Stromal Vascular Fraction Enhanced Adipose Transplantation in Hair Loss: Early Experience & Active Phase II FDA Investigation

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Introduction: Evidence demonstrates the role of adipose tissue in support of the stem cell niche and driver of the complex hair growth cycle. Additional evidence supports that the growth factors from adipose-derived stem cells can promote hair growth. Furthermore, a number of investigators reported an increase in hair *growth* after subcutaneous fat grafting.

This paper reports on a prospective, single blinded clinical trial of the effect of autologous and SVF enhanced fat grafting on hair growth for alopecia androgenica.

Material and Methods: Nine healthy patients (eight men and one woman) with pattern hair loss were treated by autologous fat transplantation enriched with stromal vascular fraction (SVF) to the scalp. Harvested lipoaspirate was separated into two aliquots. One aliquot was purified using the Puregraft system (Puregraft®, Puregraft LLC). The remaining tissue was digested to obtain concentrated stromal vascular fraction cells (SVF, Kerastem Technologies, LLC). The SVF was mixed with the purified fat tissue and injected into the affected areas of the scalp.

Patients were followed for safety, tolerability and differences in hair growth. We employed global photography and macrophotography with trichoscan analysis, to quantitatively track hair count, hair density, anagen/telogen rates (48 hours later), and cumulative hair thickness. Follow-up was at 6 weeks, 12 weeks, and 24 weeks.

Results: 6 patients were analyzed at 6-month, 3 patients were lost to follow-up. 6-month trichoscan analysis revealed an average of 14% increase in hair count compared to baseline ($p=0.01$) (mean difference of 28 hairs) along with a 34% average increase in the anagen percentage ($p=0.09$). An analysis of hair growth limited to individuals with Grade I-IV hair loss ($n=5$) showed an average of 17% ($p=0.02$) in hair count (mean difference of 30 hairs) at 6-months.

Conclusion: Initial data demonstrates that cell-enriched fat grafting to the scalp may represent a promising alternative to treating baldness in men and women. STYLE is an actively enrolling phase II study in the United States further investigating this promising therapeutic approach.