Efficacy Evaluation of Hair Removal Using the no!no!™ Thermicon™ Technology — Sustained Use & 12-Week Follow-up.

Abstract

Background: Hair removal is one the most-requested procedures in cosmetic dermatology. Laser and light-based methods of hair removal, though effective, are expensive and may be associated with adverse effects.[1]

As patients become increasingly time-starved and expense conscious, the appeal of personal devices to safely and effectively remove unwanted hair at home has driven development and growth of at-home devices.

Objective: To evaluate the efficacy and safety of a thermal, at-home treatment device (no!no!™ with Thermicon™ technology) with sustained use and 12 weeks after final treatment (follow-up phase).

Methods: Forty-four subjects with blonde, brown and black hair and self-reported Fitzpatrick skin type II-VI received twice weekly treatments on each leg (left and right, total sites = 72) and each arm (left and right, total sites = 88) for 12 weeks. Images were taken at baseline, 4 weeks, 8 weeks, 13 weeks and 24 weeks. Quantitative hair counts were made by an independent evaluator who was blinded to the subject, test site and visit date.

Results: The treated sites exhibited statistically significant ($p<0.001$) hair reduction compared to baseline.

For Legs; the overall mean hair count reduction from baseline for 13 weeks was 30.1% and 24 weeks was 20.9%. The mean percent change from baseline for 13 weeks was 28% and 24 weeks was 18.9%. The percentage of subjects (% Success) with a 30% or more decrease in hair count at 13 weeks was 58.3% and 24 weeks was 33.3%.

For Arms; the overall mean hair count reduction from baseline for 13 weeks was 38.3% and 24 weeks was 21.7%. The mean percent change from baseline for 13 weeks was 35.0% and 24 weeks was 15.2%. The percentage of subjects (% Success) with a 30% or more decrease in hair count at 13 weeks was 65.9% and 24 weeks was 33.0%.

Discussion: The results of this study demonstrate that the no!no! Thermicon device delivers safe, equally effective outcomes, without pain, in both epilation areas among subjects with different hair and skin colors.

Conclusion: With sustained use (24 treatments over 12 weeks), the no!no! with Thermicon technology safely and effectively removed hair, independent of hair color or Fitzpatrick Skin Type, with no pain. Lasting results were evident at a statistically significant level at the 12-week follow-up.

INTRODUCTION

Traditional methods of hair removal, such as waxing, shaving and chemical depilatories, are transient and require high maintenance. Laser and light-based methods of hair removal have been proven effective and grown in popularity; however, they are expensive, require multiple visits/treatments, may be associated with adverse effects (e.g. pigmentary changes, erythema and blistering)[1] and are contraindicated for users with darker skin tones (Fitzpatrick Skin Types V and VI) and ineffective on white or light color hair. These same drawbacks are relevant for many at-home, consumer laser and light-based devices. To overcome the disadvantages of those methods, an over-the-counter device for personal use was developed using thermal transference to remove unwanted hair. Because the device is not light-based, skin and hair pigmentation are not relevant to efficacy, making it safe for use on all hair colors and skin colors.

In this study (conducted in 2014), the efficacy and safety of this device with sustained use and at 12 weeks after final treatment (follow-up phase) was evaluated.

The purpose of the study was to perform a scientifically rigorous, independent measurement of the safety and efficacy of the no!no!™ with Thermicon™ technology. In designing the protocol, attention was given to the following points:

- A sufficient sample size and subject participation level was defined
- Quantitative assessment methods were used
- The use of the device was controlled and limited to the parameters of the protocol
- Treatment sites were well-defined
- Treatments and photographs were reliably made in the same anatomical locations
- Hair counting methodology was defined
- Consistently high quality photographs were taken
- Controlled hair conditions were employed for imaging visits
- Standard statistical methods were used
- The hair count evaluator was independent and blinded

METHODS

Study Design

This was a prospective, single-site, baseline controlled clinical study with blinded independent third-party hair counts. The primary objective of the clinical trial was to assess the shor-term suppression, reduction, or delay in hair regrowth with sustained use by comparing the treated area to baseline hair counts. The secondary objective of the clinical trial was to assess the long-term suppression, reduction, or delay in hair regrowth by comparing the treated area to baseline hair counts 12 weeks after final treatment.

The protocol (RIDO02-003) was IRB approved (January 7, 2014) and the trial (C13-2748) was conducted in accordance with the Declaration of Helsinki, the ICH Guideline E6 for Good Clinical Practice, the requirements of 21 CFR Parts 50 and 56, other applicable laws and regulations, and the approved protocol.

Subjects

Fifty-one subjects, 36 females and 15 males, ages 18 to 50 years, were recruited for this trial.

Materials

The device studied was the no!no! with Thermicon technology hair removal system including the device body and its replaceable Thermicon tip. Each subject was provided their own device, tip, buffer pad and cleaning brush that were stored at the study site.

Instrumentation

Cross-polarized high-resolution digital photographs using the Nikon D90 SLR camera equipped 60 mm lens and fixed lighting was captured at baseline and weeks 4, 8, 13 and 24. Cross-polarized lighting filters out surface reflections for superior visualization of subsurface detail, which aided in making accurate counts.

Treatments

Each subject had 4 body sites treated twice weekly for twelve weeks:

- Right and left arm between elbow and wrist
- Right and left leg between knee and ankle

All treatment sites were treated exclusively with the no!no! hair removal device. During the treatment phase, subjects were not permitted to use any other hair removal products/procedures other than the treatments provided during the trial.

Methodology

Potential subjects reported to the testing facility, executed an informed consent form and completed a medical history. Dermatological examinations were conducted by a trained expert grader for evidences of erythema, dryness and edema or any other anomaly according to the scale in Table 1.

0	None
0.5	Barely perceptible
1	Mild
2	Moderate
3	Marked
4	Severe

Table 1: Irritation Scale

Subjects presenting a score of 2 or greater or tattoos at the proposed test sites were disqualified.

Each subject was asked a series of questions to confirm eligibility and to capture demographic data.

For each of the 4 body sites, a test sub-site was defined. A clinical technician outlined each test sub-site (2 x 3 cm) using a reference template, designating the exact location of each treatment sub-site. At weeks 4, 8, 13 and 24, each test sub-site was marked again with the original reference template for the specific subsite.

The hair density in the treatment sub-site must be at least 3 hairs/cm^2.

The clinical technician closely observed each subject for any side effects or adverse effects at the treatment sub-sites prior to, during and immediately after each treatment, as well as the follow-up visit.

All findings were recorded on subjects' Case Report forms (CRFs).

Outcome Measures

The primary and secondary outcomes was the mean percent hair count reduction ([countbaseline count]/ baseline count x 100) and the %success was defined as the incidence of subjects with >30% reduction in hair count from baseline.

Images were taken at baseline, 4 weeks, 8 weeks, 13 weeks and 24 weeks. To capture the image and perform the hair counts, each image was saved using Mirror PhotoFile and PhotoTools medical imaging software version 7.3.8 (Canfield Scientific, Inc., Fairfield, NJ). All hair counts were made by a trained independent medical professional who was blinded to the subject, test site and visit date.

Statistics were analyzed by a professional statistician using industry-standard statistical methods and commercial software.

RESULTS

Subjects

Forty-five of the fifty-one subjects completed the treatment phase. One subject was disqualified at the baseline visit due to not meeting the inclusion criteria. Five subjects discontinued their participation due to personal reasons unrelated to the test materials. The demographics of the subjects are shown in Table 2 - 5.

Mean	38.18
St. Dev.	8.16
Minimum	18
Maximum	50
Median	40

Table 2: Age

Category	Tallies	Percentages
II	5	9.80%
III	16	31.37%
IV	16	31.37%
V	11	21.57%
VI	3	5.88%
Total	51	100.00%

Table 3: Skin Type

Category	Tallies	Percentages
Blonde	3	5.88%
Dark Blonde	1	1.96%
Light Brown	3	5.88%
Brown	17	33.33%
Dark Brown	8	15.69%
Brownish-red	1	1.96%
Black	18	35.29%
Total	51	100.00%

Table 4: Hair Color

Category	Tallies	Percentages
White	18	35.29%
Hispanic	18	35.29%
Black or African American	14	27.45%
Asian	1	1.96%
Total	51	100.00%

Table 5: Ethnicity / Race

Dermatological Evaluations

The forty-five subjects that completed the study were evaluated for any side effects or adverse effects at the treatment sub-sites prior (P) to, during (D) and immediately (I) after each treatment. This equated to 288 evaluations (4 sub-sites x 24 visits x 3 evaluations per visit [P, D & I]) per subject. Side effects were limited to barely perceptible (0.5) or mild (1) for dryness, erythema and edema using the irritation scale in Table 1. A sensation of warmth was felt with the application of the device and a transitory inflammatory reaction characterized by erythema and mild edema that was both confluent and peri-follicular would not be unexpected.

Two subjects had adverse events attributable to the test materials. One subject experienced multiple papules on the right and left arm which were diagnosed as miliaria (sweat rash) and treatment of the arms was discontinued. Another subject experienced a rash on the right and left lower legs and treatment of the legs was discontinued. Both events were resolved with the application of triamcinolone cream 0.1%.

Quantitative Hair Counts

Quantitative hair counts were taken from the captured images and statistically analyzed as described in the Methods section.

A statistically significant decrease was evident in left and right arms (total sites = 88) hair counts after 4, 8, 12 weeks of treatment and 12 weeks after final treatment (24 weeks) when compared to base line hair counts. The overall mean percent hair count reduction and mean percent change from baseline results are listed in Tables 7 and 8.

Sub-site	Wk 4	Wk 8	Wk 13	Wk 24
Arms	49.9%	40.9%	38.3%	21.7%

Table 7: Overall Mean % Hair Count Reduction

Sub-site	Wk 4	Wk 8	Wk 13	Wk 24
Arms	-48.1%	-38.6%	-35.0%	-15.2%

Table 8: Mean % Change from Baseline

In addition, a statistically significant greater number of subjects exhibited a 30% or greater, reduction in arm hair counts after 4, 8 and 12 weeks of treatment. At 24 weeks (12 weeks after final treatment), 33.0% of subjects exhibit a 30% or greater reduction in arm hair counts; this results was statistically significant. The % Success results are listed in Table 9.

Sub-site	Wk 4	Wk 8	Wk 13	Wk 24
Arms	79.5%	67.0%	65.9%	33.0%

Table 9: % Success (Sites >30% Reduction)

A statistically significant decrease was also evident in left and right legs (total sites = 72) hair counts after 4, 8, 12 weeks of treatment and 12 weeks after final treatment (24 weeks) when compared to base line hair counts. The overall mean percent hair count reduction and mean percent change from baseline results are listed in Tables 10 and 11.

Sub-site	Wk 4	Wk 8	Wk 13	Wk 24
Legs	37.0%	35.1%	30.1%	20.9%

Table 10: Overall Mean % Hair Count Reduction

Sub-site	Wk 4	Wk 8	Wk 13	Wk 24
Legs	-34.8%	-33.1%	-28.0%	-18.9%

Table 11: Mean % Change from Baseline

In addition, a statistically significant greater number of subjects exhibited a 30% or greater, reduction in leg hair counts after 4, 8 and 12 weeks of treatment. At 24 weeks (12 weeks after final treatment), 33.3% of subjects exhibit a 30% or greater reduction in leg hair counts; this result was statistically significant. The % Success results are listed in Table 12.

Sub-site	Wk 4	Wk 8	Wk 13	Wk 24
Legs	62.5%	56.9%	58.3%	33.3%

Table 12: % Success (Sites >30% Reduction)

The hair count reduction, for both arms and legs, showed no clear differences in efficacy for age groups (18-36, 37-42 and 4-50), Fitzpatrick Skin Types (II, III & IV and V & VI), Gender or Hair color.

DISCUSSION

It is widely known that that laser and light-based treatments induce hair reduction for up to 6 months after treatment, repeated treatments improve efficacy, and efficacy exceeds that of shaving, waxing and electrolysis.

Unlike laser hair removal, no!no! Thermicon works by direct thermal contact with hair, not by absorption by pigment in hair, making it "color blind" and equally effective on all hair colors and skin colors.

CONCLUSION

In a controlled clinical environment with sustained use, the no!no! with Thermicon technology safely and effectively removed hair, independently of hair color or Fitzpatrick Skin Type, with no pain and lasting results. A statistically significant greater number of subjects exhibited a 30% or greater, reduction in leg and arm hair counts after 4, 8 and 12 weeks of treatment. After 24 weeks, following 12 weeks of no treatment, a statistically significant decrease in arm and leg hair counts was observed compared to baseline with 33% of subject test sites demonstrating 30% or greater reduction.

Disclosure

Consumer Product Testing Company, Inc.'s clinical evaluation division was contracted to perform an independent efficacy evaluation of hair removal using the Radiancy, Inc. no!no! LHE under IRB approved protocol number RIDO02-003. The trial (No. C13-2748.01) was completed on August 13, 2014 and the subjects' 26th visit (Week 24) occurred on August 7, 2014.

References

1. Omar A. Ibrahimi, Mathew M. Avram, C. William Hanke, Suzanne L. Kilmer & R. Rox Anderson. Laser Hair Removal. *Dermatologic Therapy, Vol. 24, 2011, 94–107.*