Multi-Centered Double Blinded Clinical Study

Study Objectives

The study was designed to support a 510K submission to the FDA and was subjected to an IRB approval and complied in accordance with GCP (Good Clinical Practices). The objectives of the study in males were to assess the following:

- ❒ promotion of hair growth through changes in hair density
- ❒ cessation of hair loss
- ❒ overall scalp health
- ❒ safety

(The clinical trial to assess the efficacy of the HairMax LaserComb in females was just completed and will be reported on at a later date).

Study Design

The study was designed as a multicenter, randomized sham-device controlled trial conducted at four sites in the United States. Subjects were to use the device three times per week on non-consecutive days for a total of 26 weeks. Hair density measurements were performed at baseline immediately prior to randomization and again at 26 weeks. Additional clinical visits were scheduled at 8 and 16 weeks.

Subject Population and Demographics

The study population included males between the ages of 30 and 60 years with a diagnosis of androgenetic alopecia who had been experiencing active hair loss within the last 12 months. The inclusion criteria required a Norwood-Hamilton classification of IIa to V and Fitzpatrick skin types I to IV. All subjects were randomized. A biostatistition calculated the study to be of a proper size to gauge statistically significant results.

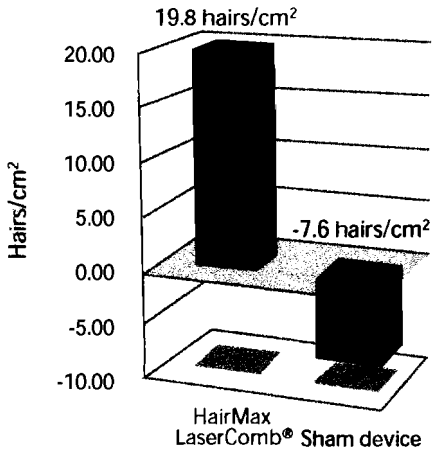
Methods

After a diagnosis of the scalp for androgenetic alopecia and exclusion of other dermatological conditions, subjects were randomized with either active or sham devices. Subjects were then photographed for global evaluation, had the target site of the scalp identified and tattooed for baseline density and were given the device without investigation usage instructions per protocol for OTC use. Subjects returned to the clinic at 8 and 16 weeks with a final visit at week 26 for clinical evaluation.

Clinical Results

Subjects in the HairMax LaserComb treatment group had significantly greater increase in mean terminal hair density (19.80 cm^2) than subjects in the sham group (-7.60 cm^2) ($p<0.0001$). Subjects in the HairMax LaserComb group also had significantly better subjective assessments of overall hair regrowth than subjects in the sham group ($p=0.010$). No subject experienced a serious adverse event and the adverse event profiles were similar between the two treatment groups.

Figure 1: Mean Baseline Change at 26 Weeks in Terminal Hair Density (hairs/cm^2).



User Benefits

Users of the HairMax LaserComb received some or all of the following subjective benefits:

- ❒ New hair growth of dormant follicles throughout the scalp including the temporal zone
- ❒ A substantial decrease in hair fallout. Some users experienced an initial increase in telogen fallout after starting treatment, but after this period, new anagen growth was observed
- ❒ Increased speed of hair growth
- ❒ More manageability of the hair
- ❒ Overall better quality and condition of hair

Product Information

The Hair Max LaserComb Internet site, **www.hairmax.com** can also provide your patients with a wealth of information on this unique device. Your visit there will also acquaint you with our International Board of Medical Advisors and provide you with links to many important dermatological resources.

Availability

The HairMax LaserComb is available to your patients to purchase by accessing our Web site:

www.hairmax.com

or by calling **866-527-3726** 24 hours a day

If you have any questions about the HairMax LaserComb, please access our Web site or call:

HM LC Physician Information Center

at **1-866-273-7795** or call **1-561-417-0200**

Introduction

Some say it is the hair that makes the man or woman. It's been called our crowning glory. It defines our style and frames our personal presentation.

In too many cases, men and women with hair loss see their futures as uncertain and painful. For some, hair loss and their hair's overall appearance becomes an overriding obsession and while there is some initial excitement about the seemingly endless amount of available treatment options, many soon become pessimistic about their chances for reversal of thinning hair and regrowth.

The fight against hair loss comes with a high physical, emotional and financial price tag. Many men deal with their condition by spending thousands of dollars on OTC therapies, vitamin supplements and so-called natural remedies which do not work in ameliorating the condition.

Now there is a well-founded hope in the battle against hair loss and the struggle to maintain a full, healthy head of hair. Lexington International, LLC has introduced the first and only medical device clinically proven to treat androgenetic alopecia and is making this device available to health care professionals such as yourself. You can recommend the HairMax LaserComb for use alone or in conjunction with other modalities and it is available without a prescription. Additionally, your patients will appreciate its ease of use and portability.

History of Light Therapy

The use of phototherapy in cutaneous medicine has a long history. In 1903, the second Nobel Prize in Medicine (Physiology) was awarded to Niels Ryberg Finsen, M.D., in recognition of his contribution to the to the treatment of diseases with concentrated light energy, 'PhotoTherapy'.

Today, PhotoTherapy devices are a mainstay in the treatment of many dermatological conditions.

Our founding director, Henry Pearl, was a pioneer in the use of laser technology at a leading hair care clinic and research center in Sydney, Australia. In the 1980's, he concentrated on the use of laser phototherapy in a clinical setting to activate hair growth. The results were dramatic with individuals experiencing substantial improvements in hair growth and the overall quality of their hair. Over the next 20 years, the HairMax LaserComb was developed and patented worldwide.

Specifications

The HairMax LaserComb is a user-friendly hand-held Class 3R laser therapy device that contains 9 individual laser modules at a wave length of 655 nm (+/- 5 nm). The patented 'teeth' component is designed to part the user's hair to ensure unobstructed path for laser delivery to the scalp at the base of the hair follicle.

Medical Indication and Use

Based on the submission of a 510K document and clearance from the FDA, the HairMax LaserComb is officially indicated to:

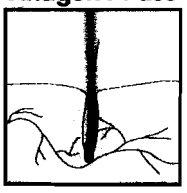
'Promote hair growth in males with androgenetic alopecia who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Skin Types I to IV'.

Mechanism of Action – Hypothesis

Although the exact mechanism is under continuing investigation, we hypothesize that the HairMax LaserComb is an 'Anagen Inductor', utilizing the mechanism of action of Photo-BioStimulation to increase vascular circulation and ATP production. Many users see an increased rate of hair fall out after starting to use the HairMax LaserComb, which is a sign of the telogen cycle being accelerated, thus reaffirming this hypothesis.

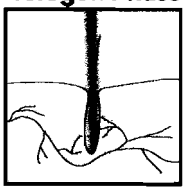
Objectives of HairMax LaserComb Treatment

Anagen Phase



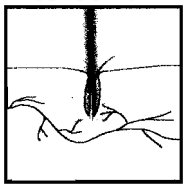
To provide energy for healthy growth.

Catagen to Telogen Phase



To stimulate root for new growth of healthy terminal hair.

Vellus Hair



To stimulate vellus follicle/ root to encourage the transformation from vellus hair back to healthy terminal hair.

Dead hair follicle

No follicle exists and thus this stage of the condition is beyond revitalization.