This article reviews the use of Formula 82M (Hair Science, LLC), a topical application in the treatment of androgenetic alopecia or hereditary male and female pattern hair loss.

Formula 82M is a pharmacy-compounded minoxidil-based solution that has been in development for over 15 years. In 2010, it was introduced to the medical community in the U.S. Currently, approximately 200 physicians are actively prescribing the product to more than 1,000 patients.

Dr. Alan J. Bauman of Bauman Medical Group, Boca Raton, Florida (BMG) was introduced to Formula 82M in early 2010 and began prescribing it six months later after having conducted extensive due diligence on the product. In the time since, Dr. Bauman has concluded that for the majority of patients who choose to use a topical minoxidil solution for androgenetic alopecia, Formula 82M has the ability to achieve better results and greater patient satisfaction as a result of the enhanced pharmaceutical compounding than over the counter or previously available compounded minoxidil formulations.

About Bauman Medical Group

As a practice dedicated exclusively to the treatment of hair loss since 1997, Bauman Medical Group provides hair transplantation as well as customized multi-therapy treatment regimens to help their hair loss patients achieve their short and long term hair restoration goals. This approach may include the use of topical medications such as minoxidil, oral prescriptions such as 5-alpha reductase blockers and low level laser therapy. Bauman Medical Group provides hair growth tracking for patients through standardized global and microscopic photos as well as cross-sectional bundle measurements performed at appropriate follow-up intervals.

Minoxidil: Topical Treatment Modality Prior to Adoption and Use of Formula 82M at BMG

Prior to March 2008, patients of Bauman Medical Group were commonly prescribed FDA-approved over-the-counter (OTC) minoxidil solutions (i.e. 2% or 5%) as part of their hair loss treatment regimen. Minoxidil has been prescribed by physicians and used by patients for over 20 years under the brand name of Rogaine®, and more recently in generic equivalents as the patents expired. Minoxidil was FDA-approved for hair growth on August 17, 1988 (NDA #19-501) and has been studied in hundreds of clinical trials. Consumers as well as the medical community are familiar with the brand, its success and broad acceptance. Although obscure at first, over time its mechanisms of action have been more greatly elucidated indicating that minoxidil’s hair growth properties may be related to its influence on specific cellular potassium channels, resulting membrane hyperpolarization and local vasodilation.

Because androgenetic alopecia results in a gradual miniaturization of follicles in both men and women, in clinical use, areas of the scalp which have experienced recent hair loss have the most chance of improvements in coverage from the use of minoxidil-containing products. Typically, the higher the number of partially miniaturized follicles in a given area of scalp, the higher the chance of improved coverage in that area with non-invasive treatment. Areas that are severely depleted of density are not likely to respond if changes have not been observed within six to twelve months of use.

Those that have used or prescribed minoxidil based compounds will observe that the available OTC formulations leave much to be desired in the form of ‘ease of use’ and barriers to use may include the twice daily discipline to apply the product, scalp irritation from the solution and its often detrimental impact on hair styling.
Issues with Minoxidil: Compliance Barriers

Despite the name brand recognition of Rogaine® and its generic formulation, minoxidil, its wide adoption by the medical community, its commercial success and availability among consumers, there were, and still remain, less than optimal results for patients who use products containing minoxidil. Common complaints by users include concerns that the product is too messy, too greasy to use, that it made hair difficult to style along with reports of scalp irritation from the twice-a-day use of the mixture that includes propylene glycol, a proven irritant. Propylene glycol is known to cause redness, dryness, flaking, inflammation and discomfort at the scalp in a significant number of users. ii Taken in part or in whole, these common side effects represent significant barriers to compliance, diminishing the potentially positive effects of a minoxidil regime. Moreover, in May of 2010, “Consumer Reports” published a consumer survey that rated Rogaine®/minoxidil as “the most disappointing hair growth treatment.” Given these reports, studies and surveys, it is clear that despite the commercial success of Rogaine®/minoxidil there is opportunity in the marketplace for a topical hair regrowth product that not only addresses these consumer concerns, but one that may also produce better hair growth results than current products.

Minoxidil Use At BMG

In 2004, BMG began the search for compounding pharmacy to assist in the preparation of off-label ‘custom’ minoxidil with a reduced amount of propylene glycol, the known irritant in the standard OTC minoxidil mixtures. Reducing the propylene glycol resulted in slightly improved compliance by decreasing the incidence of irritation. Over the years, BMG has also prescribed 6% and 7% compounded minoxidil and even higher concentrations, but attempts to increase minoxidil concentration tended to decrease the stability of the formula, commonly resulting in crystallization and other problems for patients, like hair styling issues as the formulas were thicker and more difficult to apply and impairing styling.

Through word-of-mouth, BMG became aware of MasterPharm in NY, who compounds Formula 82M minoxidil under a license from Hair Science, LLC. We initially began prescribing 82M on a trial basis—primarily to those patients who had experienced side effects with over-the-counter minoxidil or previous compounded preparations. In addition to having the benefit of several synergistic ingredients, patients noted immediately that the formulation absorbed more quickly, was less irritating to the scalp, and had much less disruptive effect on hairstyling.

Formula 82M, More than Minoxidil: A Synergistic Combination of Ingredients in a Stable, User-Friendly Formula

Formula 82M contains 5% minoxidil, tretinoin, the topical steroid 0.01% fluocinolone, and a natural 5-alpha reductase blocking agent, oleanolic acid, in addition to several other ingredients. As unique and important as the ingredient composition is the proprietary method of solubilizing and stabilizing the mixture which allows better stability, longer shelf life, and improved usability of the Formula 82M compounded configuration.

Combination Tretinoin and Minoxidil: Proven to Increase Hair Growth

There is evidence that tretinoin, when added to minoxidil, can increase its efficacy. Studies have shown that tretinoin increases the percutaneous absorption of minoxidil by three-fold. iii 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. iv 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%. v The adverse event profile of both formulations was similar. Intriguingly, in one study by Lewenberg, vi it was noted that while minoxidil appears to exert its best hair growing effects on the vertex 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 entirely clear. It has been shown to penetrate the nucleus of cells and induce protein synthesis and cell turnover. vii,viii Additionally, it prolongs cell survival and prevents apoptosis of dermal papilla cells. ix,x

Other ingredients that have been combined with minoxidil have been topical steroids, most commonly betamethasone dipropionate. xi,xii The use of topical steroids has been shown to decrease inflammation associated with the use of minoxidil, tretinoin or the combination of both. Formula 82M contains 0.01% fluocinolone stabilized within the proprietary mixture.
A First-Ever Combination of Powerful Ingredients: Unique and Enhanced Delivery System

Numerous studies support the fact that systemic blockade of type-II 5-alpha reductase using oral medication can stop and reverse some androgenetic alopecia. Topical finasteride used alone has also been shown to have a positive effect on hair growth in balding scalp. Other “natural” 5-alpha reductase inhibitors have been shown anecdotally to improve hair growth. Over 15 years ago, a pharmaceutical group in South America created several topical formulas containing minoxidil, tretinoin, a topical steroid, and more recently, a natural 5-alpha reductase blocking agent, oleanolic acid, in addition to several other ingredients. Additionally, they also developed a proprietary method of solubilizing and stabilizing minoxidil, allowing better stability and longer shelf life. This initial work led to the development of the current 82M minoxidil formulation and the formation of Hair Science, LLC.

Formula 82M: The Product in Practice

Bauman Medical Group has prescribed Formula 82M to more than 400 patients from September 2010 through July 2012. During this period, our data indicates a much higher compliance rate than the use of over-the-counter minoxidil (Rogaine® or its generic equivalents), as well as previously prescribed compounded formulations. There is a high level of patient satisfaction and reduction of complaints from patients who previously experienced side effects from the use of Rogaine® and minoxidil containing products. Patient feedback indicates that Formula 82M is non-greasy, is less irritating and caused less flaking and scaling than previously prescribed formulations. Consequently, the product attributes combined with the patient feedback indicate that Formula 82M not only addresses the major issues related to non-compliance which is a strong predictor of a patient’s satisfaction, but also with the exceptional results of the medication.

Adoption and Use of Compounded Minoxidil in Milliliters Over Time at Bauman Medical Group

Below is a summary chart representing the BMG adoption and use of compounded minoxidil formulations, including Formula 82M, 5% PG-free, 6%, and 7% minoxidil.

Compliance and Concordance Tracking:

Tracking patients’ compliance, the degree of concordance with which patients adhere to a prescribed treatment regimen, is not a simple task. Many factors play a role in compliance, including the complexity of the prescribed medical regimen, poor understanding of the treatment benefits, occurrence of side effects, cost of the medication and weak or infrequent doctor-patient communication. In 2003, the World Health Organization reported that across all specialties, half of all those whom treatment regimens are prescribed do not follow them as directed.

In accordance with Florida State Law, Bauman Medical Group is a prescribing and dispensing medical facility. Using our dispensing records, we are able to assess patient’s adherence with their topical compounded minoxidil regimen over time. All topical minoxidil products are dispensed with instructions that patient should use 1ml (~10 drops) applied to the scalp twice a day, benefits and possible side effects are explained verbally and in written form. For the purpose of this tracking,
Adverse Events with 82M:
We’ve noted that the incidence of side-effects such as skin irritation, erythema (redness) and hair styling difficulty has been greatly diminished in the 82M patients vs. OTC minoxidil and other compounded minoxidil formulations. While these side-effects can still be a barrier to compliance and therefore results for some patients, their incidence appears to be greatly reduced in our experience with the product.

Formula 82M – Proven Effective, Easy to Use
The ease of use with the unique “droptainer” applicator better fits the lifestyle of today’s “on the go” patients who desire a quick-and-easy-to-use application technology. Moreover, product enhancements that also address complaints of minoxidil users is that the Formula 82M product is non-greasy and does not flatten or weigh down the hair. Applying it twice daily allows patients to see a noticeable difference within the commonly accepted time frame of approximately 90 days.

Conclusion
So why does 82M appear markedly more efficacious than topical solutions on the market such as Rogaine®, generic minoxidil and other compounded minoxidil formulations? A review of product ingredients discussed in this article shows that higher strengths of minoxidil (5%) are reportedly more effective than lower (2%). Studies support the fact that the addition of tretinoin increases the efficacy of minoxidil. A topical steroid improves efficacy certainly reduces irritation and a natural 5-alpha reductase blocker adds additional effectiveness. Formula 82M contains all of these previously proven ingredients and more, now in a propylene glycol-free base. However, more importantly, the proprietary solubilizing and stabilizing process appears to markedly improve usability, drug delivery and shelf life.

This article is meant to serve as an overview of the Formula 82M compounded topical minoxidil formulation for androgenic alopecia. The contents of this report includes information obtained by the product manufacturer combined with the first-hand knowledge and results obtained and derived by patient tracking and monitoring during a nearly two-year period of prescribing Formula 82M at Bauman Medical Group a full-time hair restoration practice in Boca Raton, FL. Please note that our practice continues to both prescribe and monitor the product formulation and all patient results, both positive and negative.

Formula 82M is a proprietary formulation that is only available by prescription in the United States through MasterPharm Compounding Pharmacy in New York.
Formula 82M is a pharmacy-compounded minoxidil-based solution that has been in development for over 15 years.

In 2010, it was introduced to the medical community in the U.S. Currently, approximately 200 physicians are actively prescribing the product to more than 1,000 patients.
Alan J. Bauman, M.D.

Alan J. Bauman, M.D. is a full time hair transplant surgeon who has treated over 15,000 patients and performed over 6,000 surgical procedures since starting his hair loss practice, Bauman Medical Group, P.A. in 1997 located in Boca Raton, FL.

Dr. Bauman received his M.D. degree from New York Medical College and surgical residency training at Mt. Sinai Medical Center and Beth Israel Medical Center in New York. Dr. Bauman is one of approximately 100 physicians worldwide to achieve certification from the esteemed American and International Board of Hair Restoration Surgery. He has been an active member of the International Society of Hair Restoration Surgery as a participant and lecturer at numerous Annual Scientific Meetings and Live Surgery Workshops.

Dr. Bauman is an author of textbook chapters on the science of hair care and hair transplantation, including eyelash transplant surgery and has been extensively featured in the world's leading media as a medical expert and successful early-adopter of some of the most advanced technologies in the treatment of hair loss.

Hair Science, LLC

Hair Science, LLC (www.HairScienceLLC.com) is a research and development company dedicated to discovering new ways to improve hair and scalp health. Driven by over 15 years of product evolution with leading dermatologists, hair restoration physicians, biochemists, pharmacists and healthcare experts across the Western Hemisphere, Hair Science designs uniquely engineered formulations to restore weakening hair follicles to normal function. Formula 82M, is now being offered by prescription through MasterPharm Compounding Pharmacy in New York under a license from Hair Science, LLC (www.MasterPharm.com)

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xi Ferry JJ, Fiedler VC. Pilot study to evaluate the effect of topical betamethasone dipropionate on the percutaneous absorption of minoxidil from 5% topical solution [abstract]. J Invest Dermatol 1990; 94: 504


