



NEW FORMULATIONS FOR HAIR REGROWTH

CLINICAL OPTIONS FOR ANDROGENETIC ALOPECIA

Male pattern hair loss (androgenetic alopecia) is a significant cosmetic concern, with 50% of men over 50 years of age being affected. In the U.S., there are over 50 million men afflicted with this condition. Androgenetic alopecia is a genetically driven condition. DHT (dihydrotestosterone) appears to be the trigger for androgenetic alopecia in genetically-prone individuals. Testosterone is converted to DHT by the enzyme 5-alpha-reductase. Once formed, DHT attaches to the hair follicle and triggers the process of miniaturization of the hair follicle. As the follicles is miniaturized, the hair shaft diameter becomes a fine vellus hair, like peach fuzz. More recent therapies for androgenetic alopecia have focused on blocking 5-alpha-reductase (such as the oral use of finasteride [Propecia]). Minoxidil has been the number one topical therapy for androgenetic alopecia since its FDA clearance in 1988. Even after years of use, its exact mode of action is not completely understood. Minoxidil sulfate is the active metabolite which has been shown to stimulate hair growth. The proposed mechanisms of action for minoxidil are

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1. It creates vasodilatation.
2. It slows senescence of keratinocytes.
3. It increases proliferation of dermal papilla cells in the hair follicle.
4. It enhances cell proliferation.

Studies with topical minoxidil 2% or 3% show that hair regrowth tends to peak at around 1 year and that new non-vellus hairs were maintained at 4.5 to 5 years with ongoing use of the product. In addition to stimulating the growth of new hairs, minoxidil was also shown to increase the diameter of the individual hair shafts by over 30%. A randomized, placebo controlled comparison study of topical 5% minoxidil vs. topical 2% minoxidil showed the men in the 5% minoxidil group had 45% more hair growth at 8 weeks than those men using 2% minoxidil.

INCREASED HAIR GROWTH WITH TRETINOIN AND MINOXIDIL

There is also evidence that tretinoin, when added to minoxidil, can increase its efficacy. Studies have shown that tretinoin increases the percutaneous absorption of minoxidil by 3 fold. Additionally, tretinoin in one study, when used alone, was shown to be able to increase hair growth in 58% of patients, while the combination of minoxidil and tretinoin increased hair growth in 66% of subjects. Another trial showed equal efficacy between once a day use of tretinoin 0.01% mixed with minoxidil 5% compared to twice daily use of minoxidil 5%. The adverse event profile of both formulations was similar. Intriguingly, in one study by Lewenberg, it was noted that while minoxidil appears to exert its best hair growing effects on the vortex of the scalp, the combination of tretinoin and minoxidil "results in hair growth in all areas of the scalp."

The mechanism of action for hair growth from tretinoin is not clear either. It has been shown to penetrate the nucleus of cells and induce protein synthesis and cell turnover. Additionally, it prolongs cell survival and prevents apoptosis of dermal papilla cells.

After years of clinical use, it appears that patients with the most recent hair loss have the most success with regrowth from minoxidil-containing products. Therefore, those patients with partially miniaturized follicles have the most success in reversing the miniaturizing process.

Another ingredient that has been combined with minoxidil has been topical steroids, most commonly betamethasone dipropionate. The use of topical steroids has been shown to decrease inflammation associated with the use of minoxidil, tretinoin, or the combination of both. Also, the combination has been shown to have increased efficacy over minoxidil alone. Notably, Upjohn, the manufacturer of minoxidil, has a patent for the combined use of minoxidil and topical steroids.

Blockers of 5-alpha-reductase, as previously mentioned, can reverse some androgenetic alopecia. Topical finasteride used alone has been shown to have a positive effect on hair growth. Other "natural" 5-alpha-reductase inhibitors been shown to anecdotally to also improve hair growth. There are several topical formulas that contain minoxidil, tretinoin, a topical steroid, and more recently, a natural 5-alpha-reductase blocking agent, oleanolic acid, in addition to several other ingredients.

A NEW FORMULATION: SCALP SOLUTION-4

Scalp Solution-4 is a combination of minoxidil 5%, tretinoin 0.01%, betamethasone dipropionate 0.05%, and finasteride 0.2%. A proprietary method has been developed to solubilize and stabilize minoxidil, allowing better stability and longer shelf life. Some clinical trials of similar formulas have shown a markedly faster onset of hair growth and more profound hair growth than they had seen with previous minoxidil based formulas. According to one dermatologist who has had previous experience prescribing this formulation, Dr. Mark Rubin notes that "impressive efficacy has been shown after only 3 months of use. These early results are particularly significant in view of the fact that these patients are not considered very good candidates for hair regrowth, since they have had long-term hair loss with few or no visibly functioning hair follicles. The patients tolerated the therapy well, with only some mild pinkness."

Many products on the market, especially over-the-counter products used by the consumer do not always produce the results patients are seeking. According to another physician, Dr. David Michelson comments that "this is the first significant recovery product that I have ever seen, and it competes strongly with hair transplantation." Solid evidence is being seen by multiple prescribers within their patient bases.

The cost of this compounded preparation is reasonable and is not a hindering factor when a patient decides if the cost outweighs the

benefits. According to previous observations by physicians, most patients see a noticeable difference in the thickness of their hair within 2 – 3 months. Also this formulation is less irritating and has caused less flaking and scaling than what has been reported with Rogaine. "Personally I believe this formula works better than Rogaine or Propecia," said Dr. Peter Rullan, a user of this compounded formulation.

The ease of use with the drop applicator fits the lifestyle of most patients. It is non-greasy, does not flatten or weigh down the hair, and is applied once to twice daily. Addressing hormonal issues is important as some patients have thyroid or androgenic disorders that require appropriate treatments with oral medications.

CONCLUSION

So why do previous users of this formulation believe it is more efficacious than others on the market such as Rogaine and Propecia? A review of product ingredients discussed in this article shows that higher strengths of minoxidil (5%) are more effective than lower (2%). The addition of tretinoin increases the efficacy of minoxidil. A topical steroid improves efficacy and reduces irritation, and a 5 alpha reductase blocker increases efficacy. Scalp Solution-4 contains all of these previously proven ingredients in a base that markedly improves drug delivery and shelf life.

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After reading this article,
would you like to start a
prescription for a patient?

If so, please call, write, or fax in the following
prescription:

Scalp Solution-4 (minoxidil 5% / tretinoin 0.01%
betamethasone 0.05%/finasteride 0.2%)
Apply 15 to 20 drops (1ml)
to scalp _____ times daily

■ 30ml ■ 60ml



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