Tattoo Pigment Delivery with a laser-based microjet injector

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We introduce a new needleless microjet injector that uses laser pulse energy to inject tattoo pigments for Scalp Micropigmentation (SMP) directly through the skin without a needle. It has the advantage of an almost painless experience, eliminating the need for anesthesia.

How a Traditional Cosmetic Tattoo Instrument Works: The traditional SMP that we use today, employs a needle system, where three very small needles (manufactured as a single unit package in close proximity are dipped in tattoo pigment (ink) cups (like the old quill pens of the 1700's). Sometimes the tattoo pigment (inks) are placed in a well on the handpiece. The three needles reciprocate at 100 to 150 cycles per second relative to each other. The pigment is held by surface tension between the needles so there is no volume control over the pigment introduction. The needles are then inserted through the scalp. With a speed of 100 to 150 cycles per second, during a 0.25 second hold time through the epidermis, this 3-needle tattoo system will make approximately 25 to 37 holes in the epidermis. The pigments adhere to the three needles through surface tension. A portion of the pigments 'rub-off' through the epidermal hole while some of the pigment is deposited into the upper dermis.

The process of moving pigments into the upper dermis once the needles are placed there, is not an exact process. It depends upon many factors, such as (a) needle reciprocating speed, (b) the size of the needles, (c) the viscosity of the pigment which dictates the surface properties of the pigments, and (d) time the needles are left in the upper dermis. These needles create 'holes' or tracts in the epidermis that remain open one to three days before sealing. If the patient uses a shampoo before these holes seal, the detergent action of the shampoo can enter these holes and disperse the pigments in the upper dermis, changing the size, shape and depth of the tattoo pigments. Shampooing or any alcohol- based product must be avoided for three days.

These multiple 'holes' (or tracts) in the epidermis/dermal layer create several problems:

(1) the pigments always leak out of the tracts or holes as they are created and after the process is complete.

(2) the depth of the holes cannot be precisely controlled as it is dependent on the force applied by the operator, which is "felt" by the operator. It takes months or years for an operator to learn this process and not everyone can master the 'feel' requirement for efficient operation of the three-needle system.

(3) the duration that the needles are held in the skin is, at best, an estimate and varies with the operator and the operator's reflexes and judgments.

(4) the angle the needles are held in relation to the skin, vary with skin toughness and operator preferences.

(5) the operator controls the time the needles are left in the dermis based upon the 'feel' that the needles broke through the epidermis and entered the dermis.

These factors play a significant role in making it very difficult (a) to control the precise volume of pigment introduced, (b) to control a precise depth of the skin/dermal layer penetrated, (c) to

avoid leakage of the pigments out of the dermis after the process is complete, and (d) to avoid repeat patient encounters to adjust to (c) above.

With the traditional three-needle tattoo technology, the entire process is plagued by human variability. As such, the pigment left behind is an art form which is operator dependent. To control pain, SMP is most often performed, in our hands, using local and topical anesthesia. We find that the continuous needle penetrations cause considerable pain that is not tolerable in most patients. A ring block for the scalp has been our traditional approach to anesthesia.

The GriMii instrument: This new device uses *"an infrared laser beam of high energy (~3 J/pulse), which is focused inside a driving fluid in a small chamber. The pulse then induces various energy releasing processes and generates fast microjets through a micronozzle.*
The elastic membrane of this system plays an important role in transferring mechanical pressure and protecting the pigment from heat release". Essentially, the laser instantly vaporizes distilled water (the bubble in the diagram) which explodes creating a huge instantaneous pressure gradient behind the membrane, thereby pressurizing the chamber behind the membrane. The pigment (ink or drug) sits on the other side of the membrane and the pigment is instantly propelled though the nozzle into the skin.

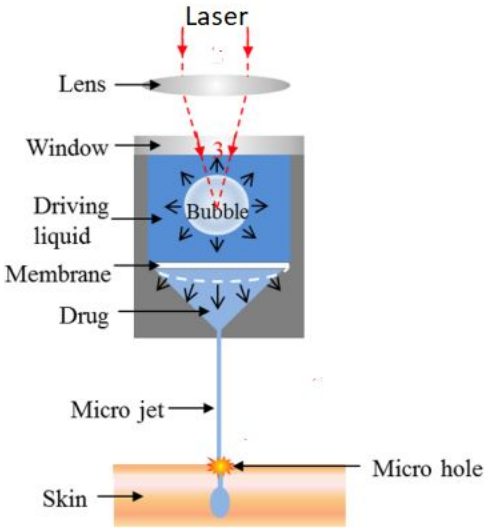

Figure 1: Schematic of pigment (drug) delivery with a microjet injection using a beam splitter (modified and taken from Hun-jae Jang et.al [2])

With proper instrument settings, controlled volumes of pigment can be released with each pulse. This device is likely to replace the standard cosmetic tattoo system that we have been using for Scalp Micropigmentation (SMP) for the past 9 years, if not in its present iteration, then most likely in the next generation system as the handpiece gets smaller for more refined work.

Since the **GriMii System** can control the depth and 'dot size', it produces an almost perfect visual 'dot' in a single pass and places the pigment into the upper dermis at the correct depth.. Dot size and depth can be controlled. There is no 'hole' created in the epidermis; therefore, there is no leakage of the pigments out of the skin. This makes the first application the last application because the dots remain after the process is complete. The hand piece, at present, is

cumbersome for detailed SMP work, but for those who want their hair appear thicker, e.g. (a) for the treatment of a depleted FUE donor area or (b) scars in the donor area, such detailed placement is unnecessary and the **GriMii** technology works well. We have used it successfully and the patients experienced minimal pain which is easily tolerated without anesthesia. Best of all, the training time is short and it is almost impossible to deliver the 'dots' at an improper depth or at an improper size. Considering the problems (explained above) that have plagued SMP providers, without significant experience, this new technology offers a way to provide a high- quality service with less human variability.

Discussion: The authors have held numerous 2-3 hour didactic courses at ISHRS meetings, teaching SMP. We find the subtleties of the operation of the three-needle system has imposed significant quality control problems for those who have taken these courses when they applied what they learned to their patients. We have, however, successfully trained doctors and technicians from other doctor's offices after they spent a week with us and gained more extensive hands-on experience. This new laser-based injector system solves the fundamental training and operational issues imposed by the three-needle system. It appears that the training time should be minimal.

SMP is becoming a rapidly growing service world-wide and is needed as more and more FUE depleted donor areas appear in the hair transplant patient population. SMP also has a role in supplementing hair transplants when the patient runs out of, or does not have enough, donor hair [(6)]. It also has a significant role in the treatment of thinning hair in post-menopausal women (possibly present in 25% by age 49 years, 41% by 69 years, and > 50% have some element of FPHL by 79 years years of age [(7)]). This new technology should make it easier for professionals to learn to perform SMP safely without the difficulties described in the three-needle system used today. It also has the distinct advantage of not requiring anesthesia.

The tattooing process does not require a medical license. It is not licensed in the United States at the Federal or State level, but it is licensed at the city or county level in most states. Different countries will have different rules for tattoo licenses, but an instrument such as described in this article, has the potential to appear in Spas and tattoo parlors around the world. We have discussed many of the problems associated with the tattoo industry in our 2015 publication [(3)] and that is, therefore, not going to be discussed further here.

Conclusion: A new tattoo technology for SMP (a) avoids anesthesia, (b) is relatively painless, (c) is a one step process, (d) is easy to learn and (e) manages patients' fears of needles. The technology use in our practices is evolving as the authors gain more experience. The hand piece is awkward to hold, the nozzle heats up with continuous use and does not work well for fine, precise placement of the dots (e.g. a hairline). It works well, however, in people with thinning hair, scalp scars, and over-harvested donor areas.

Figure 2: The Before Photo (right) showing some of the pigments deposited to the right side of the scar, the After photo on the (left)

Figure 3: Before and After photographs of Scalp Micropigmentation

Figure 4: Before and After photographs of Scalp Micropigmentation on the left,

Figure 5: GriMii hand piece in use on right

Figure 6&7: Before and After photographs of Scalp Micropigmentation in female with thinning corners. There are two sets of photos with different views

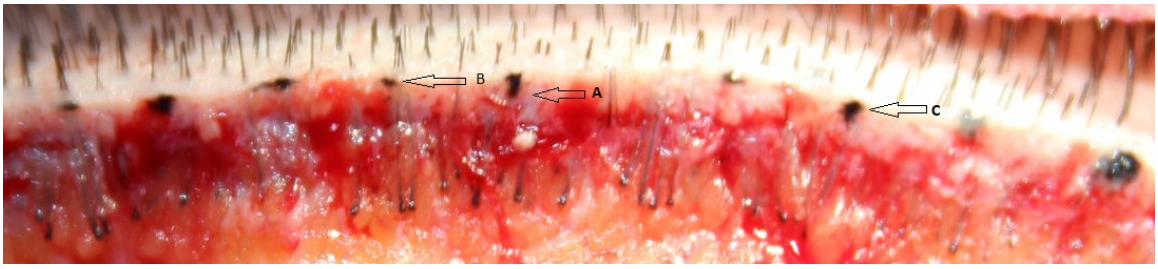

Figure 8: A strip taken 3 days after SMP was performed with the traditional three needle system. The size of the dots can be estimated by comparing it with the length of the hair shafts A= 1/5th, B= 1/7th and C= 1/5th of a hair shaft suggesting that the width and the length of the dots exceed 1mm in size. Note the variability of the dots with the traditional three needle system. The operator successfully kept the pigment deposits restricted to the upper dermis thereby controlling the depth of penetration.

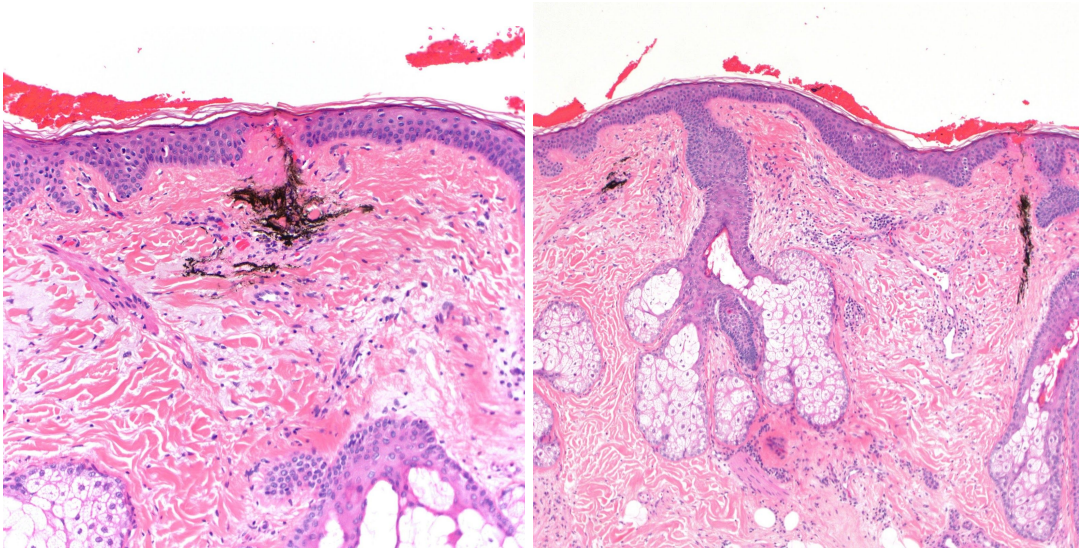

Figure 9: Histology of the pigments placed by the GriMii system. Note the pigment deposition in the upper reticular dermis. Skin biopsy shows multiple foci of pigment deposition (range: 0.05 to 0.3 mm in diameter) within the papillary and superficial reticular dermis (on the left zoomed in slide). There are also areas of pigment particle deposition along the fibrous root sheath and perifollicular stroma. The overlying epidermis demonstrates minimal disruption. The slide on the left is at 200X magnification and the slide on the right is at 100X magnification.

Reference:

1. Tae-hee Han, Jun-moo Hah, and Jack J. Yoh, Drug injection into fat tissue with laser-based microjet injector, Journal of Applied Physics 109, 983105 (2011), http://doi.org/10.1063/1.3584813
2. Hun-jae Jang, a Eugene Hur, b Yoonkwan Kim, b Seol-Hoon Lee, b Nae G. Kang, b and Jack J. Yoha,* Laser-induced microjet injection into preablated skin for more effective transdermal drug delivery; a Seoul National University, Department of Mechanical and Aerospace Engineering, 1 Gwanakro, Gwanakgu, Seoul 151-742, Republic of Korea b LG Household & Health Care R&D Center, 84 Jang-dong, Yuseong-gu, Daejeon 305-343, Republic of Korea, 2015
3. Rassman W, Pak J, Kim J. Scalp micropigmentation, a concealer for hair and scalp deformities. J Clin Aesthet Surg. 2015;8:35–42.
4. Rassman WR, Pak JP, Kim J. Scalp micropigmentation: a useful treatment for hair loss. Facial Plast Surg Clin North Am. 2013;21:497–503.
5. Rassman W, Pak J, Kim J. In: lam SM, ed. Scalp Micropigmentation: A Valuable Technique for Use in Hair Loss. 1st ed. New Delhi: Jaypee Brothers Medical Publishers; 2014; 3
6. Rassman W, Pak J, Kim J: Combining Follicular Unit Extraction and Scalp Micropigmentation for the Cosmetic Treatment of Alopecias, Journal of Plastic and Reconstructive Surgery, PRS Global Open • 2017
7. M.P. Birch, S.C. Lalla, A.G. Messenger **Female pattern hair loss** Clin Exp Dermatol, 27 (2002), pp. 383-388

Conflict of Interest: The authors have worked with the manufacturer (AddoBio) to develop the GriMii instrument for use as a clinical tattoo device for Scalp Micropigmentation. The authors have a consulting relationship with the manufacturer.