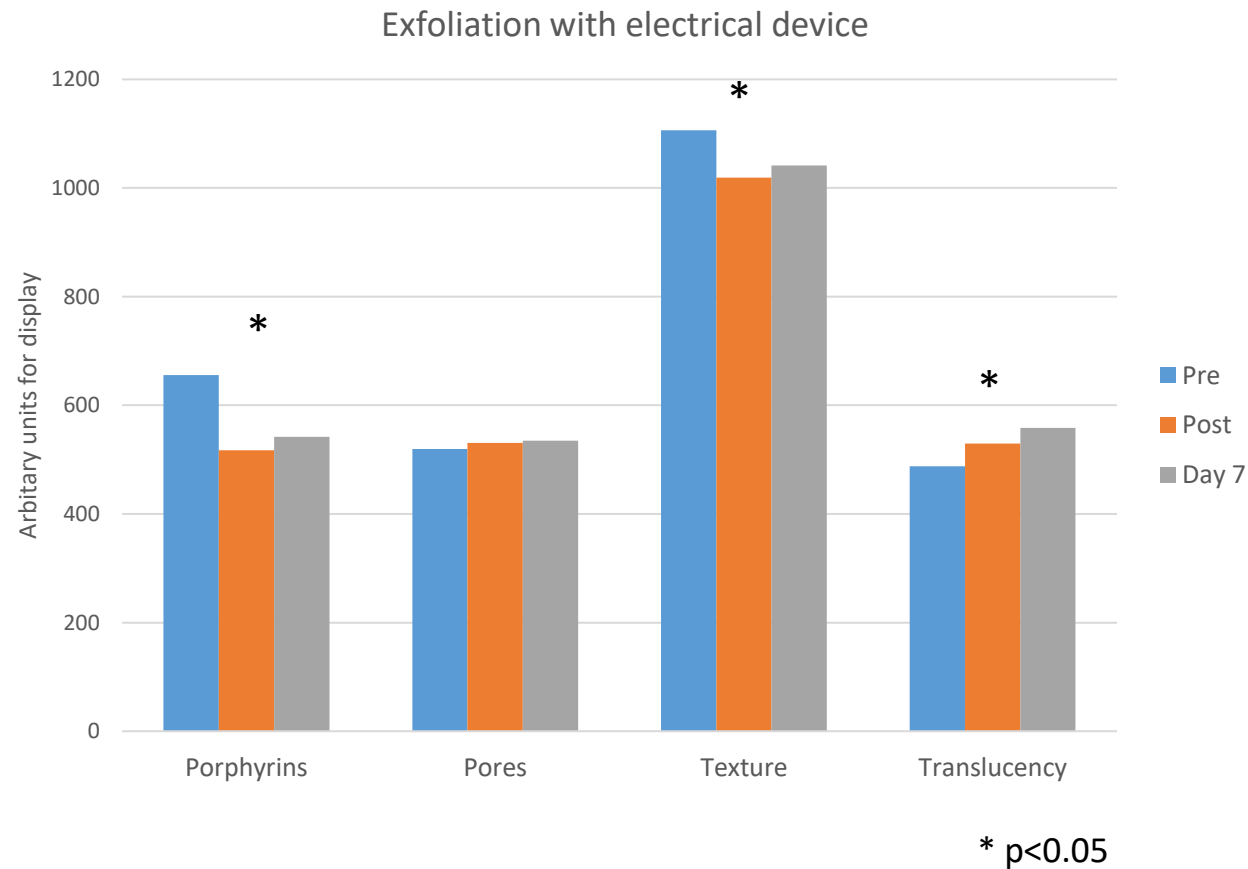


# Example: Instrumental and self-perception data: 'Reduces the visibility of stretch marks'



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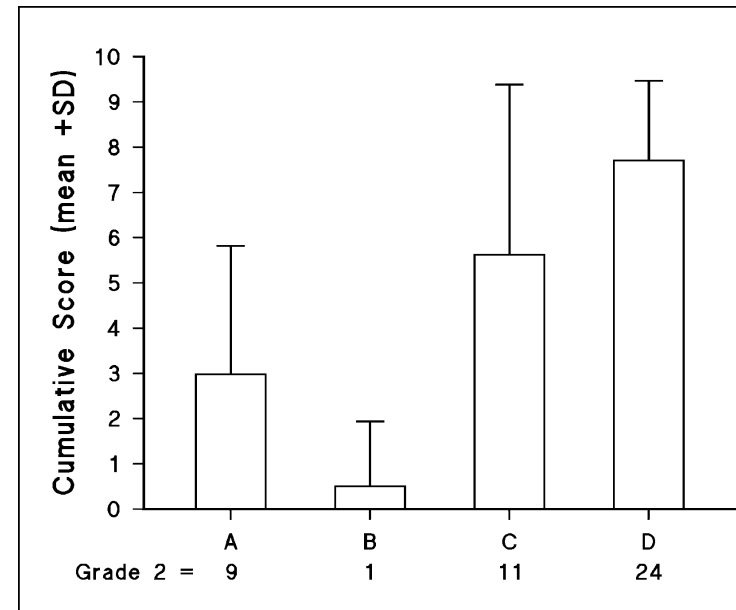
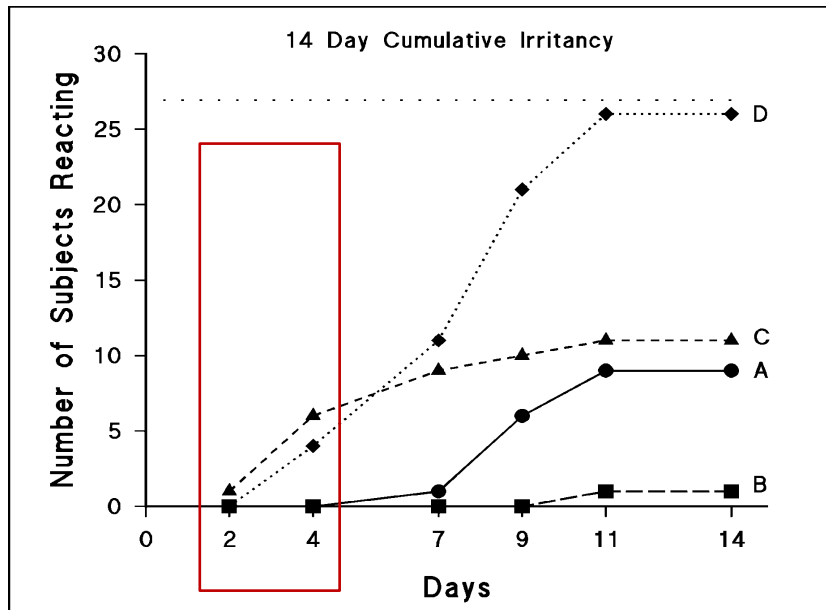
# Exfoliation benefits



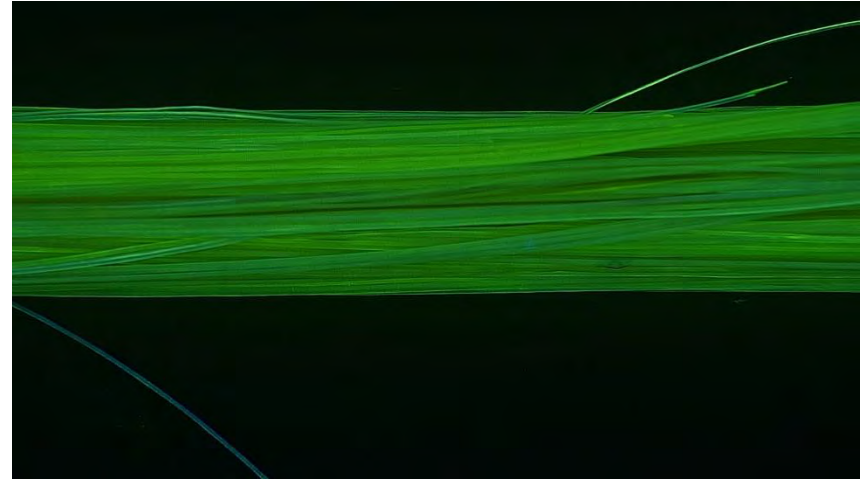
# Safety Testing

## Patch testing for irritation and sensitization

- Many protocols possible (24 hour, 14 day HRIPT etc)
- There is no such thing as a 'hypoallergenic patch test'
- Consider whether the study design is appropriate to ensure brand integrity:



# Disuphide hair bond quantitation



- Cutest have also collaborated with USW to analyse the benefits of a bond strengthening product using multispectral UV-Vis-Ir equipment

# Summary

- Claims testing methodologies need to keep evolving to meet consumer need
- With new claims, we need new approaches that are scientifically robust
- But.. **We must never lose sight of ensuring the data are consumer relevant**



