

Clinical Long-Term (6 Months) Epilation using A Home-Use IPL for Various Hair Colour and Thicknesses

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3. The Dezac Group Ltd, Cheltenham, UK





DUBAI

DASIL 5TH
ANNUAL
CONGRESS

OCTOBER
19 - 23, 2016



The following potential conflict of interest relationships are germane to my presentation:

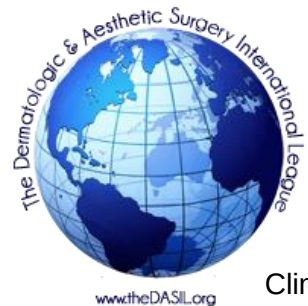
- Clinical study funded by
- Equipment supplied by

The Dezac Group, Cheltenham, UK

Clinical Long-Term (6 Months) Epilation using A Home-Use IPL for Various Hair Colour and Thicknesses – DASIL, Dubai

Study Objective

Objective: The aim of this ethics committee approved blinded efficacy study is to quantify short-term and long-term hair reduction using a novel, 7.6 J/cm², triple pulse, home-use IPL device using objective hair-counts.



Home Use Hair Removal

Over the past decade a number of Home use IPL systems have launched.



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Home Use Studies

Study	Authors	Device	Fluence (J/cm ²)	Pulse Duration	Wavelength (nm)	Spot size
Silk'n™ - A novel device using Home Pulsed Light™ for hair removal at home	Stephen Mulholland	Silk'n	4.2 J/cm ²	3ms	475-1200	6cm ²
Effect of a Novel Low-Energy Pulsed-Light Device for Home-Use Hair Removal	Tina Alster, Elizabeth Tanzi	Silk'n	4.2 J/cm ²	3ms	475-1200	6cm ²
Hair removal with a novel, low fluence, home-use intense pulsed light device	Russell Emerson, Godfrey Town	iPulse	11 J/cm ²	15ms	530-1200	3cm ²
Low energy IPL for hair removal at home	Michael Gold, Amy Foster, Julie Biron	Silk'n	4.2 J/cm ²	3ms	475-1200	6cm ²
Can patients treat themselves with a small novel light based hair removal system	Thomas Rohrer, Vandana Chatrath, Paul Yamauchi, Gary Lask	Spatouch	10 J/cm ²		400-1200	12.1cm ²
Clinical study to determine the safety and efficacy of a low energy, pulsed light device for home use hair removal	Courtney Elm, Irmina Wallander, Susan Walgrave, Brian Zelickson	Silk'n	4.2 J/cm ²	3ms	475-1200	6cm ²
Simulated Consumer Use of a Battery-Powered, Hand-Held, Portable Diode Laser (810 nm) for Hair Removal: A Safety, Efficacy and Ease-of-Use Study	Ronald Wheeland	Tria	18.8 J/cm ²	345ms	810	0.78cm ²
Clinical and Microscopic Evaluation of Long-Term Epilation Effects of the iPulse Personal Home-Use Intense Pulsed Light (IPL) Device	Mario Trelles, Caerwyn Ash, Godfrey Town	iPulse	10 J/cm ²		530-1100	3cm ²



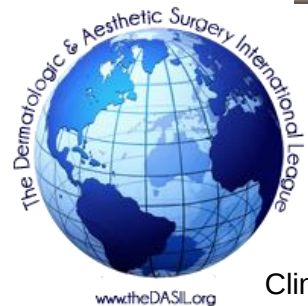
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Study Design

The study was conducted at two locations

1. Dezac HQ, Montpellier, Cheltenham
2. Dezac, Forest Value Industrial Estate, Cinderford

The study was performed as an assessor blind investigation with results compared to baseline.



Study Timescale

Sept 2012

Ethics committee approval

Sept 2012

Development and testing of custom hair counting software

Oct 2012

Recruitment

Nov 2012

Start of treatment

Oct 2013

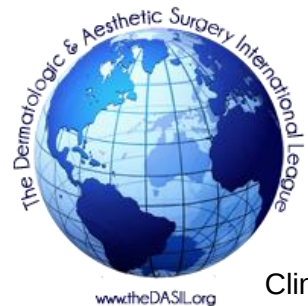
Blinded analysis by independent layperson

Nov 2013

Blinded analysis by independent layperson

Dec 2013

Study Concluded



Study Design

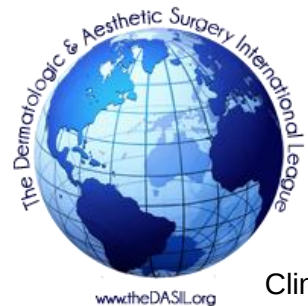
The study tested two hair removal systems side by side



**Rio Salon Laser Hair Removal
808 nm**



**Rio Evolution IPL
575-1100 nm**



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Study Design

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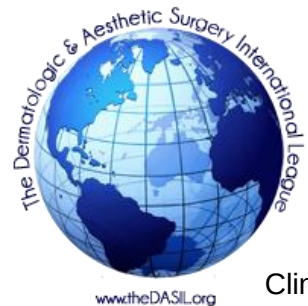
Full Axila

Full Axila

Full pubic area (IPL only)

6cm by 6cm Leg

6cm by 6cm Leg



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Full Axilla

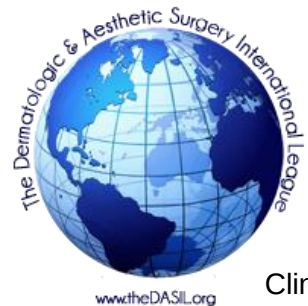
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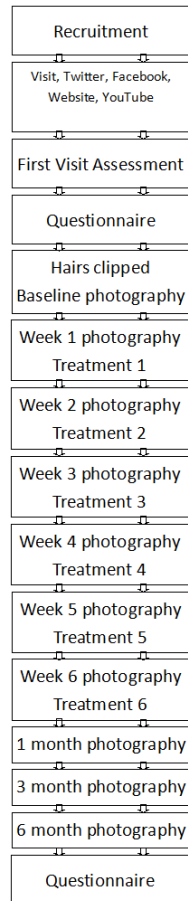
The systems were measured for energy output every 2 days using standardised methodology.



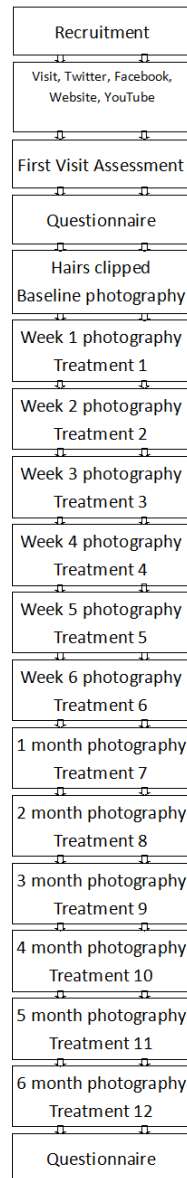
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Study Design

Cohort 2



Cohort 1



Completed consent form.
Full medical history was recorded.

The subject was given a specific
treatment diary and treatment plan.

The participant was asked to complete a
self-assessment questionnaire at
baseline.

Ensure inclusion criteria are fully met.

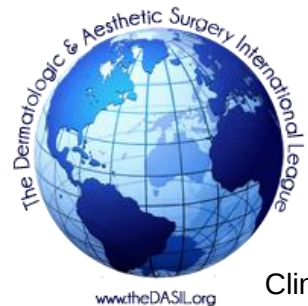
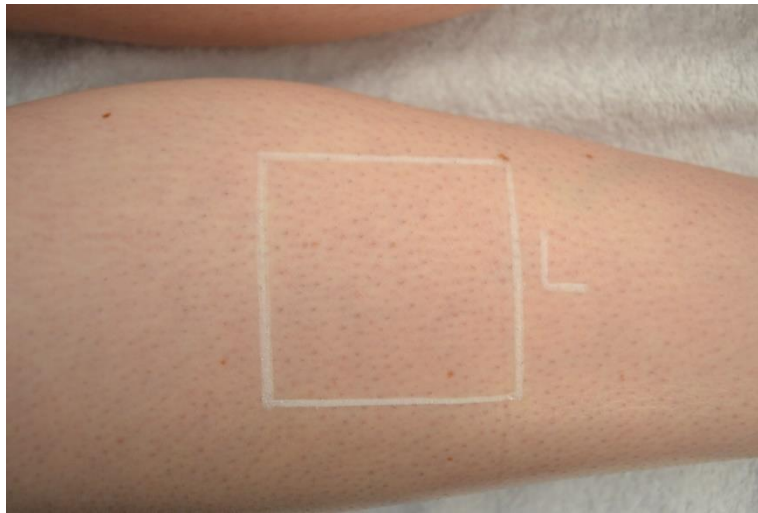
Any side effects was recorded.
Treatment and photography at week 1,
2, 3, 4, 5, 6 for both cohorts.

Subjects was reminded at each visit of
the following restrictions: not to use
any other hair removal method (except
shaving) during study.



Photography and area templating

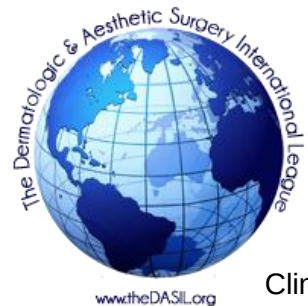
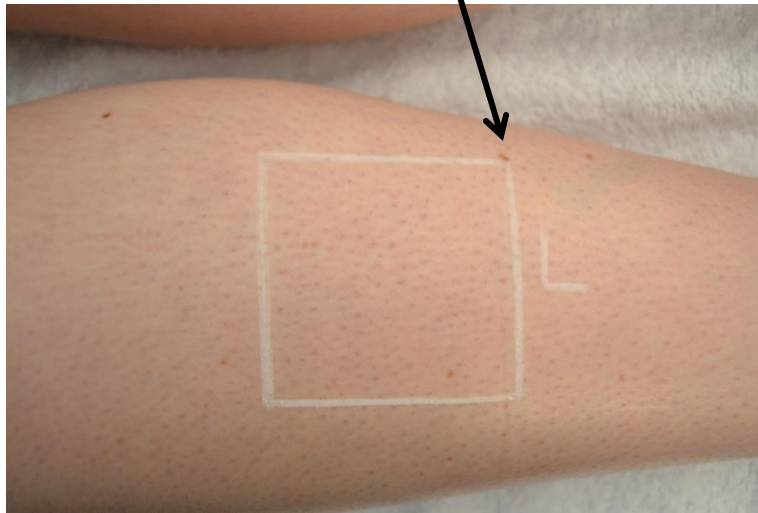
The axilla, leg and pubic areas are photographed by study researchers using a Nikon D3100 18-55 VR digital camera. All subjects are templated with a 6cm × 6cm template and white pencil on lower leg.



Photography and area templating

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Body marks give anatomical landmarks



The Device

The Evolution IPL generates a broadband spectrum of wavelengths (575-1100nm) with a 10 mm × 20 mm (2 cm²) treatment area. The finger activated safety sensor tip can only be fired when the handpiece is in complete contact with the skin.



Evolution IPL	
Device Type	Intense Pulsed Light
Wavelengths	575-1100 nm
Dosage delivered (J/cm ²)	7.6 J/cm ²
Pulse Duration	21ms (triple pulse of 3ms, 6ms off)
Spatial Profile	Even
Treatment Area	2 cm ²

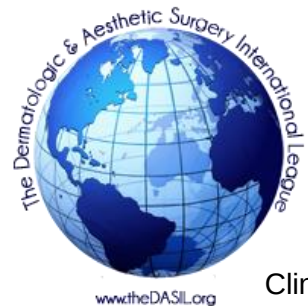


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Inclusion Criteria

The inclusion criteria that each subject had to meet in order to be enrolled in the study were as follows:

- A. All subjects will be female with brown/dark terminal hairs.
- B. All subjects are required to be between 16 and 45 years of age.
- C. Subjects to be skin tones 1-4.
- D. Subjects also had to meet a terminal hair density greater than 10 hairs per square cm² within the hair count test sites.

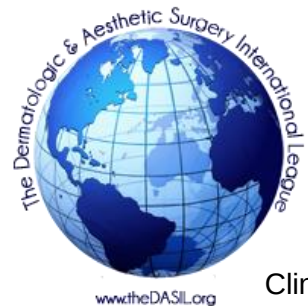


Exclusion Criteria

Subjects were excluded from the study for the following reasons:

- A. Subjects to be of skin tones 5-6.
- B. If they were pregnant or lactating.
- C. History of developing hypertrophic scars or keloids.
- D. Treatment with professional laser system or electrolysis in treatment areas in last 3 months.
- E. Epilation or waxing hair removal in the treatment areas within the last 3 months.
- F. Known diagnosis of HIV, Hepatitis B, Hepatitis C or immunodeficiency disorder.
- G. If a subject was unwilling or unable to comply with the study requirements.

Recruitment



Would you like to be
HAIR FREE
in the New Year?

If so, you could participate in a program at the Rio Beauty head office in Montpellier, Cheltenham. The program will demonstrate the effectiveness of **Laser Hair Removal**.

All participants will receive a **free consultation & treatment**

£100 Cash + **free** laser hair removal

see reverse for eligibility

Please call Dr Ash or Laura on: 01242 702381 or email us at: treatment@dezac.co.uk

Contact us before **18th January 2013** to secure your place (limited places available)

@RioTreatment RioTreatments

the beauty specialists



You can take part if ...

- You have brown/black hairs on your underarms and legs.
- You are at least 16 years of age.
- Your skin tone is suitable for hair removal treatment (*please see skin tone chart below*).
- You are able to attend a quick assessment where a photograph will be taken (free drinks provided).



Sorry you're unable to take part if ...

- Your skin type is **NOT** suitable for hair removal treatment (*please see skin tone chart below*).
- You are pregnant.
- You have waxed, tweezed or chemically removed hair in the past 2 months.



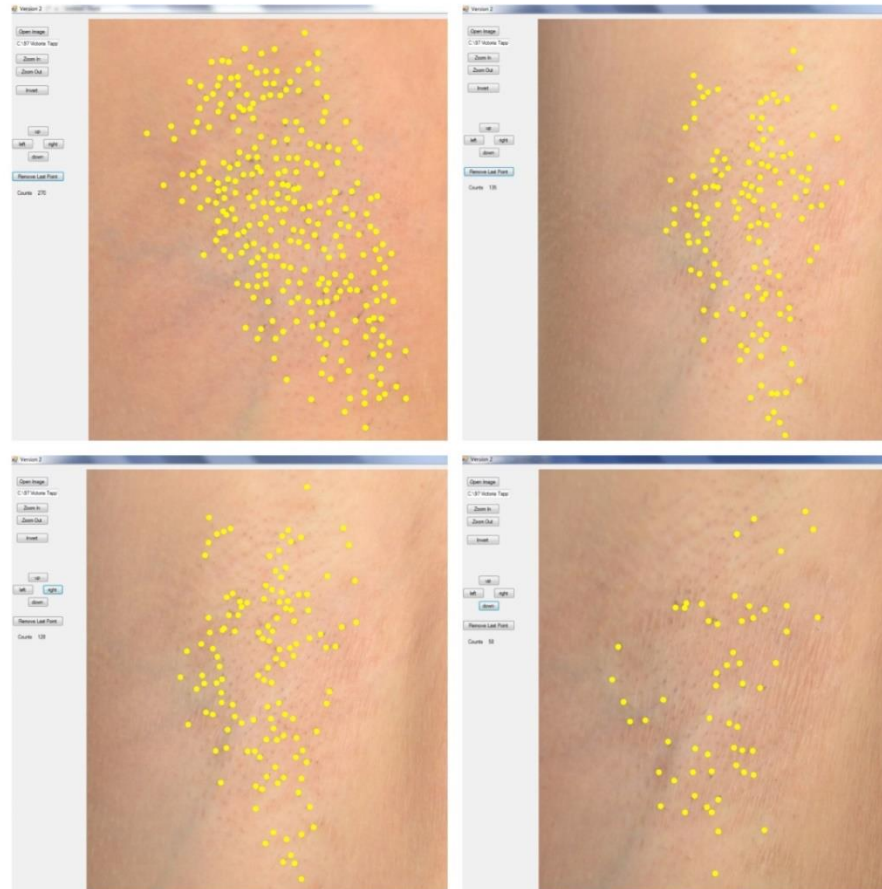
Skin Tone Chart



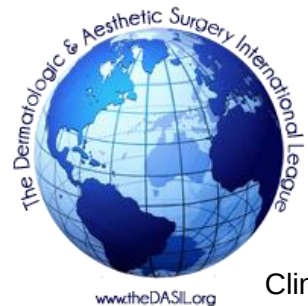
© LASERHAIR.TREATMENT

Hair Count Software

The hairs were counted from the photographs by trained, independent third parties using a custom software. The software also measured hair colour and thickness.



Quantitative Assessment of Hair Reduction and Acne lesion counts following Light based Treatment using Custom Software , Jaymie Philips, Caerwyn Ash, Louise Tooze, Rebecca Whittall, Anna Harrison

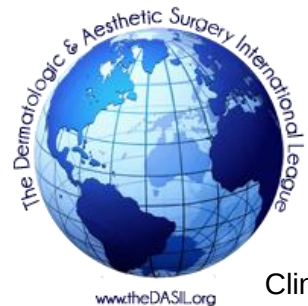


Statistics

Statistics were analysed by a professional, independent statistician using industry standard statistical methods and the commercial SPSS package. Statistical analysis was performed using Microsoft Excel

The degree of hair density reduction was analysed using the Wilcoxon Signed Rank Test.

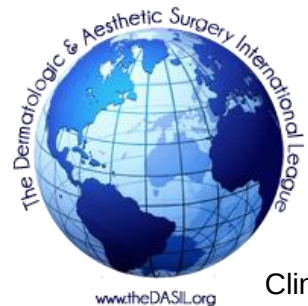
The sample size was chosen, as, on the basis of previous experience, it was determined that the N value was high enough that the study would be sufficiently powered from a statistical perspective.



Results

During treatment, no subject experienced sufficient discomfort to abandon treatment and subjects reported only bearable heat or a stinging sensation.

There was an immediate carbonization of the hair shaft and the aroma of thermal hair shaft coagulation.



Results

102 women meeting the eligibility criteria were enrolled in this ethics approved study.

The subjects varied in age from 18 to 45 years of age (mean 24.2 years). A variety of skin phototype (I-IV) were included.

84 subjects completed the study

56 Cohort 1 – 6 weekly Tx + monthly Tx

28 Cohort 2 – 6 weekly Tx + Assessment

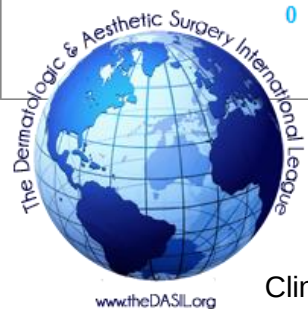
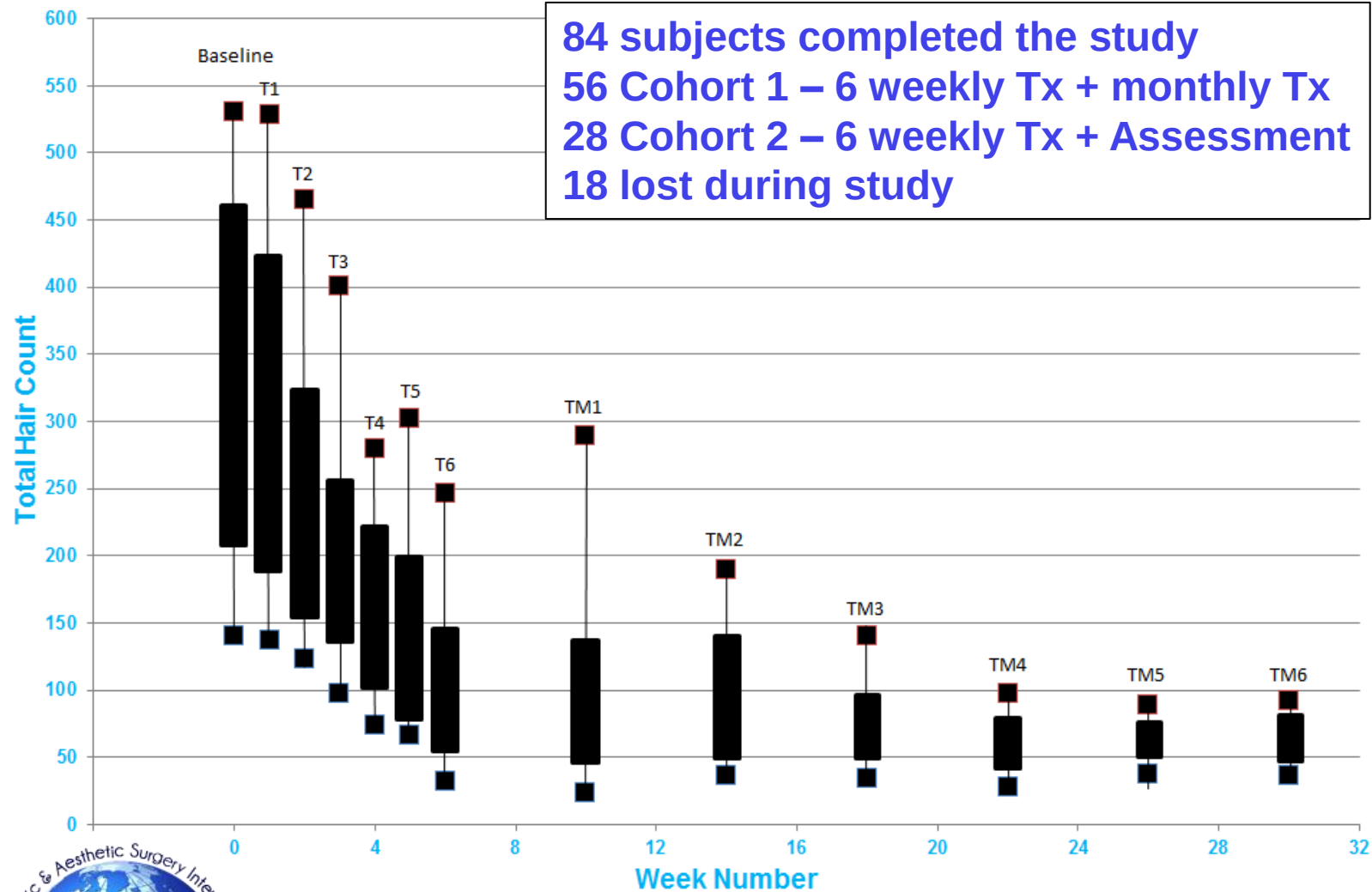
18 lost during study

25 Subjects completed pubic area testing.



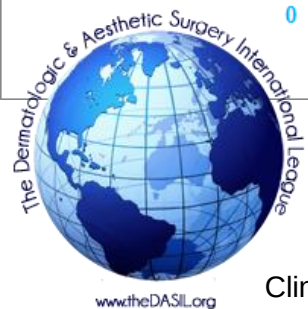
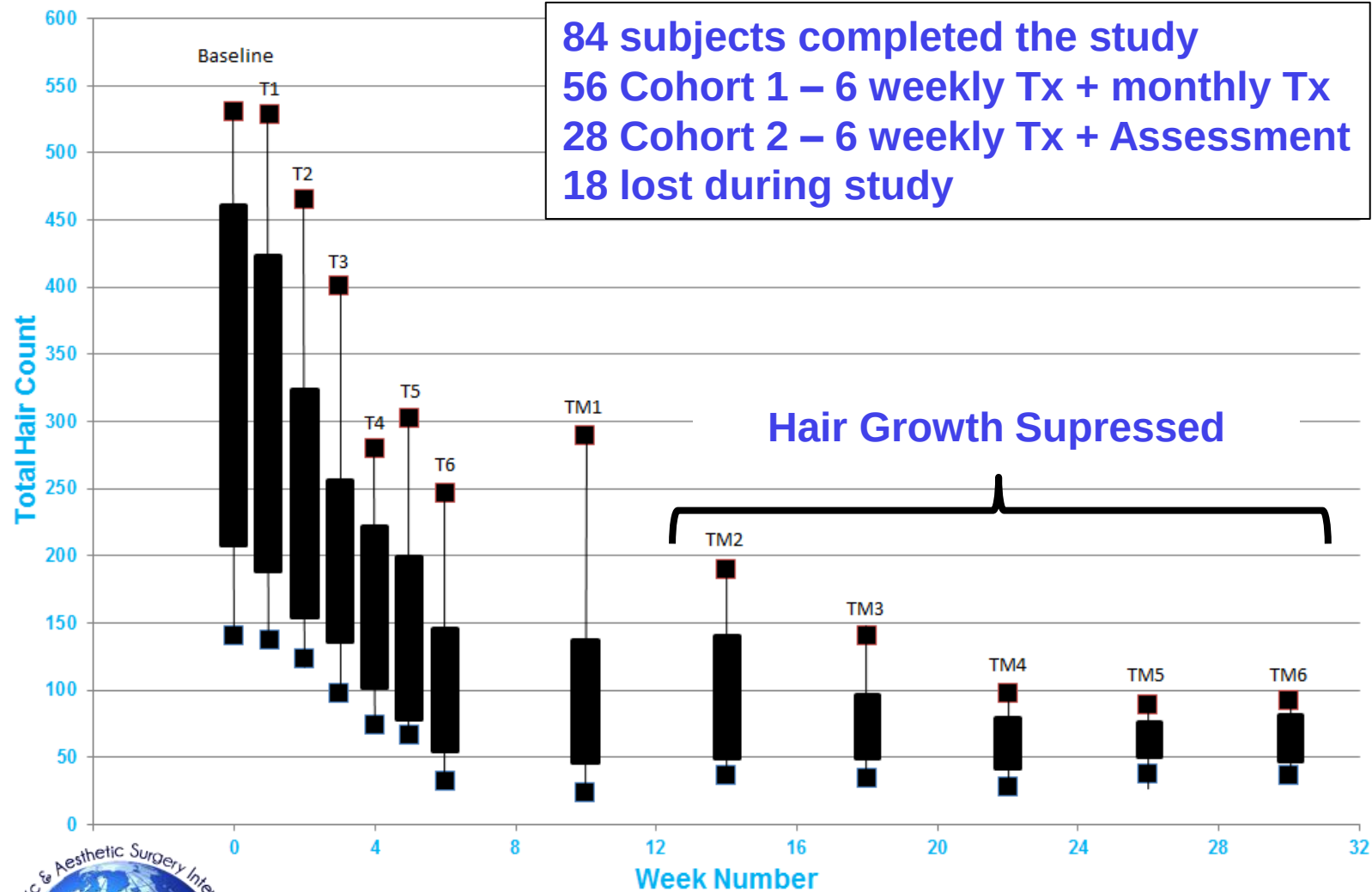
Results – 6 week Tx + monthly Tx

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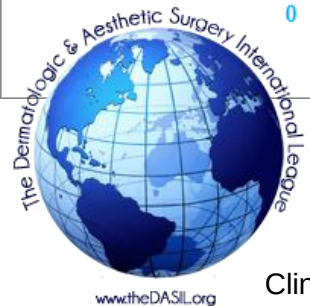
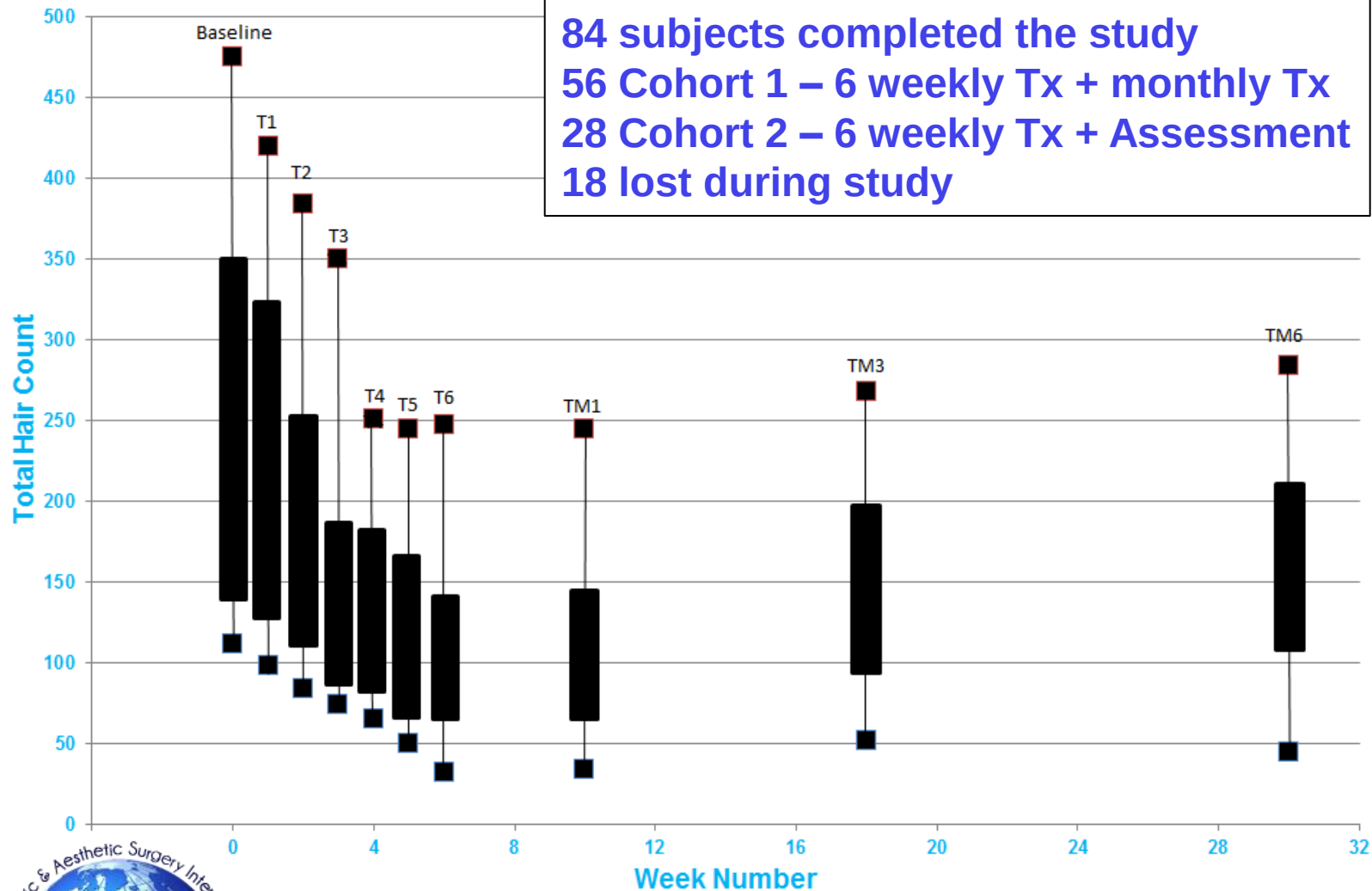
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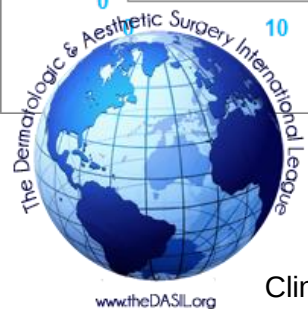
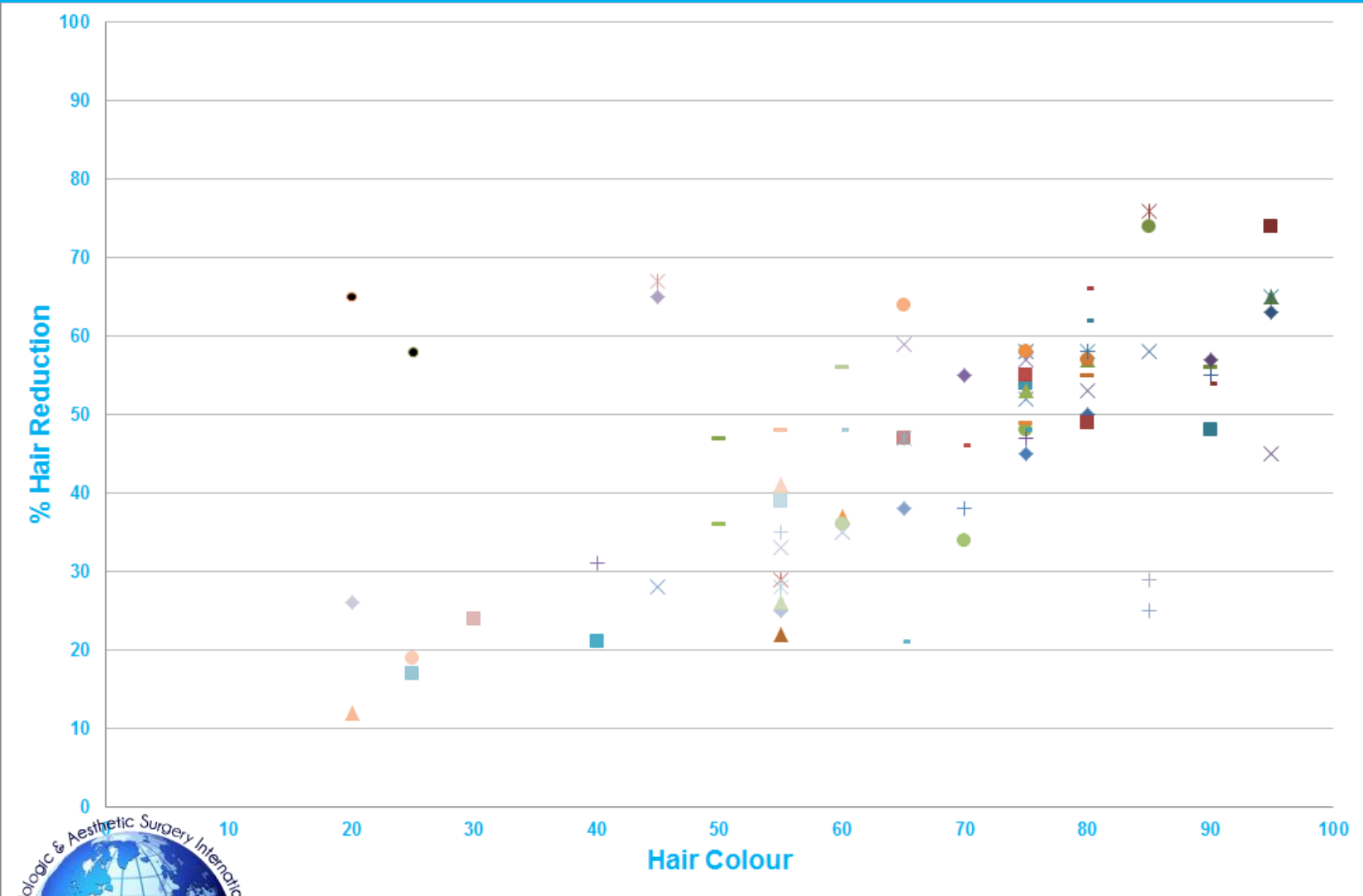


Results – 6 week Tx + Assessment

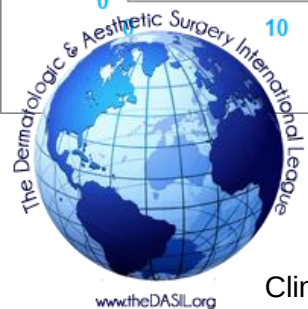
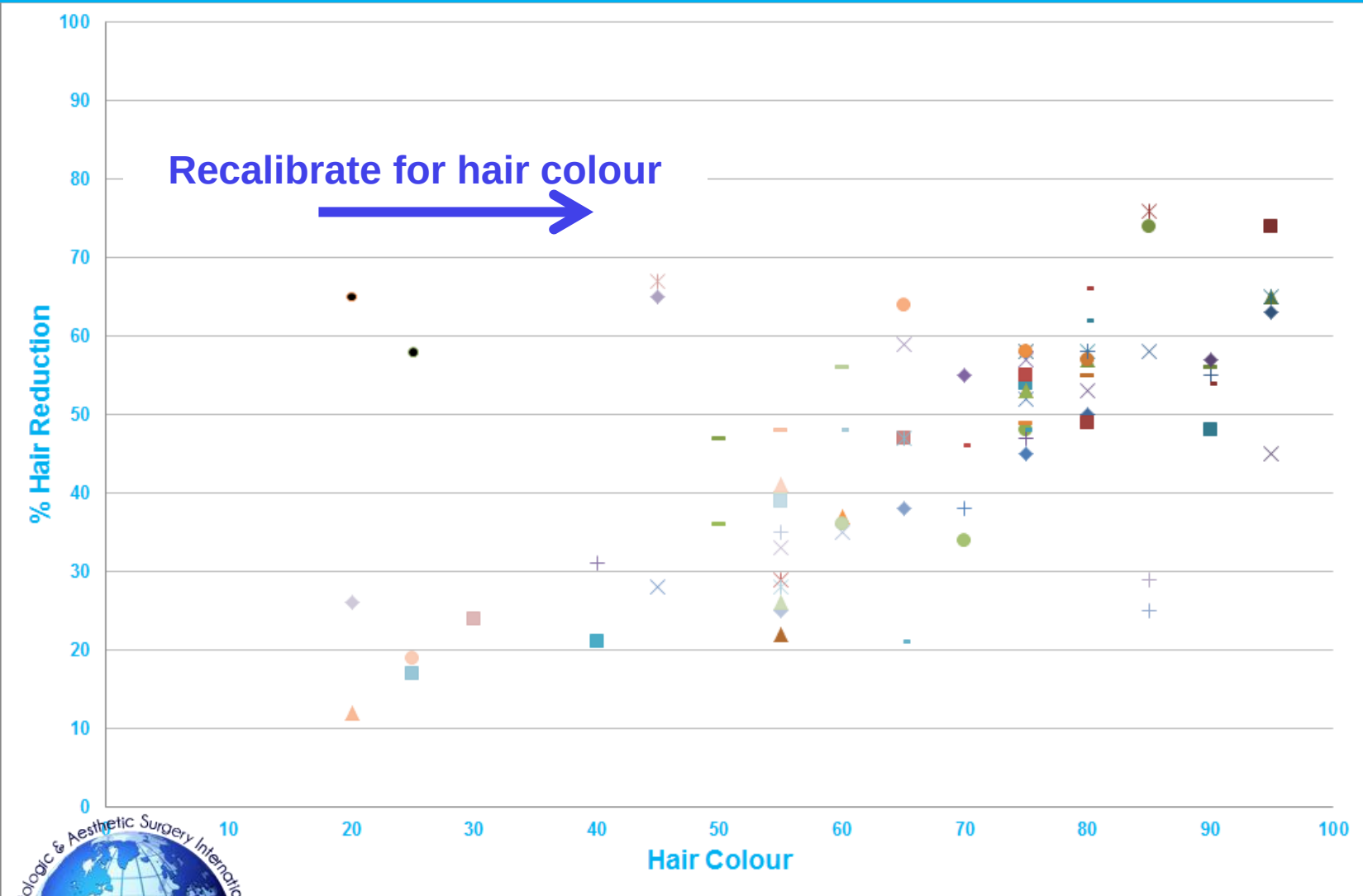
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Results – Hair Colour vs Efficacy



Results – Hair Colour vs Efficacy

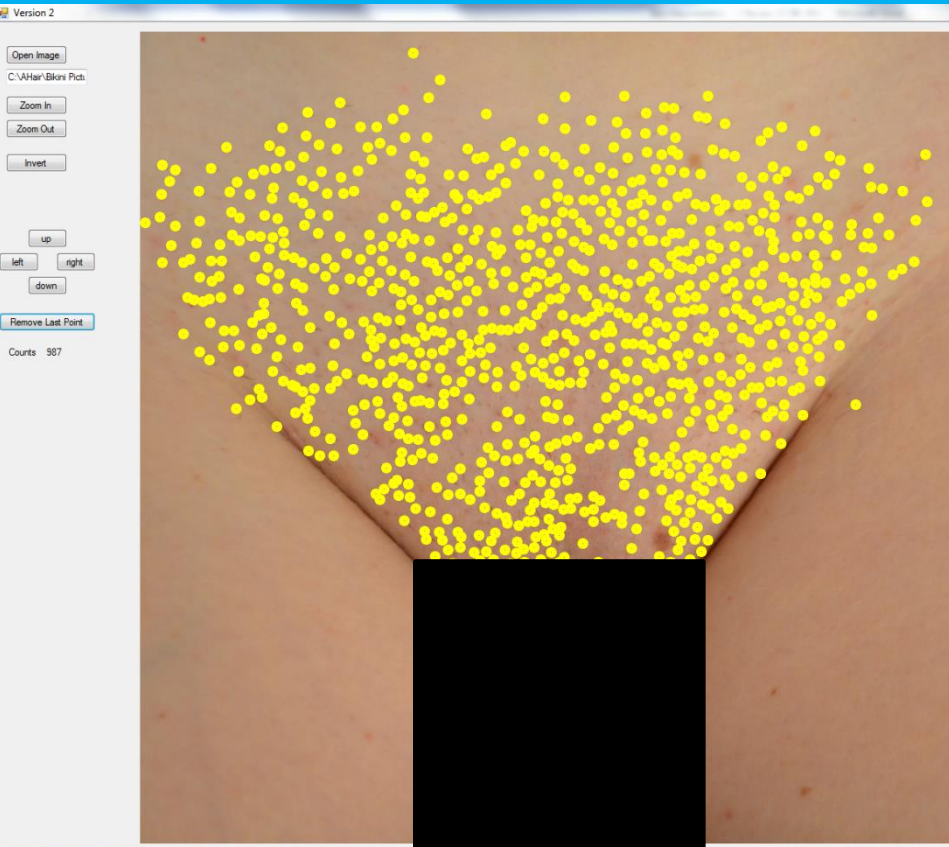


Results – Hair Thickness vs Efficacy

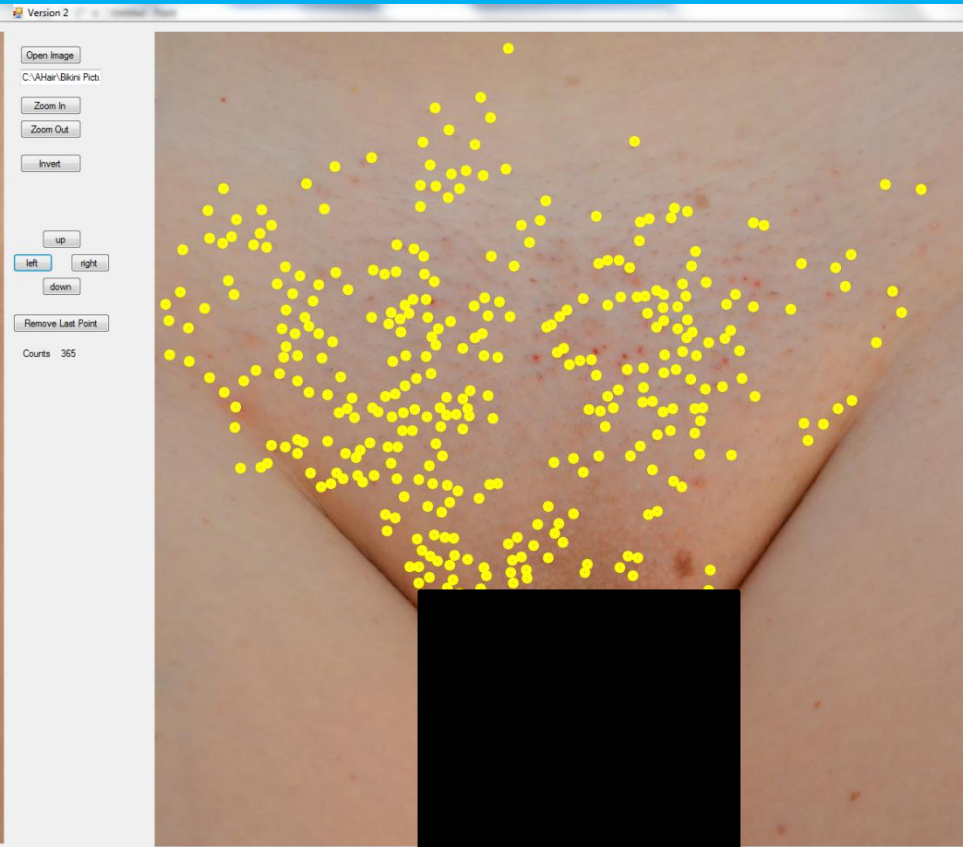
Data inconclusive – thickness calculation to be re-analysed



Results – Pubic Area



Baseline

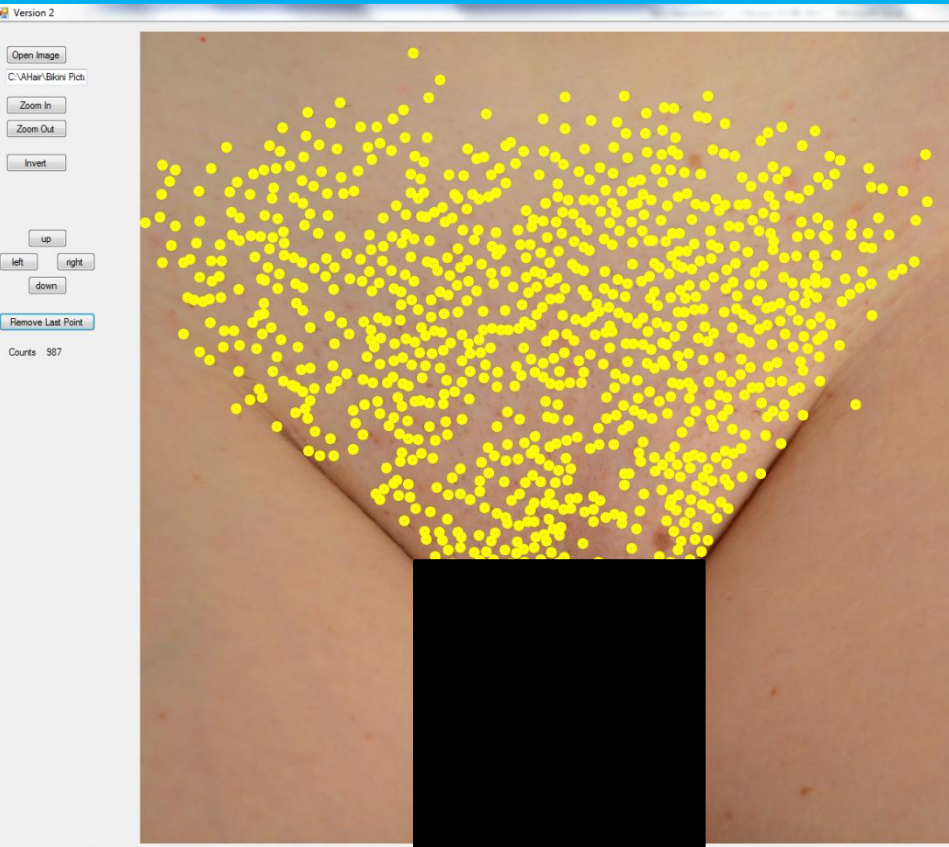


6 Months

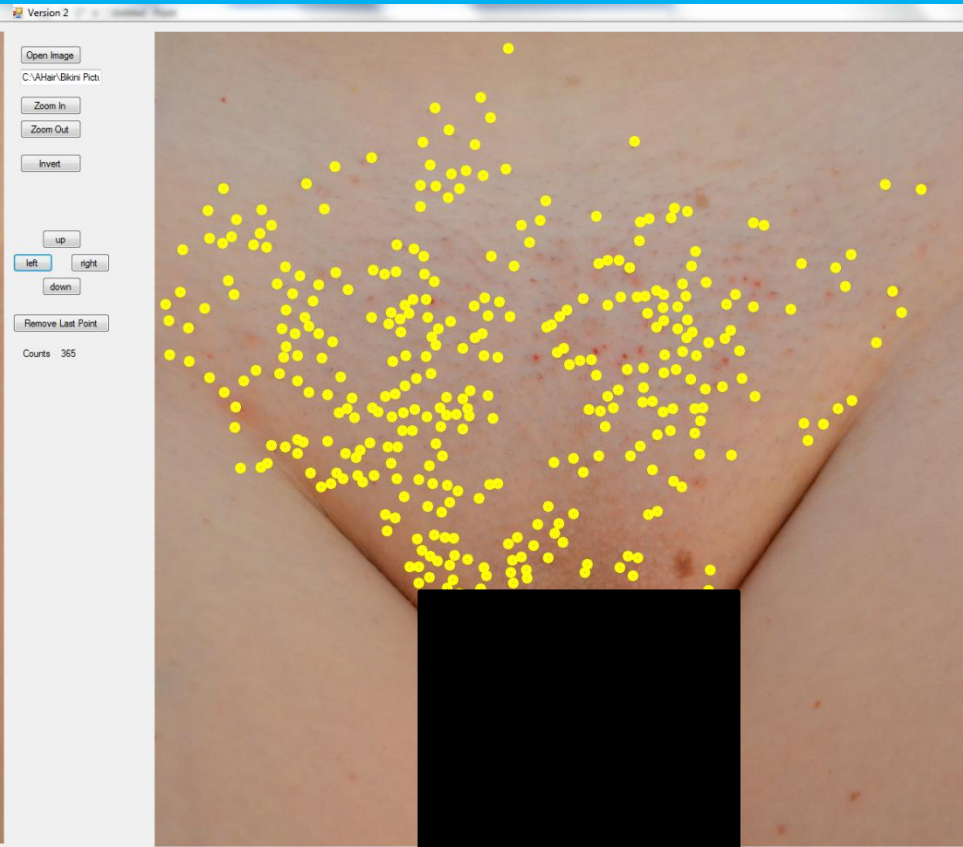


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Results – Pubic Area



Baseline



6 Months

Average 82.8% Reduction after 6 Months



Results

Cohort 1

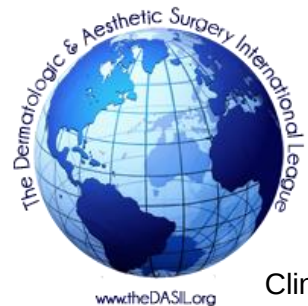
Six months after the six weekly treatments and monthly treatments, an average 76% reduction in terminal hair count ($P=0.003$) was recorded.

Cohort 2

Six months after the six week treatment, an average 51% reduction in terminal hair count ($P=0.011$) was recorded.

No treatment related side effects were reported, with little or no discomfort reported during the treatment.

83% reported that the hair that did regrow was less noticeable due to being finer and or lighter.



Conclusion

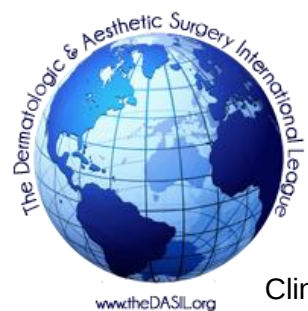
From the clinical trial performed, this novel home Intense pulsed light system is a safe and effective at home device for the removal of unwanted hair, with statistically significant results obtained in hair count numbers.

Our study confirms that the at-home IPL device described in this study can be applied safely and effectively to reduce regrowth of unwanted hair.

94% said they had reduced hairs that are less notable.

The clinical results obtained in our study are surprisingly close to the low end of the range typically reported after in-office laser and light sources.

- Further Analysis of leg data to improve statistical significance
- Review hair thickness and colour data, recalibrate.
- Submit article for peer review.



The Team



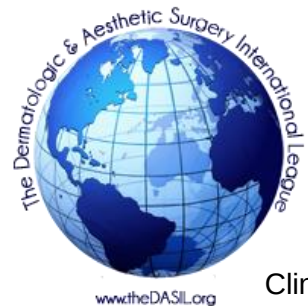
Caerwyn Ash
Principle Investigator



Anna Harrison
Clinical Assistant



Rebecca Whittall
Clinical Assistant



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Thank You

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