

New Ultrasound Technology Meets a Growing Demand for Long-term Hair Removal

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The market for aesthetic treatments has grown rapidly and continues to expand with the emergence of new technologies and products, including procedures on hair, skin, and body contouring. Evidence of this growth is the rapid expansion of medical spas, or medspas, which offer the latest trends in aesthetic procedures. According to the International Medical Spa Association, there are approximately 2500 mall-based medspas in the United States, which is a 5-fold increase since 2004.¹ Much of this growth can be attributed to the aging baby boomers who are driving much of the demand, with 12,000 Americans turning 50 years old every day, or one every 8 seconds.²

Hair removal is one of the leading aesthetic procedures performed by cosmeticians and aestheticians in medspas, clinics, and salons. It is also performed by dermatologists and other physician groups, including family practitioners and gynecologists. Consumer preferences have moved beyond the use of depilatory creams, which have been used for centuries but provide only temporary hair removal, emit unpleasant sulfurous odors, and can irritate the skin. Waxing has a long history of use and is fast and inexpensive; however, it is painful, yields short-lived results, and requires the hair to be at least ¼ inch. Electrolysis is painful, tedious, requires multiple treatments, and can cause scarring, even though the effects last longer.

Lasers and Other New Light-Based Solutions

Devices for laser hair removal were cleared by the US Food and Drug Administration in 1995. Laser hair removal can take minutes or hours, depending on the size of the treated area, and usually requires several sessions. Hair removal has become the most popular nonsurgical

cosmetic treatment. The American Society for Aesthetic Plastic Surgery, an organization of board-certified surgeons, reported that 1.4 million men and women in the United States underwent laser hair removal in 2007 at an estimated cost of \$150 to \$1000 per session (\$350 on average), which corresponds to a market that exceeds \$500 million.³ Many women wish to permanently remove hair from the face, bikini line, or both, whereas many men want to reduce the hair located on larger portions of the body, such as the back. In Spain, the number of hair removal procedures increased 111% from 2006 to 2007. Currently, there are approximately 15,000 beauty salons and 650 aesthetic clinics in the country.⁴

During the past couple of years, the competition among laser manufacturers has led to refinements and incremental improvements that have made laser hair removal easier, faster, and more effective. As demand for hair removal continues, manufacturers are making a dynamic shift toward multiuse lasers and light-based devices for use on a wider range of skin types. A newer light-based technology is intense pulsed light (IPL), which uses a broader spectrum. It differs from laser light because it is not a single coherent wavelength; it has the advantage of emitting energy over a large surface area; and it can be used for long-term hair removal, with a less intense light source than a laser. These treatments are gentler to the epidermis and are a good choice for patients with very sensitive skin. The red spectrum light targets melanin in the hair, while the yellow spectrum light reaches subsurface skin layers and targets the blood that feeds the hair follicle cells. The precise targeting usually means no cooling gel is needed.

Performance and Limitations of Lasers and Other Light-Based Devices for Hair Removal

Lasers, as with all other light-based devices, operate by heating the melanin in the hair and in the melanin-containing cells (melanocytes) around the hair follicle. As light is absorbed by the melanin, it heats up and destroys the melanocytes, which damage the hair follicles.

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The author reports no conflict of interest in relation to this article.

Therefore, light-based devices for hair removal are most effective when treating dark hair on fair skin. However, patients with a relatively higher melanin content in their skin, including people with tans, or those of Asian, Hispanic, or African origins, have less success with laser/IPL hair removal than individuals with fair skin. With tanned skin, the deeper melanin color of the skin can also become a target and in some unfortunate cases, the skin can become patchy and mottled. Similar ineffectiveness occurs when treating people with fair (ie, white, blond, red) hair. A cooling system or gel is used to neutralize the heat at the procedure site and to protect surrounding skin from damage. It is important that the patient stay out of the sun before and after having laser/IPL hair removal treatments to prevent any adverse skin reactions.

Lasers are widely used in medspas, but their use requires trained technicians or physicians on staff, depending on the regulatory requirements in each country. If performed improperly, laser hair removal can damage skin by causing blisters, scars, and burns. A patient undergoing laser hair removal should make certain that the facility is licensed and that the practitioner is properly qualified. Whereas the chances of complications are small when laser hair removal is correctly performed, doctors do see patients who, after being improperly treated with a laser, have burns, scarring, increased hair growth in adjacent areas, and permanent skin discoloration. Often, these problems are a result of laser misuse, or treating unsuitable candidates, such as people with dark or tanned skin, or people with light hair.

Devices of the Next Generation Utilize Ultrasound for Hair Removal

The application of ultrasound is the latest breakthrough in hair removal as it is for other aesthetic applications, such as body shaping and skin rejuvenation. Applisonix leads in the development of ultrasound-based devices for hair removal. This is consistent with Israel's reputation as an innovator in aesthetic devices and in commercializing leading edge technologies in the medical aesthetic markets.

Applisonix recently concluded a study that achieved, following an initial treatment, average hair reduction of 38%, which positions its efficacy within the top professional long-term hair removal solutions. The test results were examined by Daniel Cassuto, MD, a professor of plastic surgery at the University of Catania, Italy, who is an external, independent, internationally recognized expert. Dr. Cassuto verified and evaluated the findings and concluded that the new technology's efficacy is similar to the efficacy of the top commercial light-based systems, but without any side effects, regardless of hair

and skin color. These results reflect the new technology's capability of competing with expensive, professional light-based systems. From studies published in this field, it seems that with most light-based systems, one treatment can reduce the hair count by 10% to 40%, thus the results position Applisonix's technology within the highest level of hair removal technologies.⁵

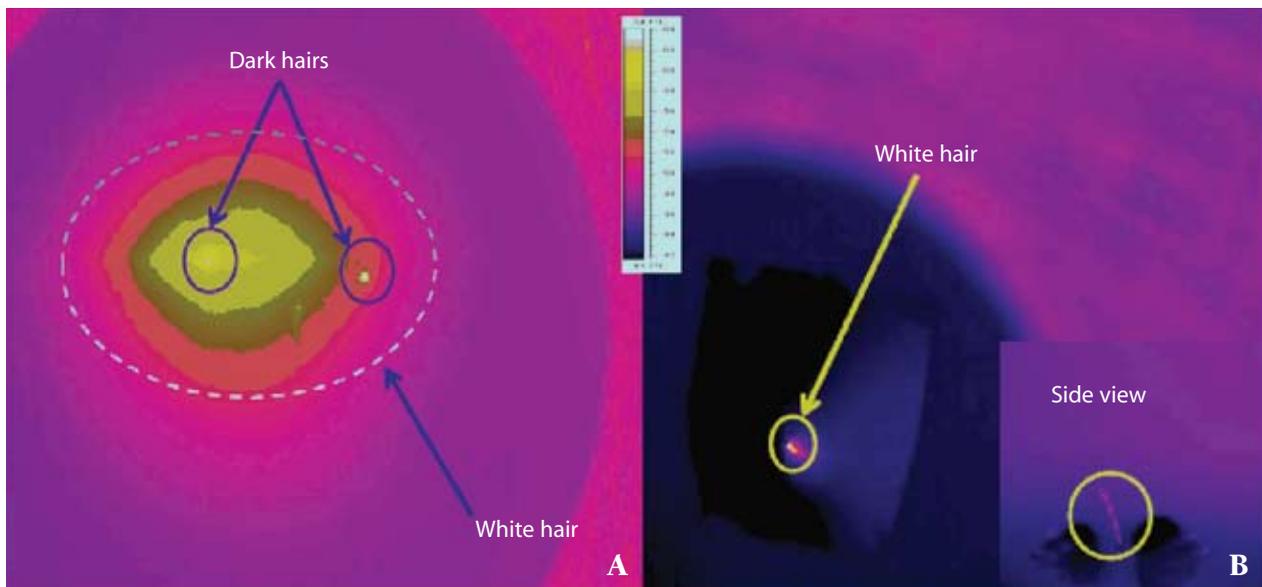
Ultrasound has distinct advantages over lasers and IPL for hair removal. It is much safer with minimal risk or side effects, and negligible pain, if any. It is effective on all skin types and hair colors, and can be used on almost all body areas. The technology used by Applisonix leverages the unique hair and skin characteristics to make the hair serve as an accurate ultrasonic waveguide. A specially engineered ultrasonic probe is used to focus the acoustic energy precisely into the hair shaft, channeling ultrasound energy directly to the hair root, where the energy is converted into heat. As a result, the hair's root temperature rapidly exceeds the level that is required to cause long-term damage to the hair's regrowth mechanism. Because the energy is accurately applied through the hair shaft, the surrounding skin is not affected (Figure).

This innovative technology from Applisonix that incorporates immediate, precise, selective acoustics (IMPRESA) is planned to be the core technology in upcoming hair removal devices for both professionals and consumers.

The IMPRESA technology offers a differentiating solution in the commoditized long-term hair removal market. It can help professionals differentiate themselves from the competition by offering a solution that is much safer, painless, applicable to all hair colors and skin tones, and more affordable than laser hair removal. It clearly provides a long-term hair reduction solution compared to depilatories and waxing, which still represent the vast majority of the professional epilation procedures market.

Selectif, an ultrasonic hair removal device, will be the first device utilizing the IMPRESA technology and will be marketed to beauty professionals with a product launch planned for early 2009. In addition, Selectif can complement currently available laser or IPL treatments by offering a solution for all hair colors and skin tones, and for precise shaping of delicate areas such as the face, eyebrows, underarms, and bikini line, which represent about 40% of professional hair removal procedures. Treatment protocol will require a series of relatively fast hair-by-hair treatments at 15 to 20 hairs per minute, followed by periodic maintenance. The device operation requires very minimal training.

For aestheticians and cosmeticians, the Selectif device offers a new opportunity to generate additional revenues



A thermal photograph of both laser and ultrasound hair removal effects, with the thermal effect of laser all over the surrounding skin (A), and the ultrasound effect focused and isolated to the hair itself, while the surrounding skin is not impacted (B). Additionally, the effect with ultrasound treatment is the same for all hair colors and skin tones.

by utilizing its advantages of affordability, safety, ease of use, and effectiveness for all hair and skin colors. The projected affordable price represents a solution with a quick return on investment. Selectif received European CE Mark in June 2008, which allows Applisonix to market the device in Europe.

The Emerging Market for At-Home Use of Long-term Hair Removal Devices

Recognizing the success of the professional hair removal business, some consumer product companies are targeting the market of at-home use of laser and thermal devices. The challenge for manufacturers is to develop affordable devices that are powerful enough to be effective, but also safe enough to be used by consumers at home.

The first handheld, light-based devices for at-home use for removal of unwanted hair have been cleared by the US Food and Drug Administration and were introduced this year in the United States. They are slower than professional treatments, but also less painful. They work best in small areas like the lower legs, underarms, and bikini lines, but are not cleared for use on the face and cannot

be used by African Americans and other people with skin of color because of the risk for burns.

Following the launch of the Selectif device for professionals, Applisonix plans to utilize the same IMPRESA technology for devices for at-home use, thereby leveraging its characteristics of safety, affordability, ease of use, and efficacy for everyone. The company has already signed an agreement with a large global company to test the technology on future hair removal devices.

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