

# A multicenter, randomized, placebo-controlled, double-blind clinical trial of a novel formulation of 5% minoxidil topical foam versus placebo in the treatment of androgenetic alopecia in men

Elise A. Olsen, MD,<sup>a</sup> David Whiting, MD,<sup>b</sup> Wilma Bergfeld, MD,<sup>c</sup> Jeffrey Miller, MD,<sup>d</sup> Maria Hordinsky, MD,<sup>e</sup> Rita Wanser, BS,<sup>f</sup> Paul Zhang, PhD,<sup>f</sup> and Bruce Kohut, DMD<sup>f</sup>  
*Durham, North Carolina; Dallas, Texas; Cleveland, Ohio; Hershey, Pennsylvania; Minneapolis, Minnesota; and Morris Plains, New Jersey*

**Background:** An alternative to currently marketed topical minoxidil solutions is desirable.

**Objective:** To assess the efficacy and safety of a new 5% minoxidil topical formulation in a propylene glycol-free foam vehicle in men with androgenetic alopecia (AGA).

**Methods:** This was a 16-week, double-blind, placebo-controlled trial of 5% minoxidil topical foam (MTF) in 352 men, 18 to 49 years old. At week 16, 143 subjects continued on an open-label phase to collect 52 weeks of safety information on 5% MTF.

**Results:** At week 16 compared with baseline, there was a statistically significant increase in (1) hair counts in the 5% MTF group versus placebo ( $P < .0001$ ) and (2) subjective assessment of improved hair loss condition ( $P < .0001$ ) in the 5% MTF group versus placebo. The 5% MTF was well tolerated over a 52-week period.

**Limitations:** There was no collection of efficacy data beyond 16 weeks.

**Conclusions:** We believe that 5% MTF is a safe and effective treatment for men with AGA. (J Am Acad Dermatol 2007;57:767-74.)

Following the initial reports in the 1980s,<sup>1,2</sup> minoxidil topical solution (MTS) has been a proven mainstay of treatment for male pattern hair loss (MPHL) or androgenetic alopecia (AGA). Two percent MTS is Food and Drug Administration (FDA) approved for both men and women<sup>3,4</sup> with AGA, and 5% MTS is FDA approved for men with AGA. The vehicle in MTS consists of water, alcohol,

and propylene glycol, the latter increasing in amount with the higher concentration of minoxidil in order to solubilize the minoxidil.

A foam vehicle for delivery of 5% minoxidil (MTF) was identified as an alternative to 5% minoxidil solution. The 5% MTF formulation is a patented, hydroalcoholic, propylene glycol-free formula that is thermolabile and designed to melt at body

From Duke University Medical Center, Durham<sup>a</sup>; Baylor Hair Research and Treatment Center, Dallas<sup>b</sup>; Cleveland Clinic Foundation<sup>c</sup>; Milton S. Hershey Medical Center, Hershey<sup>d</sup>; University of Minnesota, Minneapolis<sup>e</sup>; and Pfizer Inc, Morris Plains.<sup>f</sup> Supported by Pfizer Inc.

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Correspondence to: Elise A. Olsen, MD, Box 3294, Duke University Medical Center, Durham, NC 27516. E-mail: [olsen001@mc.duke.edu](mailto:olsen001@mc.duke.edu).

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*Abbreviations used:*

AEs:	adverse events
AGA:	androgenetic alopecia
FDA:	Food and Drug Administration
GPR:	global photographic review
MPHL:	male pattern hair loss
MTF:	minoxidil topical foam
MTS:	minoxidil topical solution
OTC:	over the counter
PK:	pharmacokinetic
TAHC:	target area hair count

temperature. Two preclinical studies evaluated comparative efficacy of the foam and solution vehicles. In the hamster ear model for assessing follicular targeting, the 5% MTF showed increased uptake of minoxidil over the 5% MTS at both 1 and 2 hours of application.<sup>5</sup> A direct comparison of the efficacy of 5% MTF and 5% MTS was performed in the stump-tailed macaque,<sup>6</sup> an animal model for AGA in humans.<sup>7,8</sup> Six macaques were treated topically with either water, 5% MTS or 5% MTF once daily for sequential 4-month trial periods with 3-month washout periods between treatment groups.<sup>6</sup> Change in target area hair weight between baseline and month 4 of each treatment period was the primary end point. The macaques had an increase in hair weight of 12.40 mg (8.23-26.00 mg) on 5% MTF compared with an increase in hair weight of 9.27 mg (4.96-17.53 mg) on 5% MTS.

Two human pharmacokinetic (PK) studies were completed.<sup>9</sup> One study compared 5% MTS to 5% MTF and showed that the systemic absorption of the 5% MTF with twice-daily application of 1 g (one-half capful) in men was about half of that observed with 5% MTS with twice-daily application of 1 cc (both 100 mg daily of minoxidil); this was evidenced by the area under the curve of serum minoxidil concentration and maximum serum minoxidil concentration. The second study was an exaggerated-use PK study in men that demonstrated that application of up to 3 g of the 5% MTF or 300 mg of minoxidil (3 times the recommended dose) twice daily resulted in systemic levels that were well below the 21  $\mu\text{g}/\text{mL}$  threshold for cardiac-related events and, thus, within acceptable safety margins. Consumer use studies<sup>9</sup> showed that the minoxidil foam vehicle was rated significantly higher on several aesthetic attributes compared with minoxidil solution, including ease of application, lack of dripping, quick absorption and drying, and ability to fit easily into a daily routine.

A double-blind, placebo-controlled study with an open-label safety extension phase was conducted to assess the efficacy and safety of 5% minoxidil topical foam (MTF) in men with MPHL. The results of this

study, upon which FDA granted approval for the over-the-counter (OTC) use of 5% MTF in January 2006, are presented herein.

**METHODS****Subjects**

Men aged 18 to 49 years with Hamilton-Norwood patterns IIIv, IV, or V MPHL who were otherwise in good health were enrolled at one of 14 sites in the United States. Subjects were excluded from study participation if they had known sensitivity to minoxidil. Subjects were also excluded if they had used (1) topical minoxidil or any other OTC or prescription medication for hair growth within the past 6 months; (2) 5 $\alpha$ -reductase inhibitors, isotretinoin, radiation to the scalp, or chemotherapy within the past year; (3) botanicals/neutraceuticals for hair regrowth for the past 3 months; or (4) systemic steroids for more than 14 days within the past 2 months prior to enrollment in the study. Men with uncontrolled hypertension or a history of hypotension, any chronic active scalp condition other than AGA, any untreated cancer excluding basal cell carcinoma and squamous cell carcinoma of the nonscalp areas, a history of hair transplants, scalp reduction, or use of hair weaves also were excluded.

Subjects must have agreed to use the same shampoo and to maintain the same hair style, hair length, and hair color during the entire study and to refrain from cutting the scalp hair shorter than 1 inch in length.

**Study design**

This study was conducted in two phases—a 16-week, double-blind, placebo-controlled phase to evaluate the efficacy and safety of the 5% MTF and a subsequent open-label extension phase to collect 52 weeks of safety data with 5% MTF.

All subjects signed an institutional review board (IRB)—approved informed consent form before participation in the study. Eligible subjects were randomized in a ratio of 1:1 to receive either 5% MTF or placebo twice a day. A 60-g can of study drug was dispensed at baseline and monthly thereafter. Subjects were instructed to dispense one half capful (1 g) of the study drug onto their fingertips and then to apply this directly to the affected vertex balding scalp twice a day. This was to be done after any shampooing or use of a hair dryer, and the study drug was to be allowed to dry naturally. Styling aids were to be applied only after the study drug had dried.

Subjects returned to the study center for compliance and safety evaluations at weeks 1 and 4 and, subsequently, for safety and efficacy evaluations at weeks 8, 12, and 16. At the completion of the

16-week, double-blind phase of the study, subjects were asked to continue on the study using active drug in order to gather a total of 12 months of safety information on 5% MTF. Subjects remained blinded to the treatment (active or placebo) that they had received while on the double-blind portion of the study until month 8 of the extension phase. At that time, if subjects had been on 5% MTF during the initial 16 weeks, the study was discontinued; if they had been receiving placebo during the initial 16 weeks, they continued on the study for an additional 4 months. Those subjects who had been taking active drug for the first 16 study weeks returned to the study center at weeks 24, 32, 40, 48, and 52. Those subjects who had been receiving placebo for the first 16 study weeks returned to the study center at weeks 24, 32, 40, 48, 56, 64, and 68.

### Efficacy evaluation

**Target area hair counts.** Target area hair counts (TAHC) were performed at baseline and weeks 8, 12, and 16. For the double-blind phase of the study, one of the two coprimary efficacy end points was the change in TAHC between baseline and week 16. The percentage change in TAHC between baseline and week 16, while not a primary endpoint, was also evaluated.

At baseline, a circular area on the anterior leading edge of the vertex balding scalp was chosen as the target area for hair counts. A permanent ink dot tattoo was placed for precise localization of the target area on subsequent evaluations. The hairs in an area slightly larger than the 1 cm<sup>2</sup> target area were clipped to 1 mm. A 35-mm Nikon camera equipped with a device that allowed it to rest on the scalp and fix the distance and lighting of the attached camera (Canfield Scientific, Inc, Fairfield, NJ) was used to take the macrophotographs of the target area. These macrophotographs were sent to Canfield Scientific for processing. The macrophotographs were enlarged to an 8 × 10 size (5.7× magnification), a clear acetate overlay was attached, and all visible (nonvellus) hairs were dot-mapped by a technician trained in the procedure and blinded as to subject, treatment, and time. Dot maps were then translated to hairs by image analysis and a nonvellus TAHC was produced (nonvellus hairs/cm<sup>2</sup>).<sup>10</sup>

**Subject assessment.** The other coprimary end point was subject assessment of improvement. Subjects were asked to fill out a questionnaire at week 16 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 baseline using a 7-point scale where -3 = significantly worse, -2 = moderately worse,

-1 = minimally worse, 0 = no change, +1 = minimally improved, +2 = moderately improved, and +3 = significantly improved. To facilitate answering the questionnaire, subjects were provided with standardized Polaroid photographs of the vertex scalp taken at baseline and week 16. For each Polaroid photograph, the subject sat on a stool with the height fixed and placed his head in the stereotactic photographic device to ensure standardization of camera angle, head position, and lighting. Before taking the photographs, the hair in the vertex region was combed radially away from the center to maximize exposure of the hair loss. An attempt was made at the week 16 visit to duplicate the hair combing at baseline in order to facilitate direct comparison between time points.

**Global photographic review.** Global photographic review (GPR), also called expert panel review or global photographic assessment,<sup>11</sup> was a secondary end point. At baseline and weeks 8, 12, and 16, global photographs of the vertex scalp were taken with a 35-mm camera with the same protocol as noted above for Polaroid photographs. The 35-mm slides of baseline and one other study time point were then shown in a side-by-side presentation independently, and in a blinded fashion, to each of 3 experienced global photographic reviewers (Drs Olsen, Whiting, and R. Savin, MD). Room lighting, distance from screen to assessor, and magnification of the projected images were standardized. The global photographic reviewer then assessed the patient's hair loss compared with baseline using the same 7-point scale as subjects. The 3 GPR ratings were then compared. When two ratings were in agreement, the majority score was taken. If all 3 scores were different, the median score was taken.

### Safety evaluation

Subjects were assessed at weeks 1, 4, 8, 12, and 16 for any intercurrent events and their potential relatedness to study drug as well as any symptoms of scalp irritation (stinging, burning, itching)—rated by the subjects as none, mild, moderate, or severe. Vital signs and visual assessment of the scalp for any dermatitis (erythema, dryness/scaling, and folliculitis) were rated by the investigator as none, mild, moderate, or severe. The returned container of study drug was weighed at each visit to determine the average dose. A complete blood cell count and serum chemistries and a urinalysis were performed at baseline and at weeks 8 and 16. If there was an event of any cardiac nature at any time point in the study (including a change in blood pressure, pulse, body weight, or hypertrichosis), investigators were instructed to draw blood for a serum minoxidil level.

**Table I.** Subject demographics by treat group—intent-to-treat population

Demographics	Treatment group	
	Placebo	5% MTF
Age, y		
No.	172	180
Range (min-max)	20.0-49.0	21.0-49.0
Mean (SD)	38.3 ( $\pm 7.34$ )	40.1 ( $\pm 6.33$ )
Race, No. (%)		
White	154 (89.5%)	151 (83.9%)
Black	5 (2.9%)	7 (3.9%)
Hispanic	7 (4.10%)	17 (9.4%)
Asian or Pacific Islander	3 (1.7%)	3 (1.7%)
American Indian or Alaskan	2 (1.2%)	2 (1.1%)
Other	1 (<1%)	—
Duration of hair loss (mo)		
No.	172	180
Mean (SD)	105.9 (67.03)	115.4 (77.03)
Median	96.0	108.0
Range (min-max)	5.0-312.0	12.0-336.0
MPHL No.(%)		
Type IIIv	63 (36.6)	77 (42.8)
Type IV	64 (37.2)	53 (29.4)
Type V	45 (26.2)	50 (27.8)
TAHC		
Mean (SD)	168.9 (48.45)	170.8 (50.4)
Median	167.5	167
Range (min-max)	69.0-324.0	79.0-329.0

MPHL, Male pattern hair loss; MTF, minoxidil topical foam; SD, standard deviation; TAHC, target area hair count.

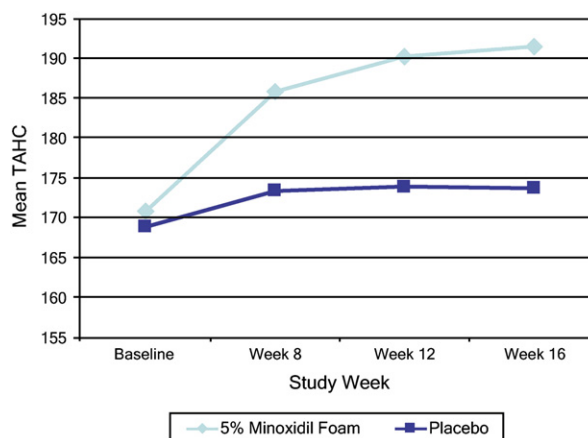
In those subjects participating in the extension study, monitoring for adverse events (AEs) and vital signs was conducted at each visit. Repeat blood tests, urinalysis, and scalp assessments for any irritation (erythema, dryness/scaling, and/or folliculitis) were completed at the final visit of the open-label extension phase.

### Statistical analysis

All efficacy and safety analyses were based on the intent-to-treat population. The intent-to-treat population included all randomized subjects.

Change in hair count was analyzed using analysis of covariance at each time point. If a subject's hair count data were not available, the last observation was carried forward. The analysis model included the treatment and center as factors and the subject's age as covariate. The mean difference of change in hair count and the 95% confidence interval of the mean difference were estimated from the model. The normality assumption of the analysis of covariance model was checked using the Shapiro-Wilk test, based on the residuals from the model.

Subject assessment of hair loss condition and the GPR score were analyzed in a way similar to that

**Fig 1.** Mean target area hair counts—intent-to-treat population.

used for change in hair count, except there was no last observation carried forward since these subject assessments were collected only once at week 16.

Descriptive analysis was performed for the safety parameters.

## RESULTS

### Baseline characteristics

A total of 352 male subjects between the ages of 20 and 49 years with MPHL were enrolled in the study; 172 were assigned to placebo and 180 to 5% MTF (Table I). The mean age of enrolled subjects was 39.2 years old, and the majority of subjects were Caucasian (86.6%). Forty percent of subjects had type IIIv, 33% had type IV, and 27% had type V Hamilton-Norwood hair loss pattern.

### Subjects completing study

Three hundred fifteen of the 352 subjects completed 16 study weeks, of which 151 subjects were receiving placebo and 164 subjects were using 5% MTF. The reason for not completing the entire 16 weeks included withdrawn consent (8.1% on placebo, 4.4% on 5% MTF), lost to follow-up (2.3% on placebo, 2.8% on 5% MTF), and a nonserious AE (1.2% on placebo, 1.7% on 5% MTF). Of the 315 subjects completing the 16-week, double-blind phase, 143 entered the extension phase of the study. One hundred fourteen subjects completed 52 weeks on active drug, including 43% of subjects initially randomized to placebo and 57% of subjects initially randomized to 5% MTF. The reason for not completing the entire open-label period included withdrawn consent (11.8% on placebo, 4.0% on 5% MTF), lost to follow-up (8.8% on placebo, 6.7% on 5% MTF), a serious AE (1.5% on placebo, 0% on 5% MTF), and a nonserious AE (2.9% on placebo, 1.3% on 5% MTF).

**Table II.** Week 16 change from baseline hair count\*

	Placebo			5% MTF			Total		
	No.	Mean	SD	No.	Mean	SD	No.	Mean	SD
Overall	156	4.7	19.7	167	20.9	22.5	323	13.1	22.6
Age group (y)									
18-25	11	14.3	17.6	3	22.7	6.7	14	16.1	16.0
26-30	13	7.3	18.3	13	27.1	19.4	26	17.2	21.0
31-35	28	4.9	21.5	19	20.7	17.9	47	11.3	21.4
36-40	33	1.6	21.9	43	18.9	28.1	76	11.4	26.8
>40	71	4.2	18.4	89	20.9	21.2	160	13.5	21.6
Hamilton-Norwood pattern									
Type IIIv	55	8.3	20.0	70	23.6	18.9	125	16.9	20.8
Type IV	62	4.2	17.7	49	15.9	25.7	111	9.3	22.3
Type V	39	0.6	21.7	48	22.0	23.4	87	12.4	24.9
Race									
White	140	4.6	19.9	140	21.5	22.9	280	13.1	23.0
Nonwhite	16	5.8	18.6	27	17.6	20.0	43	13.2	20.1
Duration of hair loss (y)									
<5	40	5.9	19.9	39	20.9	24.8	79	13.3	23.5
5-10	71	8.3	20.3	76	22.2	21.3	147	15.5	21.9
>10	45	-1.8	17.1	52	18.9	22.6	97	9.3	22.6

\*Intent-to-treat population and last observation carried forward.

### Compliance

Subject compliance was assessed from use of study drug. The mean number of days subjects were exposed to study medication and the actual/estimated daily study drug use were similar for the active and placebo groups. Mean amount of study drug used per day for each group was 2.2 g.

### Efficacy

**TAHC.** There was a steady increase in TAHCs over the 16-week, double-blind phase in subjects on the 5% MTF (Fig 1). The mean change in TAHC at weeks 8, 12, and 16 was significantly greater for the 5% MTF group as compared to placebo at all time points (15.5 vs 5.2, 19.8 vs 5.0, and 20.9 vs 4.7 TAHC, respectively,  $P < .0001$  for each) (Fig 1). Overall, following 16 weeks on 5% MTF, there was a mean 13.4% increase in TAHC over baseline, whereas the placebo group showed a 3.4% increase. As shown in Table II, the response to MTF was not affected by age, Hamilton-Norwood hair loss pattern, race, or duration of hair loss.

**Subject assessment.** There was a statistically significant difference between 5% MTF and placebo ( $P < .0001$ ) for subject assessment of improvement of hair loss condition. Of subjects on 5% MTF, 70.6% felt their hair loss had improved from baseline and only 6.2% felt that it had worsened (Table III). In comparison, 42.4% of subjects on placebo felt their hair loss had improved from baseline, and 19.2% of subjects felt their hair loss had worsened. The subject assessment difference was more striking for the

**Table III.** Summary of efficacy at week 16\*

Subject assessment of hair loss condition	Placebo (n = 172) No. (%)	5% MTF (n = 180) No. (%)
-3: Significantly worse	0	0
-2: Moderately worse	8 (4.7)	1 (0.6)
-1: Slightly worse	25 (14.5)	10 (5.6)
0: No change	56 (32.6)	32 (17.8)
+1: Slightly improved	36 (20.9)	41 (22.8)
+2: Moderately improved	28 (16.3)	47 (26.1)
+3: Significantly improved	9 (5.2)	39 (21.7)
Data not available	10 (5.8)	10 (5.6)

\*Intent-to-treat population.

subjects who felt they had moderate or marked hair growth: 47.8% on 5% MTF vs 21.5% on placebo (Table III). The subject's age, Hamilton-Norwood hair loss pattern, race, or duration of hair loss did not affect the subject results.

**GPR.** In the blinded GPR by the expert panel of investigators, there was a statistically significant difference between 5% MTF and placebo ( $P < .0001$ ). At week 16, 38.3% of subjects on 5% MTF were rated as having increased hair growth compared to 5.2% on placebo. The percentage of subjects who were rated as having moderate or marked growth was 7.8% on 5% MTF versus 0.6% on placebo (Table IV). Representative photographs are shown in Figs 2 and 3.

### Safety

In the double-blind phase of the study, the overall incidence of AEs was similar in the placebo and

**Table IV.** Frequency of global photographic review scores at week 16 compared to baseline by treatment group\*

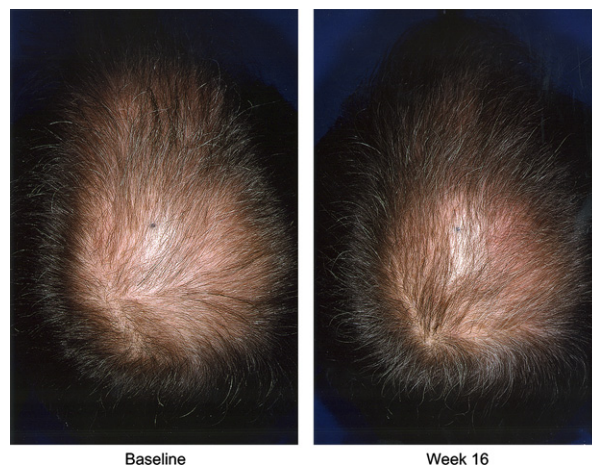
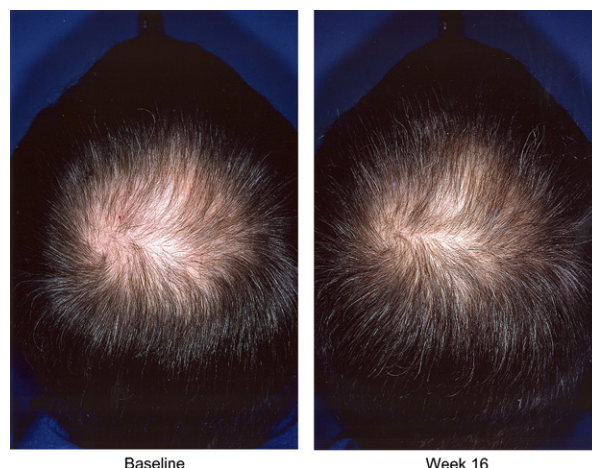
	Placebo (n = 172) No. (%)	5% MTF (n = 180) No. (%)
<b>GPR score for hair loss</b>		
-3 = Greatly decreased	0	0
-2 = Moderately decreased	0	0
-1 = Minimally decreased	4 (2.3)	0
0 = No change	134 (77.9)	94 (52.2)
+1 = Minimally increased	8 (4.7)	55 (30.6)
+2 = Moderately increased	1 (0.6)	14 (7.8)
+3 = Greatly increased	0	0
Data not available	25 (14.5)	17 (9.4)

GPR, Global photographic review.

\*Intent-to-treat population.

active groups (46.5% in the placebo group and 45.6% in the 5% MTF group). The incidence of potential drug-related AEs was 6.7% for placebo and 7% for active drug. Only headache (placebo 1.2%, 5% MTF 1.7%), pruritus (placebo 0%, 5% MTF 1.1%), rash (placebo 0%, 5% MTF 1.1%), and pain (placebo 1.2%, 5% MTF <1%) occurred in more than 1% of subjects in either treatment group. Dryness/scaling, erythema, and/or folliculitis were surprisingly common at baseline (14.0% of placebo-treated subjects and 14.4% of 5% MTF-treated subjects), and there was no significant worsening of any of these signs of irritation in these subjects in either treatment group during the study (Table V). Overall, at the end of the 16-week placebo-controlled study, only 8.1% of those on placebo and 7.2% of those on 5% MTF showed any signs of irritation. Symptoms of irritation (stinging, burning, itching) occurred in 2.3% of those on placebo compared with 5.6% of those on 5% MTF, with itching (1.2% of those on placebo vs 4.4% of those on 5% MTF) accounting for the majority of the difference in groups. Most signs and symptoms were mild and intermittent in nature and only 8 of 172 subjects on placebo and 5 of 180 subjects on 5% MTF had greater than moderate levels of irritation at any time during the double-blind phase of the study.

There was no significant change in the overall incidence of AEs in the open-label phase of the study compared with the double-blind phase. The incidence of potential drug-related AEs in the open-label phase of the study remained low, with no AE occurring in more than 3% of study subjects: headache (2.1%); hypertension (1.4%); photosensitivity, nausea, weight gain, paresthesia, acne, pruritus, and rash each occurring in fewer than 1% of subjects. At the conclusion of the open-label phase, the signs of

**Fig 2.** Subject, 41 years old, with Hamilton-Norwood type V MPHL, rated as having moderate hair growth by expert panel at week 16 on 5% MTF.**Fig 3.** Subject, 33 years old, with Hamilton-Norwood type IV MPHL, rated as having moderate hair growth by expert panel at week 16 on 5% MTF.

irritation were not vastly different than those exhibited at baseline but were more than those shown at the end of the double-blind phase (15/143 or 10.5%). Symptoms of irritation remained low at 2.9% overall. Again, most signs and symptoms were mild and intermittent in nature.

There were no drug-related serious AEs reported in the double-blind or open-label phases of the study in the placebo or 5% MTF groups.

There were no clinically significant laboratory abnormalities in subjects either on placebo or on 5% MTF. Additionally, there was no pattern of clinically relevant changes in vital signs (blood pressure, pulse, or body weight) in either phase of the study in subjects using 5% MTF.

Two subjects on placebo and one subject on 5% MTF in the double-blind phase, and 3 subjects on 5%

**Table V.** Subjects with scalp irritation\*

Study phase	Treatment group	Signs of scalp irritation (investigator assessed)				Symptoms of scalp irritation (subject assessed)			
		Dryness/ scaling No. (%)	Folliculitis No. (%)	Erythema No. (%)	Overall No. (%)	Burning No. (%)	Itching No. (%)	Stinging No. (%)	Overall No. (%)
Double-blind	<i>Baseline</i>								
	5% MTF (n = 180)	15 (8.3)	4 (2.2)	12 (6.7)	26 (14.4)	0	2 (1.1)	0	2 (1.1)
	Placebo (n = 172)	15 (8.7)	3 (1.7)	12 (7.0)	24 (14.0)	0	1 (0.6)	0	1 (0.6)
	<i>Week 16</i>								
Open-label	5% MTF (n = 180)	5 (2.8)	2 (1.1)	7 (3.9)	13 (7.2)	3 (1.7)	8 (4.4)	4 (2.2)	10 (5.6)
	Placebo (n = 172)	7 (4.1)	2 (1.2)	8 (4.7)	14 (8.1)	2 (1.2)	2 (1.2)	0	4 (2.3)
	<i>Weeks 52/68</i> (n = 143)	5 (3.5)	7 (4.9)	9 (6.3)	15 (10.5)	2 (1.4)	5 (3.5)	2 (1.4)	5 (3.5)

\*Includes slight or moderate degree.

MTF in the open-label phase had blood drawn to determine serum minoxidil levels secondary to an increase in blood pressure and/or body weight. The serum minoxidil levels were 1.17, 1.12, 1.02, and 0.397  $\mu\text{g/mL}$  in subjects on 5% MTF and less than 0.350  $\mu\text{g/mL}$  in subjects on placebo. All levels are within the range of serum levels seen with MTS, consistent with PK study results and well below the 21- $\mu\text{g/mL}$  threshold for cardiac-related events with minoxidil.

## DISCUSSION

Delivery of topical medications into the scalp is challenging. To be effective, (1) a majority of the medication must be delivered to the scalp, and medication lost on the hair or surrounding skin must be minimized; (2) the drug must be readily released from the vehicle; and (3) the drug must penetrate either the epidermis/outer root sheath of the infundibulum and/or the follicular canal and the protective layers that surround the hair shaft. Moreover, to ensure compliance, the medication must be cosmetically acceptable, especially if it is to be used daily and long term. This means it should be quick to dry, nongreasy, and should not affect the integrity of the hair by making it dry or brittle. Ideally, the constituents of the vehicle should themselves be nonirritating and of low allergic potential.

Since 1997, 5% MTS has been available OTC. GPR documents hair growth in 54% to 62% of men with Hamilton-Norwood pattern IIIv, IV, and V after 48 weeks of 5% MTS.<sup>12</sup> However, the novel foam vehicle utilized in this study appears to offer certain advantages over the solution vehicle, including the absence of propylene glycol (a potential irritant), the ability to limit spread beyond the intended application site, and less time to dry after application. Its enhanced cosmetic acceptability may also increase

compliance with treatment, increasing the overall results with topical minoxidil. The mean increase at 16 weeks in both absolute TAHC and the change in TAHC relative to baseline was statistically significant ( $P < .001$ ) between 5% MTF and placebo (20.9 vs 4.7 nonvellus hairs and 13.4% vs 3% total nonvellus hairs, respectively). Subjects on 5% MTF noted a mean 70.6% increase in hair growth versus 42.4% of subjects on placebo.

The incidence of pruritus with 5% MTF was 1.1% versus 6% seen in a separate trial of 5% MTS.<sup>12</sup> Overall, the incidence of irritation seen at baseline actually decreased during the study with both the foam vehicle and 5% MTF.

We conclude that the new 5% MTF preparation is a safe and effective treatment for MPHL.

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