

Hair Loss Remedies—Separating Fact From Fiction

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GOAL

To understand the validity of claims for hair regrowth products

OBJECTIVES

Upon completion of this activity, dermatologists and general practitioners should be able to:

1. Explain the efficacy of various hair regrowth products.
2. Describe the side effects of various hair regrowth products.
3. Advise patients of the hair regrowth products most appropriate for them.

CME Test on page 123.

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Ms. Bandaranayake and Dr. Mirmirani report no conflict of interest. The authors report discussion of off-label use for tretinoin, spironolactone, Yasmin, dutasteride, and laser light therapy.

Hair loss is a common complaint in the outpatient setting. Frequently, patients conduct their own research on hair loss diagnosis and treatment and are faced with a number of manufacturers' claims that their products will benefit hair

loss. This paper explores the truth behind those claims of hair regrowth. We intend for this information to serve as a "consumer report" for healthcare providers and patients and to help separate some of the valid claims for hair regrowth from those that are purely fiction.

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Androgenetic alopecia (AGA) is a common patient complaint, affecting approximately half of all men and women by the age of 50 years.¹ Hair loss often can have significant negative effects

on self-esteem and body image.² Clinicians may be bombarded by questions from patients who have information about hair loss remedies from the Internet or testimonials from friends. However, it may be difficult or time-consuming for doctors to learn about the dozens of products claiming to promote hair growth and to then appropriately counsel their patients. In this article, we have interposed information obtained from the Internet with that obtained from peer-reviewed journals, when available, to support or refute claims made by the manufacturers or marketers of various products. We intend for this information to serve as a “consumer report” for healthcare providers and patients and help to separate some of the valid claims for hair regrowth from those that are purely fiction.

FDA-Approved Hair Loss Remedies

Minoxidil—In 1988, the US Food and Drug Administration (FDA) approved minoxidil 2% topical solution for use in treating AGA in men. A 2% solution marketed toward women became available in 1991, and a 5% solution for use in men became available over-the-counter in 1997.³ Since that time, generic formulations of minoxidil topical solution also have become available. Minoxidil is a vasodilator and a potassium channel opener,³ but its mechanism of action in promoting hair regrowth is unknown and appears to be independent of its vasodilation properties.³⁻⁷ The most common adverse side effects of minoxidil topical solution include scalp irritation, which occurs in about 7% of patients using the 2% solution, and hypertrichosis, which is noted in women.³ Because there are both generic and brand-name formulations of minoxidil topical solution, the cost of this therapy varies depending on which solution patients choose. However, most consumers pay between \$10 and \$20 for a 1-month supply.⁸

Minoxidil 2% topical solution has been proven to be effective both in stimulating new hair growth and in helping to prevent continued hair loss in both sexes.³ A recent study comparing minoxidil 2% and 5% topical solution in men showed that the men using the extra-strength formulation had 45% more hair regrowth after 48 weeks and an earlier response to the drug.⁹ A study published in 1992 showed that a year’s treatment with minoxidil 5% was effective in improving hair density in 9 women,¹⁰ though the company has not yet obtained FDA approval for the use of this concentration in women. Minoxidil topical solution has even been found to be effective

and safe in adolescents, which is an important finding because AGA can occur in older children or teenagers and can cause significant psychological distress.¹¹

Some Web sites are claiming that products used in combination with minoxidil can increase the drug’s efficacy. For example, the Hair Loss Control Clinic Web site claims that sebum on the hair follicle at the level of the scalp prevents minoxidil’s penetration into the hair follicle, causing it to be absorbed ineffectively.¹² The site also claims that the high alcohol content of over-the-counter minoxidil can cause hair damage. The clinic is promoting a product called HLCC Scalp Therapy Dexpantenol 12% to be used prior to shampooing to dissolve sebum, theoretically allowing the minoxidil solution to better penetrate the hair follicle.¹² Another product advertised on this site is Carrier Enhancement Agent, which supposedly neutralizes the alcohol in minoxidil to prevent scalp irritation.¹² There are no peer-reviewed studies supporting these claims. Because it is unclear how minoxidil topical solution works, it also is unclear why such additives would increase its effectiveness.

Patients also may see Web sites promoting the use of retinoids with minoxidil to enhance minoxidil’s effectiveness. To date, one nonblinded study tested tretinoin 0.025% combined with minoxidil 0.5% topical solution in 36 patients and showed that the tretinoin increased the percutaneous absorption of the minoxidil. The combination of the 2 drugs led to visible hair growth in 66% of the patients tested.¹³ Therefore, the application of both topical minoxidil solution and tretinoin may give some patients better results than application of topical minoxidil alone. Patients may want to try minoxidil by itself at first and then add the tretinoin only if they are not satisfied with their initial results.

Finasteride—In 1997, finasteride was approved by the FDA for treatment of male AGA at a dose of 1 mg/d.³ This medication is a competitive inhibitor of type-2 5 α -reductase, which inhibits testosterone’s conversion to dihydrotestosterone (DHT).¹⁴⁻¹⁷ Finasteride is able to decrease serum DHT by about 70%.¹⁸ Due to the potential for teratogenic effects in male fetuses, finasteride is not FDA approved for use in women.³ The main side effects of finasteride therapy are sexual side effects such as decreased libido and erectile/ejaculatory dysfunction, which occurred in fewer than 2% of men in one trial. In one study, these negative side effects were reversed with cessation of the medication.¹⁹ Also, there have been no clinically

significant drug interactions noted between finasteride and other medications.²⁰ The cost of this drug averages between \$30 and \$60 per month.⁸

Multiple randomized double-blind clinical trials of finasteride versus placebo in men aged 18 to 41 years with both vertex and frontal hair thinning showed that patients who took finasteride 1 mg/d for one year had significantly increased scalp coverage and hair counts than patients taking placebo.^{19,21,22} With continuous treatment of finasteride daily for 2 years, approximately two thirds of men have improved hair regrowth, one third of men see no change, and approximately 1% of men actually have less hair than at baseline.³ This product has shown more efficacy in younger men than it has in men older than 60 years, most likely because of decreased scalp type-2 5 α -reductase activity in older men.³

Finasteride also has been tested for efficacy in women with AGA. A randomized double-blind study of 137 postmenopausal women with AGA who took finasteride 1 mg/d or placebo for one year showed no significant difference in hair count between the 2 groups. In fact, both groups of patients actually showed significant loss of hair during the study period.²³ Another randomized open-label study tested finasteride 5 mg/d versus no treatment in premenopausal women with hyperandrogenic alopecia and elevated serum androgens (levels >2 SD above the mean in ovulatory control patients). This study found that the women using finasteride at this elevated dose did not see any significant improvement as opposed to the women receiving no treatment.²⁴ Some clinicians have had more success with the use of finasteride in their female patients with AGA. In a letter published in the *British Journal of Dermatology*, 2 physicians describe successful treatment of AGA in a postmenopausal woman who was given finasteride 5 mg/wk. Success was measured via patient report of improved hair density and review of stereotactic photographs of the scalp.²⁵ Despite this anecdotal evidence of success, the larger body of evidence weighs against the use of finasteride in postmenopausal women with AGA.

Because there are only 2 FDA-approved treatments for AGA, patients may wonder which is more effective. In a recent letter published in the *Archives of Dermatology*, finasteride 1 mg/d was compared with topical minoxidil 2% in 99 men aged 18 to 45 years with mid frontal and/or vertex hair thinning.²⁶ The researchers found that both treatments worked equally well in stopping the progression of hair loss in patients; however,

patients given minoxidil had quicker initial improvement whereby patients given finasteride had slightly better results as treatment progressed.²⁶ Choice of treatment therefore may be more a factor of side-effect profile, expense, and preferred form of medication (oral vs topical).

Some patients may ask about combining finasteride with minoxidil. One case study described the improvement of one man's alopecia from Hamilton-Norwood class V to class III after using a combination therapy of finasteride 5 mg/d plus a topical solution of minoxidil 3% and tretinoin 0.01%.²⁷ The combined use of finasteride and minoxidil topical solution has been studied in the animal model of AGA; in stump-tail macaques, the combined use of finasteride with minoxidil had greater effects on hair loss than either treatment alone.²⁸ Because both treatments have different modes of action, it is plausible that combining them may yield better results.

Off-Label Uses for FDA-Approved Medications

Spironolactone—This medication is often prescribed for the treatment of hypertension because of its action as an aldosterone antagonist, but it also is able to inhibit the biosynthesis of androgens and to competitively inhibit androgen receptor protein binding.²⁹ The main side effects of this medication are menstrual irregularities, hyperkalemia, gynecomastia in men, and gastrointestinal distress.²⁹ Women using this medication must be warned about the potential for feminization of male fetuses if pregnancy occurs during the course of treatment.³⁰ The cost of this medication at a dose of 200 mg/d is approximately \$60 per month, though it typically is covered by insurance policies.⁸

Spironolactone has shown efficacy in treating women with hirsutism,³¹ and it also may have mild efficacy in treating AGA at a dose of 200 mg/d.³² One study examining the efficacy of spironolactone in women with AGA showed that the women taking the medication had less hair loss than control patients after one year, but the women taking spironolactone still did not have more hair after treatment than at the start of the study.³³ Another study that examined the use of spironolactone 200 mg/d in 2 men and 2 women with AGA showed that the patients had an increase in the number of hairs in anagen phase from 22% at baseline to 84.5% at the end of 6 months of treatment.³⁴ Because this medication only has weak evidence for its use as a treatment for hair loss, clinicians should consider this medication

only in addition to other, more proven, means of therapy.

Yasmin®—This is an oral contraceptive pill composed of ethinyl estradiol and drospirenone, an analogue of spironolactone. Each pill contains drospirenone 3 mg, which is equivalent to spironolactone 25 mg.³⁵ According to the manufacturer of Yasmin, this oral contraceptive antagonizes androgen receptors without affecting sex-hormone-binding globulin synthesis or affecting the binding of testosterone to sex-hormone-binding globulin. The manufacturer also claims that the drug inhibits ovarian androgen production.³⁶ The most common side effects are similar to side effects of other oral contraceptives and include breast tenderness, nausea, headache, emotional lability, dysmenorrhea, intermenstrual bleeding, and depression.³⁵ Some insurance plans will cover the cost of oral contraceptives, but for patients paying out of pocket, Yasmin costs approximately \$30 per month.⁸

Because spironolactone is sometimes prescribed for AGA, some clinicians recommend Yasmin to patients with alopecia who also are looking for effective contraceptive methods. However, to our knowledge, there are no known published studies showing that Yasmin prevents hair loss or promotes hair regrowth. Because spironolactone has shown only slight efficacy in treatment of women with AGA,³ it is unclear what the effect of Yasmin may be on hair loss. However, this may be a reasonable choice of contraceptive in a woman with AGA.

Dutasteride—This new 5 α -reductase inhibitor blocks both type-1 and type-2 isoenzymes.³⁷ By inhibiting both types of 5 α -reductase, dutasteride is able to achieve a greater than 90% suppression of DHT.³⁷ This medication was developed for the treatment of benign prostatic hyperplasia, with side effects similar to those of finasteride.³⁸ As with finasteride, women are advised not to take this product because of the potential risk of birth defects in male fetuses.³⁷ In November 2002, dutasteride was approved by the FDA for use in patients with benign prostatic hyperplasia.³⁹ This medication costs approximately \$75 for a 1-month supply.⁸

Although dutasteride is not yet FDA approved for alopecia, the manufacturers have completed phase 2 clinical trials of the medication for the treatment of hair loss and are hopeful it will be approved by the FDA in 2006.⁴⁰ There are no studies published regarding this medication's effect on AGA, but preliminary results from the manufacturer showed that dutasteride reduced scalp DHT in men to a greater extent than finasteride.⁴¹

Herbal/Dietary Remedies

Saw Palmetto—Saw palmetto, or *Serenoa repens*, is an herbal remedy that is processed from fruit of the American dwarf pine tree.⁴² It often is used to treat benign prostatic hypertrophy because of its ability to inhibit 5 α -reductase levels by 32% without affecting testosterone levels in men.⁴³ Extracts of saw palmetto also have been shown to have a partial antagonistic effect on testosterone receptors.⁴⁴ It is most likely that these 2 actions led to saw palmetto being used as a hair loss remedy. Saw palmetto is believed to be a safe herbal supplement, with a primary side effect of mild gastrointestinal distress.⁴² Also, clinical trials conducted in human patients showed that consumption of saw palmetto supplements did not result in any clinically significant alterations in laboratory parameters.⁴⁵ Saw palmetto has no known drug interactions.⁴² The cost of this supplement varies by manufacturer, but consumers should be able to find saw palmetto supplements for as little as \$3 for a month's supply.⁸

One double-blind placebo-controlled study examined saw palmetto's effect on AGA.⁴⁶ In this study, researchers studied the efficacy of a softgel containing β -sitosterol 50 mg and saw palmetto 200 mg extract (components of the HairGenesis™ Softgels discussed later) versus placebo in treating AGA. They found that 60% of patients taking the active softgel rated their hair growth as improved from baseline as opposed to only 10% of the patients taking placebo. However, this study had a limited patient population and also concurrently tested β -sitosterol, so any improvement cannot be attributed to saw palmetto alone.

Biotin—This is a water-soluble B complex vitamin that is used in the body as a cofactor for biochemical carboxylations. Patients that are deficient in this vitamin often have alopecia, brittle nails, and a scaly erythematous dermatitis.^{47,48} Biotin is water-soluble, and there are no known side effects of supplementation and no documented cases of biotin overdose.⁴⁹ As with other supplements, cost of treatment will depend on the manufacturer, but consumers should be able to find biotin for as little as \$2 for a month's supply.⁸

Dietary supplementation with biotin has been shown to improve the clinical condition of brittle nails,⁴⁸ but no studies have been conducted looking at biotin's effect on AGA. Although it is true that biotin deficiency can lead to alopecia, such a deficiency has not been demonstrated in healthy humans eating a mixed diet.⁴⁷ The only 2 situations in which human biotin deficiency has

been demonstrated are in patients with extended consumption of raw egg whites⁵⁰⁻⁵² and in patients with malabsorption syndromes receiving parenteral nutrition without biotin supplementation.^{50,53} Supplementing the diet with biotin is unlikely to harm a patient, but there is no data to suggest any improvement in hair regrowth.

Other Hair Regrowth Products

Avacor™—Sold through the Internet and directly from the manufacturer, Avacor is a hair regrowth product marketed toward both sexes for treatment of AGA.⁵⁴ The product line consists of a scalp detoxifying shampoo, an herbal supplement, and a topical solution. The purpose of the shampoo as stated by the manufacturer is to deep clean the scalp to improve the absorbency of the topical treatment. The herbal supplements are to be taken twice daily to “maintain a healthy hair follicle” and consist of bilberry, ginkgo biloba, saw palmetto, and horsetail. The topical solution, which is marketed to men only, claims to dilate blood vessels in the scalp, allowing increased nutrient and oxygen delivery to the scalp. The Web site claims that these products must be used together and that they have no known side effects.⁵⁴ The cost of this product is \$239.95 for a 3-month supply.⁵⁵

The official Avacor Web site has a summary of a clinical study performed by The New York Hair Clinic and the Hair and Skin Treatment Center in which 200 men aged 18 to 65 years used the 3-part system for 24 weeks.⁵⁵ The Web site claims that 91% of the men had a decrease in hair loss and an increase in strength and thickness of preexisting hair within 3 months.⁵⁵ However, this study does not appear to be published in any journal and consumers can only receive a copy of the study if they purchase the product.

A *Wellness Letter* highlighting dietary supplements, published by the University of California at Berkeley, showed that Avacor contains minoxidil in its topical solution despite its claims to be made from only natural ingredients.⁵⁶ In April 2003, the FDA sent the makers of Avacor a letter informing them that their products are considered drugs under section 201(g) of the Federal Food, Drug, and Cosmetic Act and should have had an approved New Drug Application prior to being marketed in the United States. The FDA also points out that the 3 individual components are mislabeled because the active ingredients are not listed on their labels.⁵⁷

Given the lack of peer-reviewed evidence of hair growth and with all of the controversy surrounding

this product, it would not be wise for clinicians to recommend this therapy to any patient.

HairGenesis™—This product line consists of 4 items: Revitalizing Oral Softgel™ supplements (β -sitosterol 50 mg and saw palmetto 200 mg extract) that claim to strengthen and protect hair; Topical Activator Serum that consists of various 5 α -reductase inhibitors; Hair Revitalizing Formulation, a shampoo that has similar components to the Topical Activator Serum; and Hair and Scalp Conditioner that also is meant to strengthen and protect hair. Although the company states that the products may be used individually, it recommends using them all synergistically, at a cost of \$200 for a 3-month supply.⁵⁸ The efficacy of the oral softgel containing saw palmetto is discussed above; there are no known research studies published about the other 3 components of the HairGenesis system.

Nioxin®—This product line is sold only through hair salons and does not aim to regrow hair; rather, it claims to “create an optimum scalp environment” for regrowth and maintenance of the current hair count. The manufacturer claims to accomplish this by clearing the scalp of excess sebum that may contain high levels of DHT. Ingredients include various vitamin-B coenzymes, biotin, saw palmetto, aloe, ginseng, and amino acids. The manufacturer claims that the Nioxin system has no known side effects.⁵⁹ As this product is sold only in salons, the cost for a month’s supply will vary depending on the place of purchase. One salon that we contacted offered a one-month starter kit for \$30. The manufacturer does not disclose its clinical studies but claims that its studies are conducted by “world-renowned” researchers who are experts in hair thinning.⁵⁹ However, there is no known published scientific evidence that any of the ingredients in Nioxin are effective in treating hair loss or maintaining hair count, or that excess sebum leads to hair thinning.

Laser Light Therapy—Low-intensity laser light therapy has been shown to be effective in promoting wound healing⁶⁰ and in improving circulation.^{61,62} For these reasons, some hair loss treatment centers are offering the use of lasers for treating alopecia in both men and women. To date, there are no known studies looking at the efficacy of these lasers for treating hair loss. The use of low-intensity laser light for treating alopecia is FDA approved for safety only, not for efficacy.²⁹ This therapy is expensive, costing as much as \$3500 for the recommended 6 months of treatment.⁶³

Although various Web sites claim efficacy based on double-blind placebo-controlled studies of laser light treatment versus placebo laser treatment,^{64,65} such studies are not available for viewing anywhere on the Web sites. To the best of our knowledge, there are no peer-reviewed articles supporting efficacy of this type of treatment for AGA. Until reliable evidence of the effectiveness of laser light therapy for alopecia is published, this treatment remains experimental, at best.

Conclusion

Any consumer looking on the Internet for a treatment for hair loss is exposed to a multitude of remedies. However, only the FDA-approved treatments for AGA, finasteride and minoxidil, have any well-studied factual evidence of efficacy. Smaller studies have shown possible benefit of combining topical tretinoin with minoxidil, as well as combining finasteride and minoxidil. Spironolactone in high doses (100–200 mg), dutasteride, and saw palmetto, also may provide benefit; however, larger studies are needed to consider these agents as first-line treatments for AGA. In addition to efficacy, clinicians need to consider patient preferences, safety profile, and cost when counseling patients about treatment options for AGA.

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