CHAPTER 8

Research and the Future of Treatment

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Numbered citations in parentheses refer to the list in Chapter 10: References.

What New Treatments for Women's Hair Loss Are Being Researched?

Our patients frequently ask us what other treatments are being investigated and could be "on the horizon" in the months and years ahead to correct female hair loss. I lecture globally on hair loss because of my research in this field, which allows me to network with colleagues around the world who are also developing innovative strategies to improve alopecia. Together, we discuss the latest drugs and other therapies that are currently under investigation.

Every week, Dr. Stuart and I are asked by patients about **new and emerging treatments for women's hair loss** that they have discovered through their own research on the internet. We explain that it can be difficult for patients without a medical background to distinguish scientific facts from exaggerated claims or misleading information. **Our practice is based upon following the science**, not science fiction. Our goal is to clarify the scientific evidence supporting these emerging treatments and help patients make informed decisions about which treatments are safe, effective, and supported by clinical research.

Clascoterone For Women's Hair Loss

Clascoterone is a topical antiandrogen that is similar to finasteride. Both medications **act to reduce the effects of dihydrotestosterone (DHT) on genetically susceptible hair follicles, but utilize distinctly different mechanisms of action**. Finasteride inhibits the enzyme 5-alpha-reductase, which converts testosterone to DHT. In contrast, clascoterone competes with both testosterone and DHT for binding to androgen receptors, **thereby blocking their effects on susceptible hair follicles**. (102, 103)

Clascoterone 1% cream (Winlevi) is already FDA-approved for the treatment of acne. A higher-concentration 5% topical solution, known as Breezula, is being developed as an investigational treatment for androgenetic alopecia. (102, 104,105)

Two large Phase III clinical trials involving a total of 1,465 men with androgenetic alopecia reported statistically significant improvements in target-area hair counts after six months compared with the vehicle control. However, these results have not been directly compared with topical finasteride or minoxidil, both of which have established clinical evidence supporting their efficacy in androgenetic alopecia. (103, 104, 105, 106)

Importantly, these Phase III trials were conducted in men, and comparable Phase III clinical efficacy data in women are not yet available. Therefore, although clascoterone represents a potentially promising new topical antiandrogen treatment, its effectiveness and long-term safety specifically for female pattern hair loss remain to be established. (104,105)

Can Exosomes Stimulate Hair Regrowth in Women?

There has been considerable interest and speculation about **using exosomes to treat women's hair loss**. But what exactly are exosomes?

Exosomes are **extremely small, membrane-bound particles released by many different types of cells**, including stem cells. Exosomes are a subtype of extracellular vesicles (EVs) that carry biologically active substances, including proteins, growth factors, and genetic material, which allow cells to communicate with one another. Unlike stem cells, exosomes are not living cells and cannot divide, reproduce, or develop into new hair follicles. [107]

Normal hair growth depends upon complex interactions between hair follicle stem cells, dermal papilla cells, and the surrounding tissues. Laboratory research suggests that **certain exosomes may stimulate cellular signaling pathways involved in hair growth and influence the environment surrounding the follicle**. These findings have generated considerable interest in their potential use for hair regeneration. [107, 108]

Although preliminary clinical studies have reported improvements in hair density following certain exosome-based treatments, most have involved relatively small numbers of patients with limited follow-up. One prospective study involving 30 men with androgenetic alopecia reported statistically significant improvements in hair density after 12 weeks, although the study lacked a placebo control group. [109] A 2025 systematic review identified 11 clinical studies, including two randomized trials, but differences in study design and exosome preparations limit the conclusions that can be drawn. [108] There is currently insufficient high-quality clinical evidence to establish that exosomes can produce predictable, meaningful, and sustained hair regrowth in women with female pattern hair loss. [107, 108]

An additional concern is that **not all exosome preparations are the same**. Their biological activity may vary depending upon the cells from which they are obtained and how they are processed. [107, 108] Furthermore, no exosome products are currently FDA-approved for treating hair loss or any other medical condition in the United States. The FDA has specifically warned patients and physicians about unapproved exosome products marketed for regenerative medicine because of concerns regarding safety, efficacy, and manufacturing quality. [110]

The central question is whether exosomes can eventually produce clinically meaningful and sustained hair regrowth beyond what established medical treatments can already achieve. Until larger, well-controlled clinical trials demonstrate their safety and effectiveness, exosome therapy for women's hair loss should be considered investigational. [107, 108]

Stem Cell Therapy For Hair Regrowth in Women

Our patients frequently ask Dr. Stuart and me about undergoing "stem cell treatments" for their hair loss after discovering this information on the internet. There is much confusion about these therapies and their role in the management of hair loss in women, so this section is designed to clear up any misconceptions about stem cells.

First, it is important for us to define "stem cells" to avoid any confusion. Stem cells have two important properties: **the ability to self-renew and the potential to develop into other specialized cell types**. Human hair follicles also contain stem cells that contribute to the normal hair growth cycle. The question is whether these stem cells can stimulate thinning hair follicles to produce thicker hair.

One of the most widely studied sources for stem cells is a patient's own fat, which is usually obtained through a small liposuction procedure. Fat contains several types of cells, including cells with regenerative properties that may help support hair growth. Scientists can isolate a mixture of these cells called **stromal vascular fraction, or SVF**. [111]

Another approach uses substances released by these cells, which include growth factors and other natural signaling molecules. This is called stem cell-conditioned media. Scientists are studying whether these treatments can stimulate hair growth by **improving the conditions surrounding the hair follicle**. These approaches are not identical, and we do not yet know which preparation, if any, produces the best long-term results. [112]

A randomized clinical trial found a 28% increase in hair counts after 16 weeks using a topical preparation derived from fat stem cells, compared with approximately 7% in the placebo group. However, only nine of the 38 participants were women. [112]

Another clinical study reported approximately 52% improvement in hair density using SVF combined with PRP, compared with approximately 22% using PRP alone. However, differences between the treatment groups limit the conclusions that can be drawn from these results. [113] A systematic review involving 188 patients reported improvements in hair density across six studies, although the studies were relatively small and used different treatment methods. [111]

Although these early results are encouraging, we still do not know whether these treatments will produce significant and lasting improvements in women's hair growth. These studies have not demonstrated that stem cell treatments can reliably produce entirely new hair follicles. [111, 112, 113]

No stem cell or SVF treatment is currently FDA-approved specifically for women's hair loss. Although these treatments are sometimes advertised as natural because they may use a patient's own cells, this does not automatically establish their safety or effectiveness. The FDA has warned about unapproved regenerative treatments being marketed before adequate clinical studies have established their safety and benefits. [110] We need larger clinical studies with longer follow-up before we can determine whether these treatments are truly effective and safe. [111]

Can Hair Cloning Cure Hair Loss in Women?

Many of our patients ask Dr. Stuart and me **whether scientists can actually clone new human hair follicles**. This is a particularly important question for women and men who do not have enough donor hair for conventional hair transplantation. Traditional hair restoration simply moves existing follicles from one part of the scalp to another. Hair cloning seeks to **create additional follicles from a patient's own cells**. Dr. Stuart and I have been directly involved in research directed toward this goal for several years.

First, it is important to understand that a human hair follicle is a miniature organ, not simply a hair shaft. Epithelial stem cells, dermal papilla cells, and multiple supporting cell populations must communicate with one another within a specialized environment known as the follicular niche. Recreating this coordinated biology has been one of the major challenges in regenerative medicine.

Our Pioneering Research with Stemson Therapeutics

Our collaborative research with Stemson Therapeutics **placed us among the early research groups worldwide developing human hair follicle structures using induced pluripotent**

stem cells (iPSCs). These are cells from human volunteers that can be reprogrammed and directed to form specialized cell populations. Our scientific collaborators developed laboratory-engineered follicular structures and demonstrated hair production in preclinical animal models. I also coauthored a 2021 article in Plastic and Reconstructive Surgery with Dr. Antonella Pinto and Dr. Alexey V. Terskikh describing the scientific basis for using induced pluripotent stem cells in hair restoration. [114]

Figure 1. Experimental follicle-like organoids and hair production in preclinical mouse models. Source: Stemson Therapeutics. Animal-model findings, not a human clinical treatment.

The research then progressed beyond growth in mouse skin. Human skin donated by patients undergoing cosmetic surgery at my practice was grafted onto immunodeficient mice. Engineered follicular units were subsequently shown to produce human hair in this human-skin xenograft environment. Fresh, intact human follicles from patients undergoing FUE hair transplantation in my practice also served as experimental controls in our studies.

Figure 2. Stemson's bioprinted follicular units and experimental hair growth in a human-skin xenograft carried by an immunodeficient mouse. Source: Stemson Therapeutics.

Much of the foundational work involved important contributions from Evan Y. Snyder, MD, PhD, Shiri Gur-Cohen, PhD, and their respective laboratories, together with the broader Stemson scientific team. Although Stemson subsequently ceased operations because of insufficient funding, these experimental accomplishments remain important. They helped establish a scientific foundation for the research we have continued through InSitura Bio.

Another Approach: HairClone and Dermal Papilla Cells

HairClone, a biotechnology company in the United Kingdom, is investigating **whether dermal papilla cells obtained from a patient's own follicles can be expanded in the laboratory and reintroduced into areas of thinning hair**. Dermal papilla cells are important regulators of the hair growth cycle. This is a serious scientific approach, but the clinical efficacy, durability, and safety of the company's current treatment program still require rigorous evaluation. We believe that focusing on one cell type may not capture all the important biology of a functioning follicle.

Our Current Research: Preserving the Entire Hair Follicle Niche

Disclosure: Dr. Stuart and I are co-founders of InSitura Bio.

Our continuing research through InSitura Bio takes a different approach. Dr. Stuart and I are working with Dr. Snyder, Dr. Gur-Cohen, and their laboratories to **investigate the regenerative potential of preserving the intact human hair follicle** and its surrounding niche. We are interested not only in stem and progenitor cells, but also in the supporting cells, signaling molecules produced by these cells—the secretome—and the surrounding vascular and lymphatic environment. Dr. Gur-Cohen's published research has demonstrated that **lymphatic vessels help regulate hair follicle stem cells and tissue regeneration**. [115]

Figure 3. Fluorescence-stained human hair follicle showing the anagen follicle and its major anatomical regions, including the stem cell niche and dermal papilla. Source: Gur-Cohen laboratory.

In our laboratory, **we have successfully cryopreserved and banked fresh, intact human hair follicles obtained from our own patients.** After thawing, the follicles were placed in culture, where we observed spontaneous outgrowth and proliferation of multiple cell populations associated with the follicular niche. Unlike simply isolating a single cell type, this experimental approach allows us to study a broader and more complex cellular environment. Our observations are promising, but we are continuing to characterize the different cell populations and their functions.

Figure 4. Fluorescent staining of follicular structures and niche-associated cell markers in the research program, including markers relevant to epithelial and lymphatic biology. Marker expression alone does not establish a functioning lymphatic network.

One possible future application is the **ability to preserve a patient's own follicles while they remain healthy and recover their cells for later study or treatment development**. Our research program includes a process for follicle collection, culture, cryopreservation, thawing, and subsequent investigation. The diagram below illustrates that research strategy; its proposed clinical applications have not yet been established.

Figure 5. Research workflow illustrating intact follicle collection, culture, cryopreservation, subsequent thawing, and proposed future uses. The transplantation steps are proposed applications, not demonstrated clinical outcomes of the current banking platform.

What Does This Mean for Women with Hair Loss?

Our long-term hypothesis is that **preserving more of the natural follicular environment may ultimately produce a more meaningful regenerative response than an approach limited**

to one isolated cell population. However, this hypothesis has not been tested in a direct clinical comparison with HairClone or other cell-based treatments. We have not yet established that the cells recovered from our banked follicles can reliably generate new hair follicles or restore hair density in patients.

This is where we believe the future of hair restoration may lead, but it is important to follow the science rather than make promises before the necessary studies have been completed. The pioneering work at Stemson, our clinical contribution of human tissue and control follicles, and our continuing laboratory investigations are very different from simply offering hair transplantation. At California Hair MD, Dr. Stuart and I are **committed not only to providing established treatments today, but also to working with leading scientists to investigate the treatments that may become available to patients tomorrow**. Our ongoing scholarship also includes a contribution intended for a forthcoming volume on regenerative therapies edited by Dr. Patrick Tonnard and Dr. Alexis Verpaele.