



ZHITTYA
— REGENERATIVE MEDICINE INC. —

FGF-1 to Treat Male Pattern Baldness

Summary

Approximately 40 million men, or 2 out of 3 men in the United States, have significant hair loss. About 25% have some form of balding by age 30, and 65% begin to bald by age 60. The two most widely-used medical treatments for male pattern baldness — Propecia® and Rogaine® — both have their disadvantages. Propecia, which blocks the production of the potent testosterone derivative, DHT (dihydrotestosterone) has now been linked to significant unwanted side effects in men, including decreased libido, sexual dysfunction, and a reduction of mature sperm count. Rogaine, although useful in preventing hair loss, only stimulates actual hair growth in less than 20% of men who use it. Thus we are still far away from an ideal treatment for male pattern baldness, which would be a safe compound that stimulates hair growth and lengthens the time that occurs before hair loss. Among the several polypeptide growth factor systems that are involved in the dynamics of hair growth, the FGF (fibroblast growth factor) system appears to play multiple roles in the physiological processes of hair growth. There is a body of very compelling evidence in animals that FGF-1 is a safe and potent stimulator of hair growth. In addition, studies in animals have shown that FGF-1 can significantly lengthen the time before hair loss occurs. With these promising pre-clinical studies, further investigations into the potential use of FGF-1 as a treatment for male pattern baldness are certainly warranted.

Introduction

Male-pattern hair loss (see Fig. 1 below) is the most common form of balding, affecting roughly 40 million men in the US. Approximately 25 percent of men with male-pattern hair loss will begin to lose their hair by age 30, and up to 66 percent will begin balding by age 60. Male-pattern hair loss is closely linked to androgens — sex steroid hormones synthesized from

cholesterol in the testes, ovaries and adrenal glands. The primary androgens are derivatives of testosterone, and dihydrotestosterone (DHT), has been identified by researchers as a primary cause of male pattern baldness. DHT is synthesized from testosterone by the enzyme 5-alpha-reductase. When DHT binds to receptors in the hair follicle, it causes the hair roots to shrink, or “miniaturize.” DHT has also been shown to shorten the amount of time hair spends in the growing (anagen) phase from as long as five years to as little as two months.

In 1998, researchers discovered that men genetically prone to male pattern baldness have significantly higher numbers of androgen receptors in the hair follicles located across the forehead and scalp — exactly those areas where hair loss first appears in androgenic alopecia. Additional research has shown that these androgen-sensitive follicles also have significantly higher levels of 5-alpha-reductase (1.5 to 3 times higher) and DHT than hair follicles from other areas of the scalp.

Over time, DHT’s miniaturizing effect can shrink large adult hairs, resulting in finer hairs only 10% as wide as normal and barely an inch long. This leads to the “peach fuzz” common to early stage balding. At this stage if the effects of DHT aren’t reversed or halted in time, the hair follicles will shrink down until they eventually vanish, resulting in complete baldness in the affected area.

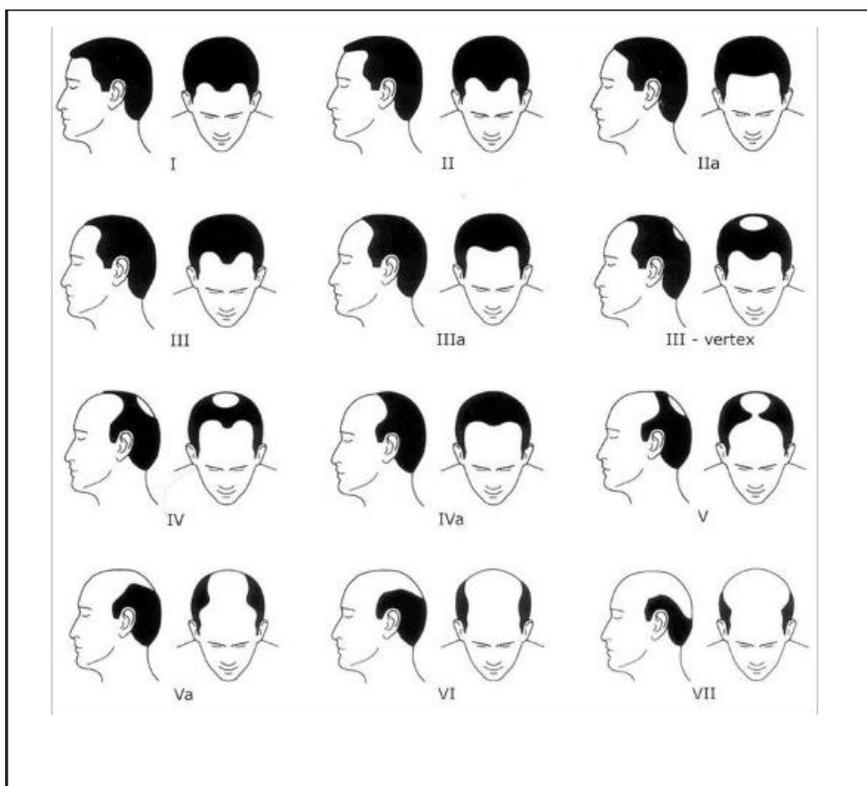
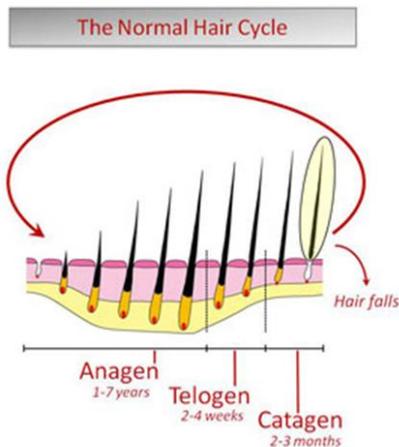


Fig. Figure 1. Progressive loss of hair as classified on the Hamilton–Norwood chart, ranging from stages I through VII.

Three Stages of Hair Growth

The normal hair growth cycle occurs in three distinct phases — growth (anagen phase), transition (telogen phase) and rest (catagen phase)— that are collectively referred to as the hair cycle in the figure below.



As can be seen in the Figure above, each hair cycle begins with a growth (anagen) phase. This is marked by rapid cell division in the hair matrix that builds up layers of keratin to form a single hair shaft that grows out from the follicle at a rate of up to one inch per month. This growth phase typically lasts two to six years. At any given time, about ninety percent of all scalp hairs are in the active growing phase.

At the end of the anagen phase, hair growth ceases and the follicle enters the transition (or telogen) phase. During this phase hair matrix cells begin to die off as the follicle base and bulb begin to shrink. Over time, this shrinkage

(miniaturization) pinches off the lower hair bulb, cutting off access to the blood vessels and circulation necessary for hair growth. At any given time, one to two percent of all hair follicles are in this transition phase, which usually lasts for between one to two weeks.

The final stage of the hair cycle is the catagen phase. During this phase, the mature hairs reside in the follicle 2-3 months before falling out. Approximately 10 percent of all hairs are in this transition period at any time, accounting for the normal shedding of thirty and fifty hairs each day.

After shedding the hair shaft, the follicle begins a new cycle of hair growth, marked by the swelling of the dermal papilla and the formation of a new capillary loop. As blood vessels reattach to the papilla, they grow and expand four-fold to provide the hair matrix with the nutrients necessary for growing new hair. The entire process — growth, transition and rest — makes up one complete hair cycle. Each hair follicle is limited to the number of hair cycles that can be completed — estimated to between 20 and 25 cycles — before reverting to vellus hairs (peach fuzz) and eventually disappearing.



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