

Cosmetics & Hygiene

Cosmetics for treating hair loss

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Dr. Ines Sellami | 09.04.2024



WHEN YOU NEED TO BE SURE

SGS



Content

- Claim support
- Anatomy of the Scalp
- Hair Growth Mechanism
- Hair Loss
- Study Concepts



Types of Claims

- Microbiological claims e.g. kills all known germs
- Analytical claims e.g. with caffeine, zinc, ethanol
- Physical claims e.g. 50% more content, 50% less packaging
- Environmental claims e.g. 85% biodegradable
- Dermatological claims e.g. for a well-groomed scalp
- Performance claims e.g. stimulates hair growth

Do the products really deliver what they promise?

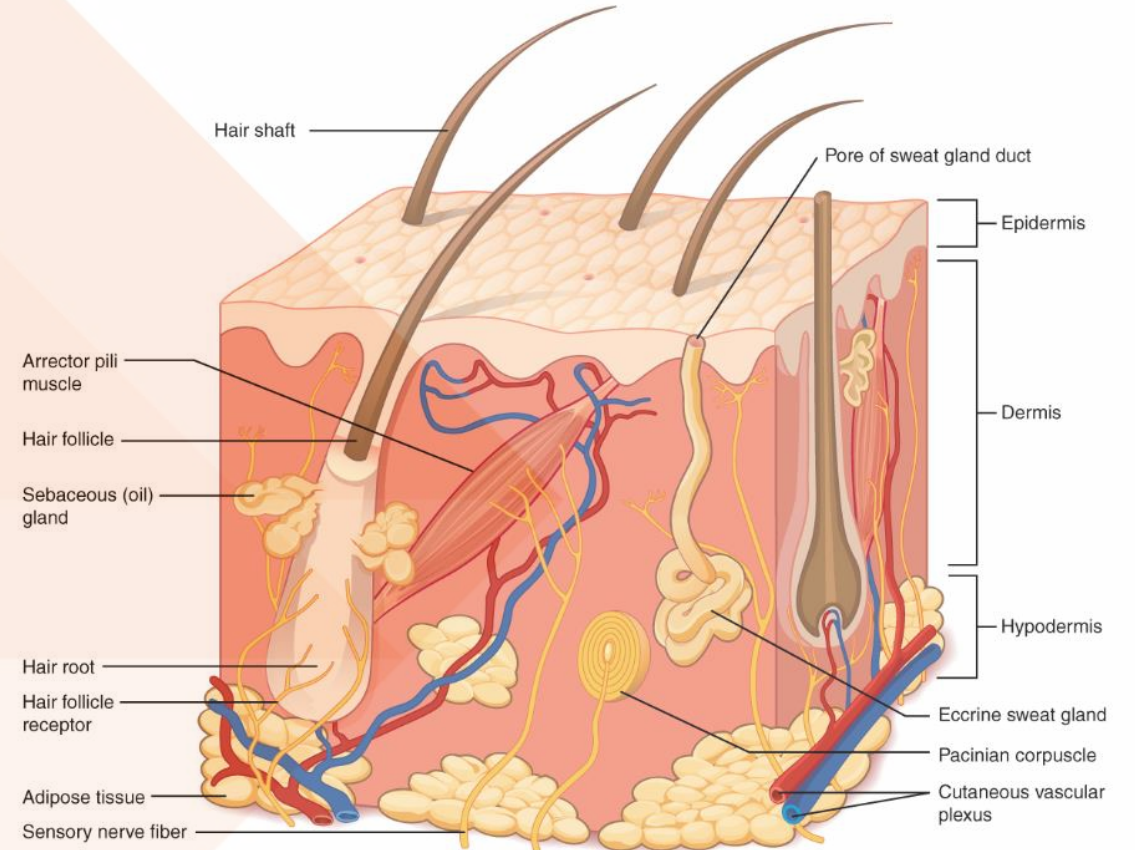


General Information on Performance Testing

- The Claims Regulation defines uniform criteria for product claims
- Proof of effectiveness is regulated in the context of EU Cosmetic Regulation 1223/2009/EC and EU Claims Regulation No. 655/2013
- Proof of effectiveness must meet the following requirements:
 - Traceability
 - Scientifically recognized methodology
 - Reproducibility
 - Statistical Significance
- Simulate consumer habits under defined test conditions

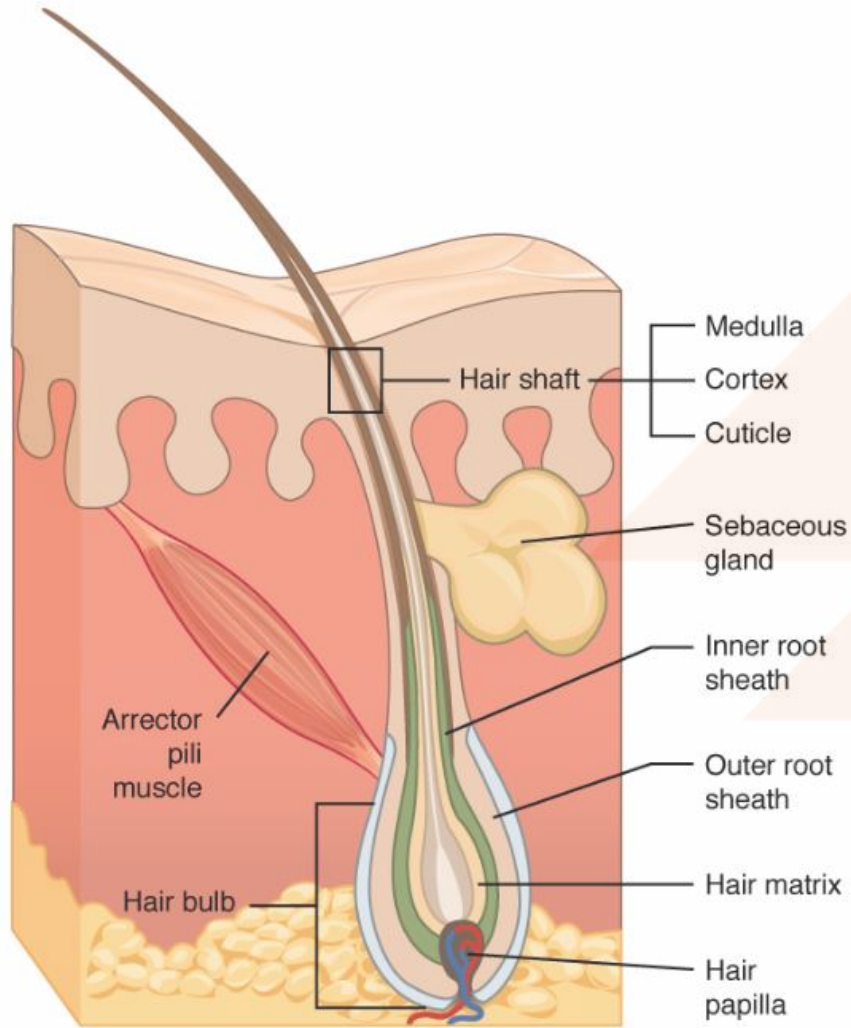
Anatomy of the Scalp

- Epidermis
- Dermis
- Hair & Hair Follicle
- Sebaceous Glands
- Blood vessels



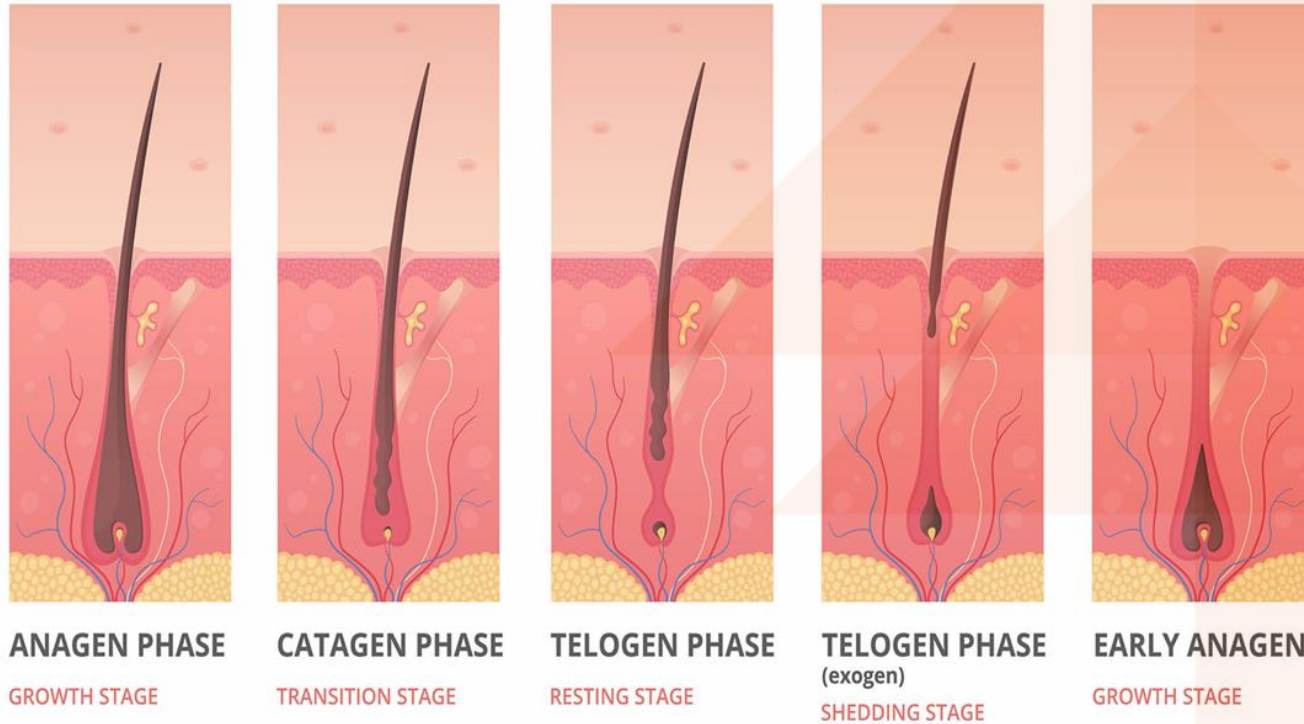
Betts, et al.; No changes made; <https://ecampusontario.pressbooks.pub/medicalterminology/chapter/integumentary-system/#Figure6.1.id>

Hair Follicle Structure



- Hair shaft - Medulla, Cortex, Cuticle
- IRS - Henle's layer, Huxley's layer, Cuticle
- ORS - outer root sheath
- Hair buldge region – between sebaceous gland and arrector pili muscle
- Hair bulb - hair matrix, hair papilla

Hair Cycle



Phases

- Anagen: Growth - Proliferation - 2 to 7 years
- Catagen: Transition - Apoptosis - 2 weeks
- Telogen : Resting - Hair removal - 12 weeks
Shedding
- Anagen: Growth stage of the new hair

Hair Loss (Effluvium)

is a symptom and not a diagnosis

- Functional or structural disorders
- >100 hairs fall out per day
- Hair follicle damage
- Cancer treatment (Chemotherapy/ Radiotherapy)
- Hormonal and nutritional disorders
- Stress etc.

Diseases:

- Alopecia Areata (AA) - patchy hair loss
- Androgenetic Alopecia (AGA) – pattern hair loss



110.000 hairs
600 cm²
50-100 hairs/day



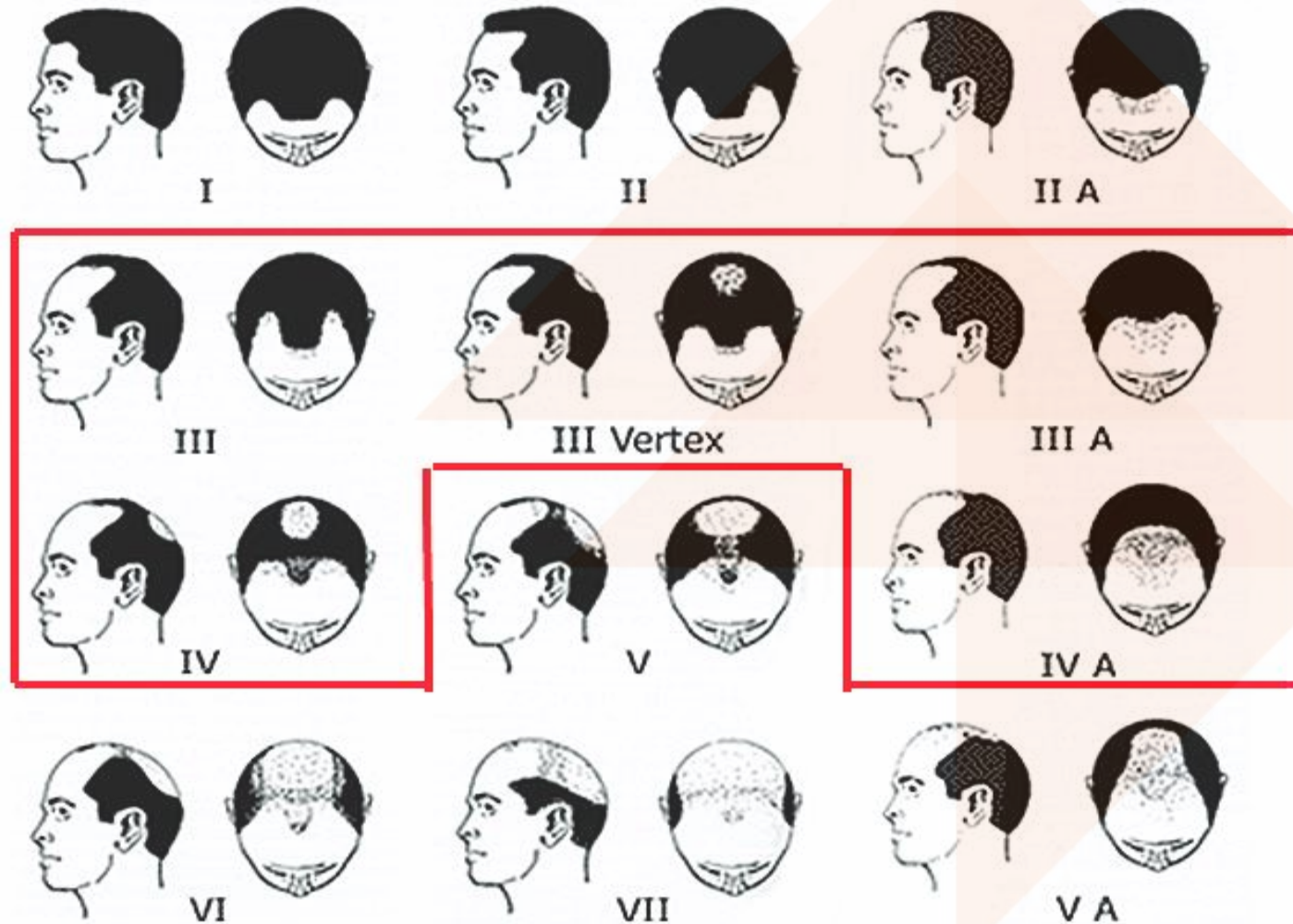
Hair Loss

In male or female pattern hair loss, a decrease of hair density on the scalp, is seen

- Anagen phase becomes progressively shorter
 - More telogen hairs
 - Less anagen hairs
 - Hairs tend to miniaturize
 - Decrease of hair density on the scalp
-
- Evaluation over 3, better 6 months



Hamilton Score



Male participants

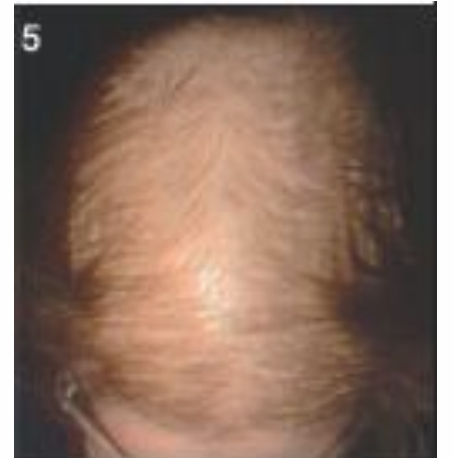
Ludwig Scale



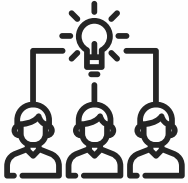
- Erich Ludwig's female pattern baldness classification system
- I: Visible thinning of the hair on the top of the head
- II: More extensive thinning of the hair than in I
- III: Full baldness

Savin Score

Female participants



Study Concept



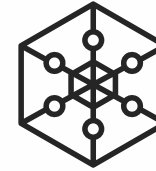
Objective measurement

Biophysical measurements in the lab or analytical lab tests



Expert grading

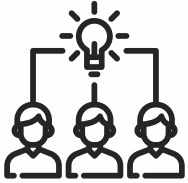
Evaluation by experts (lab assistants, hairdressers, dermatologists)



Subjective assessment by consumers

Home-use studies
Tests performed under supervision
> 8,000 panelists

Study Concept



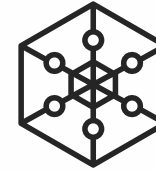
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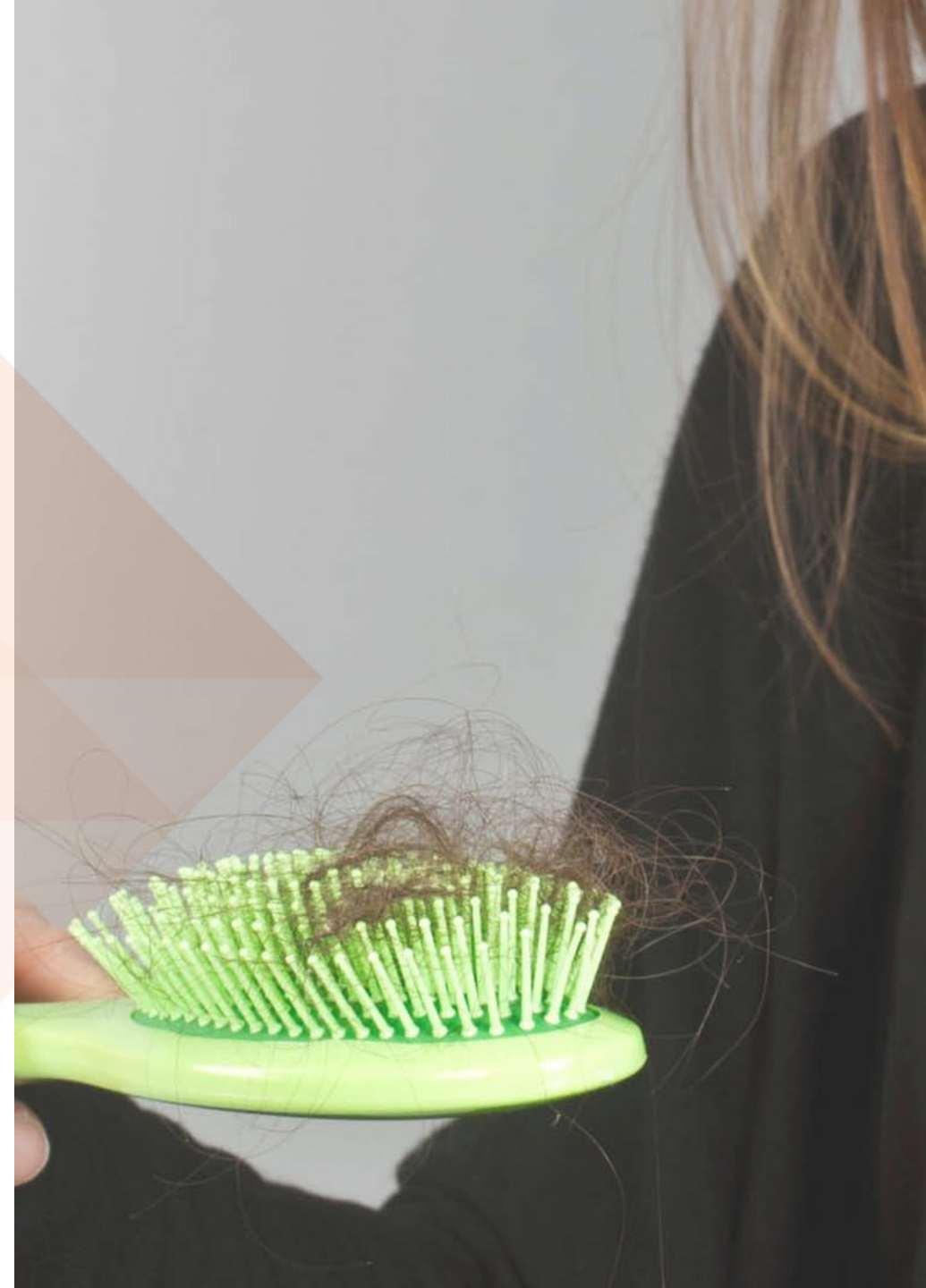
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Home-use studies

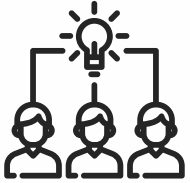
The panelists (as average consumers) assess anti-hair loss statements in the context of a home-use study by applying the products according to their usual habits. Product claims can be designed in a targeted manner by using a questionnaire. (screening)

Requirements:

- Panelists have no disease-related hair loss
- Sufficiently high number of panelists
- Sufficiently long application time
- Reproducibility
- Statistical significance



Study Concept



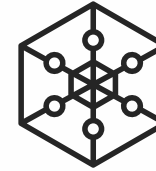
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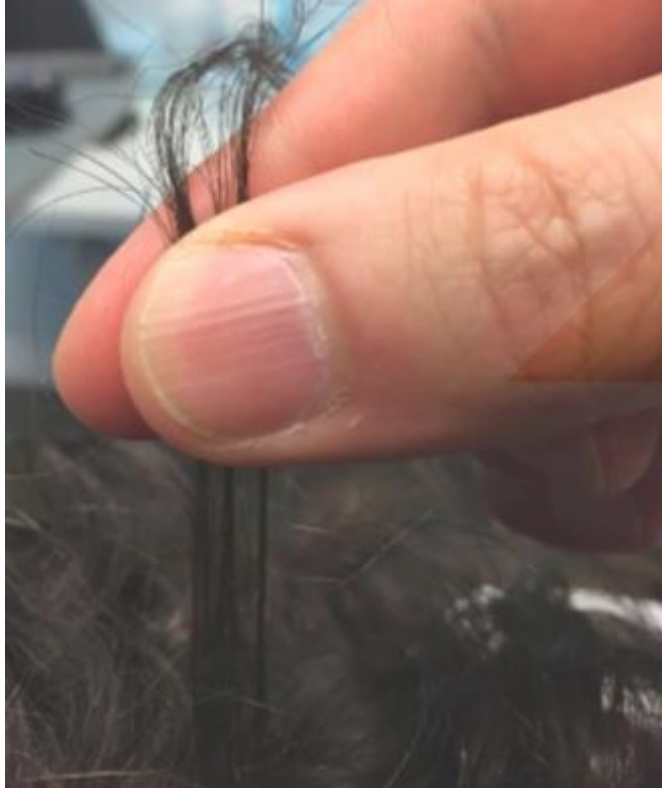
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Pull Test

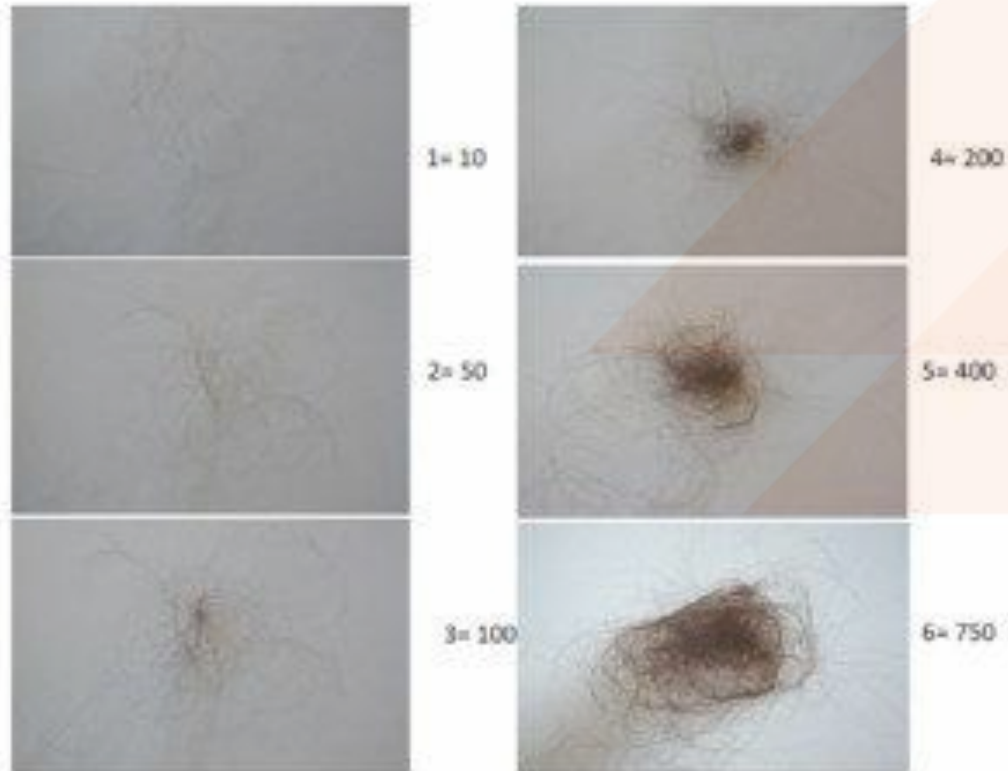


- Grasping 40 to 60 hairs between the thumb and index-finger and applying steady traction
- In general, only a few hairs can be plucked in this fashion
- < 10% normal
- >10% indicative of a pathologic process

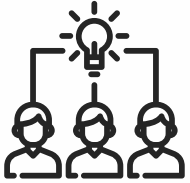
Blume-Peytavi, U., Hillmann, K., & Guarrera, M. (2008). Hair growth assessment techniques *Hair pull test* (pp. 130-131). Springer, Berlin, Heidelberg

Combing, Counting Of Combed-Out Hairs

- Combing of hair
- Manual counting of combed out hairs



Study Concept



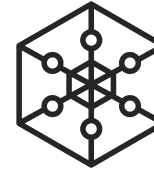
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Study Design –Vertex Image

- Vertex images (full head)
- Images of the test area for analysis (test area)
- Ranking of images (trained grader/ lay raters/ participants)
- Counting of combed-out hairs (trained technician/subjects)
- Objective (trained grader/ dermatologist) & subjective evaluation (participants):
Hair density, volume, length, growth, strength, thickness and hair quality,,
- Quality of Life [Subjects]
- Product acceptance questionnaire (Subjects)
- Assessment of tolerance (trained grader/dermatologist and participant)





Vertex Images

- Subjective rating by lay persons , same panel



Vertex Images

- Subjective rating by lay persons , same panel
- Objective evaluation by hair dresser or other experts

(Recommendation in “S3 - European Dermatology Forum Guideline for the Treatment of Androgenetic Alopecia in Women and in Men”)



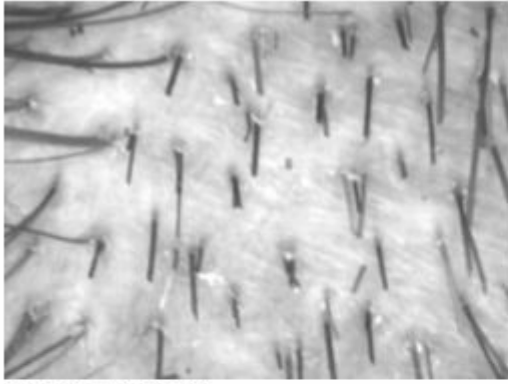
High Resolution Full Head Images



Study Design –Visia Image

- Visia images
- Half-head design
- After 4, 8 and 12 weeks
 - the length and diameter

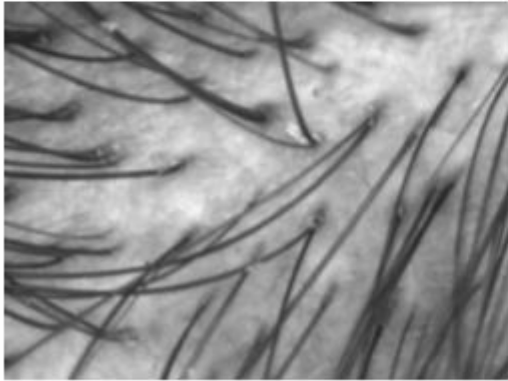




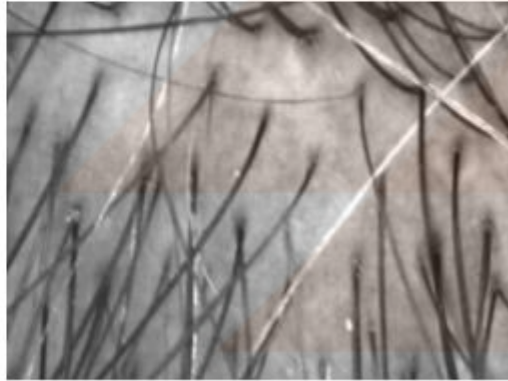
left (t0-Placebo)



right (t0-test item)



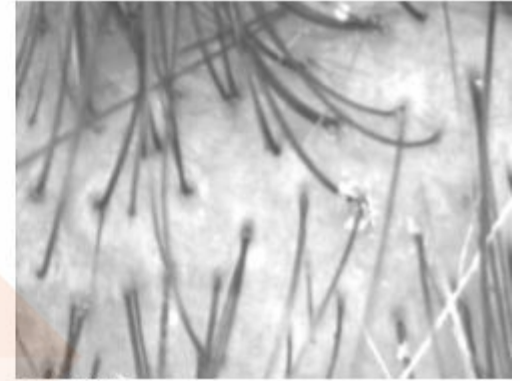
left (t1)



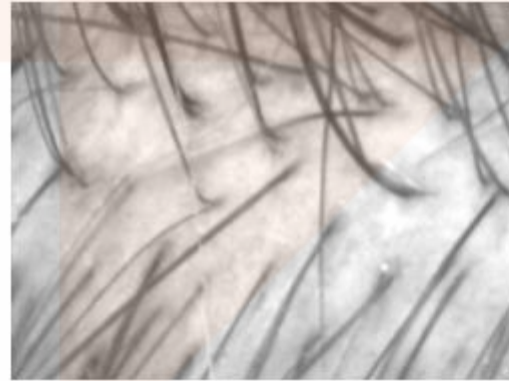
right (t1)



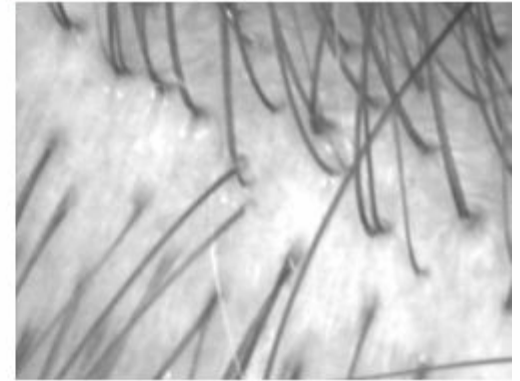
left (t2)



right (t2)



left (t3)



right (t3)

Study Design – Phototrichogram

- Inclusion; according to Hamilton Score (male) or Savin Score (female), Pull test (pull of telogen hairs) or according to self-estimation (weaker)
- Conduct : 8 weeks, 3, 4 or 6 to 12 month with compliance visits every 4 weeks
 - Day 1 Clipping of small Area on the Scalp, relocation of areas with microtattoos
 - Day 3 Images 2 days after clipping for phototrichogram Analysis
 - Image Analysis: hair density, rates of anagen and telogen hairs, anagen hair density, telogen hair density, anagen/telogen ratio, cumulative hair thickness, hair growth rate
- Test area : Full head , $\frac{1}{2}$ or defined part of the scalp



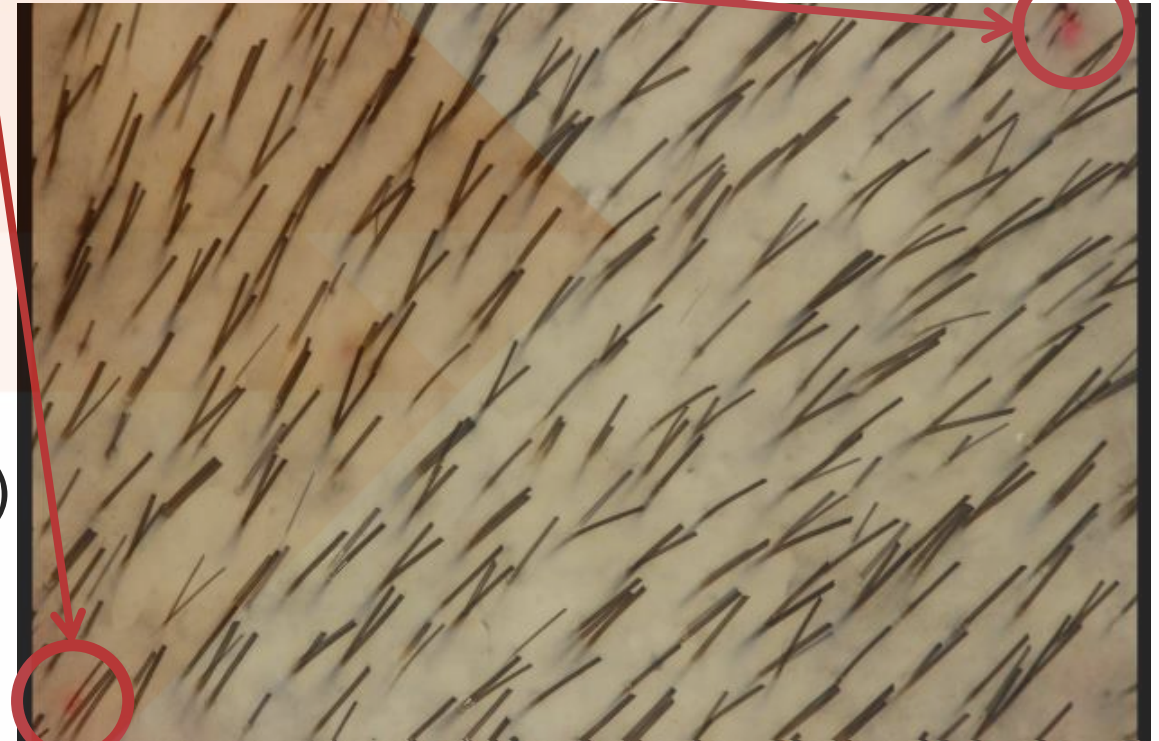
Phototrichogram method

- Clipping of hair in a small area on scalp
- Photo by Leviacam to check the shaving quality and visibility of microtattoos
- 2 days regrowth of hair
- Dying the hair

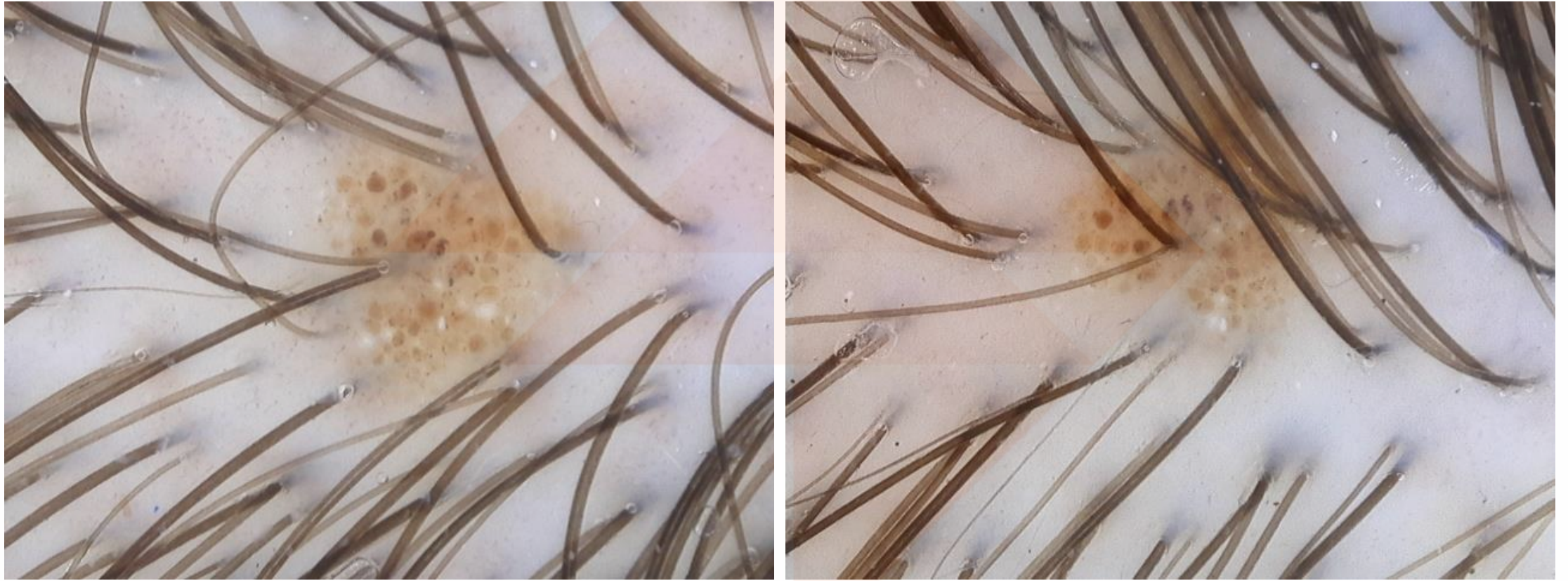


Phototrichogram method

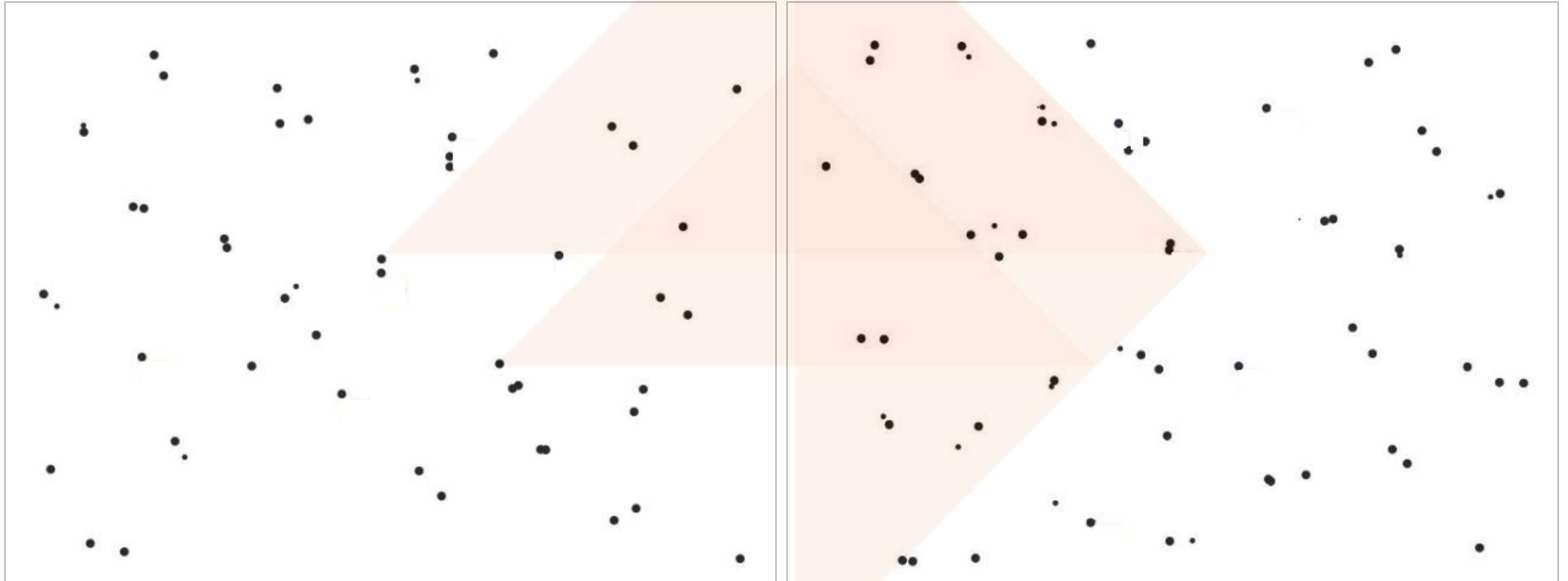
- Relocation of areas with microtattoos
- Photo by Leviacam, analysed for
 - hair density (hairs/cm²),
 - rate of anagen/telogen hairs (%),
 - ratio of anagen rate/telogen rate
 - growth rate (mm/day)
 - cumulative hair thickness (mm/cm²)
- Same procedure at further timepoints



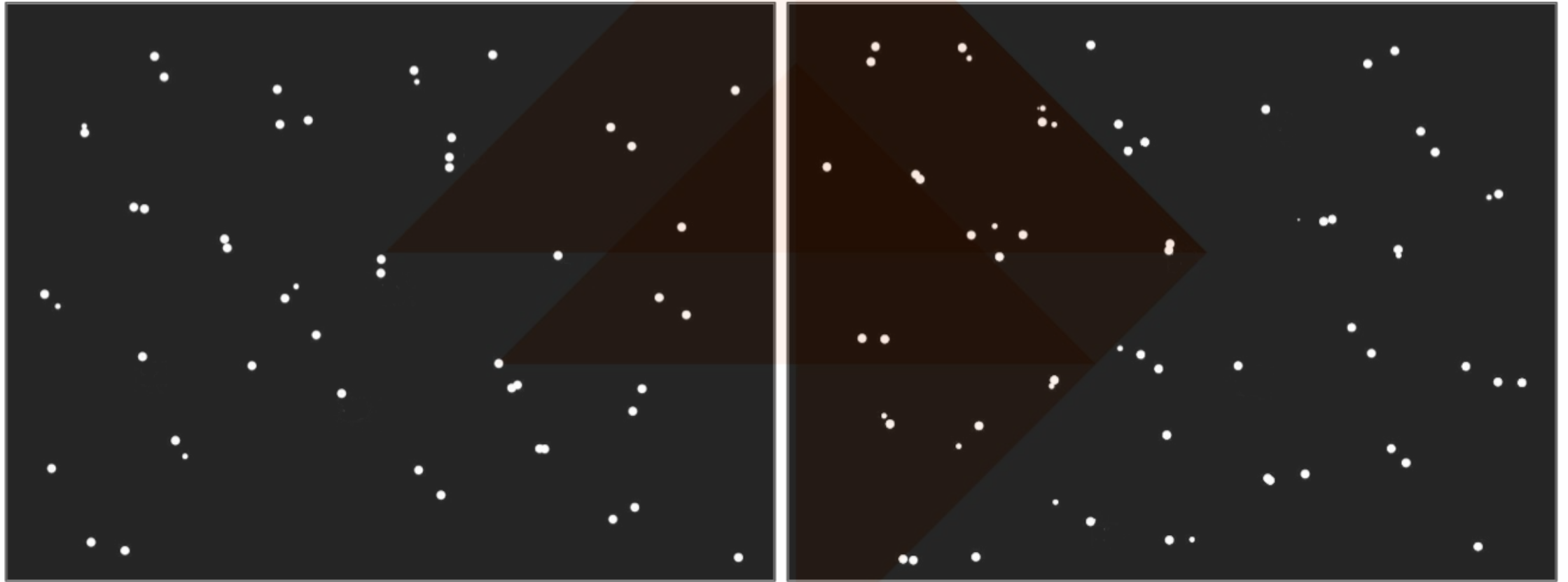
How to identify the same spot on scalp?



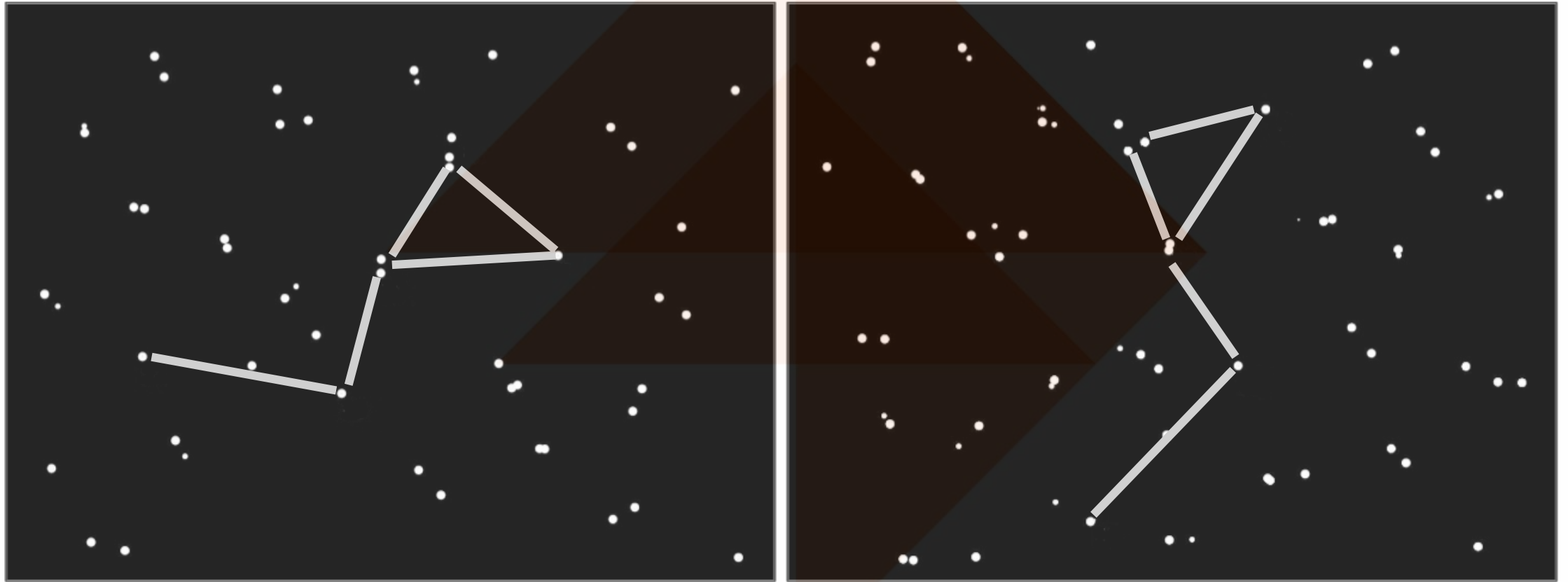
Remove hair & characteristic skin lesions from the image

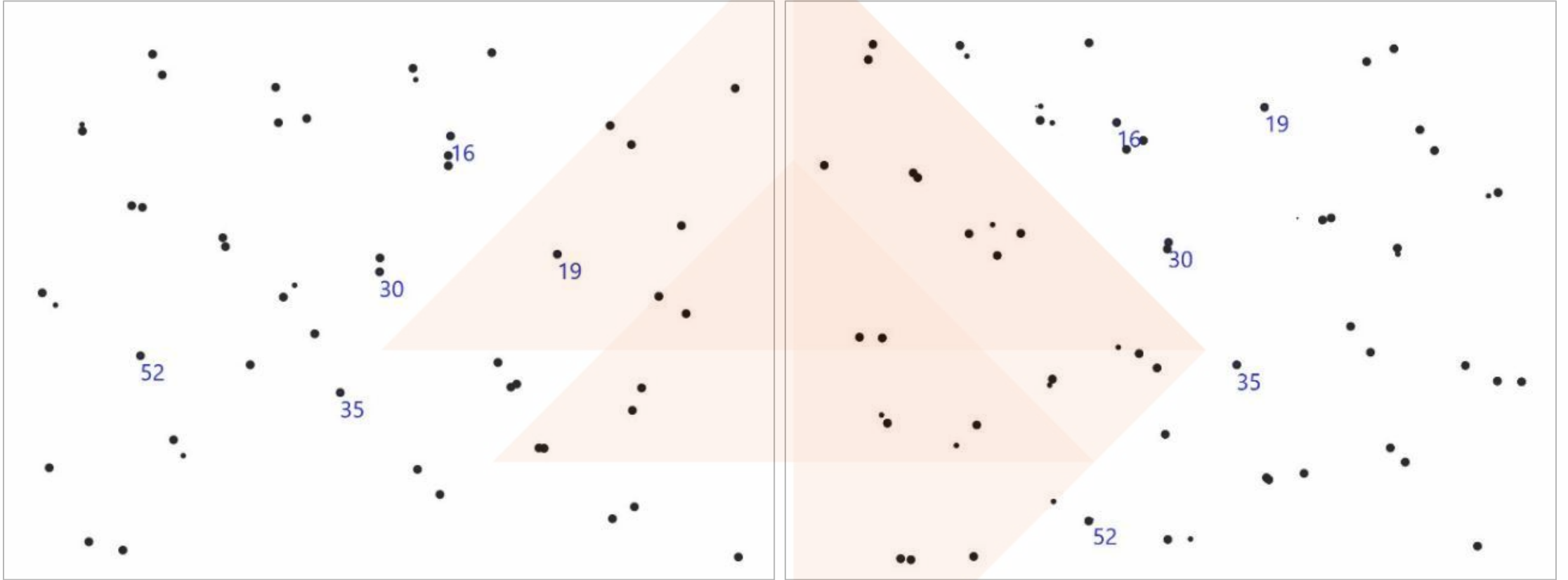


...looks like sky at night

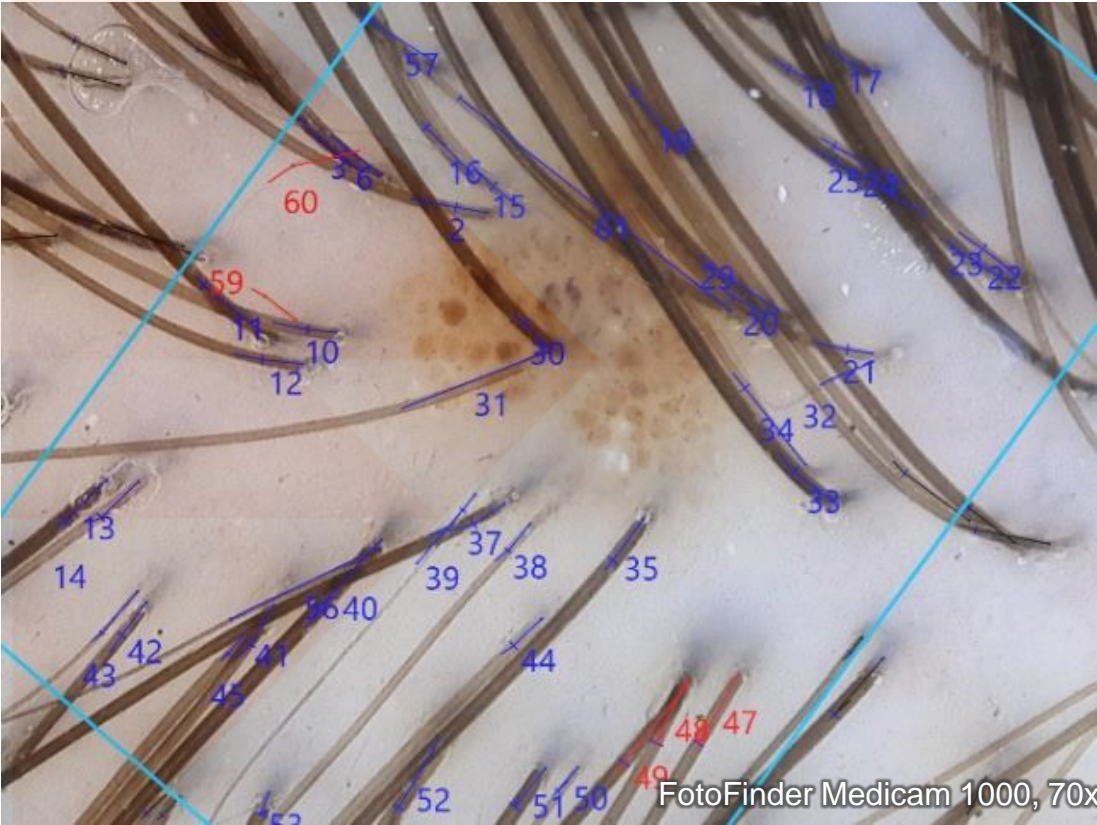


Astronomy approach:

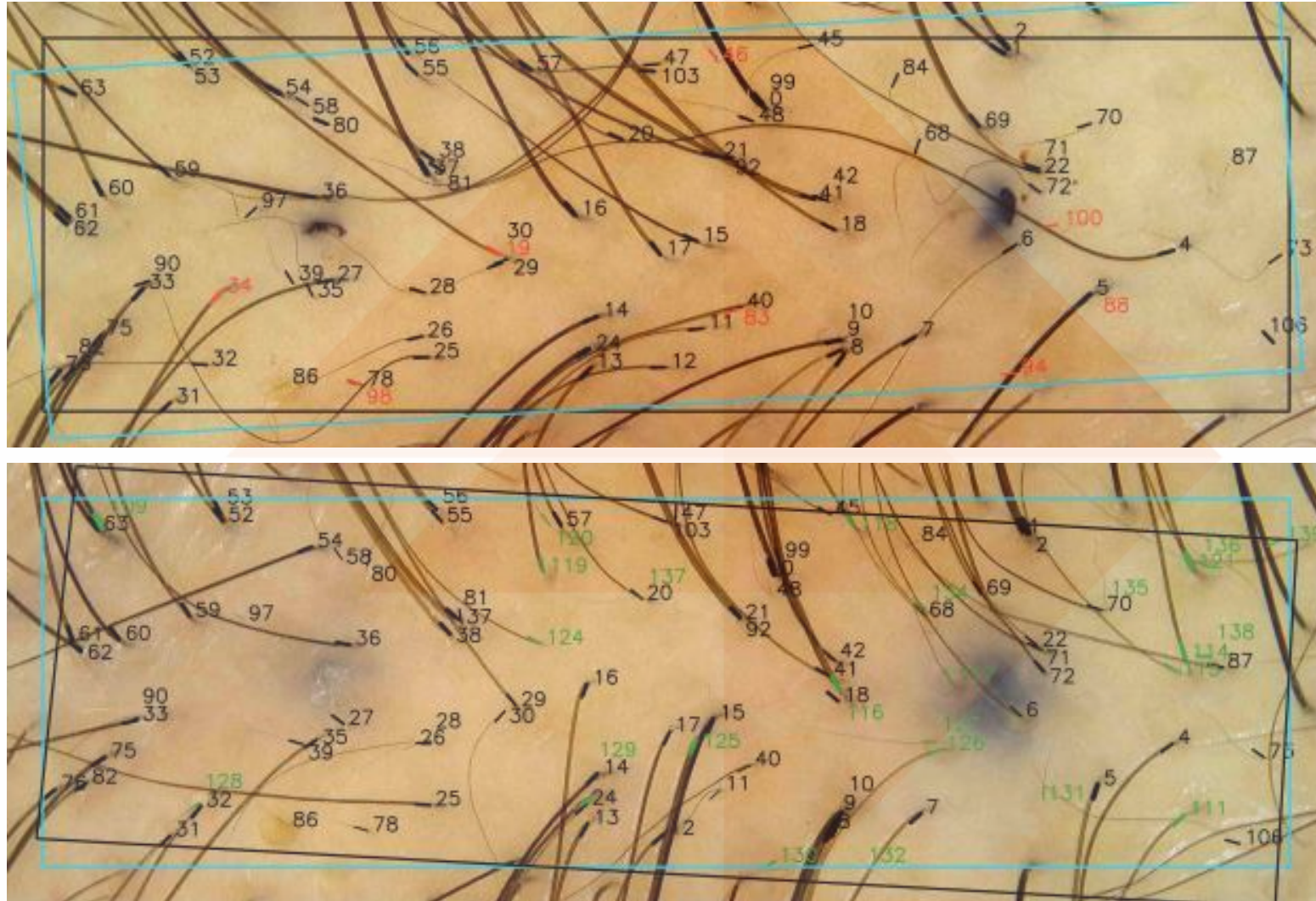




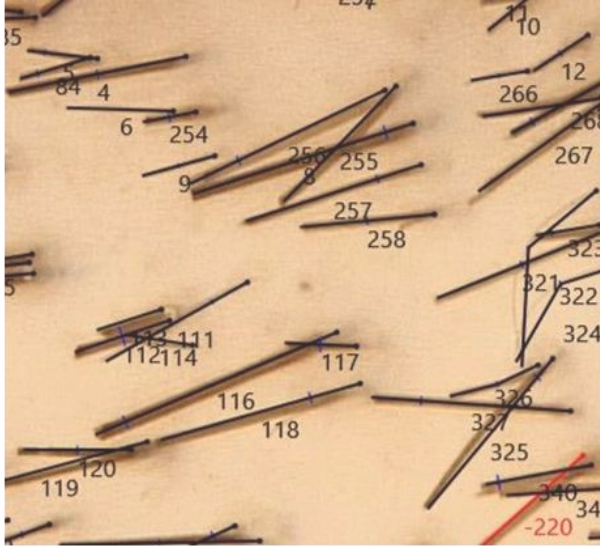
And back to trichoscopy



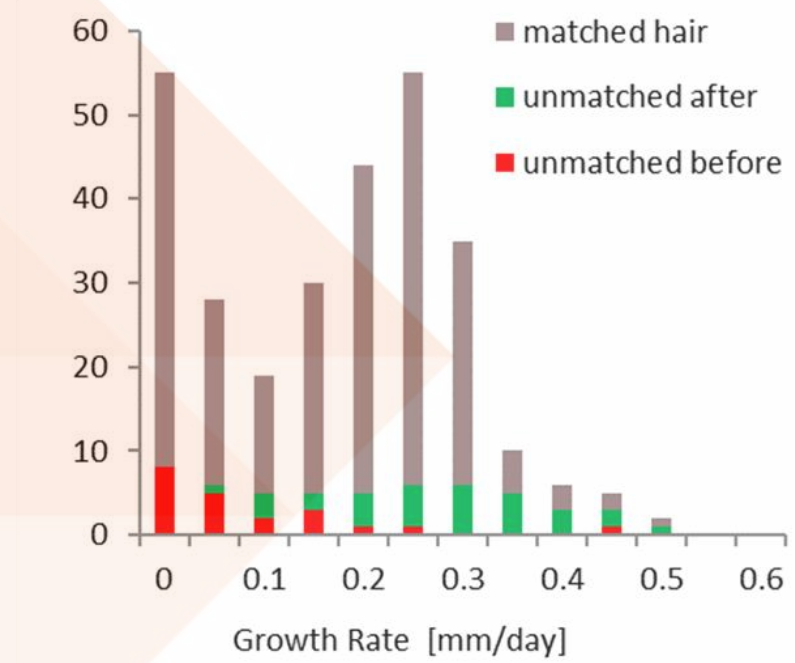
Make a comparison hair-by-hair – the H2H matching



H2H Matching of clipped Hair



Before treatment



Summary

- What kind of product is it? What is the mode of action?
- What is the purpose of the study?
- Which are the targeted Indications, claims/ marketing needs?
- ->
- Regulatory & ethical requirements, timelines, budget
- Study design, recruitment, parameters (safety & efficacy)
- Phototrichogram (H2H matching) is the ,gold standard'



Comparison of the different study concepts

- All test can be combined or used individually
 - Tests with lab equipment can support strong claims (reproducible methods, can detect even small differences)
 - Experts are trained on special parameters, can detect smaller differences
 - Tests on volunteers can only be carried out with a safety assessment
 - Tests with volunteers will answer the question on consumer acceptance
 - Some claims can only be supported by a test with volunteers
 - Volunteer group can be recruited specially for the test (thin hair, different age ranges, etc.)



Questions?