Removable Ink May Make Tattoo Regrets History

BY CHRISTINE KILGORE
Contributing Writer

A small group of physicians and investigators plan to market a removable tattoo ink next year, and if the ink lives up to the inventors' expectations, physicians will be able to remove permanent tattoos with a single laser treatment.

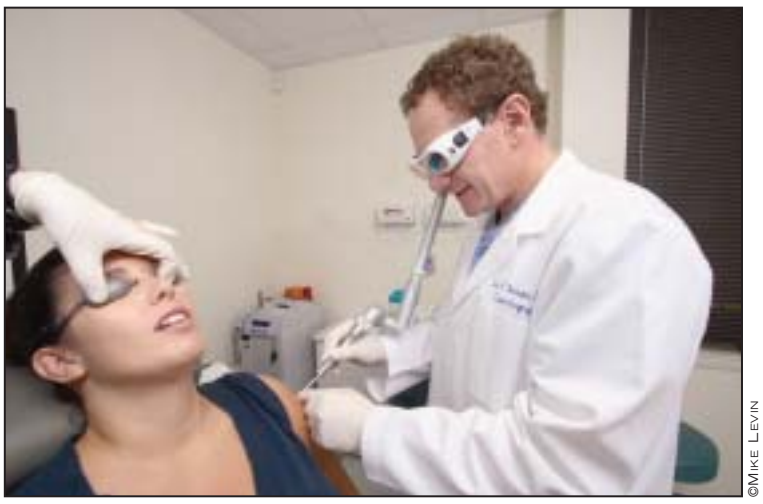
The ink is made of microencapsulated biocompatible pigments that are absorbed by the body when the capsule—beads of a polymer used in a variety of products approved by the Food and Drug Administration—is broken up by a laser treatment.

"If we can't change the lasers to take the ink out, why don't we change the ink? It's simple. And the inks are safe," said Dr. Eric F. Bernstein, a dermatologist who runs two centers for cosmetic laser surgery in the Philadelphia area.

Dr. Bernstein joined the company that has been developing the technology, Freedom-2, about 2 years ago and recently completed the first test removal of the ink. "It looks like it's going [to go] away in a single treatment," he said.

Physicians who routinely use lasers for tattoo removal say it can take anywhere from 6 to 16 sessions, and even then, removal is incomplete and possibly unsafe, given that conventional tattoo inks may contain heavy metals and other toxic and carcinogenic materials.

The market for the ink, which is not regulated by the Food and Drug Administration, could be sizable. According to a recent survey, almost one-quarter of Americans between 18 and 50 years of age are tattooed, and about one-quarter of these men and women had regrets about their tattoos. About 5% had already covered a tattoo with a new tattoo, and another 17% said they were considering tattoo removal (J. Am. Acad. Dermatol. 2006; 55:413-21).



©Mike Levin

The ink will be safe and easy to use, and it will likely take only one laser treatment to remove the tattoo, said Dr. Eric F. Bernstein.

The anticipated release of the ink will mark the culmination of years of patent filing and legal haggling, which resulted in the collaboration between Dr. R. Rox Anderson, associate professor of dermatology at Harvard University and laser treatment expert, and two plastic surgery experts, Bruce Klitzman, Ph.D., and Dr. Kim E. Koger, who met at Duke University a decade ago and who developed a removable ink for use in breast reconstruction.

Dr. Klitzman, senior director of the Kenan Plastic Surgery Research Labs at Duke University Medical Center in Durham, N.C., said that he and Dr. Koger, a plastic surgeon, had received a patent for the ink technology in 2000, when they learned that the U.S. patent office was initiating an "interference action" based on the similarities between their patent and another filed by Dr. Anderson.

The parties went before an administrative patent judge, who encouraged them to settle out of court, Dr. Klitzman said.

After about a year, the investigators agreed to merge the two companies they had formed to develop the technology and to use the name of Dr. Anderson's company, Freedom-2, for the new business.

Option Technologies, the company formed by Dr. Klitzman and Dr. Koger, "gave the rights to their invention" to the new company, and Freedom-2 provided all financing, Dr. Klitzman said.

The investigators then collaborated in their research, working to create bioabsorbable pigments that would be coated with a shell that could be disrupted with laser energy.

Dr. Anderson was not available for comment.

Martin Schmeig, president and CEO of the new company, based in West Conshohocken, Pa., said that the tattoo removed by Dr. Bernstein in the first test removal was made with a red-brown iron oxide encapsulated in beads of polymethylmethacrylate (PMMA), a polymer that is used in surgical glues, hip implants, and various other FDA-approved products. Each PMMA "microsphere" contains an absorption pigment that can be targeted by a specific laser wavelength.

Dr. Anderson and his partners are planning to recruit at least 50 people from various ethnic group, to receive test tattoos and over the course of several years, they will look at skin reactions and at the durability and vibrancy of the ink while also testing the removal process.

The long-term studies will enable the company to "build a data profile" for the FDA and European regulators, should they become interested in regulating tattoos in the future. "The Europeans are ahead of the FDA in thinking about" this, Mr. Schmeig said. "They're starting to … get concerned about ink components."

In the meantime, the company plans to market the ink in 2007, releasing it color by color. Black, the color that is least difficult to remove with a laser, will be released first.

Mr. Schmeig said it may take time for tattoo artists to change their practices and start using the ink. He said his company envisioned a consumer-driven change, that would be achieved by targeting most of its marketing toward tattoo seekers.

The company's goal for artists, meanwhile, would be "to make sure the ink acts and performs exactly like the [current] inks," he said. ■

MRSA Breaks Out Among Tattoo Recipients

Forty-four cases of community-acquired methicillin-resistant *Staphylococcus aureus* associated with tattoos were reported from June 2004 to August 2005 in Ohio, Kentucky, and Vermont, according to the Centers for Disease Control and Prevention.

The CDC reported 34 primary cases (persons who had recently received a new tattoo) and 10 secondary cases (those who had been in close contact with a recently tattooed person but who had not themselves been recently tattooed) occurring in six unconnected clusters. Time between tattoo and symptom onset ranged from 4 to 22 days for the primary cases, and most infections were mild to moderate, the CDC reported (MMWR 2006;55:677-9).

All primary cases occurred in patients who had been tattooed by unlicensed tattooists, three of whom had been recently incarcerated. The tattooists who could be found and interviewed by health and law enforcement authorities admitted they had not practiced all appropriate hygienic and sterilization measures.

—John R. Bell

Spironolactone Safe, Effective for Treating Acne in Women

BY DAMIAN McNAMARA
Miami Bureau

SAN ANTONIO — The diuretic spironolactone is inexpensive, well tolerated, and effective for most women with acne vulgaris, Dr. Steven A. Davis said at a meeting of Skin Disease Education Foundation.

"This is one of the better products" for treating acne, Dr. Davis said. "It really gets to the heart of the acne problem, at least as well as or better than antibiotics."

Hormones can play a major role in manifesting acne, as evidenced by premenstrual flare in women, acne changes with oral contraceptive and pregnancy, and exercise- and stress-induced acne flares in women and men. Spironolactone can clear acne in these patients by blunting the androgen response, he said.

"All of my patients are women—spironolactone can cause gynecomastia in men," said Dr. Davis of the University of Texas, San Antonio. "We ask them if their acne occurs right before their period and clears up after. We noticed that a lot of adolescent girls will get acne during a sport season and clear up afterward, pointing to a testosterone effect of heavy exercise."

This off-label use of spironolactone, however, is primarily indicated for women over 18 years and up to 70 years old, he said. "One of the great things is that the response is usually very fast. If someone is given 75 mg/day and there is no response in 7-10 days, it's unlikely to work." In a study at the university, treatment for a median of 15 months was considered effective for 79% of 53 consecutive female patients.

Dr. Davis' standard dosing protocol is 75 mg/day taken as two 25-mg pills in the morning and one 25-mg pill in the evening. Diuretic side effects vary widely from patient to patient and tend to occur at daily doses of 100 mg/day or greater. With this in mind, he doses higher in the morning. "I would rather they urinate frequently during the day if it occurs," he said. SDEF and this newspaper are wholly owned subsidiaries of Elsevier.

The dose can be increased to 100 mg/day, given as two 25-mg pills in the morning and two 25-mg pills in the evening if there is no response within a week, but the doses should not exceed 200 mg/day in divided doses, Dr. Davis said.

Spironolactone is available as a generic and costs $10-$20 for a bottle of 100 pills. Dr. Davis has no financial relationship with any manufacturer of spironolactone.

"It's a very safe and very clean product. I feel very comfortable giving it to a woman taking oral contraceptives," he said. "I've probably treated at least 1,000 patients with spironolactone, and it requires little or no blood testing. I don't think it's necessary to follow potassium levels in most healthy adults."

The most common side effects are menstrual irregularities, which occurred in 5 participants in the 53-patient series, "but I tend not to see this at 75 mg. As you start going up the line to 100 mg and 125 mg, the menstrual irregularities start to kick in."

In response to a question from the audience, Dr. Davis said lithium and digoxin can interact with spironolactone, so if patients taking a psychoactive drug should check with their psychiatrist about potential interactions.

"The patient satisfaction rate is very, very high. Some patients are treated for 10 or more years without side effects." ■