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Key Clinical Studies on the HairMax LaserComb

- Since 2001, 7 clinical studies have been conducted with 460 subjects
- Key clinical study on the HairMax published in peer review journal
- HairMax consistently demonstrated over 20% increase in hair counts in all studies
- Results of study used to support HairMax LaserComb FDA 510(k) submission
- HairMax demonstrated 21% increase in hair growth density
- No serious side effects ever reported from treatment with the HairMax

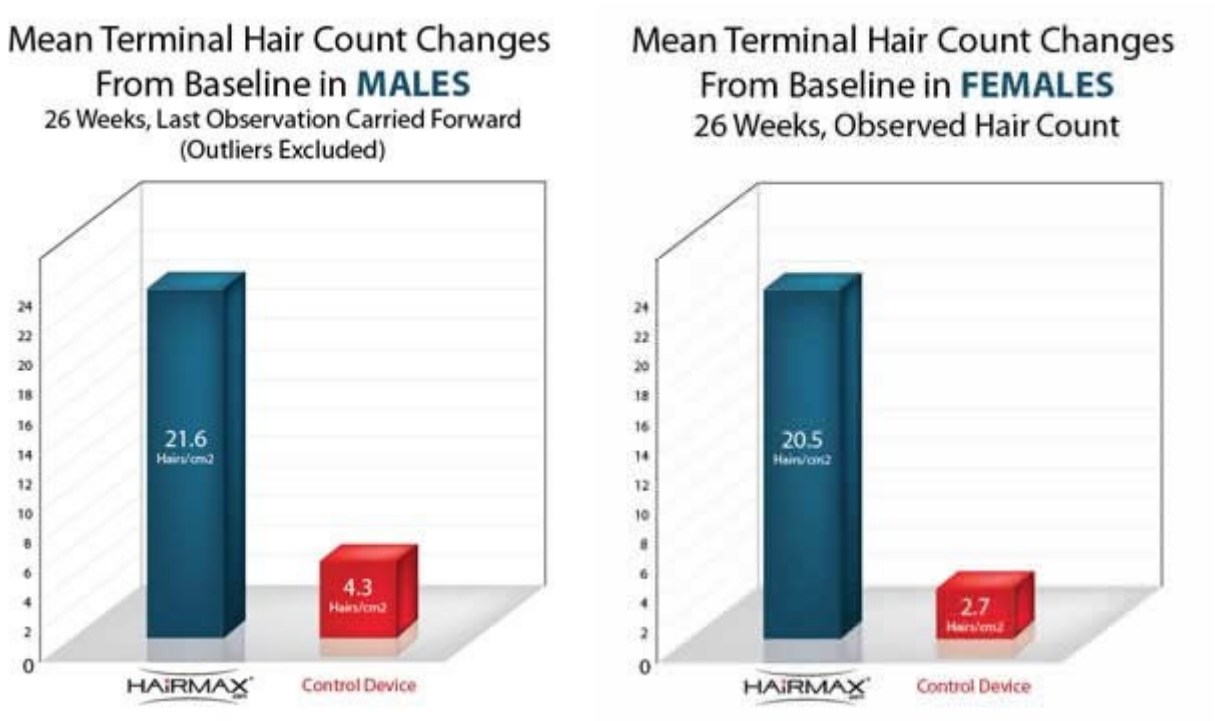
- Benefits of using the HairMax: Decrease in hair fallout, increased speed of hair growth, more manageability of hair and overall better quality and condition of hair

Since 2001, there have been 7 clinical studies conducted on the HairMax. In 2010, 2 of the studies were conducted on males and 2 were conducted in females.

Clinical Results

Subjects in the HairMax LaserComb® laser hair treatment group had:

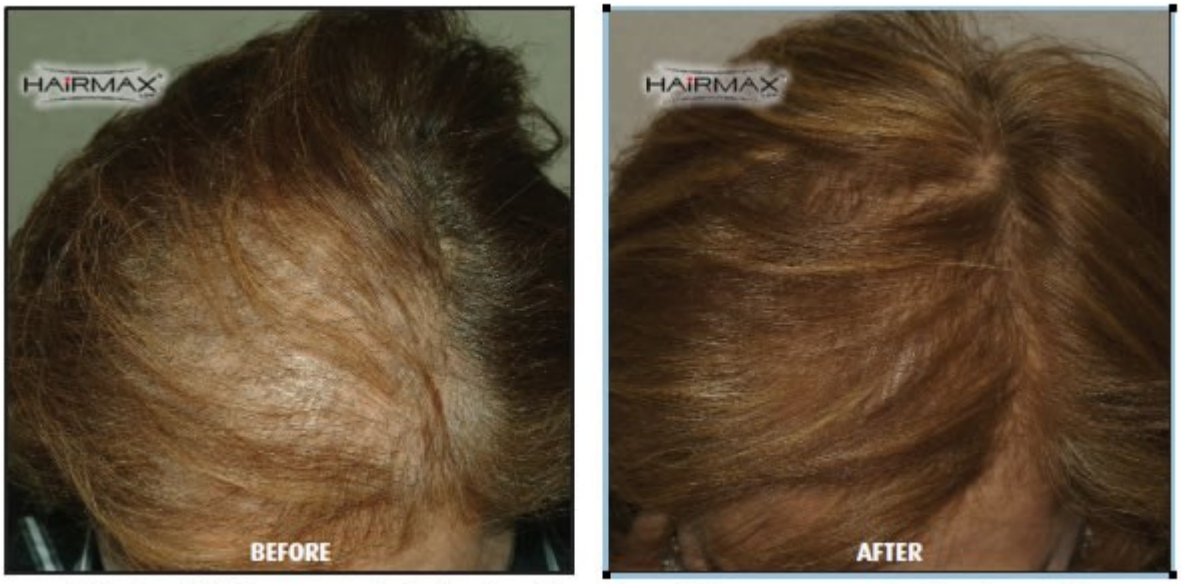
- Significantly greater increase in mean terminal hair count than subjects in the control group.
- Significantly better subjective assessments of thickness and fullness of hair than subjects in the control group.
- No subject experienced a serious adverse event from the laser hair loss treatment.
- Adverse event profiles were similar between the HairMax and control groups.



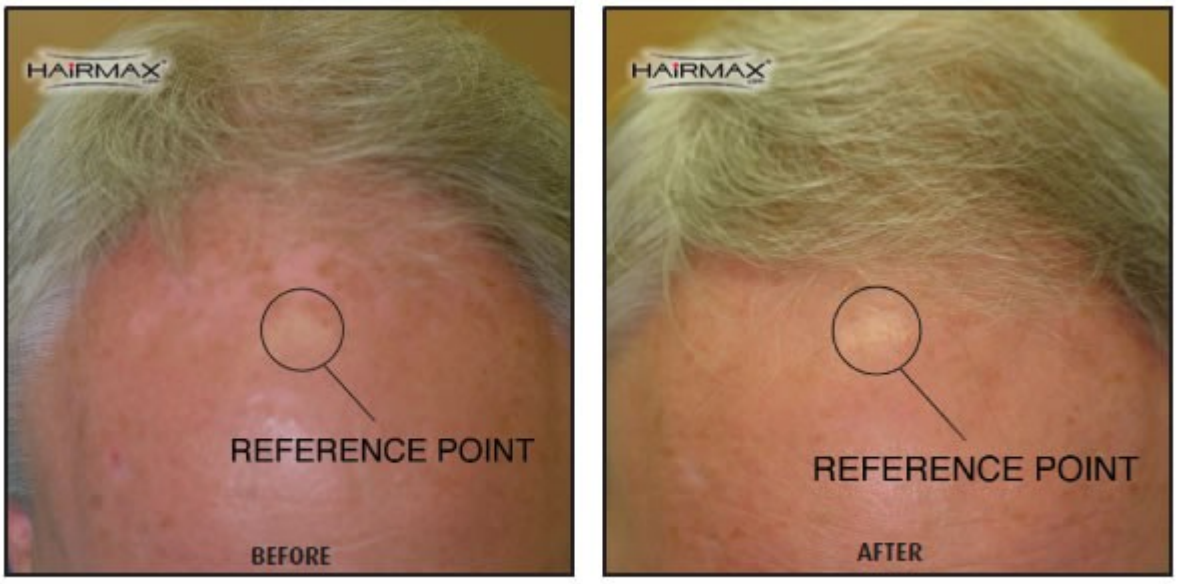
Users of the HairMax LaserComb® laser hair growth treatment* received some or all of the following subjective benefits:

- 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.

Qualified subjects had global images recorded at each visit using a stereotactic device



Substantial increase in hair density. Overall improvement of hair quality



Filling in of hairline. Substantial Increase in hair density.
Overall Improvement of Hair Quality

The photos shown above are of actual HairMax LaserComb users, but are not intended to represent results everyone who uses the device will necessarily experience. Qualified subjects had global images recorded at each visit using a stereotactic device.

Non-Vellus Hair Density Macro Images

The image below corresponds with the un-retouched Macro images shown and demonstrate a 20% increase in hair growth density.

At baseline, a circle approximately 1 inch in diameter, positioned in the transition zone of the scalp, was identified as the site for hair clipping and tattooing. Within this site was the target area for the hair density evaluation during the laser hair growth treatment. Subjects were evaluated at baseline, week 8, week 16 and week 26. Digital images captured by FUJI S2 were taken of the target site within the clipped area following the site preparation. A 19 inch monitor was used for blinded evaluation.

Photo above shows 29 hair/cm increase after 26 weeks of laser hair growth treatment.

Study Objectives

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

Study Design

All studies were designed as a multi-centered, double- blinded, randomized control-device trials conducted at eight sites in the United States. Subjects were instructed to use the laser hair growth treatment device three times per week on non-consecutive days, 10-15 minutes per treatment for a total of 26 weeks. Hair density measurements were performed at baseline immediately prior to randomization and again at 16 and 26 weeks. Additional clinical visits were scheduled to monitor the laser hair loss treatment progress and overall hair growth.

Subject Population and Demographics

The study population included males and females between the ages of 25 and 60 years with a diagnosis of Androgenetic Alopecia who had been experiencing active hair loss within the last 12 months. The inclusion criteria for males required a Norwood- Hamilton classification of IIa to V and Fitzpatrick skin types I to IV. The inclusion criteria for females required a Ludwig (Savin) classification of I-4, II-1, II-2, or frontal. All subjects were randomized for laser hair loss treatment analysis. A biostatistician calculated the study to be of a proper size to gauge statistically significant results of hair growth and hair density.

Lexington limited the skin types for the subjects in the studies to Fitzpatrick I to IV to facilitate the hair counting process. It is difficult to count dark hairs on dark skin and therefore the darker Fitzpatrick skin types (V and VI) were not included in the study.

Methods

After diagnosing the scalp for Androgenetic Alopecia and exclusion of other dermatological conditions, subjects were randomized with either our active laser hair loss treatment device, or sham device. Subjects were then photographed for global evaluation and the target site of the scalp was identified and tattooed for baseline density. Subjects were then provided a device without usage instructions from the investigator per the protocol for OTC use. Subjects returned to the clinic at 8 and 16 weeks with a final visit at week 26 for clinical evaluation of hair counts and hair growth.

The results of the key clinical study performed with the HairMax LaserComb which led to FDA clearance to market was published in the May 2009 Issue of Clinical Drug Investigation. The article entitled, HairMax LaserComb Phototherapy Device in the Treatment of Male Androgenetic Alopecia, is indexed as **Clin Drug Invest 2009: 29 (5): 283-292** in most of the biomedical databases such as MEDLINE, EMBASE/Excerpta Medica, etc.

Customer Satisfaction is of Primary Importance

- ✔ Clinically Proven to Promote Hair Growth*
- ✔ Greater than 90% User Satisfaction Reported
- ✔ Patented and Manufactured in the USA
- ✔ ISO Quality Assured
- ✔ Proud Members of the Better Business Bureau

* The HairMax Advanced 7, Lux9, and the Professional 12 models are indicated to treat Androgenetic Alopecia, and promote hair growth in males who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Skin Types I to IV. The HairMax Lux 9 model is indicated to treat Androgenetic Alopecia, and promote hair growth in females who have Ludwig (Savin) I-1, II-1, II-2, or frontal patterns of hair loss and Fitzpatrick Skin Types I to IV.