"CLINICAL STUDY ON THE EFFICACY AND TOLERABILITY OF PREFORMED GROWTH FACTORS VEHICULATED THROUGH SKIN PATTING* AND IONOPHORESIS ON VOLUNTEERS WITH FEMALE AND MALE ANDROGENIC ALOPECIA"

Michela Starace, Aurora Alessandrini, Francesca Bruni, Bianca Maria Piraccini
Dermatology, Department of Specialized, Diagnostic and Experimental Medicine, University of Bologna, Italy

Objective

The purpose of the study is to evaluate the efficacy and tolerability of a local product containing growth factors vehiculated through skin patting and ionophoresis for the treatment of androgenic alopecia in male and female patients, for a 6-month period. The evaluation was both subjective, through the judgement of the operator and the patient, and objective, by comparing global photographs and serial microphotographs (trichoscopy at Magnifications 20X, 40X, 70X).

Materials and methods

20 patients, 10 male and 10 female, aged 18 to 70 years, with androgenic androgen alopecia grade II, III, IV, and V second scale of Hamilton and female grade I, II, III second scale of Ludwig were enrolled. Subjects affected by precancerous, neoplastic, or serious systemic pathologies (diabetes, cirrhosis) have been excluded from the study. Subjects in cosmetic or pharmacological treatment by local or general way with Finasteride or Minoxidil; pregnant and lactating women. The study had a total duration of 6 months.

During the first enlistment visit (T0), patients were subjected to dermatological examination, global photography and Microphotography (trichoscopy) by Trichoscan® (FotoFinderDermoscope, Teachscreen Software, Bad Birnbach, Germany).

The Trichoscan® performs a mapping of a scalp area taking into account the number of hair present and the percentage of hair affected by miniaturisation, which is the process that identifies androgenic alopecia. This technique consists in photographing in the following months the same area, predetermined, thus making it possible to follow in time the modifications of the number and the diameter of the hair in response to the treatment.

At a distance of 3 weeks for 4 consecutive times the volunteer was evaluated clinically by the researcher. After a 6-month final visit, the patient was re-evaluated with instrumental methods. A questionnaire on the effect of treatment, on the cosmetic pleasantness of the product and its efficacy has also been given to the volunteer.

During each checkup the patient was subjected to the therapy, using topical application of a vial containing the growth factors and subsequently treatment with the device of skin patting and ionophoresis to allow the absorption of the product.

RESULTS

All 20 enrolled patients have finished the study without adverse reactions or side effects.
TRICHOLOGY

MALE PATIENTS
Trichoscopy showed an improvement in all 10 patients.

Front Area
An increase of 14.48% of the total number of hair/area of 1 cm² in diameter (average T0:1146.0, mean T6:1340.1) and a reduction of 6.58% of vellus hairs/area of 1 cm² in diameter (mediaT0:466.7%, mediaT6:437.9%) was highlighted. The barrel diameter is increased by 8.45%.

Vertex Area
An increase of 13.87% of the total number of hair/area of 1 cm² in diameter (average T0:997.1, mean T6:1273.7) and a reduction of 6.38% of vellus hairs/area of 1 cm² in diameter (mediaT0:471.9%, mediaT6:443.6%) was highlighted. The barrel diameter is increased by 11.72%.

TRICHOLOGY

FEMALE PATIENTS
Trichoscopy showed an improvement in all 10 patients.

Front Area
An increase of 12.52% of the total number of hair/area of 1 cm² in diameter (average T0:11177, mean T6:12777) and a reduction of 34.39% of vellus hairs/area of 1 cm² in diameter (mediaT0:489.6%, mediaT6:364.3%) was highlighted. The barrel diameter increased by 15.61%.

Vertex Area
An increase of 11.34% of the total number of hair/area of 1 cm² in diameter (average T0:796 mean T6:897.8) and a reduction of 26.31% of vellus hairs/area hairs of 1 cm² in diameter (mediaT0:350.5%, mediaT6:277.5%) was highlighted. The barrel diameter increased by 16.55%.

Evaluation by Researcher

After 6 months, the researcher's assessment showed efficacy in all male patients. No patient was judged stable. 4 with moderate improvement and 6 with significant improvement.

After 6 months, the researcher's assessment showed an excellent therapeutic efficacy in female patients: 2 with slight improvement, 2 with moderate improvement and 6 with significant improvement.

Evaluation by patient

The patient's assessment showed efficacy in all male patients: 4 with moderate improvement and a major improvement in 6 patients.

Evaluation of female patients showed efficacy as follows: 5 with moderate improvement and 5 patients with significant improvement.
Discussion and conclusion

Androgenic alopecia (AGA) is the most common cause of non-cicatricial alopecia, which affects respectively up to 50% of women and up to 80% of men during their lifetime (1), with a frequency that increases with age after puberty.

The disease is characterised by progressive miniaturisation of hair follicles in a selective distribution at the apex and in the anterior area of the head, in genetically predisposed individuals. The main objectives of the treatment are the arrest and/or reversal of the miniaturisation of the hair and the prolongation of the anagen phase, in order to normalize the follicular cycle. The European Evidence-based guidelines (S3) for the treatment of androgenic alopecia in women and men report efficacy values of finasteride and minoxidil, in terms of stopping the hair loss in place and inducing new regrowths, between the 40% and 60% (2).

The efficacy of conventional therapy is variable and therefore over the years adjuvant treatments have been introduced in order to obtain quicker results, especially for those patients who have not obtained results or want further improve. Skin Patting® is a patented technique in order to increase the activity of the hair follicle through 3 combined mechanisms: multiple microdermal incisions of the scalp, pressure wave and ionophoresis. The first action of the device is a controlled microdermabrasion with a sequence of micro wounds that stimulate the dermis repair process with increased vascularization, fibroblast multiplication and increased collagen production and elastin. The device also causes a radial pressure wave (mechanical action) directed on the scalp that produces three different effects: enhancement of the blood microcirculation, stimulation of cellular metabolism that facilitates the intake of Active principles, stimulation of the activity of fibroblasts with increased production of collagen and elastin.

Finally, ionophoresis determines a muscular stress caused by electro-stimulation, creating an immediate tensor effect followed by relaxation, enhancing the contractile ability of the skin and inducing dilation of the pores of the skin that facilitates Absorption of active ingredients. At the end of the treatment, the scalp is radiated with red LED light emitting a coherent monochromatic uncollimated light with a short wavelength variability (1-5%) which has a biostimulant effect on the production of fibroblasts and elastin. Many growth factors are able to stimulate or inhibit different stages in the hair growth cycle. Among the growth factors with positive effect, we must mention the vascular endothelial growth factor (VEGF) (3), the epidermal Growth factor (EGF), the basic Fibroblast growth factor (bFGF), the insulin-like factor-1 (IGF-1) (4), a factor of Keratinocyte Growth (KGF).

These growth factors can be safe, inexpensive, and non-allergenic (5-7) instruments. VEGF, essential for angiogenesis and vascular permeability, is responsible for maintaining the correct vascularization of the hair follicle during the anagen growth phase. IGF-1 is involved in the promotion of hair growth by regulating cell proliferation and migration during the development of pilosebaceous follicles. B-FGF promotes hair growth by inducing the anagen phase in hair follicles and is considered to be a potential promoter of hair growth (8).

KGF is essential to regenerate hair follicles by stimulating a more resistant growth of the stem. Finally, EGF has a direct action on fibroblasts by strengthening their action on collagen and elastin production. Platelet-rich plasma (PRP), which contains growth factors, has been studied in literature as a new method for hair growth in hair loss. Several studies have shown that PRP injections are a therapeutic option for androgenic alopecia with high overall patient satisfaction (9). However, it is a complex procedure because the patient’s blood must be taken in each session, requires special equipment and there is no standardization of the method of preparation, the effective dose, the duration of treatment and the profile of Long-term security as well as being an expensive procedure.

Through the Skin Patting® and the vehiculation of the preformed growth factors through the ionophoresis we guarantee an absorption of the same without the use of an invasive procedure, but with the same efficacy. Our study confirms the fundamental role of the association between Skin Patting® and growth factors vehiculated by the ionophoresis technique in increasing regrowth and hair diameter.

This technique is a safe and useful option to treat and prevent androgenic alopecia, by means of mechanisms that include the activation of fibroblasts and elastin on the scalp under wound healing conditions, the regeneration of Anagen phase of new hair by stimulating the microcirculation of the blood and the effect of growth factors. Furthermore, this procedure is simple for the operator and is extremely enjoyable for the patient. Our study showed a significant improvement of androgenic alopecia in both male and female patients, with reduction of hair loss and an increased hair diameter in all areas of the scalp treated.
REFERENCES


