

AFFINITY - A novel system for direct Intrafollicular infusion of liquid solutions containing active ingredients.

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### **Intrafollicular infusion**

Skin provides the largest interface between the human body and the external environment and at the same time serves as an effective barrier. It prevents excessive loss of water from the body and likewise blocks entry of most topically applied substances, except for ones which are lipid-soluble and of low molecular weight. Under physiological conditions the intact stratum corneum significantly impedes penetration of large hydrophilic, charged molecules and particulate substances through the skin.

A number of strategies are currently employed to overcome the barrier function of the skin to enhance penetration of therapeutic compounds. Substance delivery through the hair follicles has gained a lot of interest in the field of skin penetration research as the follicles represent an important pathway for topically applied substances. They function as a reservoir and also as portals of entry to viable skin. In addition, they represent invaginations of the epidermis, which significantly increase the skin surface area available for penetration. It has been shown experimentally that when follicular openings are selectively blocked during intrafollicular infusion, a subsequent decrease of concentration of the active compounds is measured in the skin. Calculation of total ducts inner surface is difficult, since it varies with age, sex, locale, etc., but it is estimated as being ten times greater than the total size of the epidermis. Therefore, the presence of large numbers of hair follicles significantly increases the penetration rates of topically applied compound. [1-3]

Hair follicles also serve as a reservoir, in which active substances are protected from shedding, and are retained for prolonged time periods, enhancing their penetration to and through the skin cells.

Furthermore, due to the follicular ducts' orientation down through the skin, the pores can serve as a channel leading to the depth of the dermis. Deposition of active compounds in the depth of the follicle may target specific cell groups there, such as follicular stem cells, important for skin rebuilding and regeneration. [4]

Following the understanding of the possible advantages of transfollicular penetration, different therapeutic approaches have been developed over the last several years. One of them is direct intrafollicular infusion of liquid solutions containing active ingredients. [5]

To achieve intrafollicular infusion, the system must fulfill the following requirements:

1. The liquid delivery source has to be directly attached to the follicular orifice. If not, due to duct resistance, liquid flow will flood the skin surface instead of being delivered into the duct.
2. The diameter of the flow source apparatus has to be smaller than that of the duct orifice. If not, the flow impact will deform the surrounding tissue to create a “check valve” having a closing effect on the duct orifice.
3. To create a short-term linkage between the duct pores and supplying nozzles to fill up the follicular reservoir, constant motion of the liquid delivery hand piece over the skin is required.

### **Affinity system**

The Affinity system was recently developed to accomplish intrafollicular delivery of active substances. The “heart” of the system consists of plastic tips, having two micro-nozzles each of 50  $\mu\text{m}$  diameter, attached to the rotating delivery apparatus. As a result, this novel design produces rotating micro-jets of solution (Fig. 1).

Installed on the ergonomic hand piece, the tip comes in direct contact with the skin surface. Then, a negative pressure is created linking the skin surface with the rotating nozzle openings. At this moment, solution begins to flow through the nozzles under moderate pressure. While the operator moves the hand piece slowly over the treatment area, each time a contact occurs between an open pore orifice and a micro-nozzle emitting a micro-jet of solution (outlet?), follicular space is filled with the solution. (Fig.2). Negative pressure (vacuum) helps to support skin and tip contact during treatment. It also recovers wasted solution, keeping the treatment area dry.

The infused solution is now “locked” in the follicular duct, walled by only two layers of epithelial cells in the depth of the dermis, with a larger potential absorption area and longer contact time. This magnifies the biological activity of the active ingredients in the solution.

The procedure is easily carried out, with the only skill needed by the operator being the ability to keep gentle contact between the treatment tip and the skin surface. Hard pressure will deform the surrounding skin and duct structure and may completely close it.

Active ingredients, including bleaching substances, antioxidants, vitamins and any other compounds targeting deeper layers of the skin, but so far blocked by the natural biological defense systems, can be delivered more effectively by the

Affinity system. Not only is penetration of these ingredients more effective through the follicular walls, but the longer contact time between the solution in the follicular reservoir and the skin cells, increases the partition coefficient of absorption (similar to the patch technique).

Other groups of therapeutic substances that can be delivered by Affinity include peeling agents such as alpha or beta hydroxy acids, trichloroacetic acid, and more. Because of the more efficient absorption, lower concentrations of the peeling agents produce more significant effects. In the case of peeling substances, while lower parts of the follicular duct are “attacked”, the upper parts remain relatively spared. In addition, the focal mode of penetration, centered exclusively on the follicles, creates fractional damage to the skin with faster regeneration.

To accommodate various treatment targets and treatment zones, Affinity's working parameters can be changed to regulate the amount of infused solution and the depth of its delivery.

### **Treatment protocol**

Treatment protocol includes a series of 4-6 weekly or bi-weekly treatments. In the maintenance phase, treatments can be spaced to accommodate the patient's wishes. While during the treatment light discomfort can be sensed (due to motion of the hand piece under negative pressure), the post-procedural course is eventless.

The results are usually already visible just a few days after the first procedure. Because the intrafollicular effect is three-dimensional, the changes to the quality of the skin take place throughout its thickness, producing the aesthetic result (Fig. 3-5).

Due to the high safety of the system, Affinity provides an unmatched opportunity to treat non-facial skin, such as the neck, décolleté and all other follicle-bearing areas.

### **Reference:**

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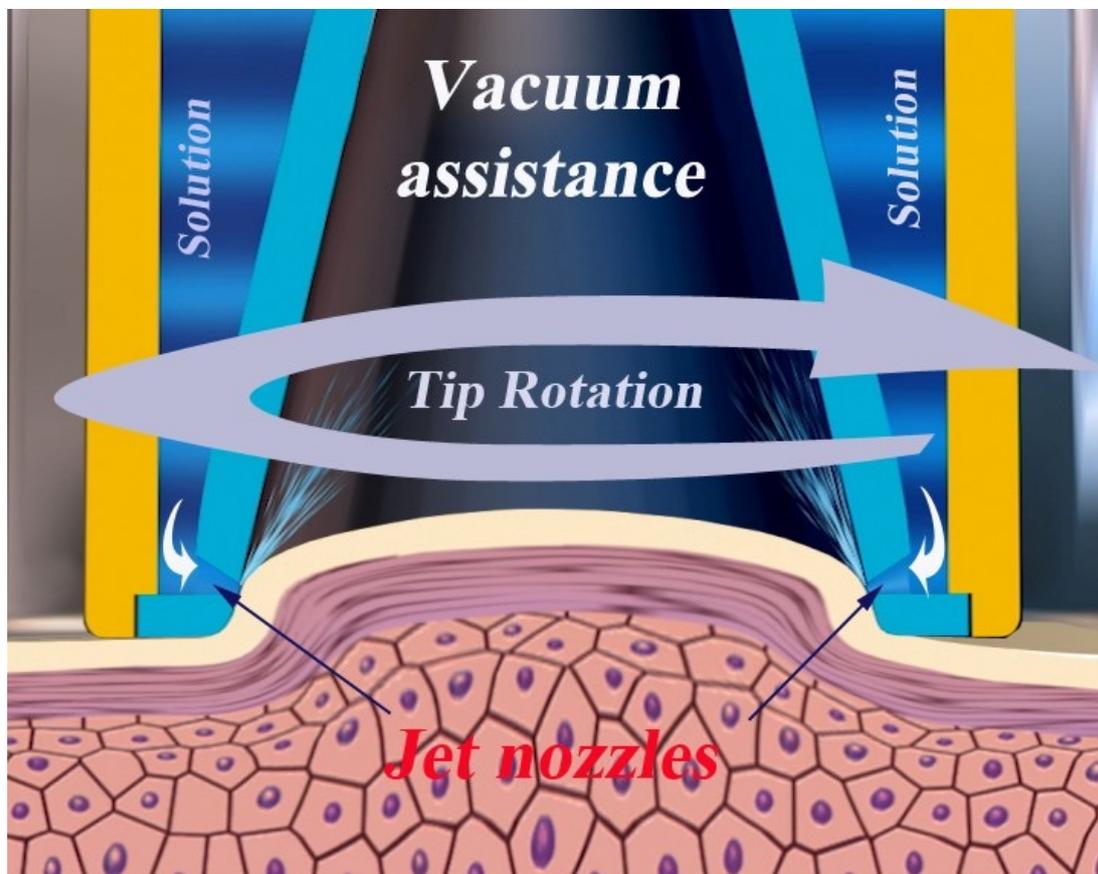


Fig. 1: Rotating micro-jets of solution are delivered through two micro-nozzles, each of 50  $\mu\text{m}$  diameter

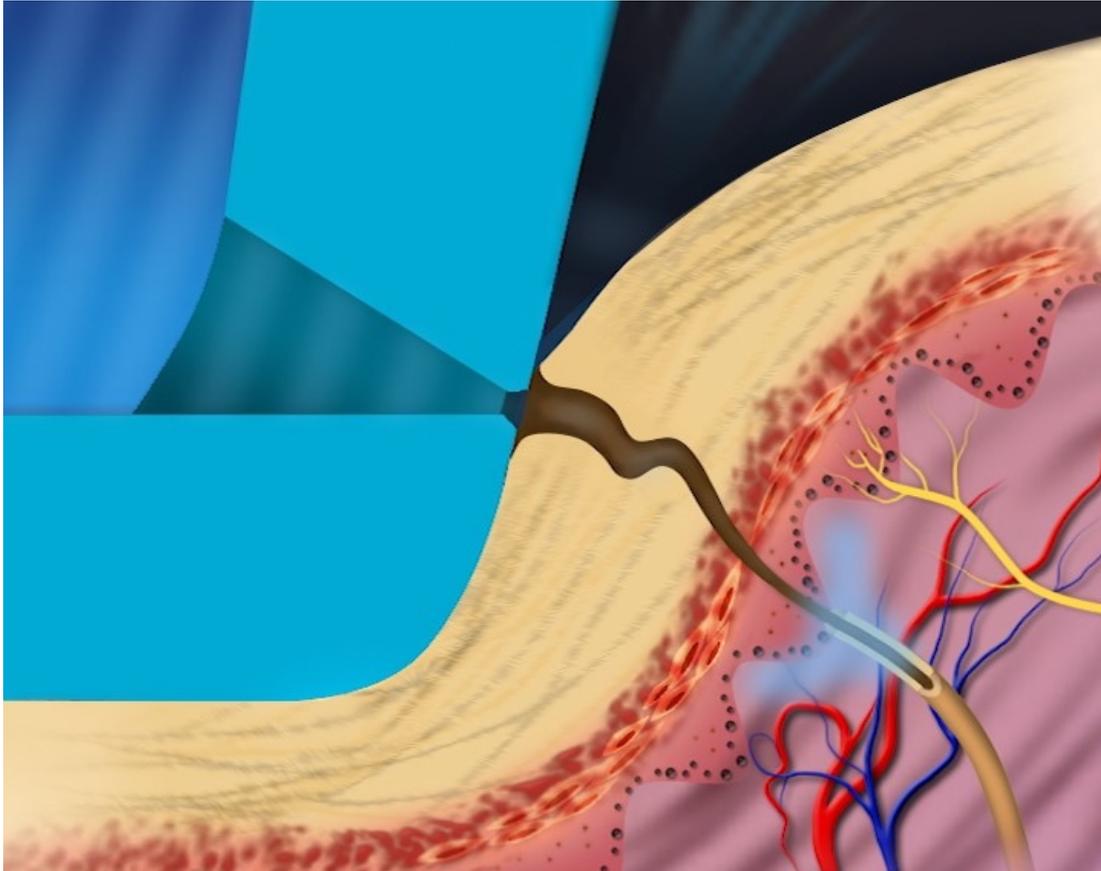


Fig. 2: Each time a contact occurs between the pore orifice and the jet nozzle, follicular space is filled with solution



Fig. 3: 67-year-old patient after 2 sessions of Affinity treatment for skin aging



Fig. 4: 46-year-old patient with acne scars after 2 sessions of Affinity treatment



Fig. 5: 42-year-old patient with melasma after one treatment session with the Affinity system