

I thought I would put all of the information I could find regarding Follica into one thread seeing as information seems to be dotted around and there seems to be no clear consensus as to what their product actually is.

## **Clinical Trial**

The only clinical trial I could find is located here: <https://www.clinicaltrialsregister.eu/ctr-search/trial/2009-018191-34/DE#A>

Title: A Study to Explore the Effect of Controlled Cutaneous Perturbation and Pharmacologic Modulation for Inducing Follicular Neogenesis

Short Title: Lithium gluconate in hair follicle regrowth

Summary: 4mm Perturbation followed by topical application of 8% (w/w) Lithium gluconate gel.

This was a Phase 2 trial completed 2011. No results or photos available.

## **Patents**

Follica have a few different patents. I understand that companies sometimes take out patents to reduce the possibility of competition but it is still interesting to see what Follica potentially have up their sleeve. I won't list them all, just the key ones and I will try to post any key information in this block of text.

### Patent 1 - 'The Device'

<https://www.google.co.uk/patents/US20110130748?dq=follica&hl=en&sa=X&ved=0ahUKEwiB1q3U7LnSAhVpDMAKHfrRDUIQ6AEINjAE>

10

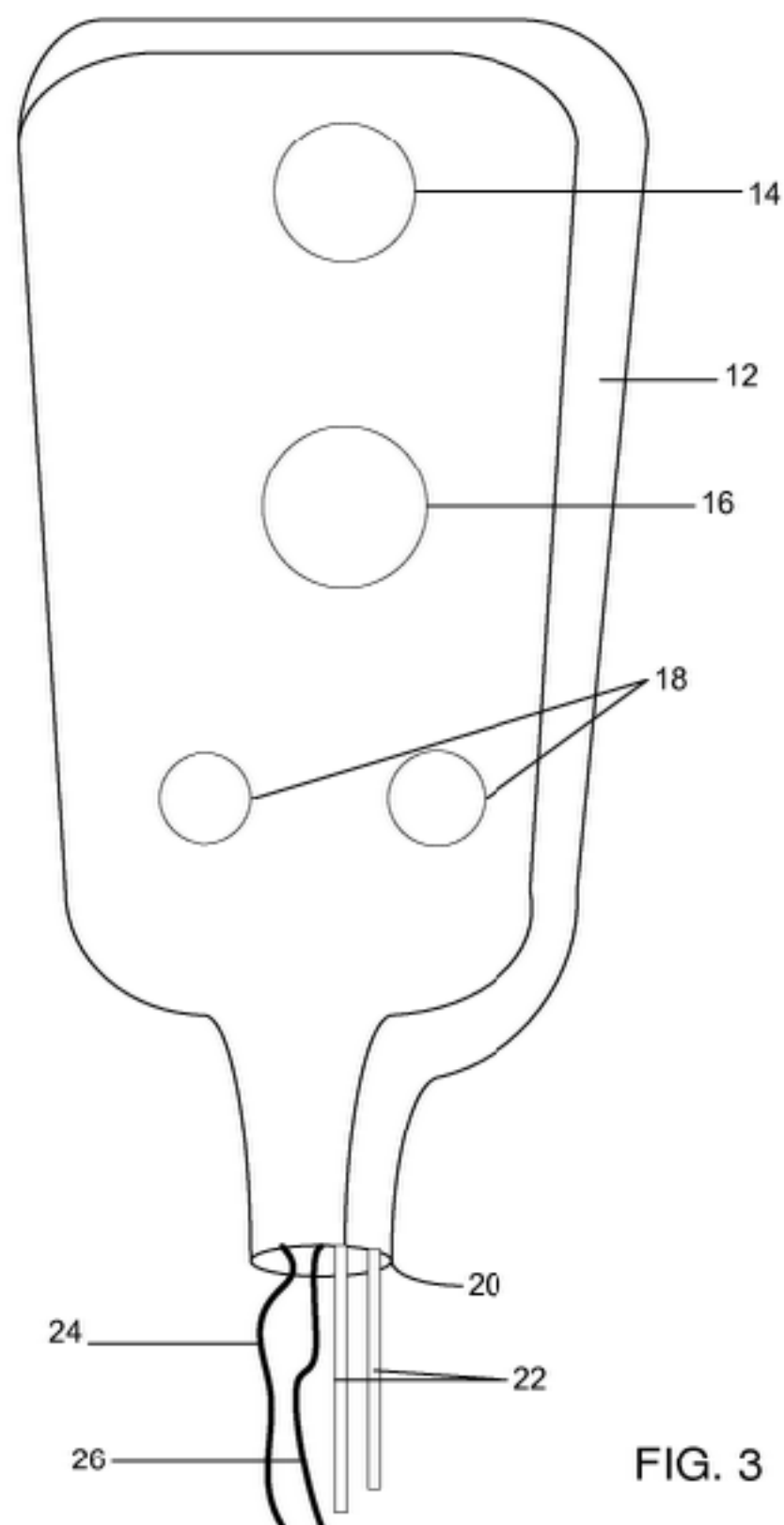
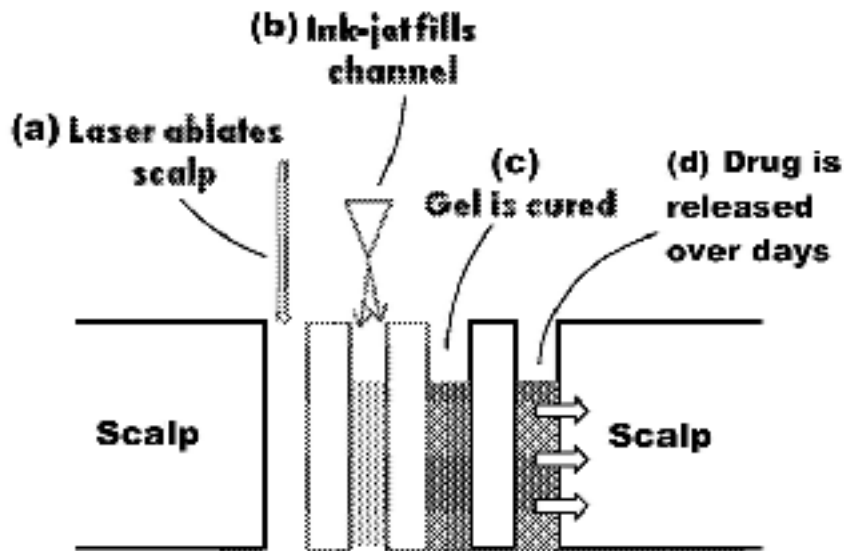
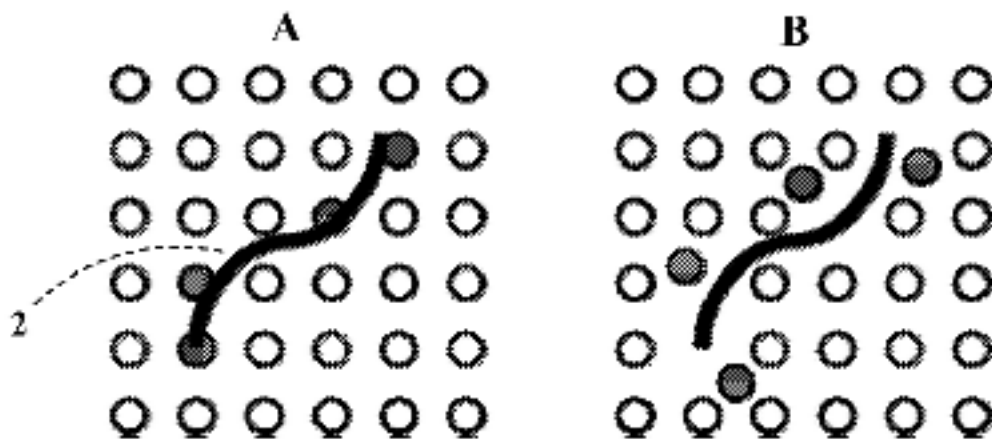


FIG. 3

**FIG. 1**



**FIG. 2**



Now this is interesting. Suggests that perturbation is achieved using a laser instead of a needle. From what I can gather, this also shows that there will be a gel (possibly the Lithium Gluconate mentioned in their trial) that will be injected into the scalp and then released over a period of days. This drawing also seems to be similar to the ones seen on their website.

## Patent 2 - 'Pulse Lithium Treatment'

Filed: 2010

Essentially lays bare the Follica method. A 4mm punch biopsy is taken and then the void is filled with Lithium Gluconate (the Patent claims that Lithium ions induce follicle neogenesis). The treatment is then followed up by a course of finasteride and minoxidil (before everyone panics, there is a later patent for topical Finasteride which will mean that side effects are vastly reduced) in order to grow the newly regenerated follicles.

## Patent 3 - 'EGFR Inhibitor'

Filed: 2007

<https://www.google.co.uk/patents/US8252749?dq=follica&hl=en&sa=X&ved=0ahUKEwiB1q3U7LnSAhVpDMAKHfrRDUIQ6AEIKDAC>

Details the use of a topical EGFR inhibitor and provides various structures.

If you click on the link you will find a number of experimental results that suggest this works.

## Patent 3 - 'GSK-3 Inhibitor'

Filed: 2011

<https://www.google.co.uk/patents/WO2012065065A9?cl=en&dq=follica&hl=en&sa=X&ved=0ahUKEwiB1q3U7LnSAhVpDMAKHfrRDUIQ6AEILzAD>

Glycogen synthase kinase 3 inhibitor. The patent again provides a number of potential structures.

Really interesting paragraph:

"the Compound can be administered concurrently or alternating sequentially with one or more of the following agents to promote or induce hair growth: a prostaglandin F2a analog, bimatoprost (Latisse), latanoprost, travoprost, tafluprost, a 5a- reductase inhibitor, minoxidil, kopexil (for example, the product Keranique™), finasteride, CaCb, or

adenosine. In another embodiment, the Compound is administered concurrently or alternating sequentially with one or more agents that prevent hair follicle cells from senescing to promote hair growth and hair follicle formation (which may, in turn, promote wound healing with reduced scarring), for example, anti-oxidants such as glutathione, ascorbic acid, tocopherol, uric acid, or polyphenol antioxidants; activators of Wnt signaling; inhibitors of EGF signaling; inhibitors of BMP signaling; inhibitors of reactive oxygen species (ROS) generation, such as superoxide dismutase inhibitors; stimulators of ROS breakdown, such as selenium; mTOR inhibitors, such as rapamycin; or sirtuins or activators thereof, such as resveratrol, or other SIRT1 , SIRT3 activators, or nicotinamide inhibitors."

Also, we have read in the news about Cotsarelis' research into scar healing. From the patent, there is possibility for this treatment to be used in scar healing. It has a paragraph that might interest everyone here:

#### 7.14 TREATMENT FOLLOWING FOLLICULAR UNIT

##### TRANSPLANTATION

[00741] A 51 year old white male with history Androgenic Alopecia undergoes Hair Transplant with the "Strip Harvesting Method" with donor area located at the posterior scalp along the occipital protuberance. Surgery requires a long scar on the posterior scalp measuring 28 cm. Starting Day 1 , topical Compound is applied only to the 14 cm "left" portion of the scar (in addition to routine wound care), one time per week. In 3 and 6 week follow-up, the right and left aspects of the scar are compared with respect to skin thickness, return of pigmentation, re-establishment of adnexal structures and global assessment the physician and patient's satisfaction regarding the cosmetic result of the 2 distinct lesions using a Visual Analogue Scale (VAS).

[00742] In a variation, hair that is regenerated in the treated donor area may be used as a source of future, repeated hair transplants in accordance with the foregoing method.

#### 7.15 TREATMENT FOLLOWING FOLLICULAR UNIT EXTRACTION

[00743] A 51 year old white male with history Androgenic Alopecia undergoes Hair Transplant with the "Follicular Unit Extraction" with donor area located at the posterior scalp above and below the occipital

protuberance. In total 1000 punch graft were taken from the posterior scalp and left to heal with secondary intention. Starting Day 1 , topical Compound is applied only to the "left" portion of the donor area (in addition to routine wound care), for one time per week. In 3 and 6 week follow-up, the right and left aspects of the scar are compared with respect to skin thickness, return of pigmentation, re-establishment of adnexal structures and global assessment the physician and patient's satisfaction regarding the cosmetic result of the 2 distinct lesions using a Visual Analogue Scale (VAS).

[00744] In a variation, hair that is regenerated in the treated donor area may be used as a source of future, repeated hair transplants in accordance with the foregoing method.

Basically, Follica may soon be able to heal transplant scars, leading to donor regeneration. Also those who have FUT scars may be able to get those sorted.

#### Patent 4 - 'Topical Minoxidil, Finasteride and Prostaglandin'

Filed: 2015

<https://www.google.co.uk/patents/WO2015176161A1?cl=en&dq=follica&hl=en&sa=X&ved=0ahUKEwiB1q3U7LnSAhVpDMAKHf rRDUIQ6AEIPTAF>

The invention relates to a composition comprising 2% to 5% minoxidil, 0.01% to 15% finasteride and 0.01% to 15% of a prostaglandin analogue.

This patent is annoying. It describes what sound like photos (something we've never had from Follica) but they won't load! One of the figures also contains the amounts of chemicals you need to make this topical yourself (it states the method in the text).

Interesting paragraph:

#### Results

A. Treatment With Composition Comprising Finasteride, Latanoprost and Minoxidil

Each participant first had his hair analysed as described above and photographs taken. Following the first analysis, each participant was provided with a solution comprising 0.1% finasteride, 0.03% latanoprost and 5% minoxidil prepared as described in Example 1 above. The participants applied 1 ml to the scalp, once a day after cleansing. The 1 ml was applied as 10 metered dose sprays of 0.1 ml. The results for three participants are provided. Participant 1 was a male of 61 years of age (Figure 1). Participant 2 was a male of 23 years of age (Figure 2) while participant 3 was a male of 29 years of age (Figure 3). All three participants had androgenetic alopecia, as did the participants of the comparator groups.

Figures 1 , 2 and 3 clearly show a marked decrease of hair loss and an increase in hair regrowth in all three participants.

They then repeated the experiment with each drug taken individually. "The improvements shown in the reduction of hair loss and the increase of regrowth hair for the composition of the invention are superior to the improvements seen for each of the components of the composition taken individually and the results obtained to date suggest that the improvements may be superior to those of the sum of the said components."

- So the solution of all three combined is more effective.

### Other

Most of the patents mention Wnt modulation and even provide some possible drug structures. We know already that this is the approach Samumed are taking, so if Follica can somehow replicate a bit of what Samumed are doing along with everything else they have, it might turn out to be a very promising treatment.

### **Summary**

I am expecting the Follica product to include:

- 4mm Perturbation with a laser
- Lithium Gel to be placed into the resulting gap
- This treatment will then be followed by a daily application of a combined topical of Finasteride, Minoxidil and Prostaglandin.

Will be interesting to see how ERFR and GSK-3 inhibitors and Wnt activators fit into the equation.

Overall this will be far more complex than the simple 'dermarolling plus minoxidil' treatment people are expecting.