

## **Minoxidil 5% study**

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### **Two New Studies Confirm Effectiveness of 5% Minoxidil in Treating Male-Pattern Hair Loss**

Two new studies of the effects of 5% minoxidil in treating male-pattern hair loss report that a majority of patients found:

- rapid onset of action in promoting new hair growth;
- very effective to effective results in promoting new hair growth over the period of treatment,
- decreased hair loss; and,
- minimal side effects.

Minoxidil is a topical hair restoration agent that is marketed in the U.S. under the brand name Rogaine®. It is available in 2% and 5% solutions; the 5% solution is approved for use only by men in the U.S.

Results of the studies were evaluated by both patients and physicians; in one of the studies, physicians with male-pattern hair loss were included in the study population.

Both studies were conducted by physician investigators in Germany under post-marketing conditions. The studies were funded by Pfizer Group, the maker of Rogaine®.

The topical hair restoration agent minoxidil has been approved for use in treating male-pattern hair loss for more than 15 years. Available first as a 2% solution, it has more recently been approved for use in 5% solution. In the U.S., the 5% solution is approved for use only in men; the 2% solution is also approved for use in treating hair loss in women. The 5% solution has been generally found to be more effective than the 2% solution in treatment of pattern hair loss. (For more information on minoxidil, see [Nonsurgical Options For Hair Restoration](#).)

The two post-marketing studies of 5% minoxidil were reported at the 62nd Annual Meeting of the American Academy of Dermatology, February 6-11, 2004, Washington, DC.

#### **One-Year Observational Study**

Dermatologists conducted a 1-year observational study in 984 men with male-pattern hair loss. The study evaluated the effectiveness of a 5% minoxidil topical solution in halting hair loss and stimulating new hair growth, as well as the patients' perceptions of efficacy and side effects. Over the 1-year period of the study, patients applied 1 milliliter (ml) of 5% minoxidil solution twice day to hair-loss areas of the scalp. Every 3 months during the study, patients collected hair lost in a hair washing and sent the collected hair to a laboratory for counting.

##### **At the end of 1 year:**

- The dermatologist investigators reported that hair loss areas of the scalp had become smaller in 62% of the patients, unchanged in 35.1% and larger in 2.9%.
- In evaluating minoxidil effectiveness in stimulating hair regrowth, the investigators found the 5% solution very effective in 15.9% of patients, effective in 47.8%, moderately effective in 20.6% and ineffective in 15.7%.
- Hairs lost during washing numbered a mean 69.7 at the beginning of the study, and a mean 33.8 at the end of the study-a measure of the effectiveness of 5% minoxidil in halting hair loss in the patients studied.
- The mean score of patient satisfaction on a scale of 0 (extremely dissatisfied) to 10 (very satisfied) increased from 2.9 at study beginning to 4.4 at study end. Patient satisfaction scores were lower than the estimates of the physician investigators: the investigators rated efficacy of treatment as good or very good 25% more often than did the patients.
- Side effects, mostly dermatologic, were reported by 3.9% of patients in the study. None of the side effects was classified as serious.

## Four-Month Surveillance Study

A 4-month surveillance study involving 743 men with male-pattern hair loss was designed to evaluate (1) how quickly men using 1 ml of 5% minoxidil solution twice a day began to notice reduced hair loss and/or new hair growth, (2) efficacy of 5% minoxidil solution in improving hair density in areas affected by male-pattern hair loss, and (3) side effects associated with use of 5% minoxidil solution.

All results were evaluated and reported by the men involved in the study; 150 physicians with male-pattern hair loss were among the 743 patients studied.

### At the end of 4 months:

- The scalp area affected by male-pattern hair loss (the "balding" area) was judged smaller by 67.3% of the men, unchanged by 31.9% and larger by 0.8%.
- The 5% minoxidil solution was judged very effective in stimulating new hair growth by 7.5% of the men, effective by 55%, moderately effective by 31.3% and ineffective by 6.2%.
- Hair density (the "fullness" of scalp hair) was judged improved by 74.2% of the men, unchanged by 24.3% and worsened by 1.5%.
- Of the 669 men who reported when results of minoxidil treatment were first noticeable, 13.9% reported results in the first month, 52.3% during the second month, and 33.8% during the third month.
- Skin-related side effects were reported by 13 patients.

Results reported by the 150 physicians in the study did not differ substantially from results reported by the other men in the study.

Results of these two post-marketing studies generally confirm results of previous studies of the efficacy and safety of minoxidil. While many persons are benefited by 2% or 5% minoxidil in treatment of pattern hair loss, results vary from person to person for a variety of reasons including individual responses to the agent and relentlessness of hair loss progression. Results that are satisfactory to some patients are unsatisfactory to others, perhaps because results do not meet pre-treatment expectations.

Best treatment results are likely to be realized when the person with hair loss consults a physician hair restoration specialist. Rational expectations for treatment outcome are most reliably based on (1) diagnosis of the cause of hair loss, (2) assessment of the characteristics of hair loss in the individual patient, and (3) a treatment plan based upon diagnosis and assessment, and agreed upon by the patient and physician hair restoration specialist. A physician hair restoration specialist is able to monitor the effectiveness of medical therapy clinically and through use of comparison photos, as well as provide other medical and surgical options to augment the benefits of minoxidil. Minoxidil solution is even more effective when combined with the oral medication finasteride (Propecia®), and is also compatible with hair restoration surgery. For example, a patient may have follicular unit transplantation to create a natural looking hairline near the front of the scalp, and use minoxidil and finasteride to preserve the hair on top of the scalp.