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Efficacy and safety of 5% minoxidil topical foam in male pattern hair loss treatment and patient satisfaction

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Abstract

Introduction: Male pattern hair loss is widespread around the world. Its prevalence indicates the importance of finding the best treatment modalities. This study evaluates the efficacy and safety of minoxidil 5% topical foam in male pattern hair loss treatment and patient satisfaction.

Methods: This study was a before-and-after trial on 17 male patients with male pattern hair loss. Subjects were instructed to apply one capful (1 ml) of minoxidil 5% topical foam on the scalp daily for 6 months. Efficacy was assessed through hair counts, subject assessment, and global photographic review.

Results: Seventeen male volunteers were recruited, and three volunteers were withdrawn; 14 participated in the trial for 16 weeks, and 12 continued up to 24 weeks. The average hair count with a camera at week 16 (181.87 ± 52.42) and week 24 (194.58 ± 62.82) and with an eye count at week 16 (62.57 ± 15.28) and week 24 (69.91 ± 15.61) increased significantly compared to the baseline after intervention.

Conclusion: This study confirmed that minoxidil 5% topical foam is a safe and effective treatment for MPHL. The effect of it is evident after 24 weeks of use.

Keywords: minoxidil, foam, hair loss, alopecia

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Background

Male pattern hair loss (MPHL), or androgenic alopecia, is the most prevalent type of hair loss in men. It affects 30 to 50% of men by age 50 (1). The prevalence of hair loss type III or greater in men 18 to 49 years old has been estimated to be at least 42%. Within the age range of 40 to 49 years, 53% of men have moderate to extensive hair loss (2).

MPHL is often regarded as a relatively minor medical condition, but it may result in anxiety and depression in some men because it impacts self-image (1). MPHL caused low self-esteem, depression, and dissatisfaction with body appearance in a multinational study. The result of the study showed that 96% of men in the United States, France, Germany, Spain, Japan, and Korea 25 to 49 years old reported concerns about their hair loss, and 75% mentioned they were extremely concerned. Only 16% of men reported they had not attempted any treatment, whereas 34% of men had tried one or two treatments before the study, 24% tried three or four, and 26% tried five or more self-treatments. A total of 24.4% of men in this study said that they were dissatisfied with their physician consultations, and most of them indicated that their dissatisfaction was a result of a specific treatment recommendation, remaining unanswered questions, or physician discomfort or disinterest in discussing hair loss (3).

Most treatment modalities for MPHL are not FDA-approved and overall are not significantly effective. Minoxidil 5% topical solution (MTS) is FDA-approved for men with MPHL. Substituting for MTS, a foam vehicle has been developed to deliver minoxidil. Consumer use studies have shown that the foam formula was rated significantly higher on several aesthetic attributes compared to MTS (4–6).

Our study assessed the efficacy and safety of a 5% minoxidil topical formulation in a propylene glycol–free foam vehicle in men with androgenic alopecia.

Patients and methods

Design: A phase 2 before-and-after trial was carried out on 17 patients with MPHL for 6 months at the Pharmaceutical, Cosmeceutical, and Hygienic Evaluation Lab (Derma Lab) of the Center for Research & Training in Skin Diseases & Leprosy, Tehran University of Medical Sciences (TUMS) in Tehran, Iran. Inclusion criteria were men with MPHL between 18 and 49 years old, Hamilton–Norwood pattern III–V, with normal health status, and providing written informed consent. Exclusion criteria were sensitivity to minoxidil, using any topical OTC or prescription medication for hair growth within the past 3 months, using 5α-reductase inhibitors within the past year, using isotretinoin within the past year, radiation to the scalp within the past year, chemotherapy within the past year, using botanicals/nutraceuticals for hair regrowth for the past 3 months, using systemic steroids for more than 14 days within the past 2 months prior to enrollment in the study, uncontrolled hypertension, history of hypotension, any chronic active scalp inflammation or infection, any untreated cancer excluding basal cell carcinoma and squamous cell carcinoma of non-scalp areas, scalp reduction, and use of hair weaves.

The subjects were instructed to apply one capful (1 ml) of minoxidil 5% topical foam (Delta Darou, Iran) to the scalp and then massage it into the vertex and frontal balding scalp once a day and not wash it for at least 6 hours.

Efficacy assessment: The following assessments were made at baseline and at 16 and 24 weeks after treatment:

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1) Target area hair counts:
   A) A semi-permanent ink-dot tattoo was placed for precise localization of the target area.
   B) A camera was used to take photographs of the target area and the entire scalp in precisely fixed situations.
   C) All visible hairs were dot-mapped and counted by a technician trained in the procedure and blinded to the intervention.
2) Subject assessment:
   Subjects were asked to fill out a questionnaire that rated their overall hair-loss condition in the vertex region compared to baseline. They rated their perception of their hair-loss condition compared to the baseline using a five-point scale, on which −2 = moderately worse, −1 = minimally worse, 0 = no change, +1 = minimally improved, +2 = moderately improved.
3) Global photographic review (GPR):
   GPR was carried out at baseline and at 6 months after treatment. The baseline and post-treatment pictures were shown in a side-by-side presentation and were rated independently by a blinded dermatologist using the same five-point scale as above.

Safety assessment: The patients were asked and examined for possible side effects, including signs of scalp irritation such as dryness/scaling, folliculitis, and erythema.

Data collection and analysis: A specific case report form was prepared and completed for each patient to collect data. Percentage and frequency were used to describe qualitative data, and mean and standard deviation were used for description of quantitative data. The comparison of quantitative data before and after the test was performed by non-parametric equivalent. Estimation of all the tests was performed at a significance level of 5%.

Ethics: All patients signed an informed consent form prior to inclusion. The Ethics Committee approved the project and the Declaration of Helsinki was followed throughout the study.

Results

Seventeen volunteers were enrolled in this study. One of them was excluded due to irregular use of the drug despite satisfaction with the treatment. Another one left the study due to lack of satisfaction with the drug. One patient reported desquamation and further hair loss after 2 months of use and was excluded. In the end, 14 patients participated in the study for 16 weeks, and 12 continued up to 24 weeks. The mean (± SD) age of the participants was 30.35 (± 8.4), range 18 to 44 years. The characteristics of the participants and hair-loss features at the baseline are shown in Table 1.

Table 1 | Characteristics of participants and hair-loss features at baseline.

Characteristic	Grade	*n*	Percent
Male pattern hair-loss	3	5	35.7
grade based on the	4	5	35.7
Hamilton–Norwood scale	5	4	28.6
Use of drug	Completely regular	11	78.6
	Regular	3	21.4

Table 2 | Subject assessment of hair-loss condition at weeks 16 and 24.

Scale	Week 16, *N* = 14 *n* (%)	Week 24, *N* = 12 *n* (%)
−2 Moderately worse	0	0
−1 Minimally worse	0	0
0 No change	5 (35.7)	3 (25.0)
+1 Minimally improved	6 (42.9)	6 (50.0)
+2 Moderately improved	3 (21.4)	3 (25.0)

Upon assessment of hair loss at weeks 16 and 24, 64.3% and 75.0% of the volunteers, respectively, confirmed that their hair-loss condition had improved after using the drug (Table 2).

As Table 3 shows, the average hair count with a camera at week 16 (181.87 ± 52.42) and week 24 (194.58 ± 62.82), and with an eye count at week 16 (62. 57 ±15.28) and week 24 (69.91 ±15.61) increased significantly compared to the baseline after intervention. Figure 1 confirms this improvement in the hair count for two volunteers after 24 weeks.

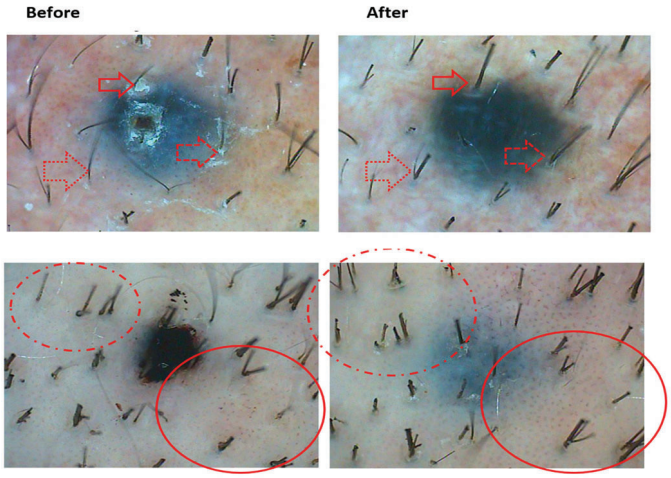

Figure 1 | Two volunteers with moderate improvement in average hair growth at week 24 (before, after).

The global photographic review by an expert after intervention indicated that 21.4% showed no change, 28.6% showed minimal improvement, and 50.0% showed moderate improvement (Table 4 and Fig. 2). The satisfaction with efficacy (reduction in the amount of hair loss, new hair growth, or increase in hair thickness) at weeks 16 and 24 showed that 50.2% and 75.0% of the participants were very satisfied, respectively. Regarding the drug dosage form and ease of use at weeks 16 and 24, 85.7% and 91.6% of the participants were very satisfied, respectively (Table 5).

Among the participants that regularly took the drug for at least 4 months, two people reported mild itching on the neck. No serious side effects were seen during the treatment.

Discussion

Androgenic alopecia is the prevalent cause of baldness occurring through progressive hair loss (7). Because the prevalence rates are so high in the Asian studies mentioned above, a more standardized protocol is necessary. The different types of hair loss and family histories of Asian patients with androgenic alopecia may affect treatment response (8).

This study was conducted to evaluate the efficacy of minoxidil 5% topical foam in Iranian men.

The results showed that the average hair count (with camera and eye) increased at weeks 16 and 24 compared to the baseline with a significant difference (Table 3 and Fig. 1).

A study by Olsen et al. comparing 5% minoxidil foam with a placebo in androgenic alopecia showed that the mean target

Table 3 | Week 16 and 24 changes from baseline hair count.

Variable	Before intervention *N* = 14 Mean (SD)	After intervention week 16, *N* = 14 Mean (SD)	*p* value (weeks 0 and 16)	After intervention week 24, *N* = 12 Mean (SD)	*p* value (weeks 0 and 24)
Target area hair count (camera)	162.85 (45.93)	181.87 (52.42)	.015	194.58 (62.82)	.019
Target area hair count (eye)	54. 92 (14.06)	62.57 (15.28)	.003	69.91 (15.61)	.002

Table 4 | Global photographic review after intervention.

Scale	Results, *N* = 14	
	n	%
−2 Moderately worse	0	0
−1 Minimally worse	0	0
0 No change	3	21.4
+1 Minimally improved	4	28.6
+2 Moderately improved	7	50.0

Table 5 | VAS score of drug effect, form, and ease of use at weeks 16 and 24.

VAS scores	Drug effect		Dosage form and ease of use	
	Week 16 *N* = 14 *n* (%)	Week 24 *N* = 12 *n* (%)	Week 16 *N* = 14 *n* (%)	Week 24 *N* = 12 *n* (%)
0–2.5	2 (14.3)	0	0	0
2.5–5	4 (28.6)	3 (25.0)	2 (14.3)	1 (8.3)
5–7.5	4 (28.6)	6 (50.0)	1 (7.1)	1 (8.3)
7.5–10	4 (28.6)	3 (25.0)	11(78.6)	10 (83.3)

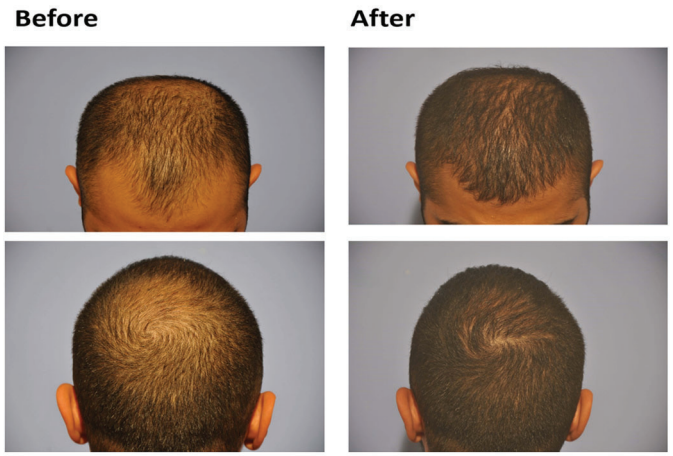

Figure 2 | A subject, 32 years old, with moderate improvement in hair growth as rated by an expert panel at week 24 (before, after).

area hair count increased significantly compared to the baseline (20.9% vs. 4.7%) (5).

In another study, Hillmann et al. reported that application of minoxidil 5% topical foam improved the front temporal and vertex target area hair count and width compared to the baseline up to week 16. At 24 weeks, significant improvement in scalp coverage for the target area was reported (9). A placebo control assessment of minoxidil 5% topical foam in hair density, width, and scalp coverage in the vertex and front temporal areas showed that minoxidil 5% topical foam is effective in the target area of men in 104 weeks (10).

In our study, an expert panel review of global photographic assessment, which is a useful follow-up tool and a way to assess treatment response, showed a 78.6% improvement in treatment response (Fig. 2). This outcome confirms the result by Mirmirani et al. Their study of 16 men demonstrated that minoxidil topical foam induced hair growth on the vertex and frontal scalp of patients with androgenic alopecia (11). Further studies on the efficacy of minoxidil 5% topical foam for treating female pattern hair loss have shown that this kind of formulation can be attractive (12, 13).

All of the studies above mentioned greater effectiveness of minoxidil 5% topical foam in improving hair growth in men and woman. However, some studies compared minoxidil topical foam and minoxidil topical solution. Preclinical studies comparing the efficacy of 5% foam versus 5% solution vehicles on hamster ears showed a greater uptake of minoxidil 5% topical foam (14). Another study, in which six macaques were treated topically with the two formulations above, demonstrated increased hair weight of 12.4 mg with minoxidil 5% topical foam versus 9.27 mg with minoxidil 5% topical solution from the baseline (15). More studies are needed on the effects on hair growth with minoxidil 5% topical foam versus minoxidil 5% topical solution.

Assessment of the condition of volunteers at weeks 16 and 24 revealed that hair loss after using the 5% minoxidil topical foam improved (64.3% and 75.0% improvement, respectively). This outcome is similar to the results reported by Olsen et al., which showed that 70.6% of participants stated that their hair loss had improved from the baseline and only 6.2% were not satisfied (5).

Our results showed that the participants were satisfied with the drug efficacy at week 16 (50.2%) and week 24 (75.0%) and with the drug form and ease of use at week 16 (85.7%) and week 24 (91.6%). This is comparable to a consumer use study that reported similar satisfaction regarding application such as lack of dripping and quick absorption and drying (5, 16).

None of the participants experienced any skin burning, itching, erythema, swelling, or scaling after applying minoxidil 5% topical foam. Adverse effects after the use of minoxidil 2% topical solution on the scalp (such as itching, dryness, and redness) were observed in 7% of patients. These complications are higher after the use of minoxidil 5% topical solution because the concentration of propylene glycol is a key factor in the sensitivity of irritated skin and is known as a factor in allergic contact dermatitis. Because the foam is free of propylene glycol, the side effects are therefore less than with the solution (16). Our research results showed that the tolerability profile was high and the low rate of irritant contact dermatitis was the same as in the results reported in the study by Kanti et al. (10).

Conclusion

Androgenic alopecia is one of the most prevalent dermatological illnesses that causes patients to seek treatment. There are limited options for treating it effectively. This is why androgenic alopecia remains an important area for further research to obtain more information regarding its pathogenesis and newer therapeutic options that are now being developed. Our study indicates that minoxidil 5% topical solution is a safe and effective treatment for MPHL and increasing hair count.

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