Clinical Evaluation of Pilogics Hairegen Hair Regrowth Device

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Abstract

The Pilogics Hairegen device is intended for hair regrowth of men and women suffering from AGA (Androgenetic Alopecia). Clinical trial grade observations were collected from consenting customers who were among the first customers of the device. Healthy men and women have used the device for up to 12 months, and also attended follow-up meetings that included interviews and photography of the treated areas. Photography was both global and local before treatment started at follow-up visit. Hair analysis was performed using Trichoscan software. Results show that Hairegen is a safe device and that it is effective in promoting hair regrowth in men and women of all ages and AGA NH levels of II to VI.

Introduction

Androgenetic Alopecia (AGA) is the most common hair disorder, affecting both men and women (Blume-Peytavi U) (Wang). AGA is characterized by a non-scarring progressive miniaturization of the hair follicle in predisposed men and women, usually in a specific pattern distribution. Its aetiology is multifactorial and polygenetic (Blumeyer).

Male AGA

In men, AGA is an androgen-dependent trait. The terminal hair follicle becomes susceptible against dihydrotestosteron, which leads to shortening of anagen phase and miniaturization of terminal to vellus hair. The development of male AGA is predominantly hereditary. In men family analyses showed strong concordance rates in twins and increased risk for sons with bald father.

Male AGA occurs in all populations. The prevalence is highest in Caucasians, reaching around 80% in men aged over 70 years. In the Asian population, a prevalence of 46·9–60·0% has been reported in males older than 70 years. There is scant published information on the frequency of balding in African men. One older study reported that balding is four times less common in African-American men than in Caucasians. The frequency and severity of male AGA increase with age in all ethnic groups. Initial signs of AGA, including some recession of the frontal hair line and at the temples, usually develop during teenage years. Progression to deep frontal recession and/or vertex balding may also start shortly after puberty, although in most men the onset is later. By the age of 70 years, 50–60% of Caucasian men are bald (Hamilton–Norwood VI–VII).

Female AGA

Less is known on the aetiology of AGA in female patients. Possibly, early and late onset female AGA have different genetic traits. The androgen dependence is likewise uncertain in women, that is to say, other factors seem to be involved. Nevertheless, it is important to consider, that there is a subset of women with AGA and associated hormonal dysregulation.

As in men, the population frequency and severity of AGA increase with age in women. Two studies in Caucasian women in the U.K. and the U.S.A. reported prevalence rates of 3–6% in women aged under 30, increasing to 29–42% in women aged 70 years and over. The frequency is lower in Oriental women compared with those of European descent. There are no published data on the frequency of AGA in African women.

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Current Treatments

The medical treatments with the best level of evidence classification for efficacy and safety for male AGA are oral finasteride and topical minoxidil solution (Varothai). For female AGA, topical minoxidil solution appears to be the most effective and safe treatment. The medical treatments corresponding to the next level of evidence quality are some commonly used therapeutic non-FDA-approved options including oral and topical anti-hormonal treatments. Surgical treatment of follicular unit hair transplantation is an option in cases that have failed medical treatment although there is high variation in outcomes.

LLLT-based medical devices have been approved by the FDA as safe and effective for treating AGA in males and females. Low-level-laser-therapy is used as monotherapy or as a concomitant therapy with Minoxidil or Finasteride. The LLLT devices use 630-660nm light sources of up to 5mW power per light source (Kim H) (Munck).

Scalp-Baldness Relationship

An in-vivo study (Hori) examined the relationship between the thickness of each scalp skin layer and the baldness level, in men and women. The results show there is a significant reverse relationship: as baldness advances, the skin becomes thinner, especially in men. Another study (Choy) investigated the relationship of scalp shape and how active massage over 300 days influenced the skin thickness and the state of baldness. The findings showed that intensive massage softened the skin and promoted hair regrowth over almost a year.

HAIREGEN DEVICE

Pilogics Hairegen (Figure 1) is a personal, hand-help home-use device for hair-regrowth. It applies multiple forms of stimulation on the scalp, in a so-called PCLT (Pinpoint Current Light Therapy) of highly-localized, high-gradient form. The device includes a set of 8 uni-axial metallic disks (Figure 2), alternately coated with zinc and made of brass (or initially coated with Copper). The disks are approximately 32mm in diameter, with about 100 points each.

The user rolls the disks back and forth on the treated scalp. The points provide mechanical stimulation that may cause discomfort but no unintentional wounding.

Figure 1: Heiregen device

Figure 2: Pointy metallic disks

Hairegen device includes a chargeable applicator that applies small AC current (up to 100Hz) via the disks. All zinc disks are equi-potential, and all the brass disks are equi-potential, thus the current flows between disks of dissimilar coating. The voltage is up to 32V, and the currents have been limited to 200µA. Electrical stimulation as hair growth promoter was studied by few (Maddin) with fields of up to 4,000 V/m. Via the metallic disks, Hairegen device produces up to 8,000 V/m.

In addition, the device includes a vibration element that moves the spikes in an orthogonal direction to the scalp surface (in/out) and in sideways direction relatively to the movement path of the spikes on the scalp.

The zinc and brass (Zn and Cu alloy) were chosen as known beneficial trace elements in inhibiting 5-alpha-reductase (Sugimoto), a major factor of AGA onset. Via electrical current and natural electro-chemical

interaction with the skin, trace amounts of zinc and copper ions are deposed on the skin in contact points of the metallic spikes.

Thus, the mechanical stimulation, the electrical stimulation, and the biochemical stimulation all occur in highly localized regions. As the user rolls the disks back and forth for several minutes, thousands of such points are stimulated over the target scalp area.

The device is controlled by a programmable micro-controller. The device shuts off after pre-determined time. The use receives audible feedback on the treatment, for example when the electrical contact of the disks with the scalp is poor. Operational logs are kept at 1-second resolution, for compliance and performance analysis.

STUDIES

Hairegen devoce was marketed as a cosmetic home-use device for a limited client group. The clients received consultation and treatment from a clinic run by Mr. Benitah, a highly experienced trichologist (St. Louis Hospital, Paris, France), in Israel and Germany.

Suitable clients who chose home treatment with Hairegen device were observed as part of the standard operating procedure of the clinic.

Inclusion Criteria

Healthy clients of varying ages, 22 to 61, males and females, that have not used other drugs for AGA, and consented to use the device for several months and undergo regular observations, were included in this study. For men, Norwood-Hamilton II to VI were included. For women, Ludwig I to II were included.

Treatment

The clients were instructed to use the device several times a week, for 5 minutes each time. Meetings and measurements took place before the treatment started, and about every 2 months. The actual use was observed by interviewing the clients during their follow-up meetings and by checking the operational logs of the devices.

Measurements

The participating clients had 1 to 3 zones marked on their scalp. The zones chosen were on the balding areas characterized by AGA's pattern, and also on borderline areas. Global photographs were taken with the head in a fixation harness (Figure 3), under controlled lighting and controlled camera, for repeatable results. Small areas around the marks were trimmed, and macro photographs were taken with a dermoscope (Figure 4). Hair was colored prior to photography when necessary, in accordance with TrichoScan guidelines (Hoffmann).

Each zone was photographed 3 times each visit (to average results and overcome photography probems such as stray hair etc.). Each photograph was analyzed (Figure 5) with TrichoScan software V3.4.18.104 (TRICHOLOG GmbH). There was no 3-day preparation of the measured area to measure telogen hair, due to the non-formal, non-obligatory nature of the clinic visits. The software provides measurement of hair density and differentiation into terminal and vellus hair (Figure 6).

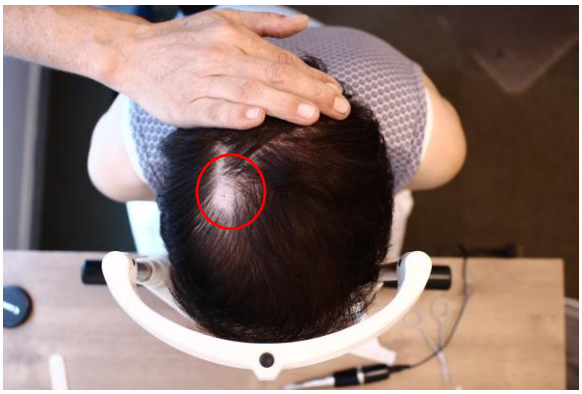

Figure 3: Head fixation, marked stop

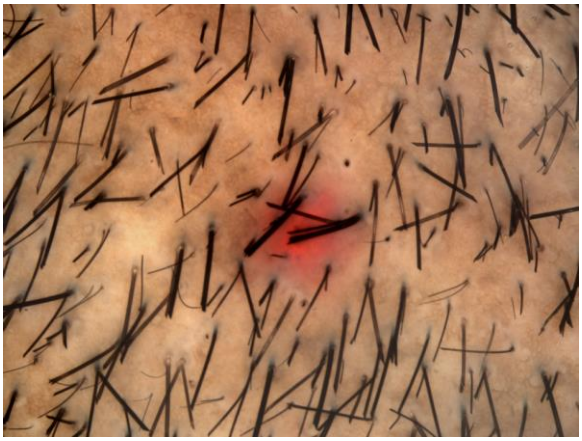

Figure 4: Photo-trichogram with marked spot

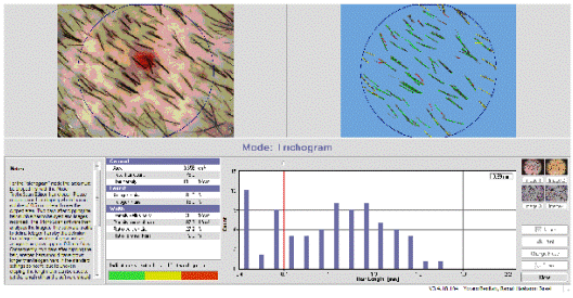

Figure 5: TrichoScan analysis

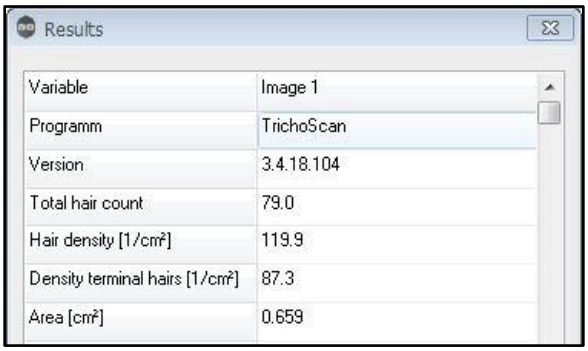

Figure 6: TrichoScan analysis results

Results

Clients that significantly from the clinic's guidelines were excluded from the final results, as well as clients that had a severe malfunction of the device, as discovered by a technician during the follow up visits and the log files collected (for example, a malfunction in the electrical current output via the disks, a problem unobservable by the client itself if the audible alert is ignored). Furthermore, some clients took frequent prolonged trips abroad (two weeks and longer). Some took the device with them, but its battery drained quickly, while others did not use the device sufficiently. Such extreme cases were also excluded from the final results. Furthermore, the non-formal, non-incentivized nature of the clinic caused considerable drop-off rate, which was normal for such clinics but high relatively to formal clinical trials.

Also excluded from the results were improper photo-trichograms, and extreme results that after re-analysis of all photographs and analysis were deemed erroneous due to measurement problems.

A total of 56 clients (Table 1) and 67 measured zones were included in the results. Due to the nature of observation, there was usually a single follow-up measurement of sufficient quality, hence each zone is represented by a pair of end-points, the first one is the pre-treatment status.

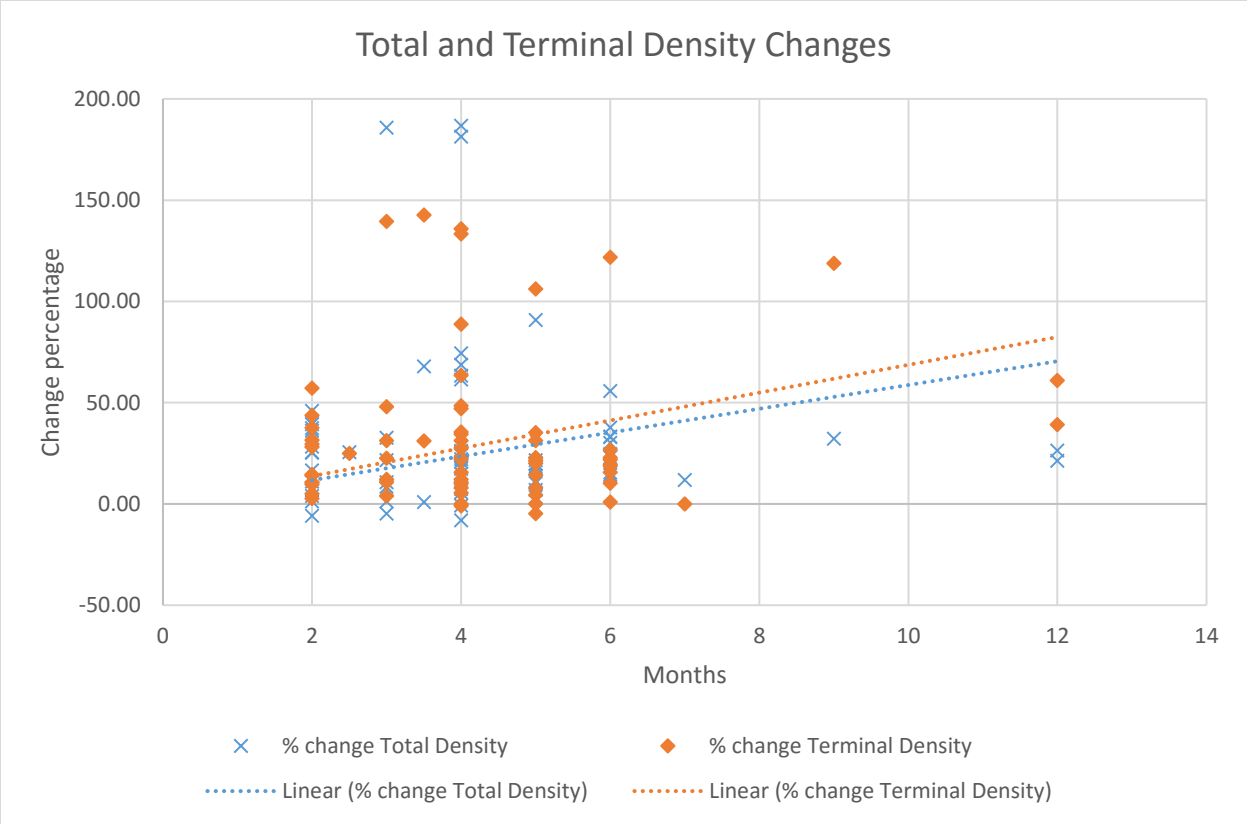

Figure 7: Results of measurements

Sex	No. of Clients	Med. Age	Min. Age	Max. Age
Female	5	58	42	61
Male	51	38	22	59
All	**56**	**39**	**22**	**61**

Table 1: Clients participating in study

The results (Figure 7) show the change in total hair count, and the change in terminal hair, of each zone, in percent. In addition, the linear trends for each measurement type is drawn.

Results per Norwood-Hamilton initial class (women were mapped to comparable level) are detailed in Table 2. The results include the number of zones and the median changes in Terminal Density and Total Density.

Results per age group are detailed in Table 3. The results include the number of zones and the median changes in Terminal Density and Total Density per age group.

During the observation period, none of the clinic's clients complained about adverse effects or seemed to suffer from side-effects, under the supervision of the clinic's expert.

Table 2: Results per NH class

NH Class	Measurements	med. change % Terminal Density	med. change % Total Density
2	10	32.80	27.11
2.5	7	31.10	10.65
3	14	15.10	20.74
3.5	2	105.30	20.77
4	18	22.20	23.82
4.5	2	73.30	93.55
5	6	15.00	21.74
6	8	19.30	19.58

	Sex					
	Female			Male		
Age Group	Measurements	med. change % Total Density	med. change % Terminal Density	Measurements	med. change % Total Density	med. change % Terminal Density
2x				18	19.64	28.11
3x				18	23.35	20.65
4x	1	37.37	43.75	12	19.61	16.08
5x	3	39.37	34.34	14	24.16	25.57
6x	1	11.02	5.00			

Table 3: Statistics of participants per age group

Discussion

The results demonstrate a marked improvement in both the hair count and the terminal hair count for both genders, all age groups, and all NH classes. The authors chose the measure median results instead of averages, since medians are less sensitive to extreme results, even though averages results are higher.

In the author's opinion, for practical reasons the most important visual metric is the terminal hair count. During the de-miniaturization process, small vellus hair regains its former width and color over time, and thus becomes visible to the naked eye, even from a distance. The terminal hair is probably what is considered "hair regrowth" by the target client population.

Another important observation is the quick response to treatment: During the first 4 months a marked improvement is seen, sometimes within 2 months. This is important for motivating the user to continue using the device as instructed. In subsequent months the rate diminishes.

It is evident the drop-out rate is considerable, as previously explained. Furthermore, the 7-8 month period may be offset by those clients with the highest response rate and the highest motivation. Therefore, the authors feel the 7-8 month result has lower significance than the prior ones.

An important conclusion, during the observation of the clinic's operation and the clients' behavior, was the importance of direct feedback and operation logging of the device usage. It is a human tendency to skip treatments, shorted them, or reduce the intensity of the treatment (mainly pressure of the device onto the scalp). Devices with malfunctioned direct feedback produced lower results and were less used, to the point of excluding their result. Comparing the logs to their client's testimony during follow-up visits also showed sometimes considerable differences, with the client always overestimating the number of treatments and their period.

The authors suggest the baldness process is related to natural long-term changes in the scalp, but it could be reversed by providing stimuli to the scalp, triggering self-healing mechanism and by invigorating the scalp to its prior healthier condition, promote hair-regrowth. It is also likely that as the hair follicles de-miniaturize, they help the skin heal itself, perhaps via the large reservoir of stem cells present at the bulge of the hair follicle (Garza).

Further clinical trials are expected in early 2017 with serial production units. The new model will be similar to the current model with same PCLT technology. The inclusion of a sham device is still investigated, given the difficulty to hide the difference between a sham device and a real device, especially by the spikes along the circumference of the metallic disks.

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