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A close-up profile of a woman's face, looking towards the right. A syringe with a needle is positioned near her nose, as if about to administer a treatment. The background is a soft, light blue.

**TREATING
THE LIPS**
A STEP BY STEP GUIDE

SKINCEUTICALS
CELEBRATING 25 YEARS

RHINOPLASTY

The Four Point Rhino

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CX-2858C.1

Serendia, LLC
Exhibit 2066
Jeisys v. Serendia
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Ex. 2066-001

SYLFIRM X REVOLUTIONISES THE CLINICAL APPLICATIONS OF RF MICRONEEDLING

Martin Braun discusses his experience using the SYLFIRM X and the results he achieves on skin of colour



MARTIN BRAUN, MD,
Medical Director, Vancouver
Laser and Skin Care Centre
Inc., Canada

CONVENTIONAL radiofrequency (RF) microneedling has been widely used for skin rejuvenation, tightening, and scar treatment by delivering the thermal effect of radiofrequency into the skin with needles. SYLFIRM X, developed and manufactured by VIOL Co. Ltd., South Korea, is the world's first and only RF microneedling device equipped with dual-wave RF (continuous and pulsed waves). The Sylfirm X was introduced into the medical aesthetic arena to provide innovation by the expansion of clinical applications of RF for pigmented and vascular lesions, such as melasma and rosacea, as well as skin rejuvenation and scar treatments. I would like to share clinical information and my experience gathered with the use of the SYLFIRM X.

The typical RF microneedling device is an energy-based platform that causes denaturation and coagulation of skin tissue by the frictional heat generated with the flow of an electric current delivered to the skin by microneedles. This heat induces wound healing and collagen production. Unlike lasers, RF does not depend on the absorption coefficient of chromophores such as melanin. Thus RF has the advantage of being able to safely and effectively treat all skin types. However, conventional RF was unable to treat a wider range of skin conditions, including pigmented and vascular lesions due to the limitation of the mechanism of action, which only induced wound healing and collagen production. The revolutionary SYLFIRM X breaks this limitation.

SYLFIRM X

SYLFIRM X can produce dual-wave RF pulses: both continuous waves (CW) and unique pulsed waves (PW). CW is the typical RF pulse generated by existing RF microneedling devices. CW is a single long pulse similar to a long-pulsed laser. CW RF produces strong heat in the tissue resulting in coagulated collagen and is used primarily for treatment of wrinkles, large pores, skin laxity, and acne scars. On the other hand, PW is the world's first RF irradiation method developed and applied by VIOL Co. Ltd., which produces a string of short pulses similar to Q-switched lasers. Through numerous studies and experiments, SYLFIRM X uses a train of four different pulses to effectively treat a greater variety of skin conditions.

It is common knowledge that electricity conducts very well in water. Furthermore, conductivity is different for each skin tissue. When radiofrequency is transmitted to the skin using the relatively lower energy of the PW settings, highly conductive tissues such as the basement membrane and microvasculature selectively react, resulting in structural changes rather than denaturation or coagulation. This appropriate heat stimulus can be applied to the treatment of pigmented lesions such as melasma, which often worsen or have undesirable side effects when treated with strong heat. PW technology also treats vascular problems such as rosacea.

My clinic is located in Vancouver, Canada. Vancouver is home to more Asians than any other city outside of Asia, with 43% of residents having an Asian heritage¹. It is the third most diverse city in the world, and over 200 patients of various skin types and skin problems visit my clinic on a daily basis for private aesthetic treatments. Many patients with skin type III-V are concerned with pigmentation, especially melasma. Skin types III arrive with vascular lesions, especially rosacea. Melasma is a photoaging pigmentation disorder caused by hypermelanogenesis. The pathology is multifactorial including hyperactive melanocytes, a disrupted basement membrane, increased vascularity, and increased senescent fibroblasts. In general, past pigmentation treatments focused only on attempts to lighten the pigment using a Q-switched laser and/or topical agents. Only the

Figure 1 (A) Before and (B) after photos of SYLFIRM X treatment by Dr. Martin Braun



"SYLFIRM X, developed and manufactured by ViOL Co. Ltd., South Korea, is the world's first and only RF microneedling device equipped with dual-wave RF."

melasma symptom was treated, whereas the underlying factors influencing the pigment were not addressed, leading to recurrence. The SYLFIRM X's PW technology improves hypermelanogenesis by treating the underlying pathology producing the melasma. Using our Sylfirm X, we have produced enduring results for refractory and recalcitrant melasma cases. Rosacea is also improved by selectively targeting the microvasculature and other underlying influencing factors.

In order to treat the influencing factors of melasma and rosacea, it is necessary to target the superficial papillary dermis as well as the basement membrane, at a depth of approximately 0.3mm. SYLFIRM X appears to be the only RF device that accurately targets and treats at 0.3mm of skin depth. Also, pulsed RF treatment at a depth of 0.3mm has the advantage of little procedural pain with virtually no prolonged redness or downtime. At a depth of 0.3mm, we can treat a melasma or rosacea patient without applying anaesthetic cream, and the patient can return to their daily routine immediately after the procedure.

Of course, many patients are interested in anti-ageing, skin rejuvenation, skin lightening and lifting regardless of skin type. The SYLFIRM X is equipped with dual-wave RF to treat all these indications. The needle depth can be adjusted from 0.3-4.0mm, so we can treat thin facial skin, as well as the body such as skin on the abdomen or buttocks. There are four different PW and CW settings providing 8 different modes allowing the practitioner to perform delicate and customized treatments taking into consideration each patient's skin type, skin condition and body area.

Microneedling

In addition to the Pulse Wave technology, the SYLFIRM X has many differentiators from other RF microneedling devices. SYLFIRM X uses non-insulated microneedles, whereas many other devices use insulated microneedles. Insulated microneedles are used to avoid heat damage to the epidermis, and these insulated needles only treat the tissues with heat emitted at the tip of the needle. Since insulated needles have less diffuse thermal effect than non-insulated microneedles, the therapeutic effect is lower and pinpoint bleeding is profuse due to the lack of diffuse coagulation. Conversely, the SYLFIRM X uses non-insulated microneedles in combination with 2 MHz bipolar RF and pulse durations up to 300ms. The heat action commences at each tip of each electrode and develops into a water droplet shape of thermal energy. This is termed the Na effect, providing safe effective treatment because the tear drop shaped thermal effect minimises heat damage to the epidermis and maximises the therapeutic effect at the target. Also, unlike other RF microneedling devices, where the needle is inserted and strongly ejected rapidly like a staple gun, the needle tip of SYLFIRM X is designed to be inserted into the skin very smoothly, reducing pain, skin tearing, bleeding and bruising issues. I can personally attest to the Na effect of tear dropped thermal energy dispersion as I had a treatment with 1000 pulses on my face using the 25 needle cartridge, which equals 25,000 needle insertions with no pinpoint bleeding! Redness dissipated within one hour, attesting to sparing of the superficial epidermis.



Figure 2 (A) Before and (B) after photos of SYLFIRM X treatment by Dr. Martin Braun

Conclusion

The technology behind the SYLFIRM X truly represents a paradigm shift in the treatment of melasma and rosacea. We now use the Sylfirm X as a first line treatment of melasma, and only employ Picosecond lasers to clean up any remaining melanosomes after repairing the basement membrane and underlying hypervascular pathology. There are also specialized RF tips to treat active cystic acne and the results have been very impressive. The feedback from patients who have undergone procedure with the SYLFIRM X is uniformly positive. The Sylfirm X has an excellent safety profile with dark skin tones, amazing versatility with virtually any skin condition or colour, and thus receives my recommendation as a must-have device in any clinic. 

For more information, please visit www.violmedical.com

References

1. Douglas Todd. Vancouver is the most Asian city outside Asia. Vancouver Sun. Vancouver; March 27, 2017. Available at: <https://vancouversun.com/life/vancouver-is-most-asian-city-outside-asia-what-are-the-ramifications/> [last accessed 5/5/2022]