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

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Introduction

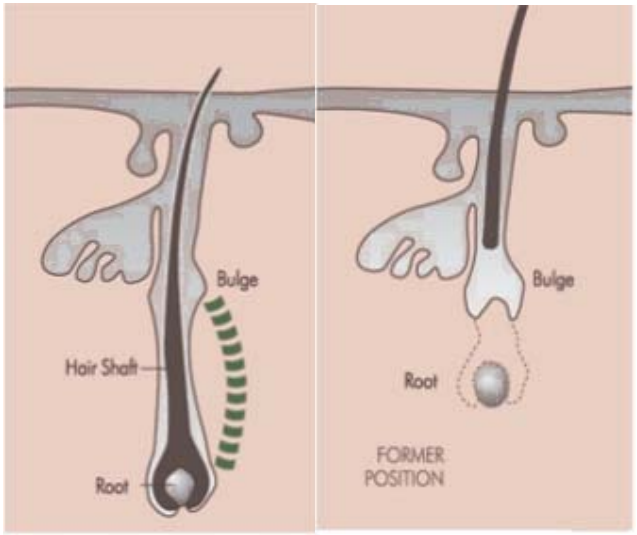
Lasers and intense pulsed light sources have become a popular method for long-term removal of unwanted hair. While effective, for small and large skin areas, ranging from bikini lines to full legs, hair removal with these devices is expensive and requires extensive experience to operate the devices effectively. 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.

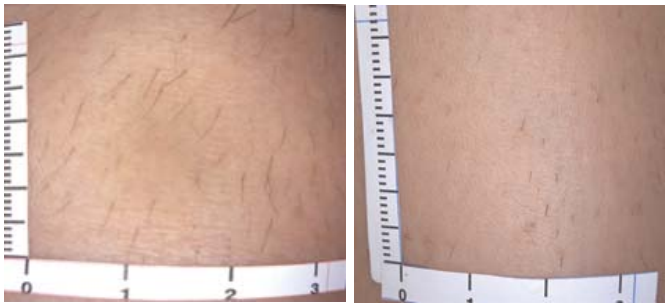
Following one week of no!no! treatments, average hair count reduction from basline was 27%. Hair reduction increased weekly to a level of close to 40% at week 12. Further study treatments show that hair reduction with the no!no! increased to a level of greater than 45% (Figure 5) at 28 weeks.

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

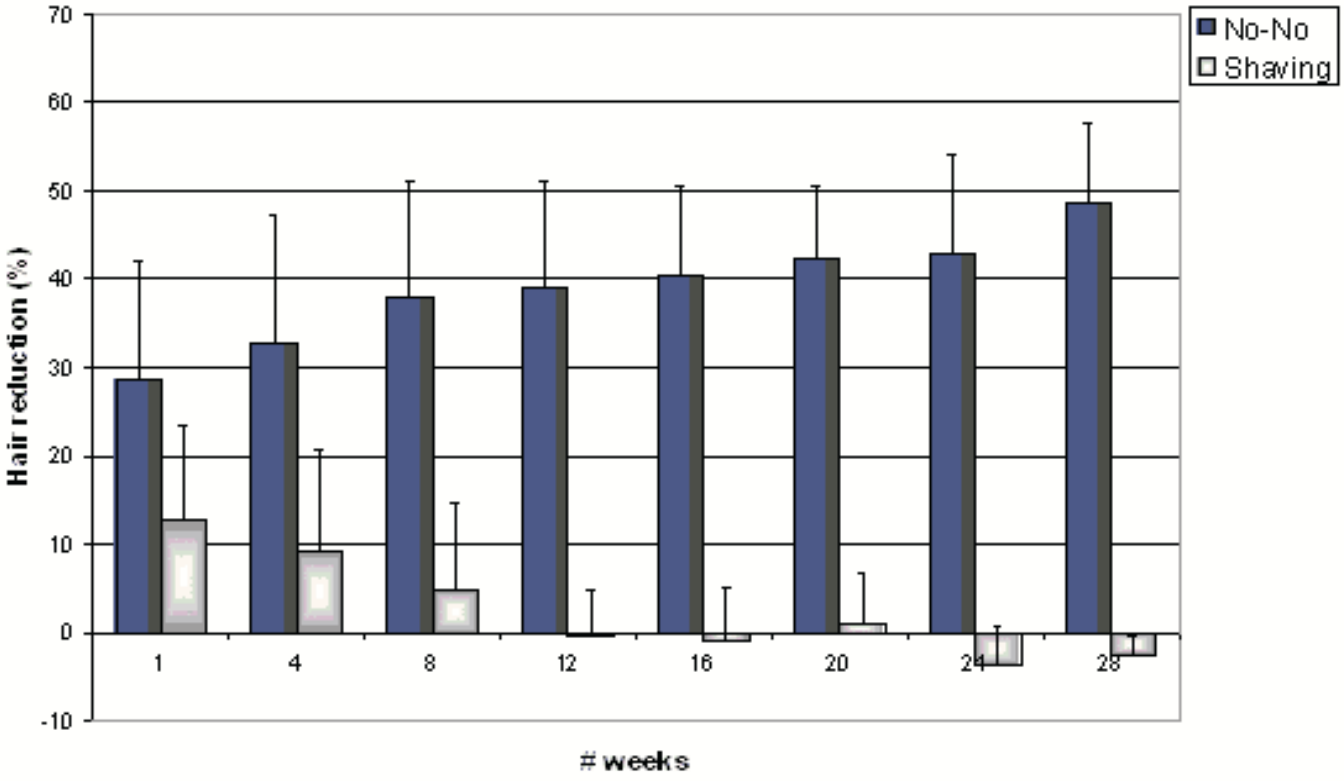


Figure 6: no!no! vs. Shaving hair reduction results – Follow up phase

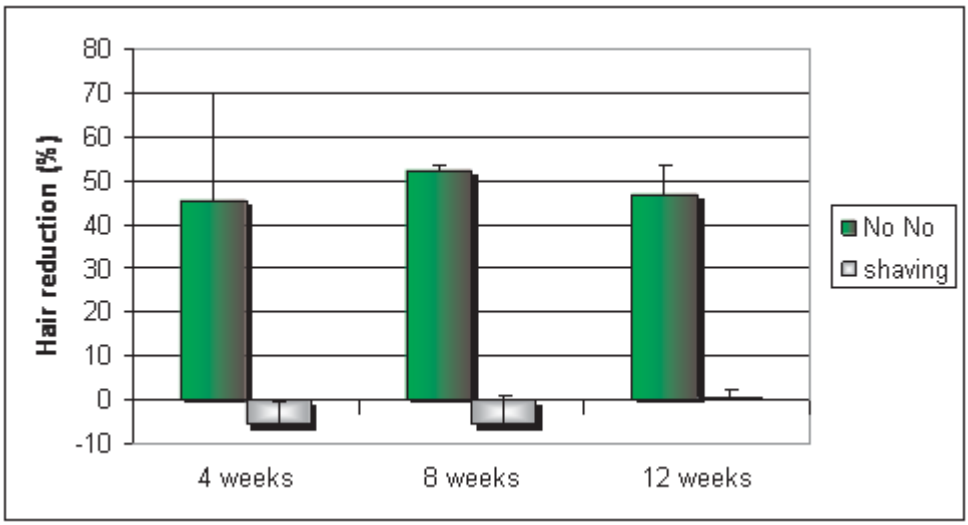
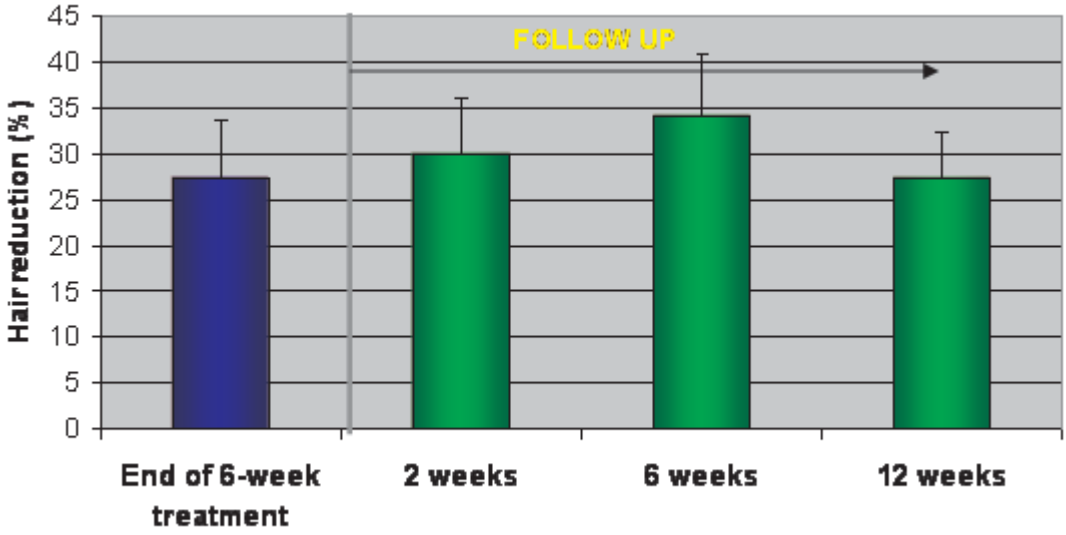


Figure 7: Hair length following no!no! vs. shaving treatments

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