CLINICAL EVALUATION OF HANDHELD SELF-TREATMENT DEVICE FOR HAIR REMOVAL

James M. Spencer MD
Spencer Dermatology and Skin Surgery, St. Petersburg, FL

Abstract

Background and Objectives: Laser and light-based methods for hair removal, though effective, are expensive and may be associated with adverse effects. Our objective was to evaluate the efficacy and safety of a thermal, handheld self-treatment device (no!no!™ Thermicon™, Radiancy Inc, Orangeburg, NY) for removing unwanted hair.

Methods: Twelve of the 20 enrolled subjects underwent 6 supervised and 6 unsupervised self-treatments of their lower legs and umbilicus-bikini areas at twice-weekly intervals for 6 weeks. Follow-up visits were scheduled at 2, 6, and 12 weeks after the final treatment. Results were evaluated by pretreatment, post-treatment, and follow-up hair counts.

Results: For legs, the median clearance percentages were 48% post-treatment and 43.5% at 12 weeks. For the umbilicus-bikini area, the median clearance percentage was 15.0 % at 12 weeks.

Conclusions: The efficacy and safety of the no!no! Thermicon device for hair removal of the legs appear to be comparable to those of laser devices.

Introduction

Traditional hair-removal methods such as waxing, shaving, and chemical depilatory treatments are often inconvenient. Permanent methods such as electrolysis are painful, expensive, and have a risk of adverse effects.

Areas typically treated include the face, neck, axillae, back, and extremities.[1] Laser and light-based techniques have gained popularity in recent years. Laser procedures target melanin in the hair bulb. When melanin absorbs laser energy of the appropriate wavelength, the absorbed energy is converted to heat that selectively destroys the hair bulb. The presence of melanin in the epidermis limits the efficiency of laser-based procedures for hair removal because part of the laser energy is absorbed by epidermal melanin. In subjects with dark skin and light-colored hair, the concentration of melanin is high in the epidermis and low in the hair. When these subjects are treated with laser energy, the epidermis may be damaged because so much of the laser energy is absorbed by the highly concentrated epidermal melanin. Conversely, epidermal damage is reduced in subjects with dark hair and light skin because the concentration of melanin in the hair is higher than in the epidermis. For these reasons hair removal is more successful in subjects with dark hair and light skin, and subjects with darker skin, including tanned skin, have a greater risk of blistering and pigmentary alteration.[2] Adverse effects associated with various types of lasers used to remove hair are shown in Table 1.[3]

Hair has also been removed successfully with intense pulsed light devices,[1,4,5] which, though effective, are sometimes associated with adverse effects such as postinflammatory pigmentation,[6] pain, discomfort, and crusting.[7] The use of a combination radiofrequency and intense pulsed light source has also been evaluated.[8] All these methods remove hair by a thermal mechanism. The hair is heated, the heat is conducted to the hair follicle, and the follicle is destroyed by heat.

Removing hair with laser or light-based treatments is expensive and requires multiple visits to medical clinics or spas. To overcome these disadvantages, an over-the-counter device for personal use has been developed to thermally remove unwanted hair. Because the hand-held device is not a light-based therapy, skin pigmentation is not relevant to efficacy. The device therefore may be safely used for all hair colors and skin colors. The purpose of this study was to evaluate the safety and efficacy of this new device for removing hair of a variety of colors in subjects with skin types I through VI.

Materials and Methods

The hand-held (3.2" x 1.5" x 1.3") self-treatment device (no!no! Thermicon, Radiancy Inc, Orangeburg, NY) is designed to remove unwanted hair from all parts of the body excluding the face (except sideburns), ears, neck, and genitals. The device consists of an AC/DC power converter and a hand piece that houses control electronics, contact rollers, and a replaceable thermal filament. The filament delivers heat to the hair shaft as the mechanism of action. A green light-emitting diode (LED) indicates that the rollers and filament are correctly positioned and that the device is moving at the correct pace. A red LED indicates a problem with the filament. During treatment, the hair shaft is heated and singes slightly, leaving residual hair to be brushed away. When motion stops or is reduced below a threshold, the filament retracts from the skin and instantly cools.

Twenty healthy adult women enrolled in the prospective study. Twelve subjects (aged 38.2 ± 9.2 [mean ± SD]) underwent 6 supervised and 6 unsupervised self-treatments at twice weekly intervals for 6 weeks after a wash-out period of 2 weeks. Hair was trimmed before treatment. Subjects pro-

vided signed informed consent and agreed to avoid other hair-removal treatments during the study period. Exclusion criteria were a history of abnormal scarring, open lesions in the treatment areas, and the use of oral or topical medications that could influence outcome.

Subjects self-treated their lower legs and the areas between the umbilicus and the top of the bikini lines. Each treatment area included at least 10 hair shafts trimmed to 3 to 4 mm when necessary. Follow-up visits were scheduled at 2, 6, and 12 weeks after the final treatment. The areas to be treated were photographed before treatment and at each subsequent visit; adverse effects were recorded.

With the aid of a 2x2-cm ruler, hairs were counted by the study investigator from digital photographs taken before the first treatment, after the final treatment, and at each follow-up visit. Efficacy was expressed as the percentage clearance and was calculated from the following formula: Clearance (%) = ([preTx hair count – postTx or follow up hair count]/ preTx hair count) x 100 where Tx = treatment.

For the 12-week follow-up data, regrowth (%) was calculated as (postTx hair count/preTx hair count) x 100. At the end of the study, subjects were asked if they were pleased, mildly pleased, or not pleased with their treatment and results.

Results

Twelve of the 20 subjects completed the study. Eight withdrew because they were unable to comply with the treatment protocol (n=4), decided to become pregnant (n=1), required knee surgery (n=1), sought hair removal with a razor (n=1), or withdrew consent due to development of a mild erythema and crusting in the striae of suprapubic area (n=1), which resolved without scarring.

The median percentage clearances are shown in Table 2 and Figure 1. The clearance rates were higher for the legs than for the umbilicus-bikini line area for 11 of the 12 subjects.

For the legs, 90.6% of the post-treatment clearance rate was maintained for at least 12 weeks. For the umbilicus-bikini line area, the 12-week clearance rate (15%) was triple the post-treatment clearance rate (5%).

The percentages of subjects at various median clearance rates at the 12-week follow-up visit are shown in Table 3 and Figure 2. For the legs, clearance rates ranged from 37% to 73% for 75% of the subjects. For the umbilicus-bikini lines, clearance rates ranged from 4% to 25% for 75% of the subjects.

Table 1. Reported adverse effects associated with laser and light-based procedures for hair removal.

Laser or Light Type	Adverse Effects
Ruby laser	Pain, blistering, crusting, erosions, purpura, thrombophlebitis, hyperpigmentation, hypopigmentation, and scarring (higher incidence of pigmentary alterations and scarring with darker skin types)
Alexandrite laser	Pain, blistering, crusting, purpura, postoperative extrusion of damaged hair shafts, hyperpigmentation, hypopigmentation, and hypertrichosis
Diode laser	Moderate to severe pain, blistering, crusting, erosions, hyperpigmentation, hypopigmentation, and hypertrichosis
Nd:YAG (QS/long-pulsed)	Purpura, folliculitis, pain, rarely hyperpigmentation, and hypopigmentation (safer for darker kin types)
IPL hair removal systems	Moderate pain, crusting, erythema, hyperpigmentation, hypopigmentation, paradoxical hair growth in untreated areas in close proximity, and temporary/permanent leukotrichia

QS = Q-switched; IPL = intense pulsed light.
Adapted with permission from Lim SP, Lanigan SW. A review of the adverse effects of laser hair removal. *Lasers Med Sci.* 2006;21:121-125.[3]

Table 2. Median percentage clearance (96.1% CI) in hair counts immediately after the final treatment and at follow-up visits.

Area	PostTx	2 Weeks	6 Weeks	12 Weeks	
				Clearance (%)	Regrowth (%)
Legs	48 (29.00-63.00)	38* (13000-80.00)	64 (22.00-75.00)	43.5 (24.00-58.00)	56.5 (42.00-76.00
Umbilicus-bikini lines	5 (-11.00-18.00)	23.5 (-7.00-28.00)	22.5 (5.00-36.00)	15 (4.00-29.00)	79.00 (64.00-96.00)

*98.8% CI. CI = confidence interval; Tx = treatment.

Figure 1. Median clearance (%) after treatment and during follow-up visits.

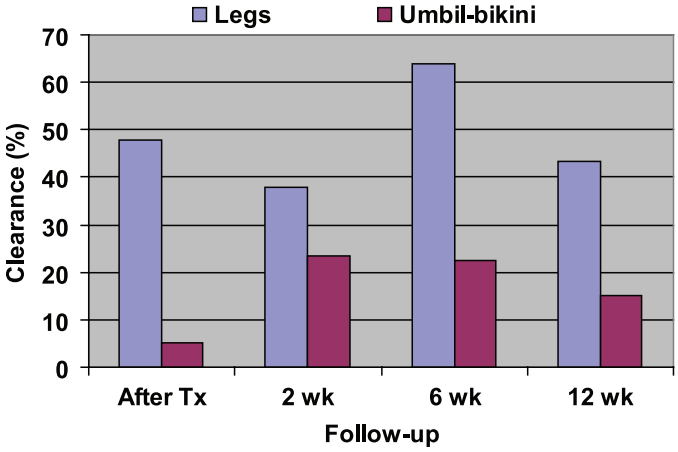


Figure 2. Percentage of subjects at various median clearance rates at the 12-week follow-up visit.

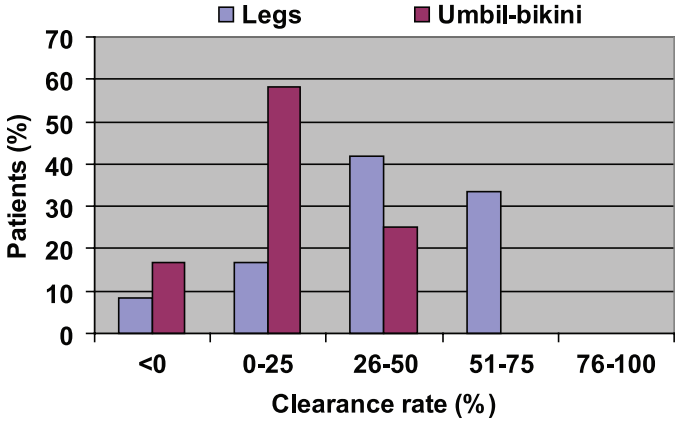


Table 3. Percentage of subjects at various median clearance rates at 12-week follow-up visit.

Area	<0%	0%-25%	26%-50%	51%-75%	76%-100%
1 (Legs)	8.3	16.7	41.7	33.3	0
2 (Umbil-bikini)	16.7	58.3	25	0	0

*98.8% CI ; CI = confidence interval; Tx = treatment.

Table 4. Clearance and regrowth rates of laser and light-based treatments to remove hair.

Reference	Device	No. Treatments	Treatment Site	Follow-Up (Mo.)	Clearance (Hair Reduction) (%)	Regrowth (%)
Allison et al (2003)[9]	Ruby laser	2-3	Lip, axilla, legs	5	18.5 (3 tx)	81.5 (3 tx)
Bjerring et al (2000)[10]	Intense pulsed light	3	Chin, neck	6	49*	51*
	Ruby laser	3	Chin, neck	6	21†	79†
Handrick et al (2001)[11]	Alexandrite laser	3	Axilla	6	37-46	63-54
Hussain et al (2003)[12]	Alexandrite laser	1-3	Axilla, extremities, face	9	55 (3 tx)	45 (3 tx)
Fiskerstrand et al (2003)[13]	Diode laser	3	Upper lip	6	49	51
Lorenz et al (2002)[14]	Long-pulsed Nd:YAG laser	1-5	Legs	12-16	>50 (5 tx)‡	<50 (5 tx)‡

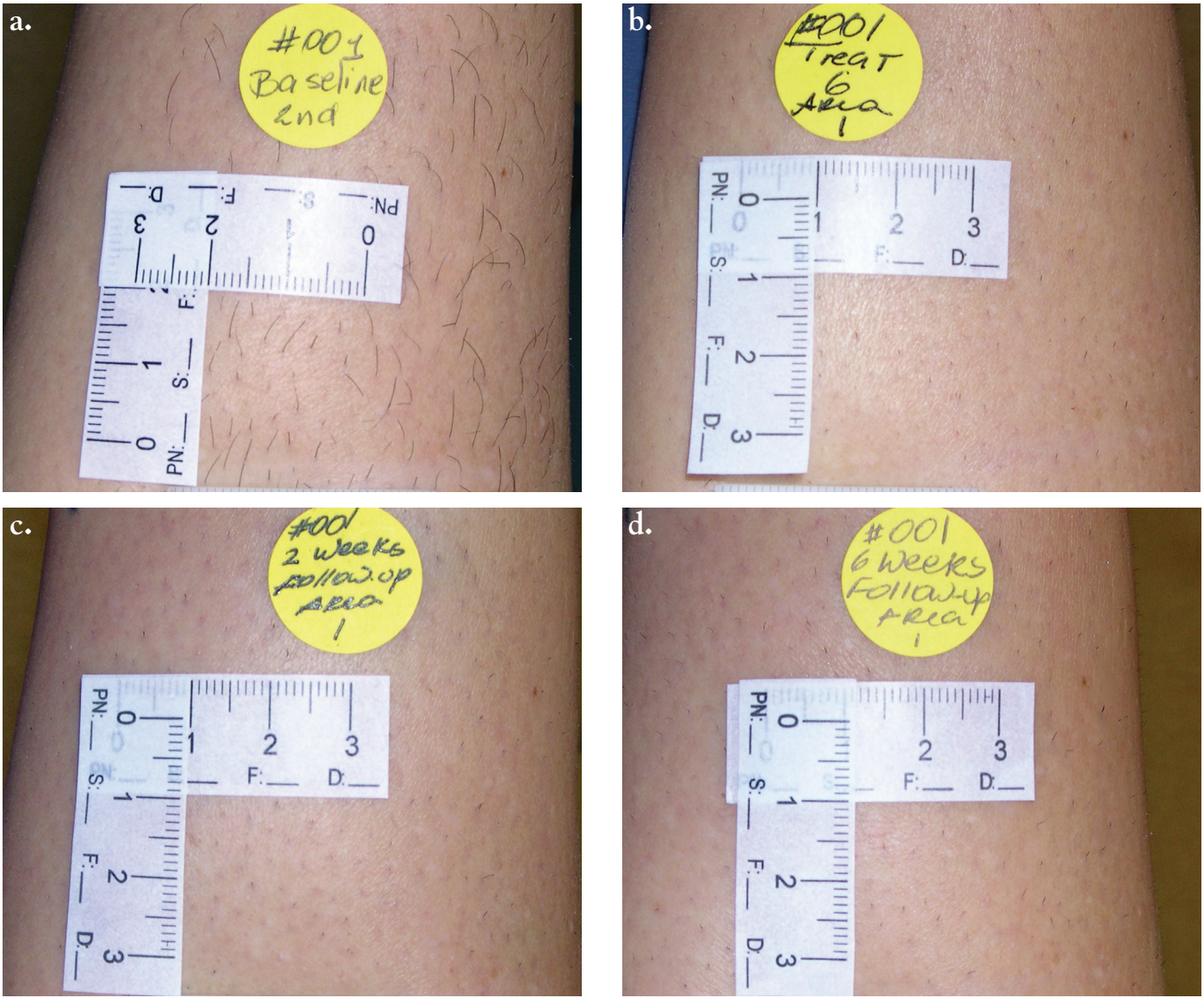
*Obtained by 94% of the patients. †Obtained by 55% of the patients. ‡Obtained by 40% of the patients.

The majority (67%) of subjects were pleased with the no!no! treatment and results. Although not measured directly, regrowing hair appeared to be thinner and lighter colored than original hair, adding to the cosmetic benefit. Adverse effects were limited to mild erythema with crusting in three subjects who completed the study and in one subject who did not complete the study. All adverse effects resolved without scarring, hypopigmentation, or hyperpigmentation.

Discussion

The no!no! device operates by a mechanism similar to that of laser or light devices: it heats hair, the hot hair heats the follicle, and the follicle is damaged or destroyed by the heat. The results (Table 2) show that after 6 weeks of therapy the no!no! device cleared approximately 48% of hair from the legs immediately after treatment (64% at 6 weeks) and approximately 43% clearance persisted 12 weeks after stopping treatment. The no!no! device also cleared nearly 25% (median) of hair from umbilicus-bikini line areas during the 12-week study period. For the legs, 90.6% of the immediate post-treatment clearance was maintained for at least 12 weeks after the final of 6 supervised, subject-administered treatments spaced 2 weeks apart. For the umbilicus-bikini line areas, although initial clearance was low (5%) immediately after the final treatment, the clearance rate increased to nearly 25% at 2 weeks and remained at nearly that level for

Figure 3. The anterior leg of a 35-year-old subject (skin type IV) treated with the no!no! device. The subject self-administered 2 treatments weekly, one at home and the other during a supervised office visit. Photographs were taken at the investigator's office before treatment: **a)** baseline (hair count = 44) and **b)** treatment 6 (hair count = 18, reduction = 59%). Follow-up photographs were taken after the final treatment at **c)** 2 weeks (hair count = 15, reduction = 66%), **d)** 6 weeks (hair count = 9, reduction = 80%), and (e) 12 weeks (hair count = 12, reduction = 73%). The ruler is graduated in centimeters. Area 1 is the legs. The patient was pleased with the result.



6 weeks after the final treatment. Most subjects were at least mildly pleased with treatment and adverse effects were limited to mild erythema with crusting. Clinical examples are shown in Figure 3.

An evidence-based review of light and laser-based methods of hair removal[1] showed that (1) light and laser devices induce "partial short-term hair reduction" for up to 6 months after treatment, (2) repeated treatments improve efficacy, (3) efficacy exceeds that of shaving, wax epilation, and electrolysis, (4) some types of lasers may induce hair removals lasting longer than 6 months, (5) no evidence is available for "complete and persistent hair removal efficacy," and (6) post-treatment side effects are low for lasers.

Data for laser and intense pulsed light devices used to remove hair from various anatomical sites are shown in Table 4. These studies were selected because the investigators treated the areas multiple times and provided follow-up data. Hair reduction (%) was considered the same as clearance (%) when tabulating the data.

For the legs, the median clearance rate (43.5%) of the present study is considerably higher than that obtained with the ruby laser (overall of lip, axilla, legs,[9] chin, and neck[10]), similar to or somewhat lower that of the alexandrite laser (axilla[11] and overall of the axilla, extremities, and face[12]), and slightly lower than that of the diode laser (upper lip)[13] and intense pulsed light (chin, neck).[10] The higher clearance rates (>50%) with the long-pulsed Nd:YAG laser (legs)[14] were achieved by only 40% of patients, so it is difficult to compare these results with those of the present study.

The data of Tables 1 and 4 suggest that the efficacy and safety of the no!no! device is comparable to that of established laser and light-based methods of hair removal for the legs. In the legs and umbilicus-bikini regions the clearance percentage decreases with time after the final treatment, which is consistent with observations associated with laser treatments.[15]

The clearance rates of the legs were considerably higher than in the umbilicus-bikini region. This may be due to differences in the growth cycles, which are known to vary with anatomic location.[16] Additional treatments may increase the clearance rate of the umbilicus-bikini region. The encouraging results justify additional studies with more subjects, different hair colors, more treatment sessions (10 to 15 sessions), and different anatomic sites to more fully evaluate the efficacy and safety of the handheld self-treatment device.

In laser hair removal, laser energy is absorbed by pigment in the hair. For this reason blond and white hair cannot be removed by lasers because there is no target for the laser light. In contrast, the no!no! device works by direct thermal contact with hair and therefore hair color and skin color do not influence efficacy. The hair follicle is heated by simple thermal conduction down the hair shaft. In theory this device should remove both blond and white hair. This will require experimental confirmation.

Another disadvantage of laser and light-based devices is that melanin in the skin is a competing chromphore for melanin in the hair shaft. This competition is irrelevant with the no!no! device because the no!no! device operates by a thermal mechanism.

As for safety in home use, the device does not touch the skin. The heating element (a hot wire 90 microns in diameter) has a low thermal mass. The hot wire generates enough energy to cut hair strands with low thermal mass. The wire cools down if it touches an object with high thermal mass (eg, as the skin).

The device also includes 2 mechanical safety mechanisms to protect the skin from heat: 1) the wire is heated only when the device moves along the skin (without contacting the skin) and 2) as soon as the movement along the skin slows to a speed lower than the device's setting, the hot wire moves higher above the skin.

Conclusions

The efficacy and safety of the no!no! device in hair removal appear to be comparable to those of more expensive, in-office methods.

Disclosure

This study was supported by a research grant from Radiancy Inc.

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ADDRESS FOR CORRESPONDENCE

James M. Spencer MD
Spencer Dermatology and Skin Surgery
900 Carillon Parkway, Suite 404
St Petersburg, FL 33716
Phone: 727-572-1333
Fax: 727-572-1331
e-mail: jgspencer@tampabay.rr.com

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.*

Thermicon Clinical Evaluation

no!no! Hair Removal System

Dr Rodolfo Klein G.(Dermatologist)
Med. Stu. 4th year. Ms. Paula Klein S.
Proff. Dr Ivo Sazunic Y. and colls
Santiago - Chile, June 2006

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SUMMARY

Hypothesis: the Thermicon technology is an efficient and long-lasting hair removal system.

General Objective: to show, through comparative testing, the effectiveness of Thermicon hair removal technology.

Specific Objectives: to prove that, through the correct application of Thermicon hair removal system, this provide with a long-lasting hair removal.

To prove that this system produces a significant change in hair structure.

PATIENT AND METHODS:

20 Patients were used to carry out the test. They were asked to remove hair with the Thermicon technology, during 6 month.
To analyze the effectiveness of this technology, 6 patients of the group were picked out and underwent biopsies in order to calculate the treatment's effectiveness; they were also analyzed through photos.
The biopsies were made in 2 samples; one from the leg treated, at the beginning and at the end of the treatment, using common histological techniques to analyze them in an optical microscope.

To carry out the analysis above described, 20 hair removal machines with Thermicon technology were used. These machines are known in the market as no!no! The biopsies were taken by Dr Rodolfo Klein and were extracted using a 3 mm PUNCH. Later; they proceeded to the statistic analysis of the results.

The test was carried out by Dr R. Klein and the medicine student, Paula Klein. The optical microscopy biopsies were analyzed by Dr Ivo Sazunic and the statistic study was made by Professor Waldo Aranda.

Conclusion: According to the results observed, the Thermicon system is effective for long-lasting hair removal, in a 6 month term of use. More information is needed to evaluate the treatment in a longer term.

OBJECTIVES AND METHODOLOGY

1. Objectives

The objective of this protocol is the assessment of security and effectiveness of the Thermicon hair removal treatment (no! no!)

2. Epilation System Description

The Thermicon system (no! no!) is a new pain free, long-lasting hair removal system. The kit comes with two parts, one for short hair and the other for long hair. It includes also a sponge (Buffer) for soothing the skin surface.

Thermicon is a system, which works generating high temperatures in a filament. This filament enters in contact with the hair and makes good use of its thermal conductivity. Heat is transfer through the hair towards its shaft causing hair root to damage, in a harmless way for the rest of the adjacent structures. This filament is protected in order to avoid direct skin contact.

The system comes with a thorough user's instruction manual and an explanatory DVD.

3. Methodology

Participants:

A total of 20 Women were evaluated in this test

Inclusion Criteria:

- Women between 18-50 years old

- Every participant expressed their consent to take part in this testing. They were explained each part of it and they promised to carry it out according the protocol.

-The hair in the treatment zones should be fairly uniform and easy to see, for a better evaluation of the results.

Visit Schedule and information record per patient:

WEEK	0	1	2	3	4	5	6	7	8
Visit to the Doctor	V0	V1			V2				V3
Patient Register and Inf.	X								
Photography	X	X			X				X
no! no! Treatment at Home	XX	XX	XX	XX	XX	XX	XX	XX	XX
Treatment Register	X	X	X	X	X	X	X	X	X
Report	X	X			X				X
Summary Questionnaire									

WEEK	9	10	11	12	13	14	15	16	
Visit to the Doctor				V4				V5	
Patient Register and Inf.									
Photography				X				X	
no! no! Treatment at Home	X	X	X	X	X	X	X	X	
Treatment Register	X	X	X	X	X	X	X	X	
Report				X				X	
Summary Questionnaire									

WEEK	17	18	19	20	21	22	23	24	
Visit to the Doctor				V6				V7	
Patient Register and Inf.									
Photography				x				x	
no! no! Treatment at Home	DN	DN	DN	DN	DN	DN	DN	DN	
Treatment Register	X	X	X	X	X	X	X	X	
Report				X				X	
Summary Questionnaire								X	

D.N = According to the needs of each patient

PROTOCOL DETAIL:

The patients carried out the treatment in designated areas of their body, during a 6 month term.

The treatment should be applied according to the manufacturing instructions, which are detailed in the user's manual and DVD. The treatment should be used 2 times per week, during the first 2 months; once a week, the following 2 months and after the fourth month, it must be applied according to the hair removal need of each patient.

Areas to be treated:

Each patient carried out the treatment in one leg, in the zone under the knee, additionally she could use no!no! on another zone like: arms, underarms, bikini line, etc.

Photos:

Photos of the treated zone (leg) were taken at the beginning of the treatment (V0) and in every patient visit, in order to check hair density and uniformity.

The photos were taken with a 4.0 mega pixel coolpix 4300 Nikon camera, a lens of Dermalite Dermatoscopic Photo was added for hair count. (Example in annex 2)

Biopsies:

The Biopsies were performed in the treated zones (legs), in 6 patients, before starting the treatment, in Vo and when the 6 months of study finished, in V7

In Vo:

The patients went to the first visit, when at least 4 days had passes since their last hair removal in the study zone, in order to distinguish the number of hairs present when the photos were taken.

The patients filled a personal information register.

In Vo the first photo was taken and was used as the base of comparison throughout the study.

Each patient was given a no! no! and the necessary consumables to carry out the study, besides, they were induced in the use of, and prepared for a correct use the treatment at home.

The patients filled a register of the treatment in every application, in which they wrote down the date of the application and their personal comments.

The first follow-up was made in V1 visit, after a week of treatment (2 applications). This visit's objective was to confirm the patient to have fully understood, how to use no! no!. In the subsequent visits V2 – V7, photos of the treated area were taken. This follow-up was made on a monthly basis.

Monthly visits were coordinated and carried so the patient would be controlled at least 4 days after the application of no! no! in the area to be surveyed (leg). This was made in order to clearly distinguish in the photos, the development and length of the hair in that zone.

In every visit, the monitor filled out a report about the evaluation and results of the patient.

In the last visit V7, each patient had to complete a summary questionnaire, which included their feelings about the effectiveness and satisfaction-evaluation of the results obtained.

Duration:

Period of treatment: 6 months

Effectiveness and Security

Will be determined by the evaluation of the zones to be treated

Information:

The registration and patient information was entered by the patient in the first visit (V0)

The registration of the treatment was filled out by each patient in every application of no! no!
The Summary Questionnaire was filled out by the patient in the last visit (V7)
The Report was filled out by the monitor in every patient visit to the office (VO-V7)

Supervision and Monitoring:

Apart from the specified activities, the monitor had to call the patients once a week to supervise that the treatment was being used correctly, to talk about the progresses and to answer the possible questions.

Study's Results:

Data picked up and used for the analysis.

Numero Paciente	Patient's age (years)	Former Depilatory System	Initial Count	1st count month	2nd count month	3rd count month	5th count month	4th count month	6th Final count month
Patient 1	36	Shaver and/or wax	31	36	27	25	20	W / I	14
Patient 2	20	Electric Rotary Epilators	13	19	32	30	22	8	6
Patient 3	50	Wax and/or Electric Rotary Epil	20	20	25	26	17	W / I	9
Patient 4	28	Shaver	15	11	12	12	11	14	14
Patient 5	47	Wax	15	9	15	18	15	17	15
Patient 6	23	wax	24	33	26	34	32	25	16
Patient 7	26	Electric Rotary Epilators	24	29	26	23	18	17	23
Patient 8	46	Electric Rotary Epilators	8	10	W / I	5	5	6	1
Patient 9	23	Wax and/or Electric Rotary Epil	19	21	12	7	11	W / I	12
Patient 10	30	Wax and/or Electric Rotary Epil	31	13	11	W / I	20	W / I	4
Patient 11	28	Wax and/or Electric Rotary Epil	19	26	28	13	15	10	21
Patient 12	26	Electric Rotary Epilators	31	30	32	30	30	14	26
Patient 13	21	Shaver	63	40	23	W / I	42	43	44
Patient 14	35	Electric Rotary Epilators	19	15	13	26	13	12	7
Patient 15	22	Shaver	50	48	36	43	40	25	11
Patient 16	31	wax	22	11	8	17	23	W / I	6
Patient 17	18	Electric Rotary Epilators	30	15	W / I	37	28	21	13
Patient 18	27	wax	14	20	15	6	13	W / I	17
Patient 19	20	Shaver and/or wax	35	28	20	23	10	12	24
Patient 20	47	wax	35	33	25	W / I	13	24	20

W / I Without information, Patient did not come to the monthly control.

HAIR TENDENCY ANALYSIS OF THE SAMPLE TWENTY WOMEN

In the following charts it may be observed: in the first column, the average number of hair in each one of the periods (months) surveyed; in the second column the standard deviation; the third column shows the percentage of remaining hair, compared with the initial value; the fourth column shows the percentage of hair reduction, compared with the initial measuring and the fifth column shows the percentage of hair reduction, compared to the previous period.

COMPLETE SAMPLE ANALYSIS

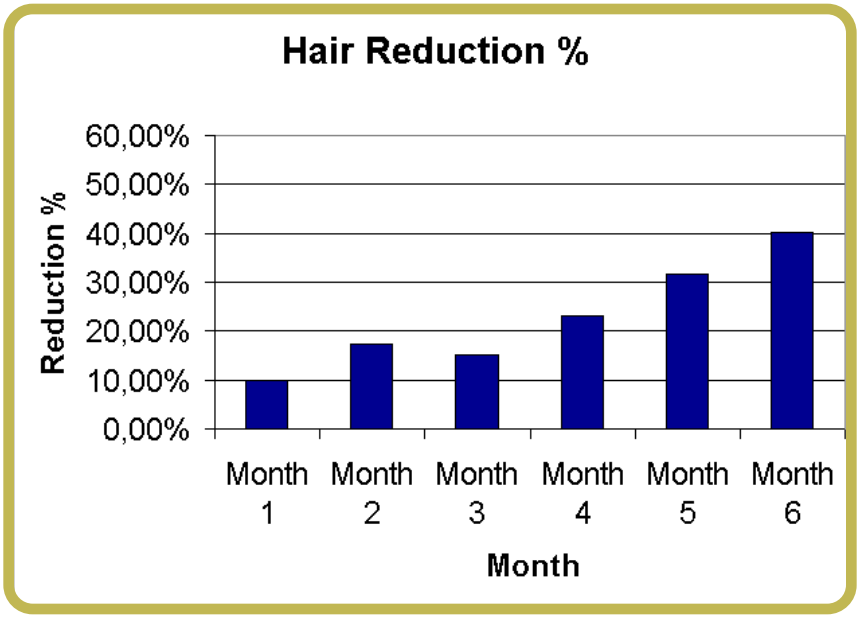
TABLE N^{er}1

Complete Sample Analysis

COMMENT:

The percentage of present hair is lower than the initial value in all the surveyed periods, and with an accentuated tendency to be lower and lower, ending in the last period in just 59.8% of the initial value, with a reduction percentage of 40.1%
When observing the monthly reduction, compared to the previous month, it can be noticed that from the fourth month on, the reduction percentage is constant and significant, ending in a 12.4% reduction, compared to the fifth month.

	Average	Standard Dev.	Remaining % compared to the initial value	Decrease % compared to the initial value	Decrease % compared to the previous month
Initial Value	25.9	13.1	100%	----	------
First Month	23.4	11.0	90.2%	9.8%	9.8%
Second month	21.4	8.4	82.6%	17.4%	8.4%
Third month	22.0	11.1	84.9%	15.1%	+2.8%
Fourth month	19.9	10.0	76.8%	23.2%	9.5%
Fifth month	17.7	9.5	68.3%	31.7%	11.1%
Final Value	15.5	9.6	59.8%	40.1%	12.4%



ANALYSIS BY AGE

TABLE N^{er} 2
Sample Analysis from 18 to 23 years old

COMMENT :

The present hair percentage is lower than the initial value in all the observed periods with an accentuated tendency to be lower and lower, ending in the last period in just 53.9% of the initial value, with a reduction percentage of 46.1%
When observing the monthly reduction , compared to the previous month, in the third month there was an increase of 16.9% and from the fourth month on, the reduction percentage is constant and significant, ending in 19.3%.

	Average	Standard Dev.	Remaining % compared to the initial value	Decrease % compared to the initial value	Decrease % compared to the previous month
Initial Value	33.4	17.7	100%	----	------
First Month	29.1	11.9	87.1%	12.9%	12.9%
Second month	24.8	8.5	74.3%	25.7%	14.8%
Third month	29.0	12.6	86.8%	13.2%	+16.9%
Fourth month	26.4	12.8	79.1%	20.9%	8.9%
Fifth month	22.3	12.3	66.8%	33.2%	15.5%
Final Value	18.0	12.7	53.9%	46.1%	19.3%

TABLE N^{er} 3
Sample Analysis from 24 to 29 years old

COMMENT:

This group presents a different situation from the other age groups. The percentage of present hair is lower than the initial value, only in four periods. A tendency to fall may be observed from the third month on.
When observing the monthly reduction, it's noticed that just in three months a lower average than the one of the previous period was achieved, showing an irregular behaviour.

	Average	Standard Dev.	Remaining % compared to the initial value	Decrease % compared to the initial value	Decrease % compared to the previous month
Initial Value	20.6	7.0	100%	----	------
First month	23.2	7.8	112.6%	+12.6%	-----
Second month	22.6	8.6	109.7%	+ 9.7%	2.6%
Third month	16.8	9.5	81.6%	18.4%	25.6%
Fourth month	17.4	7.5	84.5%	15.5%	------
Fifth month	13.8	2.8	67 %	33.0%	20.6%
Final Value	20.2	4.7	98.1%	1.9%	-------

TABLE N^{er} 4
Sample Analysis from 30 to 40 years old

COMMENT:

In this age group, we can observe one of the best performances of the epilation system. The percentage of present hair is lower than the initial value in all the observed periods and with an accentuated tendency to be lower and lower, ending in the last period in only 30.4% of the initial value, with a reduction percentage of 69.6%.
When observing the monthly reduction, compared to the previous month, from the fourth month on, the reduction percentage is constant and significant, ending in 35% of reduction.

	Average	Standard Dev.	Remaining % compared to the initial value	Decrease % compared to the initial value	Decrease % compared to the previous month
Initial value	25.7	6.1	100%	----	------
First month	18.7	11.6	72.8%	27.2%	27.2%
Second month	14.7	8.4	57.2%	42.8%	21.4%
Third month	22.6	4.9	87.9%	12.1%	------
Fourth month	19.0	4.2	73.9%	26.1%	15.9%
Fifth month	12.0	0	46.7%	53.3%	36.8%
Final value	7.8	4.3	30.4%	69.6%	35.0%

TABLE Ner 5

Sample Analysis from 41 to 50 year old

COMMENT:

In the second month there is a higher quantity of hair than the initial value. From then on, the tendency is for the amount of hair to fall, ending in the last period in only 57.5% of the initial value, with a reduction percentage of 42.5%.
When observing the monthly reduction, compared to the previous month, it is noted that in two months there was a larger hair quantity than in the previous month, although 28.7% is a very significant reduction percentage, in the last period.

	Average	Standard Dev.	Remaining % compared to the initial value	Decrease % compared to the initial value	Decrease % compared to the previous month
Initial value	19.5	11.4	100%	- ----	------
First month	18.0	11.2	92.3%	7.7%	7.7%
Second month	21.7	5.8	111.3%	------	------
Third month	16.3	10.5	83.6%	16.4%	24.9%
Fourth month	12.5	5.2	64.1%	35.9%	23.3%
Fifth month	15.7	9.0	80.5%	19.5%	------
Final value	11.2	8.1	57.5%	42.5%	28.7%

ANALYSIS ACCORDING TO THE FORMER HAIR REMOVAL SYSTEM

TABLE N^{er} 6
Sample analysis discriminating hair renoval system used prior to No!No!:
The shaver

COMMENT:

In all the periods observed, the percentage of present hair is lower than the initial value with an accentuated tendency to be lower and lower, ending the last period in just 44.9% of the initial value, with a reduction percentage of 55.1%.
When observing the monthly reduction, compared to the previous month, it is noticed that from the fourth month on, the reduction percentage is constant and significant, ending in 8.9%.

	Average	Standard Dev.	Remaining % compared to the initial value	Decrease % down compared to the initial value	Decrease % compared to the previous month
Initial value	38.8	18.3	100%	----	------
First month	32.6	14.0	84.1%	15.9%	15.9%
Second month	23.6	8.8	60.8%	39.2%	27.6%
Third month	25.7	12.8	66.3%	33.7%	-------
Fourth month	24.6	15.4	63.4%	36.6%	4.3%
Fifth month	23.5	14.2	60.6%	39.4%	4.5%
Final value	21.4	13.5	44.9%	55.1%	8.9%

TABLE N^{er} 7
Sample analysis discriminating hair removal system used prior to No!No!:
Electric Rotary Epilators

COMMENT:

In the initial periods, there was an increase in the average quantity of hair, but an important hair reduction begins from the fourth month on, ending in 60.6% of the initial value, with a reduction percentage of 39.4%.
From the third month on, the monthly reduction percentage begins to decrease slightly, but in a stronger way from the fourth month on.

	Average	Standard Dev.	Remaining % compared to the initial value	Decrease % compared to the initial value	Decrease % compared to the previous month
Initial value	20.8	9.2	100%	.....	.....
First month	19.6	8.1	94.2%	5.8%	5.8%
Second month	25.7	8.9	123.5%	.....	.....
Third month	25.1	10.9	120.6%	.....	2.3%
Fourth month	19.3	9.4	92.8%	7.2%	23.1%
Fifth month	13.0	5.5	62.5%	37.5%	32.6%
Final value	12.6	9.9	60.6%	39.4%	3.1%

TABLE N^{er} 8
Sample analysis discriminating hair removal system used prior to No!No!:
Depilatory Wax

COMMENT:

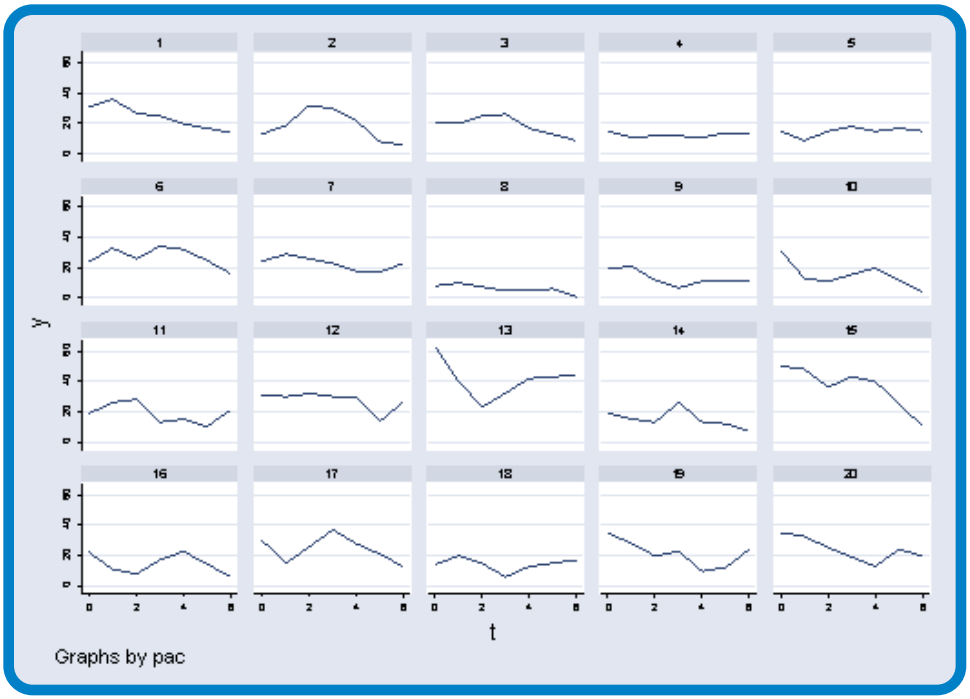
The percentage of present hair is lower than the initial value in all the observed periods with an accentuated tendency to be lower and lower, from the fourth month on, ending the last period in just 60.2% of the initial value, with a reduction percentage of 39.8%. When observing the monthly reduction, compared to the previous month, it is noticed that in two months there was a slight increase, nevertheless, the reduction percentage in the last month compared is 30%

	Average	Standard Dev.	Remaining % compared to the initial value	Decrease % compared to the initial value	Decrease % compared to the previous month
Initial value	22.1	6.9	100%	.....	.....
First month	20.6	8.8	93.2%	6.8%	6.8%
Second month	18.3	7.6	82.8%	17.2%	11.1%
Third month	17.2	10.0	77.8%	22.2%	6.0%
Fourth month	17.6	6.5	79.6%	20.4%	.....
Fifth month	19.0	6.9	86.0%	14.0%	.....
Final value	13.3	6.0	60.2%	39.8%	30.0%

STATISTIC ANALYSIS:

TENDENCY ANALYSIS IN 6 COUNTS PER PATIENTS: 20 PATIENTS

1.TENDENCY OF THE NUMBER OF UNITS PER PATIENT: GRAPHIC DESCRIPTION



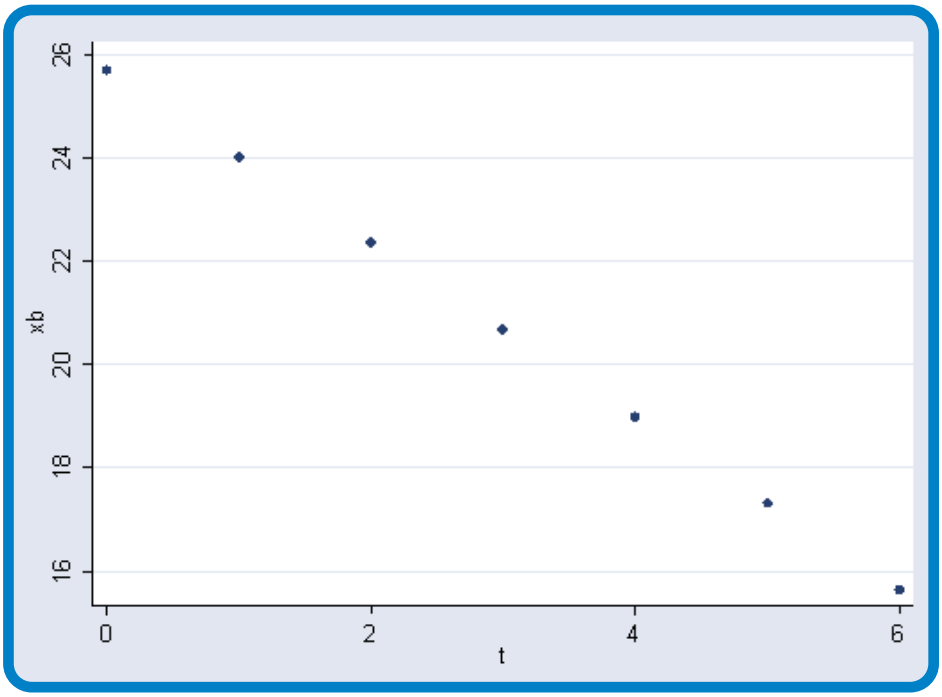
2. VARIANCE ANALYSIS OF ITERATED MEASURES THROUGH THE GEE MODEL

```
. xtgee  y t, i( pac)

Iteration 1: tolerance = .02443802
Iteration 2: tolerance = 6.019e-06
Iteration 3: tolerance = 1.320e-09

GEE population-averaged model                   Number of obs      =       129


Group variable:                       pac       Number of groups   =        20
Link:                            identity       Obs per group: min =         5
Family:                          Gaussian                      avg =       6.5
Correlation:                 exchangeable                      max =         7
                                                Wald chi2(1)       =     32.02
Scale parameter:                 106.3887       Prob > chi2        =    0.0000

------------------------------------------------------------------------------
           y |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
           t |  -1.680703   .2970257    -5.66   0.000    -2.262863   -1.098543
       _cons |   25.70485   2.023939    12.70   0.000       21.738     29.6717
```

CONCLUSION:

THE DECREASE IN THE NUMBER OF UNITS IS STATISTICALLY SIGNIFICANT CONSIDERING THE SAMPLE AS A WHOLE (P<0.001) WITH AN INITIAL AVERAGE VALUE OF 25.7 UNITS. THE LOSS AVERAGED is 1.68 UNITS BETWEEN EACH MEASURING.
THE FOLLOWING CHART ILLUSTRATES THE COMPREHENSIVE SITUATION

3. DECREASE TENDENCY IN THE NUMBER OF UNITIES, IN THE SAMPLE AS A WHOLE



BIOPSY RESULTS:

The optical microscopy biopsy results are summed up in the following table

	Biopsy 1 (V0)		Biopsy 2 (V7)	
Patients	Hair Presence	Hair follicle inflammation	Hair Presence	Hair follicle inflammation
A	Normal	No	Normal	No
B	Normal	No	Small non specific changes	No
C	Normal	No	No	No
D	Normal	No	Perifolicular fibrosis	No
E	Normal	No	No	Yes
G	Normal	No	No	No

CONCLUSIONS:

Discussion:

We can conclude that in a 6 month term of treatment, we can see, according to the statistics, an average decrease of 40% in hair quantity. This is widely corroborated with the biopsies, in which we can see the absence of hair in half of them and a marked decrease of 37%, either by atrophy or inflammation and only in 16% we can observe a follicle without variation.

An increase of the treatment's effectiveness may be observed in almost all patients from the 4th month on, which may be explained by the hair getting shorter after an epilation, especially with wax and/or by traction, which would redound in a lack of hair-hot blade contact in the treatment's first months. This problem would be minimized from the fourth month on.

The increase in the first 2 or 3 months might be due to the previous factor in addition to the inflammation produced by the increase in local temperature caused by the use of equipment in a zone where hair had not appeared on the surface. This would not only make hair appear, it would also make hair to get thicker. After the 4th month, this effect would go in marked decrease.

It is worth to emphasize that only one patient, carrier of type 1 (Fitzpatrick) skin, presented a slight irritation, which did not impede her to continue with the treatment. This argument presents evidence to support the affirmation that the product is completely safe to use.

Conclusion:

We think that Thermicon Technology is an efficient system for long-lasting hair removal. We accomplished the study's expectations, but we have to wait at least 12 months of treatment to re-evaluate the result obtained in hair decrease and to observe how long it takes for hair to reappear when the treatment is stopped.

Annex 1: Biopsy Photographs **Hematoxylin Eosin**

fig1

fig 2

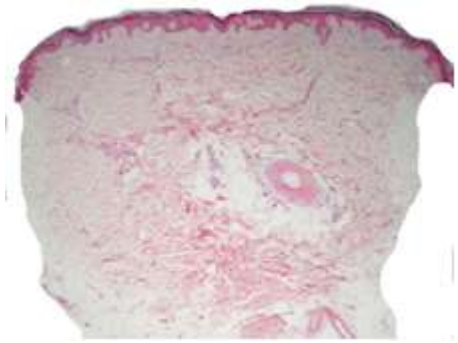


fig 3

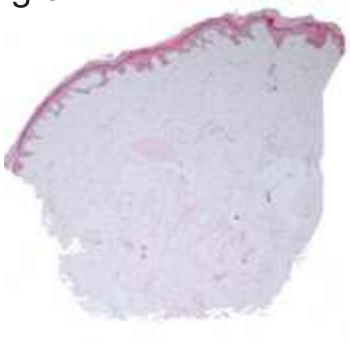


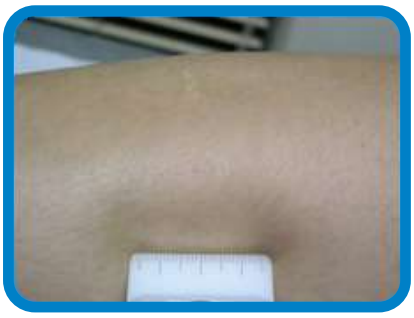
Fig 1.- Corresponds to a Hematoxylin Eosin punch, 2x magnifier in which a normal epidermis, and a normal dermis are visible. We can appreciate pilose baseus structures (hair follicle), around which, there are inflammatory mature linfocitic infiltrate.

Fig 2.- Corresponds to a Hematoxylin Eosin punch, 4x magnifier in which a normal hair follicle, and a normal epidermis are visible. in this hair structure there is not inflammatory infiltrate.

Fig 3.- Corresponds to a 4x magnifier, Hematoxylin Eosin, there is nothing observed, but piloerector muscle and absence of hair follicles

Annex 2 : Photographs before and after the Treatment

initial



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AUTHORS

Dr Rodolfo Klein
Tel: (56 2) 2453216
Address: Del Inca 4446, Office: 601 ; Las Condes, Santiago-Chile.
Mail: drklein@kleinyklein.cl

RADIANCY
RADIANCY INC.
40 Ramland Road South, Suite 10 Orangeburg, New York, 10962, USA
Tel: + 1 845 398 1647 Fax: 1 845 398 1648 Toll Free: 1 888 661 2220
Visit Radiancy's web site in: www.radiancy.com
Visit no! no! web site in: www.my-no-no.com

no!no! Thermicon: A Novel, Home-based Hair Removal Device

Dr. Mira Barki
Yavne, Israel

May 2006

Introduction

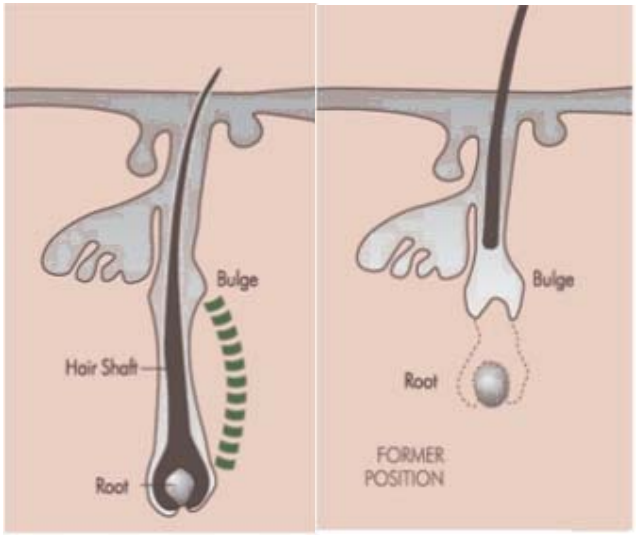
Lasers and intense pulsed light sources have become a popular method for long-term removal of unwanted hair. While effective, for small and large skin areas, ranging from bikini lines to full legs, hair removal with these devices is expensive and requires extensive experience to operate the devices effectively. Light-based hair removal has therefore mostly been performed in medical clinics or cosmetic salons and spas. To overcome limitations with availability for personal use, Radiancy, one of the world's leading manufacturers of light-based hair removal systems has developed the no!no! Thermicon. The no!no! Thermicon is a novel, personal use thermal hair removal device, which has demonstrated potential for delivering long-term hair reduction after repeated use for several months.

BACKGROUND: Understanding Hair Growth

While many aspects of human hair growth have been known for centuries, it is only within the past 10-15 years that scientists have started to understand the molecular basis and the biochemical controls for this complicated process. Hair grows out of follicles in the skin. These follicles undergo cyclic growth phases during which they produce and cease to produce hair. The anatomical structure of a hair follicle is described in Figure 1. The upper portion of the follicle is a permanent structure that contains both an oil producing sebaceous gland and a group of stem cells known as the bulge. The bulge is a swelling that stores the stem cells which initiate formation of the new hair shaft. The lower portion of a fully formed hair follicle contains the hair root or bulb. The bulb is a transient structure that appears as part of the follicle only during the hair growth phase.

Each hair follicle separately completes a three-phase cycle composed of an anagen growth phase, a catagen regression phase and a telogen rest phase. After the completion of telogen, the follicle once again begins a new anagen phase. During anagen, new cells are added in the bulb and are pushed upward to form the new shaft. In this stage, hair typically grows at a rate of about 0.35 mm per day or 1 cm per month. In catagen, production of new hair cells in the follicle stops. The shaft and bulb become seperated and the bulb together with the lower transient part of the follicle degenerates and disappears. In telogen the follicle

Figure 1: The hair; anatomical structure and life cycle



Anagen Phase *Telogen Phase*

rests. The hair shaft falls out or remains in the telogenic follicle until a new hair from the next cycle pushes it out.

The percentage of hairs in the anagen and telogen phases at any given time, as well as the length of time in that phase, depends largely on the body site and on each individual's personal physiology. Human scalp hair grows long because the anagen phase can last up to 5 - 6 years, while body hair is short because the anagen cycle lasts only 2 - 4 months. On the face, 60-70% of the hair

is in the anagen phase at any given time while only 20-30% of hair on the lower body is in this phase.

Though not yet fully understood, it is presently theorized that hair growth cycles are controlled by molecular signals between the bulge and the bulb. Proteins called Wnt play a major role in this signaling process. Disruptions in this cell communication process can slow or stop hair growth cycles reducing hair growth.

Thermal Effects on Hair Growth

Over the past decade, significant knowledge has been gained from the use of lasers and intense pulsed light sources that thermally treat human hair follicles for long-term hair removal (photoepilation).

In photoepilation, intense pulses of visible or infrared light are directed on skin areas where hair removal is desired. Light photons penetrate the skin's dermis and are selectively absorbed by the pigment melanin present in the hair shaft. Absorbed light energy is transformed into thermal energy, which selectively heats the hair follicle to temperatures that cause tissue necrosis.

This process is termed "selective photothermolysis." The amount of absorbed light energy converted to heat is directly related to the amount of melanin in the skin, hair shaft and follicle. Hair shafts and follicles in the anagen phase are selectively targeted for long-term hair reduction, and light energy parameters are selected to minimize skin heating and maximize hair shaft and hair follicle heating. Since all hair in a treated area is not in anagen at the same time, photoepilation requires multiple treatments, often as many as 10-15 sessions spaced 6-12 weeks apart. Hair reduction with photoepilation is a gradual process, which eventually leads to both a reduction in the number of hairs as well as a weakening of the follicles in the treated area. These weakened follicles produce thinner, lighter hair.

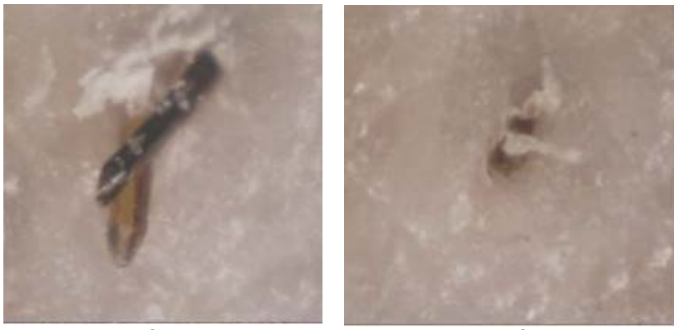
In addition to light photons, Radiancy's professional photoepilation systems, using Light and Heat Energy (LHE™) combine an additional thermal source to conduct heat down the hair shaft. This additional heat source has been shown to improve results on lighter thinner hairs, which are resistant to standard photoepilation.

no!no! Thermicon

Based on experience gained using LHE photoepilation systems in medical clinics and aesthetic centers throughout the world, Radiancy has developed the no!no! Thermicon, a personal-use hair removal device.

The no!no! Thermicon employs the principles of selective thermal hair removal. Thermal energy is delivered to the hair follicle through an innovative process termed Thermicon. A high temperature thermodynamic wire glides just above the skin and singes hair at the skin surface while conducting thermal energy through the hair shaft down the follicle. Heat energy from the no!no!, transiently stored in the hair shaft, completes the thermolysis process (Figure 2).

Figure 2: Hair shaft before and right after heat pulse



Before *After*

Repeated treatments with no!no! weakens the hair follicle and disrupts the molecular communication pathway between the bulge and the bulb. This leads to long-term effects on hair growth cycles and reduced hair growth.

A sophisticated electro-mechanical system monitors no!no!'s movement over the skin and controls the delivery of Thermicon energy. The system contains a precise movement detection sensor. Whenever this sensor detects that the speed of no!no! over the skin's surface is below a predetermined threshold; heating of the wire stops and a mechanical mechanism rapidly raises the heating wire away from the skin. Skin safety and treatment efficiency are thus assured.

Dermascope comparisons of the no!no! and razor shaved hair stubbles shows a mushroom-like edge on the no!no! stubble vs sharp edges on the razor stubble (Figure 3). This may lead to

Figure 3: Dermascope comparison of hair stubble

Mushroom like edge on no!no! stubble *Sharp edge on razor stubble*

reduction in ingrown hairs following no!no! hair removal.

Results

To test the efficacy and safety of the no!no! device, a group of women, aged 18-50, who normally shave were recruited for a controlled clinical trial. Specific anatomical sites such as legs, arms or axilla, with at least 4 hairs/cm^2 were selected on each participant for study. One side was treated with the no!no! and the other side shaved. Subjects were instructed to perform treatments 2-3 times a week for the first two months, and afterwards less frequently, as necessary. Once a month, close up photographs of 3x3 cm. symmetrical areas were taken on the no!no! and shaving study sites. Hair counts were recorded by the study monitor directly from the photographs (Figure 4).

While this controlled clinical study is still in progress, initial results indicate safety, efficacy and compared to conventional shaving a greater treatment effect.

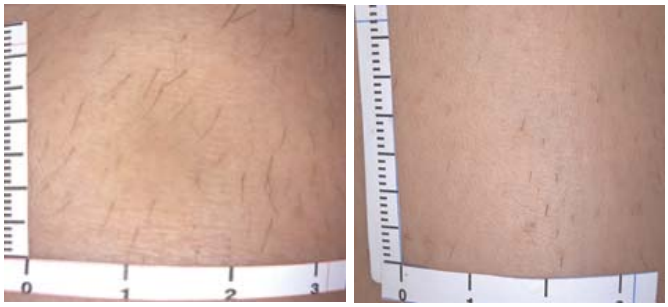
Following one week of no!no! treatments, average hair count reduction from basline was 27%. Hair reduction increased weekly to a level of close to 40% at week 12. Further study treatments show that hair reduction with the no!no! increased to a level of greater than 45% (Figure 5) at 28 weeks.

Several study subjects have entered the follow-up phase where all hair reduction treatments have stopped and study subjects are evaluated at 4-weeks, 8-weeks, and 12 weeks after their last treatment. Initial indications are that hair reductions achieved, remain for at least 12 weeks without further treatment (Figure 6).

After the first week of treatments, control sites showed a 12% hair count reduction. This is possibly due to the more frequent shaving allowed in the study. However, the shaving hair reduction quickly diminished to only 2% by 12-weeks of shaving treatment.

Subjects participating in this study reported slower hair growth following no!no! treatments compared to shaving. While actual hair growth rates were not measured in this study, this appears to be evident in many study photographs (Figure 7). Many subjects also reported thinning of new hairs possibly indicating gradual weakening of hair follicles after repeated no!no! treatments.

Figure 4: Close up photographs for hair counts



Base line: 72 hairs *After 16 weeks of no!no! Treatments: 35 hairs*

In a separate study conducted in the U.S., a group of 13 female subjects completed 6 weeks of bi-weekly no!no! treatments. Results from follow-up hair counts at 6 and 12 weeks after the last treatment indicate that average hair reduction on the no!no! treated sites was 30% at 12 weeks after 12 treatments. (Figure 8).

An additional study was conducted to evaluate safety and effectiveness of the no!no! device for hair removal on men's legs (10 male subjects). None of these legs were shaved prior to the study. An interesting difference between no!no! and razor shaving was noted. When treatments on the shaved control sites were stopped, a significant increase in hair count above pre-study baseline values was recorded. This phenomenon of hair growth stimulation by shaving is anecdotally known. It is theorized that repeated shaving stimulates hair growth by synchronizing the growth cycles and shortening the telogen phase. The increase in hair growth on control shaved sites persisted for 10-15 weeks before hair counts returned to baseline values.

On sites treated with the no!no! device , the phenomenon of hair growth stimulation was not observed. When treatments were stopped, a gradual increase in hair counts was observed until hair counts in the study areas returned to baseline values at 15 to 20 weeks after the last treatment.

Throughout all three clinical studies, no significant side effects were recorded.

Figure 5: no!no! vs. Shaving hair reduction results – Treatment phase

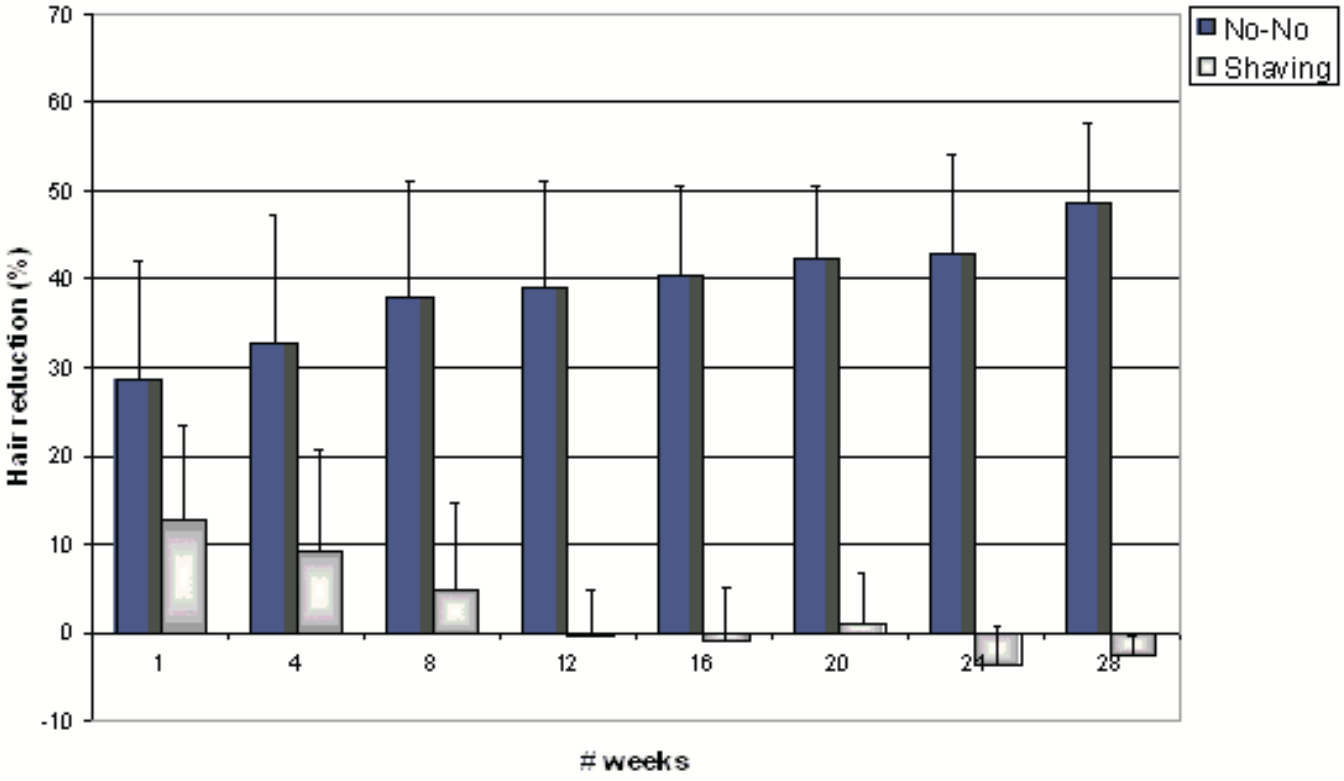


Figure 6: no!no! vs. Shaving hair reduction results – Follow up phase

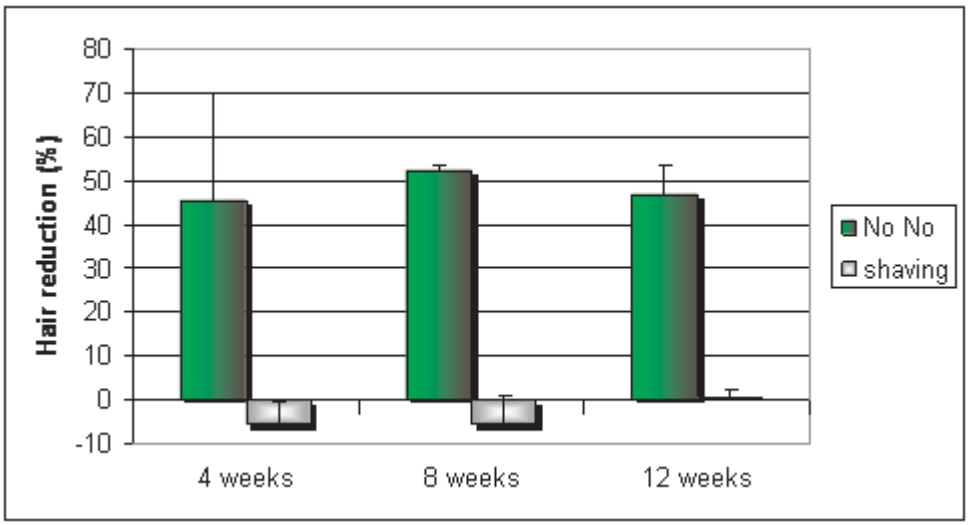
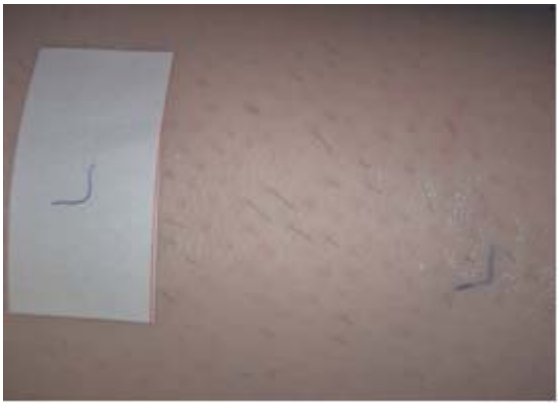


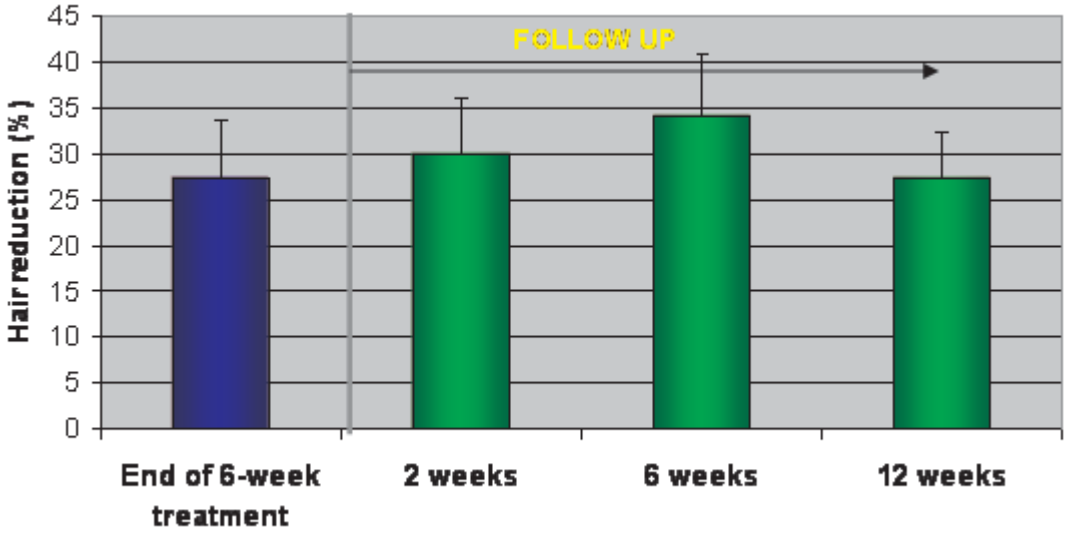
Figure 7: Hair length following no!no! vs. shaving treatments

Shaving



no!no!

Figure 8: Hair reduction – U.S. study



Summary

The no!no! Thermicon is a novel, home use thermal hair removal device, which has the potential to provide long term hair reduction following use over a period of several months. The system is easy to use and incorporates sophisticated safety mechanisms to avoid any undesirable side effects to the skin. Unlike photothermal hair removal devices such as lasers and intense pulsed light sources, the no!no! treats all hair, including fine, light colored or white hairs, and minimizes risk to surrounding skin. The no!no! device's thermal effect is confined to the hair shaft and hair follicle.

The no!no! device