An essence containing niacinamide, diaminophyrimidine oxide, biota orientalis leaf extract, adenosine and coffee seed extract in improvement of androgenetic alopecia in Chinese subjects

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Introduction:

There are 170 million androgenetic alopecia (AGA) people in China, and the demand for preventing AGA is getting younger and younger. For people with mild/moderate hair loss, choosing appropriate cosmetic scalp care essence rather than medicine or surgery is the easiest way to insist on. Although there have been studies on the cosmetic ingredients treatment of androgenetic alopecia (AGA) in Caucasian [1-2] and Japanese [3-5] populations, there are few data on Chinese population. The objective of the study was to evaluate the safety and efficacy of a scalp care essence containing niacinamide, diaminophyrimidine oxide, biota orientalis leaf extract, adenosine and coffee seed extract in improvement of AGA in Chinese subjects, using image analyses technique and subject self-assessments.

Materials & Methods:

Clinical research.
12 Chinese subjects (11 males and 1 female, average age 33.5±6.2 years) with androgenetic alopecia completed the study. Men with androgenetic alopecia in stages III to V of the Hamilton-Norwood classification [6-7] were selected; women with androgenetic alopecia in stages I of the Ludwig classification [8] were selected for inclusion. The product was applied on the balding zone twice daily. At approximately comparable days within months, subjects came into the laboratory for a consecutive two-day presence (Day0 and Day2). Visits were repeated monthly from mid-June to mid-September. At Day0, a small scalp area (1.7cm by 1.2 cm) of the hair loss region was shaved until the hair length was 0.5-1.0mm, then pictures were taken by a dermatoscope (PhotoMax) with 30x magnification. Two days later the same target site was photographed again (Day2).

Image analysis method.
For each month and subject, these two consecutive digital photographs were processed through image analysis using Image-pro-Plus (IPP) software, which allowed to get the hair growth parameters including hair density (n/cm2), hair growth rate (mm/day), hair diameter (mm), and anagen/telogen ratio. Accurate image evaluation can be achieved through IPP: first draw all the hair contours of the area of interest （AOI） accurately. Hair density (n/cm2) is equal to the total number of hair roots in the AOI divided by the area of the AOI. The average diameter (mm) of the hair can be automatically calculated. The length of hair growth within 2 days (mm) can also be automatically calculated. Hair growth rate (mm/day) is equal to the length of hair growth within 2 days (mm) divided by 2 (2days). The method to judge whether the hair is in the anagen phase or the telogen phase is: if the hair is obviously growing within 2 days after shaving, judge it to be in the anagen phase; if the hair does not grow significantly within 2 days after shaving, it is judged to enter the telogen phase.
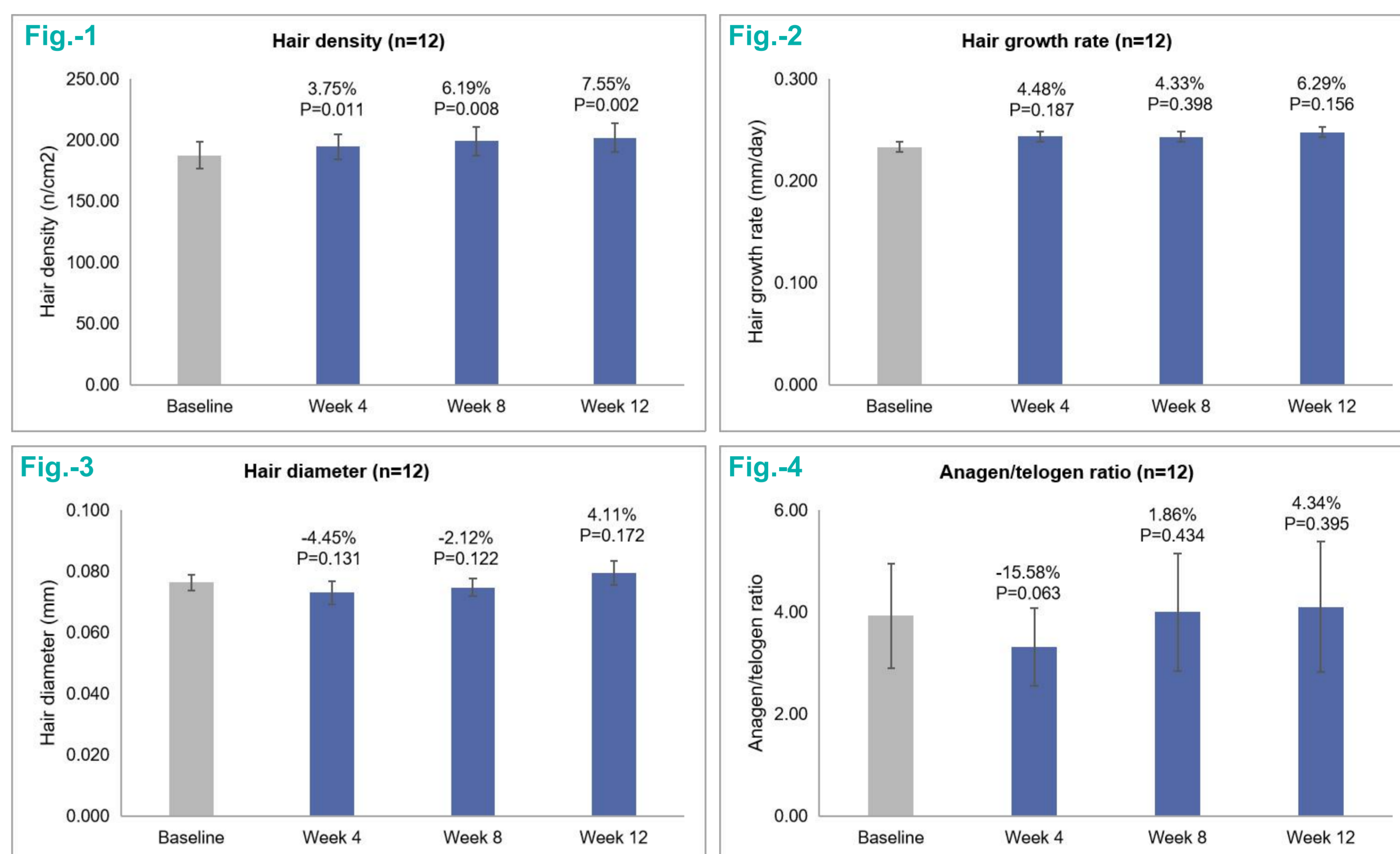
Subject self-assessments.
Besides the image analysis method, subject self-assessments through questionnaire on the efficacy of the product was also conducted in the trial. Subject self-assessments is to evaluate product performance through subjects feedback, and fill out a self-evaluation questionnaire after 12 weeks of use. The questionnaire contains the following closed-ended questions: Does hair loss decrease? Is this a hair loss prevention product? Stronger hair? Regeneration of fine hair? Improvement of scalp itching? Is the daily pillow/floor hair loss improved? Is hair loss improved during daily shampooing? The questionnaire was conducted on a scale of 1 to 7, and the proportion of subjects whose score was greater than or equal to 4 was counted.

Statistical analysis.
SPSS was used for data statistics, and paired t test method was used to detect the significance of the test data. The significance level was p<0.05. Improvement (%) of week 4 /8/12= (test value of week 4/8/12-baseline value)/baseline value, it is used to observe the improvement degree of each parameter.

Results & Discussion:

Fig.-1 Hair density (n=12)

Fig.-2 Hair growth rate (n=12)

Fig.-3 Hair diameter (n=12)

Fig.-4 Anagen/telogen ratio (n=12)

Hair density.
After using the scalp care essence for 4 weeks, the hair density was significantly improved by 3.75% (P=0.011), and continuous use brought continuous and better improvement. After 8 weeks and 12 weeks of use, the hair density was significantly improved by 6.19% (P=0.008) and 7.55% (P=0.002) respectively (Fig.-1). It shows that the product has obvious anti-hair loss effect.

Hair growth rate.
After using the scalp care essence for 4 weeks, 8 weeks, and 12 weeks, the hair growth rate improved to varying degrees. By the 12th week, the improvement rate reached 6.29% (P=0.156) (Fig.-2).

Hair diameter.
The parameter of hair diameter did not improve at the beginning, but after using the scalp care essence for 12 weeks, the hair diameter also improved, with an improvement rate of 4.11% (P=0.172) (Fig.-3).

Anagen/telogen ratio.
Anagen/telogen ratio did not improve at first, but after 8 and 12 weeks of treatment, anagen/telogen ratio also improved, with an improvement rate of 1.86% (P=0.434) and 4.34% (P=0.395) respectively (Fig.-4).

Subject self-assessment.
After using the scalp care essence for 12 weeks, 92% of the subjects thought that hair loss was reduced; 100% of the subjects recognized the essence as a hair loss prevention product; 83% of the subjects reported that the hair was stronger; 83% of the subjects participants could feel the regrowth of fine hair; 83% of subjects reported improvement of scalp itching; 92% of subjects reported improvement of daily pillow/floor hair loss; 83% of subjects reported improvement of hair loss during daily shampooing.

Conclusions:

This essence enriched with a mixture of niacinamide, diaminophyrimidine oxide, biota orientalis leaf extract, adenosine and coffee seed extract is safe and effective as a topical hair-loss treatment in Chinese AGA subjects, as proven by the improvement in objective parameters of hair density, hair growth rate, hair diameter and anagen/telogen ratio, as well as subject self-assessments. Whereas the results awaits further controlled study in a larger group of subjects. Furthermore, an image analysis method of hair growth parameters has been developed, which can be used to achieve quantitative and accurate evaluation of anti-hair loss products.

Aknowledgments:

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