EFFECTS OF A TOPICAL HAIR GROWTH PROMOTER CONTAINING 5% NANOXIDIL™ ON HAIR SHEDDING IN WOMEN WITH EARLY FEMALE PATTERN HAIR LOSS (FPHL)

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INTRODUCTION

FPHL often first presents with increased hair shedding. This study investigated the effects of a topical solution containing 5% Nanoxidil (a nanosomes encapsulate potassium channel opener) and other hair growth promoters in 49 women with early FPHL who also complained of excessive shedding.

METHODS

49 women (ageing 18 to 60 years, mean age 45.25) with early FPHL, confirmed by trichoscopy, and excessive shedding, indicated by a positive pull test, were enrolled in the study. Patients with known hair shaft or scalp diseases other than FPHL, and history of use of minoxidil and other treatments affecting hair growth within 6 months prior to study entry were excluded from the study. The topical Nanoxidil™ solution (Spectral.DNC-N® from DS Laboratories) was applied by the subjects twice a day on clean and dry hair. Study duration was 3 months and 49 subjects completed the study.



SPECTRAL.DNC-N°
ANTI-HAIR LOSS TREATMENT
WITH NANOXIDIL™

EFFICACY EVALUATED AT 3 MONTHS

Primary endpoints:

- · Hair shedding scale evaluated by both investigator and by patients
- · Hair Mass Index (Trichometer)
- Changes in the pull test
- · Variation in the global photography evaluated by investigator

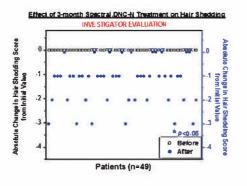
Secondary endpoints:

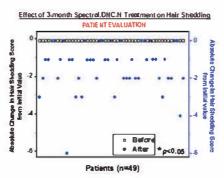
- · Changes in Sinclair scale
- Tolerability Assessment
- Product perception evaluated by patients

RESULTS

1) Hair shedding scale:

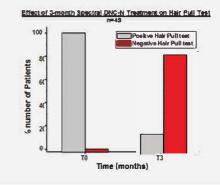
A visual scale (chosen on the base of subject's hair type and length) was shown to the subjects, who then indicated their perceived shedding according with the scale value. After 3 months of treatment, a significant decrease in hair shedding score was noticed both by patients and the investigator.

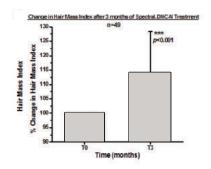




2) Pull test:

Most patients (~ 84%) had a negative hair pull test after 3 months of treatment, indicating significant improvement in hair strength and anchoring.





3) Hair Mass Index:

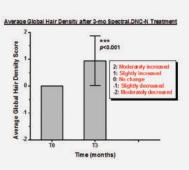
The hair mass index was measured using the Cross-Section Trichometer, a handheld device for measuring hair mass.

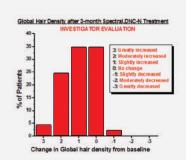
Average hair mass Index showed statistically significant increase from 75.83 \pm 25.10 at baseline to 84.31 \pm 23.83 mm²/cm² after 3 months of treatment. % Change in hair mass index (~14%) from the baseline was also statistically significant.

4) Global Photography Assessment:

The investigator scored changes in hair density evaluated from standardized photographs of a vertex view of the whole scalp, with hair parted in the center and combed away. Global images taken at week 12 were compared with baseline photographs. Hair density was assessed using the following 7-point scale (-3 = greatly decreased; -2 = moderately decreased; -1 = slightly decreased; 0 = no change; +1 = slightly increased; +2 = moderately increased; +3 = greatly increased).

Most patients showed an increase in the global hair density as evaluated by investigator. Also, the average hair density was significantly increased from baseline.



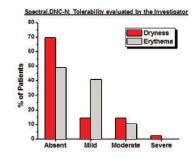


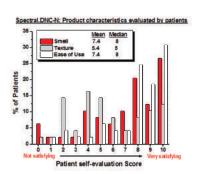


5) Local tolerability:

The local tolerability assessments included: stinging, burning, and itching (rated by the subject), and dryness/scaling, erythema, edema, pigmentation, and folliculitis (rated by the investigator).

The product was overall very well tolerated with only few subjects complaining of erythema or dryness and most patients were very satisfied by treatment. No cases of edema, pigmentation or folliculitis were detected.





CONCLUSION

Results of this study show that 3 months treatment with Spectral.DNC-N® considerably reduced hair shedding evaluated by pull test and shedding visual scales. It also statistically increased the hair mass, which is expression of hair density and thickness. Clinical improvement of the global photography was observed in more than 60% of patients. Treatment was very well tolerated and judged very satisfactory by patients.

