TrichoScan-Validation with Canon Powershot A95

1. Introduction

Hair loss or thinning hair is a common complaint in clinical dermatology, but patients seeking advice for hair loss are not necessarily completely bald and may only have thinning hair. In addition, the effects of treatment attempts are hard to measure. Consequently, there is a need for a sensitive tool to monitor hair loss and response to treatment. Such a method must be able to analyze the biological parameters of hair growth, which are: 1: total hair density ($1/cm^2$), 2: terminal hair density ($1/cm^2$), 3: hair diameter (µm) and 4: hair growth rate (mm/day). Previous experience has shown that the TrichoScan method (see www.trichoscan.com) is very sensitive to determine these parameters. This method combines epiluminescence microscopy (ELM) with automatic digital image analysis for the measurement of human hair.

However, conventional visual hair counts are still performed and although no side-by-side comparison is available, visual hair counts are defined as the most precise method of measurement. In our view, this might be the case when only the number of hairs in a very small scalp area is counted. However, a rather large scalp area (up to 2 cm^2) with about 400 hairs (fig. 1) is nearly impossible to accurately count for total, terminal and vellus hairs, hair thickness and hair growth rate.

Fig. 1: Image with about 400 hairs

Furthermore, manual hair counts, even when made by trained technicians, will result in variable results when the same image is counted two or more times. As a digital tool, the TrichoScan will always analyse the same image consistently and calculate the same results time and time again. We believe it is also considerably quicker than manual counting and allows relatively inexperienced technicians to obtain consistent and accurate results. One must keep in mind, too, that a larger area with more hairs gives more reliable measurements. This fact is a simple statistical knowledge which is also true for hair measurement.

2. Aim

The aim of our study was the comparative assessment of TrichoScan analysis versus conventional manual evaluation of hairs by hand on the basis of digital images taken from 10 male and female subjects with androgenetic alopecia (AGA). Furthermore, data variability of manual evaluation by one evaluator and comparison between different evaluators was analysed.

3. Investigational plan

Digital images (Canon Powershot A95) for TrichoScan were taken from 10 subjects with AGA, Norwood-Hamilton grade III – IV/ Ludwig grade 1 or 2 with a tattoo location mark present in the measurement area. The measurement area (approx 2 cm^2) on the vertex of the scalp was shaved on day 1 and 48-hours later the hair was dyed. At Tricholog, all images were analysed using the most recent TrichoScan Research Edition . In addition, three evaluators manually counted the described hair fiber parameters in every image three times by hand.

The images were numbered 1, 2, (x), - 30. No information was given about who took the image and from which volunteer the image was taken. Furthermore, all images were analysed randomly in a result-blinded fashion.

For the conventional manual evaluation, each image was entered into a software measurement program (Datinf® GmbH, Germany) and each evaluator used a computer mouse to outline the start, end, and thickness of each hair fiber on each image (fig. 2). He/she had to click on every hair where the hair leaves the scalp skin, then follow the hair and release the mouse button at the end of the hair tip. All such marked hairs then appeared in yellow in the software program. The thickness of the yellow line (the hair) was adjusted to the actual hair thickness with a scroll wheel present on the computer mouse. When the yellow line had the same thickness as the actual underlying hair, the correct thickness of this hair was determined. Hair density (number per unit area on the image) and hair thickness (hair diameter) was recorded automatically by the software.

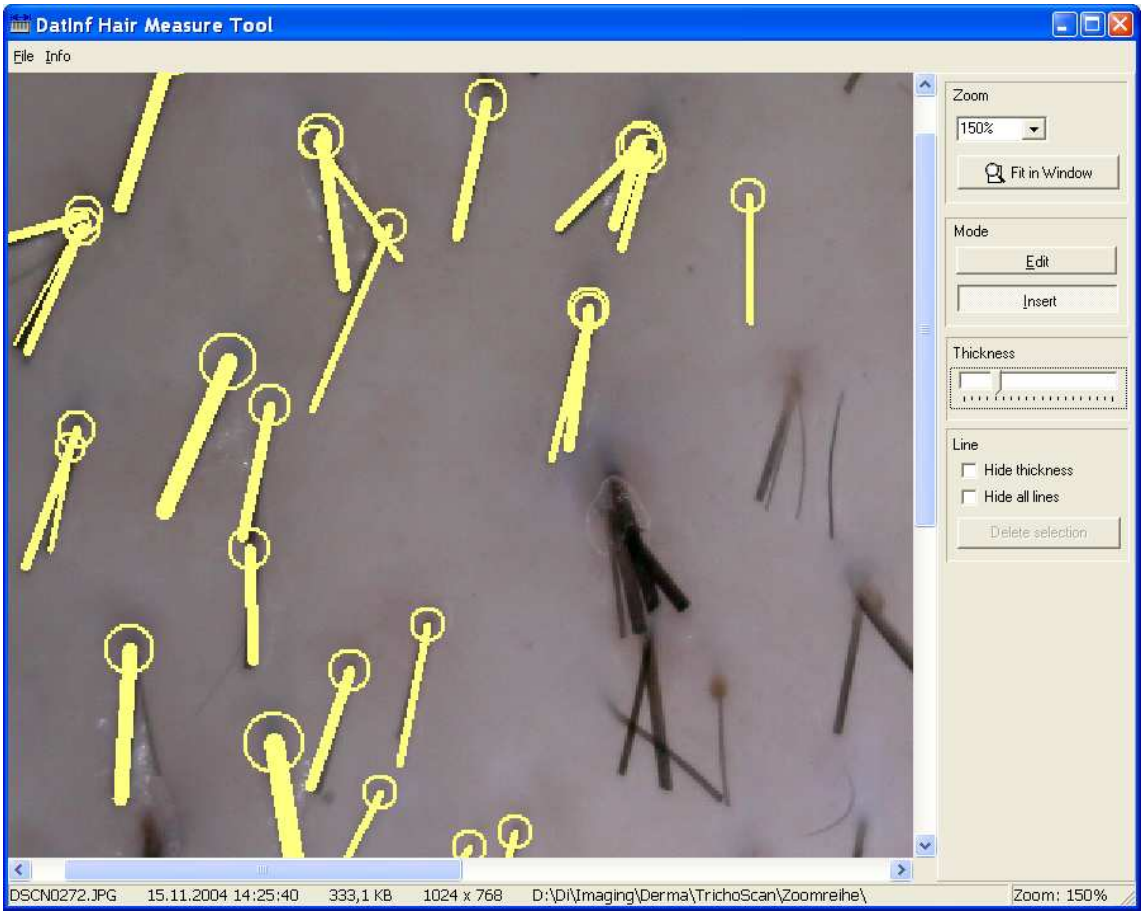

Fig. 2: Screenshot of the software for manual hair evaluation, yellow: marked hairs; no color: hairs yet to be analyzed.

The hand evaluator did not see the calculated results for hair density and thickness, thereby he/she was unable to compare different analyses. In total 27,245 hairs were analyzed by hand. All results were listed on appropriate Excel-files and statistics were subsequently performed.

4. Results

For the important parameters, hair count and cumulative hair thickness, the results of the evaluations by hand as well as by TrichoScan are shown in fig. 2 and 3.

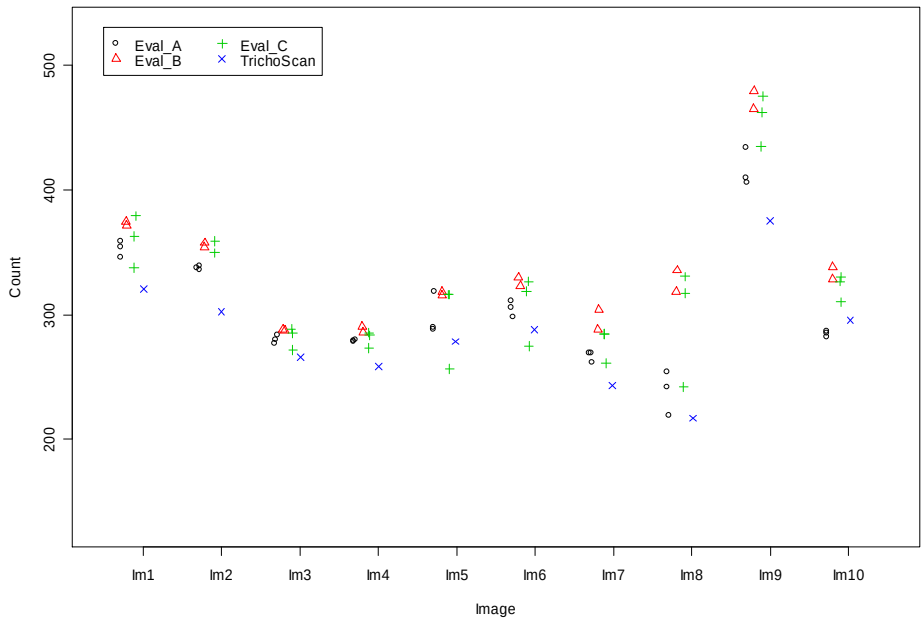

Fig. 3: Hair count measured by TrichoScan three times and three different evaluators: As a digital tool with a detection limit of about 9 µm, the TrichoScan underestimates the total hair count, because tiny vellus (below 9 µm in thickness) hair are not counted. Three different TrichoScan measurements of the same images showed identical results, whereas evaluation by hand resulted in considerable data variability.

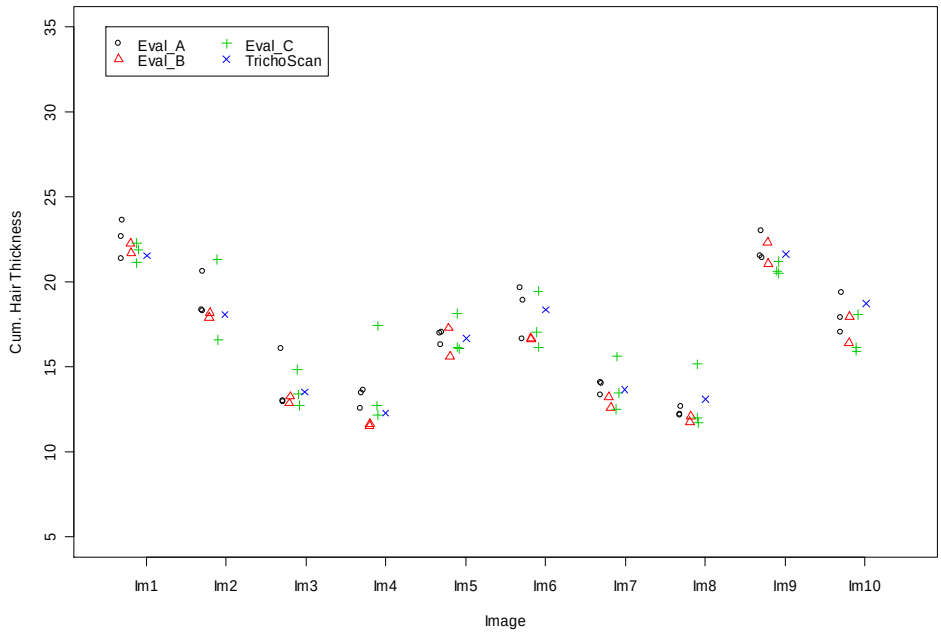

Fig. 4: Cumulative hair thickness in mm measured by TrichoScan three times and three different evaluators: Three different TrichoScan measurements of the same images showed identical results, whereas evaluation by hand resulted in considerable data variability. Cumulative hair thickness measured by TrichoScan was within the data range of the hand evaluations.

The results of hair count, thickness and cumulative thickness for the TrichoScan, and the manual evaluation as well as the absolute and relative differences, are shown in table 1. The results for the three evaluators are averaged. The cumulative hair thickness is identical for the TrichoScan and the manual evaluation. The differences in total hair density between TrichoScan and hand evaluation are due to the different resolution of the human eye and the digital camera less than (or equal to)11,9%. As the TrichoScan cannot count the very thin hairs, the mean hair thickness is higher.

Variable	**TrichoScan**	**Evaluators**	**abs. Diff.**	**rel. Diff.**
Count	284.4	320.3	-35.9	-11,9 %
Cum. Thickness [mm]	16.7	16.7	0.0	0.0 %
Cum. Thickness Term [mm].	14.8	14.8	0.0	0.0 %
Mean Thickness [µm]	58.6	52.2	6.4	11.6 %

Table 1: Means and differences of TrichoScan and evaluation by hand (averaged over evaluators). It is important to note that all TrichoScan data follow systematic software procedures. The fact that we overestimate mean hair thickness by 6.4 µm means, that this is done systemtically for every hair in every situation. Therefore, any change in hair diameter can be measured.

The Pearson correlation coefficient shows a very good correlation between the TrichoScan and the manual evaluation. Except for the thickness for all hairs, all the coefficients are higher than 0.93 (table 2).

Variable	**Correlation coefficient**
Count	0.933
Count Term.	0.981
Cum. Thickness	0.980
Cum. Thickness Term	0.964
Mean Thickness	0.779
Thickness Term.	0.944

Table 2: Correlation coefficients by Pearson between TrichoScan and manual evaluation for different variables.

For the manual evaluation of hairs the intraclass correlation coefficients (ICC) for inter- and intra-evaluator variability are given in table 3. The thickness shows low values of the ICC whereas count and cumulative hair thickness show a better reliability. Nevertheless, the repeatability with almost 47 hairs and the reproducibility with almost 66 hairs are not too small.

Variable	Repeatability	Reproducibility	ICC (inter)	ICC (intra)
Count	46.98	65.93	0.814	0.896
Count Term.	43.62	52.26	0.897	0.926
Cum. Thickness [mm]	3.67	3.81	0.852	0.861
Cum. Thickness Term [mm]	5.35	5.97	0.744	0.783
Thickness [µm]	18.02	20.48	0.304	0.361
Thickness Term. [µm]	14.15	15.06	0.358	0.388

Table 3: Variability of manual evaluation

Furthermore, the repeatability and reproducibility of TrichoScan analysis is shown. The value "0.00" means that the TrichoScan measures the same image always the same way with no data variability.

Variable	Repeatability	Reproducibility	ICC (inter)	ICC (intra)
Count	0.00	0.00	1.00	1.00
Count Term.	0.00	0.00	1.00	1.00
Cum. Thickness [mm]	0.00	0.00	1.00	1.00
Cum. Thickness Term [mm]	0.00	0.00	1.00	1.00
Thickness [µm]	0.00	0.00	1.00	1.00
Thickness Term. [µm]	0.00	0.00	1.00	1.00

Table 4: Variability of TrichoScan evaluation

In addition we calculated the data variability of the same image if hand evaluation or TrichoScan is performed.

Variable	Evaluators	TrichoScan
Count	6.01 %	0.00 %
Count Term.	2.84 %	0.00 %
Cum. Thickness [mm]	7.57 %	0.00 %
Cum. Thickness Term [mm]	9.27 %	0.00 %
Thickness [µm]	12.55 %	0.00 %
Thickness Term. [µm]	10.05 %	0.00 %

Table 5: Data variability of manual evaluation and TrichoScan. Due to the digital nature of the TrichoScan, the same image are always analysed with the same results, whereas manual evaluation showed considerable data variability.

5. Discussion

In a previous validation study using images taken with a Nikon Coolpix 4500 camera, we reported about the reliability of the TrichoScan-data when one or different TrichoScan-operators take the images (http://www.datinf.de/trichoscan/engl/reliab_nikon/reliab_nikon01_en.htm). For both hair density and hair thickness we observed an intraclass correlation coefficient between observers larger than 97%. In the study presented here we now show that the TrichoScan indeed measures hair accurately! The correlation of TrichoScan and hand evaluation for terminal hairs is 0,98. In addition, we observed a marked variability of manually evaluated data, most likely due the fact that more then 320 hairs per image cannot be measured with 100% reproducibility by hand. In contrast, the TrichoScan reproducibility is 100% with the same image.

In summary, we were able to show a very good correlation of TrichoScan versus hand evaluated hair counts. In addition, we saw considerable variability in the results from manually evaluated images. A clinical trial is nearly always designed and conducted with the smallest possible sample size that is calculated to permit statistically significant data to be obtained. The wide margin of error and consequent data variability from manually evaluated images would necessitate a much larger study sample size to overcome the effect of the variability in collected data on the statistical significance of the results. With the TrichoScan this is not the case. As results are much more reproducible with TrichoScan, the smaller margin of operator error and the consistency in the collected data allow statistically significant results to be obtained from studies with a smaller sample size.
However, every image must be suitable for TrichoScan analysis. Therefore, all hairs without hair dye, hairs which are too short, or images with dark spots within the target area, are not suitable for analysis. In clinical trails we overcome this fact by strict quality control of incoming images.