



## **STATISTICAL REPORT**

### **STUDY: INDX001**

The effectiveness of the Power Grow Comb to stimulate hair growth in men with androgenetic alopecia

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Date: December 17, 2008  
Version: Version 0.3



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# 1 INTRODUCTION

This report gives a detailed description of the statistical methodologies used and data listings and summary tables made in the analysis of the data in the Power Grow Comb study.

The statistical data analysis, described in this document, was intended to provide unbiased and valid conclusions concerning the objectives of the study.

## 1.1 Study population

Adult males (age greater than 18 years) with androgenetic alopecia (AA) stage IV to VII according to the Norwood-Hamilton scale and who satisfied all inclusion and exclusion criteria, as described in the protocol, are enrolled in this study.

## 1.2 Planned study design

This was a prospective, interventional, single-arm study in subjects who have AA. Men were screened for eligibility according to the in- and exclusion criteria.

Thirty five men were screened for this study, 28 men completed the 6 months study period. At baseline the number of hairs on four square centimeters of scalp area have been counted. The men received a Power Grow Comb device and instructions on the use of the device. After a period of 6 months the number of hairs on the same area of the scalp have been counted. During the intermediate period the subjects were checked for compliance. After 4,8,16 and 20 weeks this was conducted by a remembering mail message and at 12 weeks after baseline visit with a follow up call to remind people to use the Power Grow Comb. Possible adverse events have been collected at the telephone call at 12 weeks and at the 6 month follow up visit.

Action/assessment	Pre-screening	Baseline visit (T <sub>0</sub> )	Intermediate period	6 months visit (T <sub>1</sub> )
Preliminary eligibility	√			
Informed Consent		√		
In-/Exclusion criteria		√		
Medical History		√		
Device information/training		√		
VAS		√		√
Photographs		√		√
Device satisfaction				√
Compliance checks (email and phone)			√	
(S)AE assessment			√	√



### 1.3 Primary study objective

The primary objective of this study was to assess the effect of low level laser therapy with the Power Grow Comb on hair growth in men with androgenetic alopecia.

The primary endpoint of the study was the change in number of hairs per 4 cm<sup>2</sup> after 6 months of use of the Power Grow Comb in comparison to baseline. The area in which hair count took place was the peripheral zone of the bald area. Hair counts were performed on close-up photographs of this area of the scalp at baseline and after 6 months of Power Grow Comb use. All the hair in a 4 cm<sup>2</sup> area has been counted by two independent assessors in two pairs of assessors. Pair 1 counted the hairs on photographs of 18 subjects, pair 2 counted the hairs of the remaining 10 subjects. The mean count of the two assessors is used for final evaluation. Standardized photographs were taken at the start of the experiment (baseline) and then again after 6 months.

### 1.4 Secondary study objectives

The secondary objectives in this study were the evaluation of the user satisfaction with the result of the treatment and the user satisfaction with the device.

Secondary endpoints were

- Patient's Visual Analogue Scale satisfaction assessment (using a 100 mm VAS) measured at Baseline and 6 Months
- Subjects Device Opinion based on two questions each with a 5 scale answer measured at 6 Months.

## 2 ANALYSIS POPULATIONS

The following analysis populations have been distinguished in this study:

All Subjects Participating: The ASP population contained all members of the All Subjects Enrolled (ASE) population who completed the Baseline visit and received the instructions to use the Power Grow Comb device.

Study Completers: This population contained subjects that were not lost to follow up.

Screening data are listed and summarized for the ASP and Study Completers population. The analyses are performed for the Study Completers.

## 3 STATISTICAL AND ANALYTICAL METHODS

### 3.1 General statistical considerations

All data are listed in individual subject listings. For continuous variables, descriptive statistics [the number of subjects (n), the mean, standard deviation (SD), median, minimum, and maximum values] are presented. For categorical variables, the number and percentage of participants in each category are reported. All descriptive tabulations are made by visit,



where appropriate. All statistical tests are carried out at the one-sided 0.05 level of significance.

### 3.2 Missing data handling

No imputation of missing data has taken place.

### 3.3 Patient disposition

Table 1 shows that 35 males entered the study and received a Power Grow Comb. 28 of these subjects completed the study and were willing to partially shave the crown of their heads for the month 6 hair count.

### 3.4 Demographics

The mean age of the subjects was 43 years, with a range of 18 – 69 years (Table 2.A). The median baldness score was 30%, ranging from 10% to 75%.

### 3.5 Primary endpoint

The hair counts are summarized in Table 3. Remarkable is the discrepancy between both assessors in the hair counts of the baseline photographs. The intra-class correlation, a measure for the agreement between assessors, taking into account the 2 pairs of assessors, is moderate (intra-class correlation = 0.72). Figures 4A and 4B show the count results of both assessors. In pair 1, assessor 1 scored significantly more hairs than assessor 2.

The mean number of hairs per 4 cm<sup>2</sup>, averaged over the two assessors, at baseline was 217 hairs with a range of 30 - 414, after 6 months the mean number of hair was 251 with a range of 13-508.

The mean increase in number of hairs between baseline and 6 months of 34 hairs is statistically significant ( $p= 0.02$ ), as tested with a one-sided Wilcoxon signed rank test (Table 4).

Performing this test per pair of assessors shows that the result of the test is assessor dependent (Table 4A). Hair counts performed by pair 1 show a statistically significant increase in number of hairs. Hair counts performed by pair 2 show an increase of 18 hairs, which is not statistically significant.

Box plots of hair counts are shown in Figure 1.

### 3.6 Secondary endpoints

The satisfaction with their hair is scored on a 0-100 VAS scale at baseline and at the 6 months follow up visit. The results are summarized in Table 5 and in Figure 2.

The increase of 5.3 points between baseline and 6 months is not statistically significant ( $p=0.114$ ), as tested with a one-sided Wilcoxon signed rank test.

The opinion on the device is summarized in Table 6 and Figure 3. The question “The Power Grow Comb is easy to use” is agreed on by 89% of the study completers. The result of the Power Grow Comb was indicated as positive by 29% of these men, another 29%



completely disagreed with the allegation “The Power Grow Comb gives a satisfactory result”.

### **3.7 Follow up Questionnaire**

The answers on the follow-up questionnaire, answered after 3 months after baseline, are summarized in Table 7 for all subjects participating in the study. 88% of the men indicated to use the Power Grow Comb every other day for 10 minutes.

The comments given on these questionnaires are listed in Listing 5. All other comments gathered during the study are listed in Listing 6.

## **4 CONCLUSION**

The mean increase of 34 hairs per 4 cm<sup>2</sup> in men with androgenic alopecia who used the Power Grow Comb during 6 months, is statistically significant ( $p= 0.02$ ), as tested with a one-sided Wilcoxon signed rank test . This test was performed on 28 volunteers who used the Power Grow Comb during 6 months, every other day for 10 minutes per day.

Under the conditions employed in this study, Power Grow Comb was observed to be effective in the treatment of hair growth in men with androgenetic alopecia.