



Hair Restoration Gel

CLINICAL STUDY

Cosmetic hair tonics have been peddled for the better part of the last century, mostly in the form of inert tonics and pigmented creams that promised to restore hair growth and improve your appearance – often to little avail and much chagrin.

Fortunately, there are a variety of first generation products on the market today that can and do improve hair loss to varying degrees for both men and women. All of these products target the testosterone metabolite, dihydrotestosterone (DHT), as a key player in the hair loss process. DHT's significance rests in its ability to interfere with the levels of various growth factors at the hair root, resulting in a gradual decrease in hair growth. As the hormonal and nutritional environment supporting hair growth deteriorates, the hair follicle thins and eventually sheds. Controlling DHT levels at the hair follicle has been shown to retard this process.

Extensive research into the hormonal environment at the base of the hair follicle has now clearly defined the hormonal soup that affects the hair cycle. With this new knowledge, the ability to more effectively counteract hair loss increased significantly. The result of this research has been the development of the second generation product Regenscalp™, which more significantly decreases hair loss, increases hair growth and volume, and improves the environment for maintaining hair growth.

THE HAIR CYCLE

The hair cycle is divided into three phases that last between two to five years from beginning to end. An ability to influence the hair cycle is key to creating a useful hair growth product. The phases and their relative roles are as follows:

- Anagenic Phase: During this growth phase, cells at the base of the dermal papilla divide, elongate and fill with keratin to create hair growth. Cellular division occurs every 12 hours.
- Catagenic Phase: During this transitional phase, hair growth stops and the hair bulb detaches itself from the papilla and rises toward the surface.

- Telogenic Phase: During this resting phase, the hair is loosely anchored and may remain for several months before being expelled. The loss of between 50 to 100 hairs a day is normal. Hair loss in excess of this rate may give rise to the appearance of thinning and alopecia (baldness).

PILOT STUDY

Ten healthy male volunteers between 26 and 50 years of age with moderate hair loss were enrolled in a twelve week study. Study volunteers were instructed to massage Regenscalp™ on their scalp daily before bedtime, while refraining from the use of any other comparable treatments. The study was conducted under the supervision of a dermatologist specializing in hair loss.

Phototrichogram

At the beginning of the study, each volunteer had an area of hair around the crown cut very close to the scalp in order to take an initial photograph of their hair called a phototrichogram. Three days later, a second photograph was taken of this same cut area. By superimposing the photographs for analysis by a specialized computer, the relative percentage of hairs in the anagenic, catagenic and telogenic phases of the hair cycle could be recorded for comparison later in the trial. All study volunteers were started on Regenscalp™ after completing this baseline phototrichogram protocol.

During the eighth and twelfth week of the study, the same photographic protocol initially performed at the beginning of the study was repeated in order to determine if there was any change in hair cycle, hair volume or hair regrowth rate.

Seborrhea Detection

Since an abnormally dry or oily scalp can contribute to hair loss, it would be beneficial if oil secretion could be normalized in study participants.

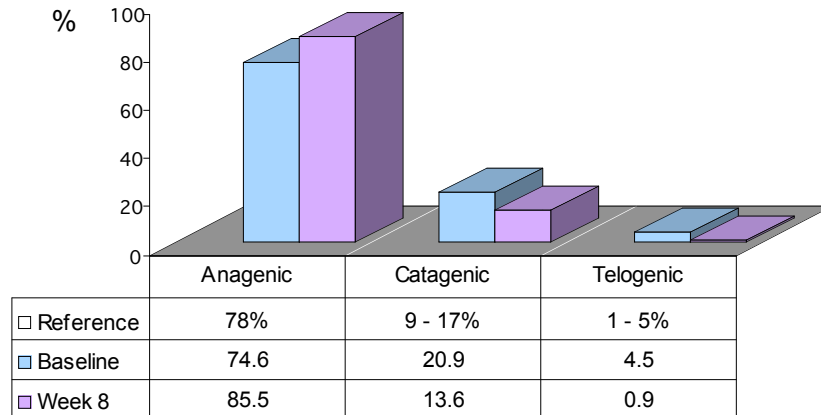
The rate of sebum production in all study volunteers was measured using “seba tape” at the beginning of the study and then after twelve weeks of Regenscalp™ application. By applying the tape patches near the hairline and conducting a computer-based image analysis of the used tape, researchers could determine the number of active sebaceous glands, their distribution and their size.

RESULTS

Effect on Hair Cycle

In order to determine whether Regenscalp™ had any influence on hair loss, the phototrichograms collected at baseline and week eight of the study were compared by computer analysis. In this way it was possible to distinguish whether Regenscalp™ had any influence on any of the three stages of the hair growth cycle. The averaged results for all study volunteers are illustrated in Figure 1.

**Fig 1: Hair Cycle Change
Baseline vs. Week 8, Averaged Results**



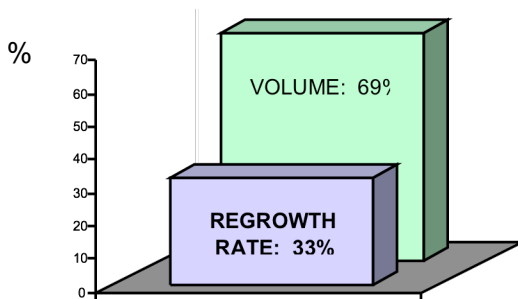
Computer analysis revealed a significant change in the hair growth cycle of *all study volunteers* while using Regenscalp™. **Indeed, the number of hairs in the growing anagenic phase of the hair cycle increased by 15% ($p \leq 0.01$) in study volunteers, while the average number of hairs in the transitional catagenic phase or resting telogenic phase decreased by a combined 43% ($p \leq 0.01$).**

Study volunteer's reports at trial's end (week 12) supported earlier observations, with the the majority reporting a favorable decrease in hair loss. **In particular, of the ten study volunteers, seven reported a decrease in their hair loss, one reported a cessation of hair loss, one reported no change at all, and one volunteer reported an increase in loss.**

Hair Volume & Regrowth Rate

During a comparison of the phototrichograms taken at the beginning of the study and at week 12, two highly favorable observations were documented that essentially confirmed the observed change in hair cycle at week 8. **In particular, both hair volume and the rate of hair regrowth were significantly increased after using Regenscalp™. Hair volume, which represents the thickness of growing hair, increased an average of 69% in the volunteer population. The hair regrowth rate, which combines the change in hair number, thickness and length per area of scalp into one comprehensive number, increased by 33% at trial's end.**

WEEK 12: AVERAGE INCREASE IN HAIR VOLUME & REGROWTH RATE



Study volunteers confirmed these technical findings in their own reports at trial end. Of the five (5) volunteers that categorized their hair as fine, all five participants considered that their hair was thicker at trial end. Volunteers with “normal” or “thick” hair noticed no change in hair volume.

Seborrhea

It is commonly appreciated today that the causes of hair loss are multiple, and include a mixture of genetic, hormonal and environmental influences. One of the environmental factors that may contribute to hair loss is an abnormality of sebum production on the scalp. De-regulated sebum production, which can result in either an unfavorably dry or greasy hair, may contribute to hair loss by creating a hostile environment for continued hair growth. **The seba tape method utilized in this study revealed an average 62% reduction in sebaceous gland activity when using Hair Restoring Gel.**

Study volunteers again reported favorable cosmetic changes in their hair after using Regenscalp™ when questioned about hair dryness or greasiness. Of the four study volunteers that reported dry hair at study outset, all four reported a decrease in hair dryness at study conclusion. Of the five participants that reported greasy hair, three reported an improvement and two cited no change. One volunteer with initially normal hair did not report any change.

CONCLUSION

The development of Regenscalp™ opens a new chapter in topical hair growth products. Regenscalp™ demonstrated significant objective efficacy at stimulating hair growth, reducing hair loss, increasing hair thickness and improving the environment for normal hair growth. More importantly, however, were study volunteer's own reports that highlight the ability of Regenscalp™ to positively affect hair loss. Eighty percent of study volunteers reported that Regenscalp™ decreased hair loss after just eight weeks of topical application. Of the study volunteers that classified their hair as thin at study outset, all of them reported noticeable thickening of their hair by study conclusion. That is the principle objective of Regenscalp™ Hair Restoration Gel.

In closing and as a point of reference, first generation hair growth products typically work on less than 33% of users at reducing hair loss after anywhere from 12-16 weeks of application. Occasionally, users must wait for up to one year to observe any benefit. Any hair regrowth that is reported is typically thin and ineffective at resolving the appearance of thinning hair.