Expanding the Clinical Application of Fractional Radiofrequency Treatment: Findings on Rhytides, Hyperpigmentation, Rosacea, and Acne Redness

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ABSTRACT

While radiofrequency has been used medically for decades to treat a wide variety of conditions, its use therapeutically to target conditions affecting the skin is relatively new. With the development of fractional radiofrequency, which allows for the heat energy to be delivered in a more targeted manner through the use of needles as electrodes, this technique is now the preferred medical treatment option for many skin conditions given the reduction in recovery time and fewer number of reported side effects. The current study examined the clinical effectiveness of SmartScan™ Nano-Fractional RFTM treatment. Participants included 12 healthy female volunteers who reported varying degrees of rhytides, hyperpigmentation, or acne redness. Participants each received one treatment of SmartScan Nano-Fractional RF. The areas receiving treatment were photographed in a standardized way, using high-resolution macrophotography, at baseline (prior to receiving the treatment) and one month after treatment. Baseline and post-treatment photographs were then visually compared for treatment effects and analyzed through software-assisted quantification of variation in pigmentation and skin texture. The results indicated that this SmartScan technique for Nano-Fractional RF is effective in improving skin texture, and pigmentation.

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INTRODUCTION

In recent decades there has been a growing demand for safe, efficient, and non-invasive treatments for treating striae, rhytides, hyperpigmentation, rosacea, acne redness, and scarring. Radiofrequency (RF) treatments, which are titrated to be non-ablative, have thus been regarded as an optimal treatment option, given the fewer side effects and reduced recovery time. The use of RF energy is not a new concept. In fact, RF ablation is a technique that has been around for the last several decades, which utilizes an oscillating current of electricity.[1-2] By oscillating the electrical current, charged molecules and ions collide against each other, generating energy in the form of heat. This heat energy can be used to stimulate or even ablate targeted tissue within the body.

There are a wide number of clinical applications of RF energy, which depend on the depth of the targeted tissue, the specific frequency used during treatment, and how the tissue itself is cooled following the treatment.[2] RF energy is most commonly used in cosmetic dermatology as a noninvasive method of skin tightening and facial rejuvenation. These effects are produced within the heated area through several mechanisms, including ablation and necrosis of adipose tissue, stimulation of tissue inflammation, and improved blood circulation, which leads to the recruitment of fibroblasts to the area.[2-3] This ultimately leads to the production of new collagen through the body's natural regeneration process.

In contrast to earlier forms of RF treatment, newer devices are associated with fewer side effects when used to treat dermatologic conditions. Previous treatments have been associated with a number of adverse side effects, including erythema, hyperpigmentation, ecchymosis, and burning. Newer RF devices that utilize fractional technology have been shown to improve the appearance of fine lines and wrinkles in the dermis, while significantly reducing the risk for adverse side effects. This fractional technology, piloted in 2009,[4-5] uses needles as electrodes to deliver the RF energy to the targeted tissue and have been regarded as successful in treating a variety of dermatological conditions. These new fractional RF devices have been shown to improve facial brightness, tightness, and skin pigmentation.[6-8] More work is necessary, however, to evaluate the safety and effectiveness of using RF to treat various skin conditions.

The current study examined the clinical effectiveness of a single treatment with Venus Viva™ (Venus Concept, Toronto, Canada) SmartScan™ Nano-Fractional™ Radio Frequency in treating several skin conditions, including striae, rhytides, hyperpigmentation, rosacea, acne redness, and scarring, in order to improve the appearance of the skin.

MATERIALS AND METHODS

Participants included 12 healthy female volunteers who reported varying degrees of rhytides, hyperpigmentation, or

TABLE 1.

[[[AQ: Provide table title]]]

Skin Condition	Number of pts	Number of Areas Assessed
Texture	6	10
Medium Texture	9	20
Melanin	7	14
Hemoglobin	2	2
Wrinkle	4	4
Wrinkle Medium	4	4

acne redness. Study participants were enrolled in the study after meeting all inclusion and exclusion criteria, as well as providing informed consent. Upon enrollment, study participants were assigned confidential identification numbers in order to protect privacy and confidentiality.

"In contrast to earlier forms of RF treatment, newer devices are associated with fewer side effects when used to treat dermatologic conditions."

Study participants engaged in a pre-treatment screening assessment and baseline photograph of the facial skin to be treated. The areas receiving treatment were photographed in a standardized way, using high-resolution macrophotography, at baseline and one month after treatment. Photographs were processed to highlight and measure texture using Antera software. Baseline and post-treatment photographs were then visually compared for treatment effects.

Each study participant received one treatment with the Venus Viva device using SmartScan Nano-Fractional RF. The Venus

TABLE 2A.

Hemoglobin

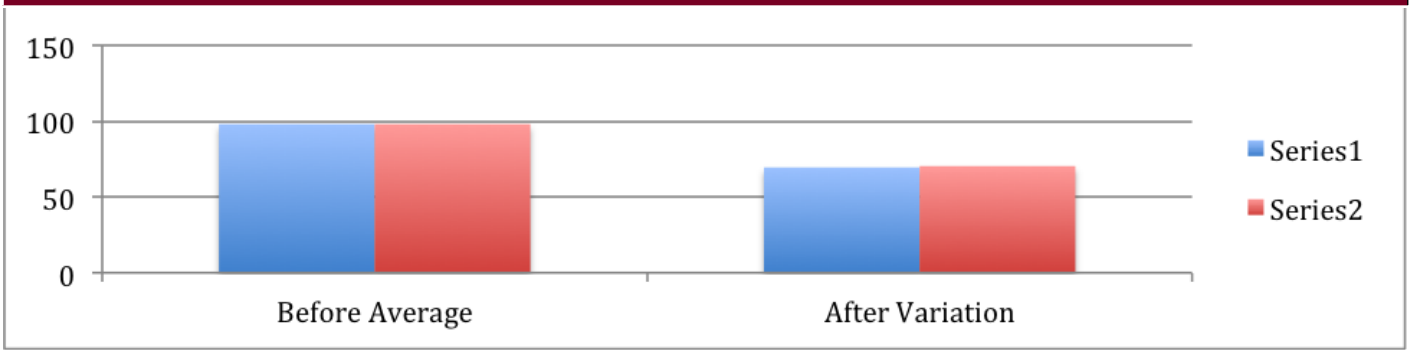


TABLE 2B.

Texture <1mm

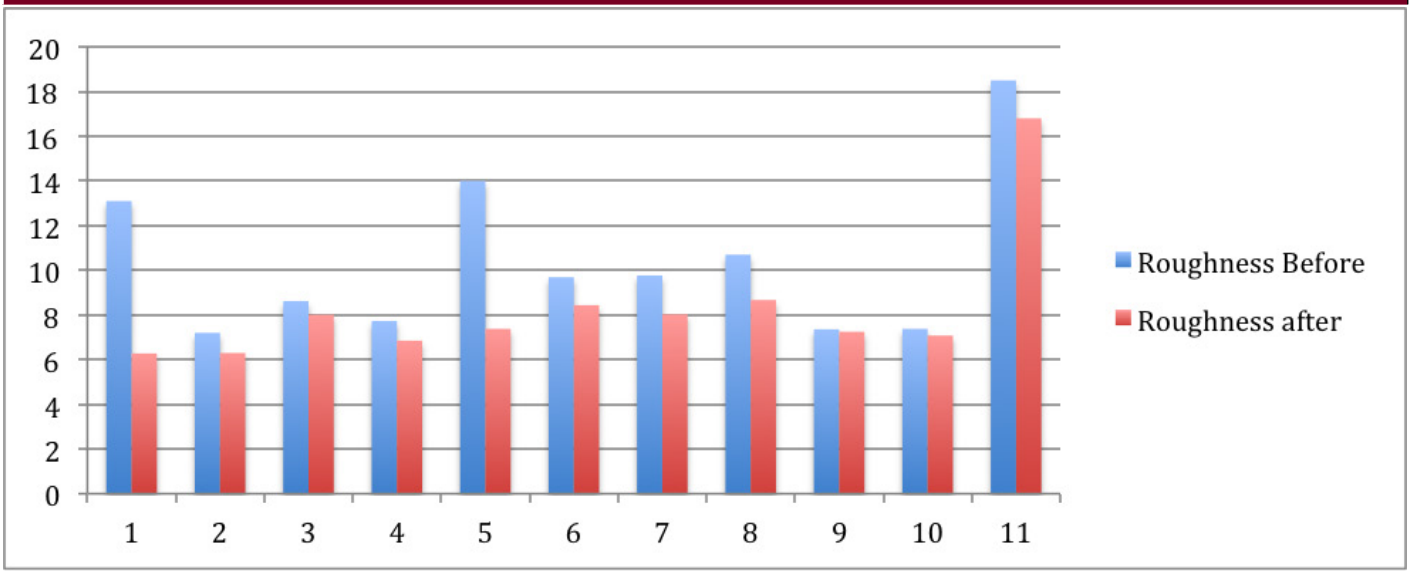


TABLE 2C.

Texture >1mm – <2mm

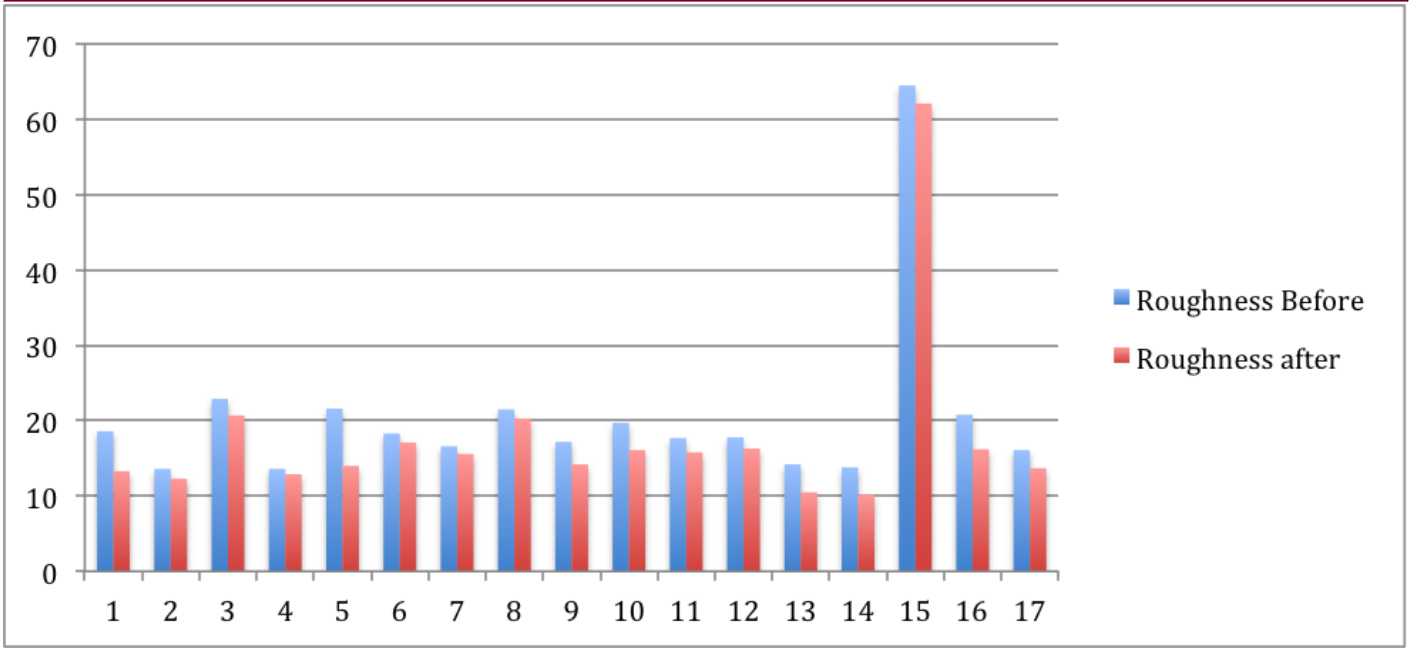
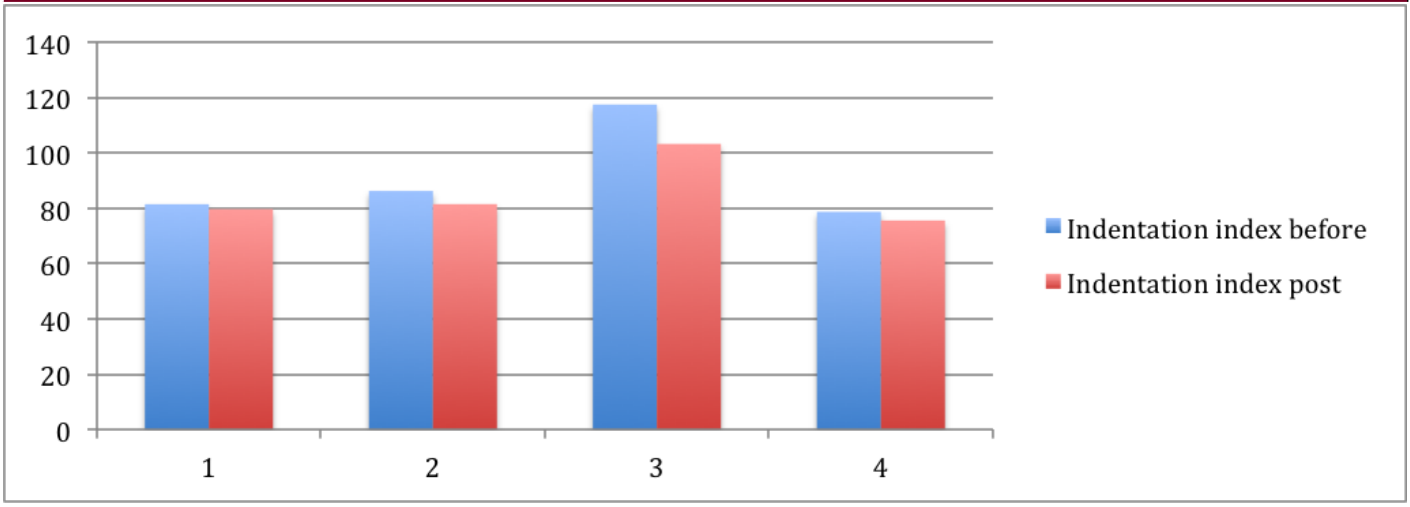


TABLE 2D.

Wrinkle <1mm - >2mm



Viva is a non-invasive device intended for use in Dermatologic requiring ablation and resurfacing of the skin. The procedure is intended to provide a noticeable;

- Wrinkle reduction
- Increase of skin tightening
- Cellulite reduction

This device provides targeted density control of the heated zone by delivering RF energy individually through 160 pins per tip with 62mj per pin. Energy was delivered at 225 volts and applied at a pulse rate of 20 milliseconds. In order to evaluate treatment safety, areas that had received treatment were assessed visually for any adverse side effects, including erythema, edema, thermal burn, localized infections, or changes in skin pigmentation, immediately following treatment.

Clinical effects were assessed at one-month follow-up. Outcome measures included visual comparisons of baseline and

one-month follow-up images and measurements gathered on: average skin pigmentation (measured in hemoglobin or melanin counts); mild skin roughness (ie excessive texture, measured in roughness under 1.0mm of lateral skin size); moderate skin roughness (measured in roughness under 2.0mm of lateral skin size); mild wrinkling (measured in an indentation index under 1.0mm of lateral skin size); moderate wrinkling (measured in an indentation index under 2.0mm of lateral skin size) and the variation of pigmentation (measured in hemoglobin or melanin counts).

RESULTS

All subjects completed one SmartScan Nano-Fractional RF treatment on a problem area most approapriate for RF treatment. There were no unexpected adverse side effects from the treatment reported or detected during the study. A portion of the

TABLE 2E.

Wrinkle >1mm

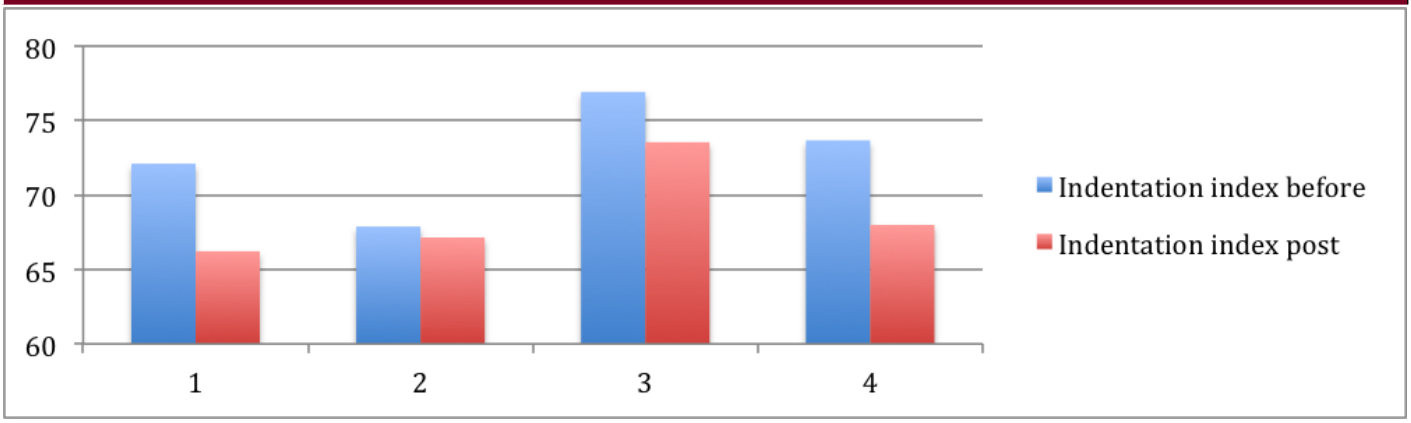


TABLE 2F.

Melanin

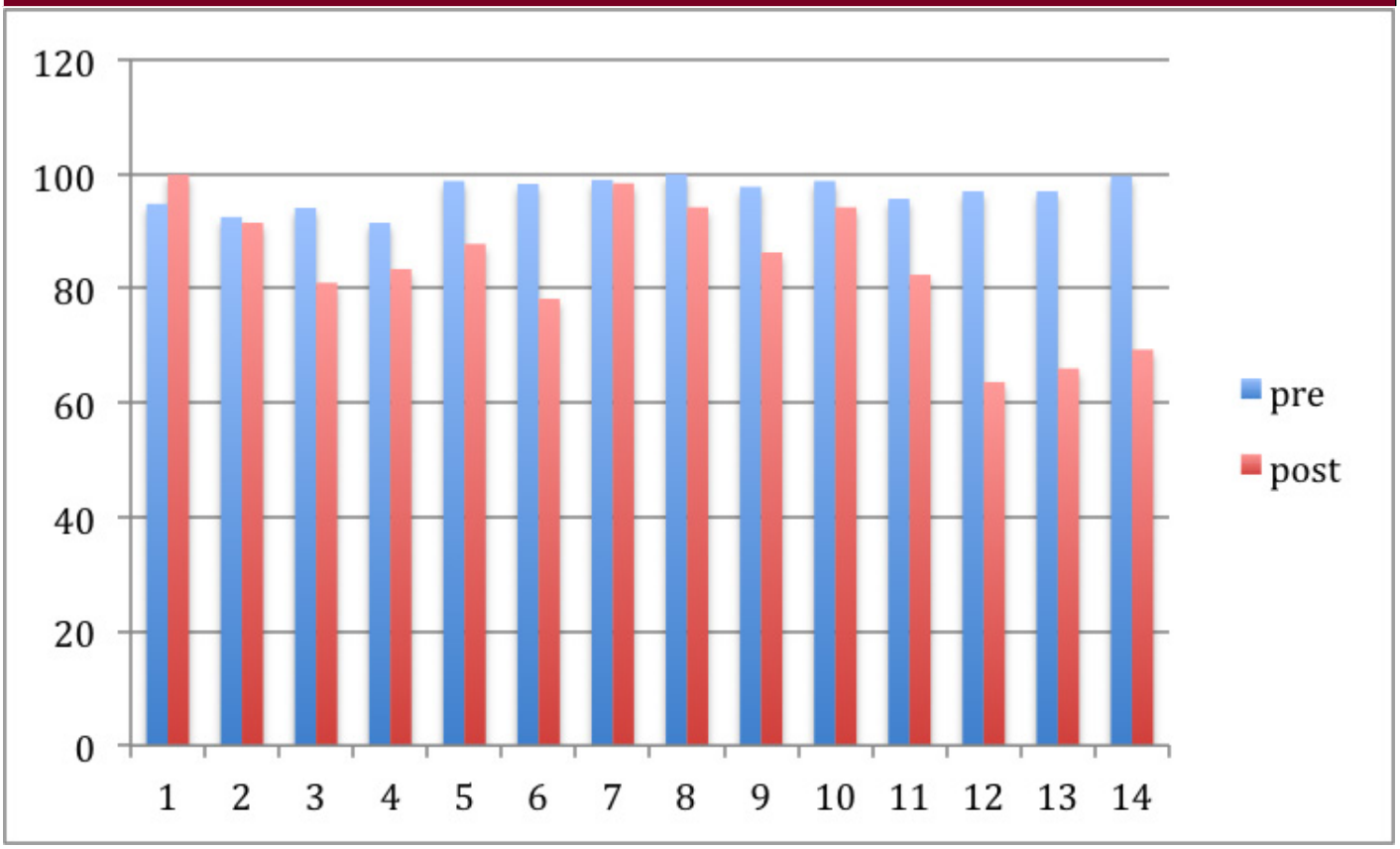
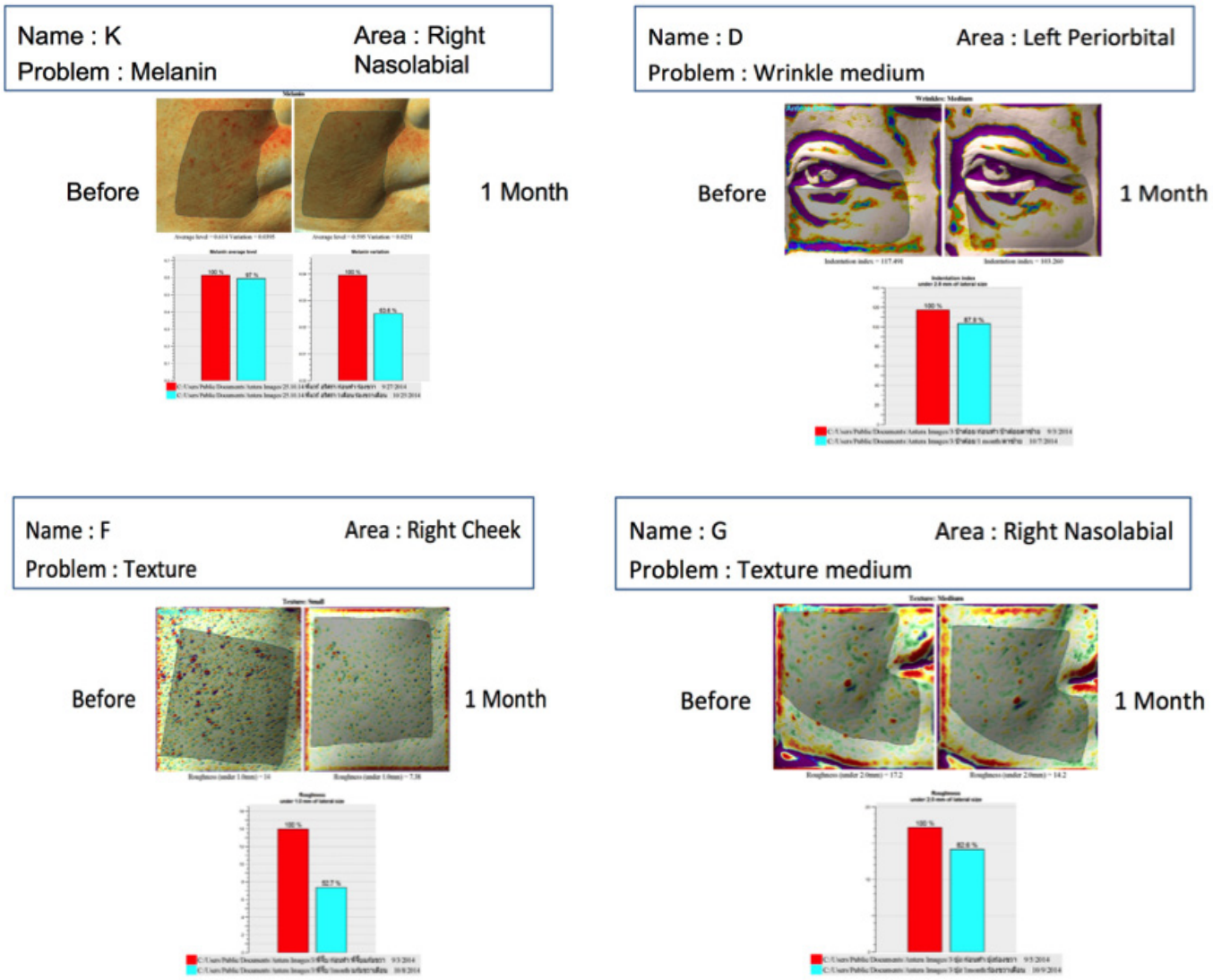


FIGURE 1. Skin abnormalities measured.



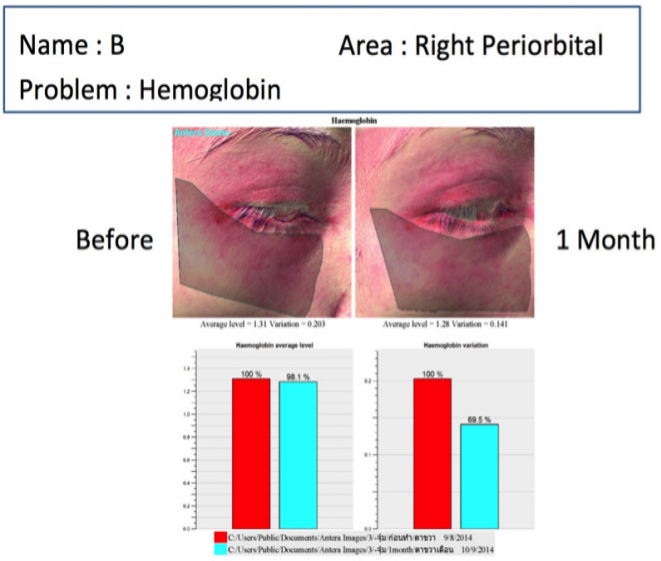
participants reported moderate skin erythema and edema within the treated area. These symptoms tended to resolve within one to two days without further treatment. During this healing phase, tiny pin-point epidermal crusts were noted to appear at each micro-ablated spot. These crusts naturally exfoliate following several days, leading to epidermal resurfacing. None of the participants reported experiencing any more severe side effects, such as burns, skin irritation, or scarring. Subjects were treated for their corresponding skin complaints, as outlined in Table 1.

There were no noted increases in the incidence of hyperpigmentation, even in subjects with melasma. The most notable results occurred within participants exhibiting pigment variation, which showed an average of 0.054 for hemoglobin and 0.008 for melanin. These corresponded to an average decrease of approximately 30% and 17% respectively. Mild skin roughness was reduced by an average of 2.087 (approximately 17%) and moderate skin roughness was decreased by an average of 2.776 (approximately 15%). The results for mild and moderate wrinkling showed an average decrease in their appearance of approximately 5% and 6% respectively.

DISCUSSION

Findings from the outcome measures of mild to moderate skin rhytides indicated overall improvement across participants. These changes, however, were not as substantial as those noted for pigmentation or skin texture. This may suggest that single treatments using SmartScan Nano-Fractional RF may be more ideal for treating cosmetic conditions related to hyperpigmentation or texture than for rhytides. Indeed, skin conditions, such as rhytides, may warrant more than one treatment; however, further studies are warranted.

FIGURE 2. Hemoglobin measured.



Results from this study suggested that one treatment with SmartScan Nano-Fractional RF led to notable improvements in overall skin texture and in hyperpigmentation. Moreover, one treatment using SmartScan Nano-Fractional RF was not associated with any severe side effects in the current study and participants recovered from the procedure within several days following the treatment.

The SmartScan Nano-Fractional RF device has also been tested on two patients with complaints of facial striae or stretch marks. These patients were given one treatment with SmartScan Nano-Fractional RF and high resolution photographs were taken pre-treatment and one month post-treatment. Though only two patients were analyzed, improvements were noted in terms of skin roughness. More specifically, skin roughness was reduced by an average of 2.526 (approximately 6.7%) following treatment with SmartScan Nano-Fractional RF.

LIMITATIONS

The current study is not without limitations. Of note, there was very limited statistical power due to the low number of data points generated for many of the outcome measures. For example, the outcome of facial hemoglobin reduction was only tested in two subjects. As such, results indicating changes hemoglobin must be interpreted with caution. Despite the fact that the number of subjects included in this study is typical for a pilot trial, study design led to a disproportionate number of data points across groups (ie two allocated for one outcome compared to a group of six for another). While it was not necessary to compare groups, this limits the conclusions drawn from these findings. Pilot studies of a larger scale with a greater number of subjects eligible for treatment affecting this outcome measure are necessary to confirm these findings.

CONCLUSION

A single treatment with SmartScan Nano-Fractional RF resulted in positive effects on excess facial pigmentation, texture and/or wrinkling for all subjects in this study. Treatment using SmartScan Nano-Fractional RF also resulted in aesthetic improvements for each subject, as measured by visually comparing images taken at follow-up to those taken prior treatment. This is particularly true for those treated for variations in skin texture or pigmentation. These findings support previous studies that have shown fractional RF as an effective treatment for abnormal collagen formation, while promoting the formation of new dermal proteins to give the appearance of smoother, clearer skin. The skin improvements seen in this study were due to the increased penetration of radiofrequency through advanced technology utilized by SmartScan Nano-Fractional RF.

In addition, this study supports SmartScan Nano-Fractional RF as an ideal treatment to correct some cases of hyperpigmentation. Further, findings from this study also corroborate previous studies that show RF as a safe and tolerable treatment option for the many cosmetic skin complaints. The increased efficacy, due to its improved control of both power and pulse duration, resulted in improved control of tissue ablation or coagulation ratio. The reduced pin footprint also resulted in decreased side effects related to pigmentation (eg redness). This study also demonstrates that SmartScan Nano-Fractional RF provides homogenous RF treatment with increased density control, which leads to a greater frequency of painless radiofrequency exposure. Indeed, it may be that SmartScan Nano-Fractional RF is an appropriate tool for treating other skin conditions, though more work is necessary in this area.

Overall, while this study showed that the increased dermal coagulation afforded by SmartScan Nano-Fractional RF profoundly affected the dermal vascular plexus, additional research based on this study is needed to confirm its use as a treatment for wrinkles, scars, discrepancies in skin tone, rosacea and variations in pigmentation related to acne (Figure 1, Figure 2).

DISCLOSURES

Dr. Gold is a consultant and shareholder in Venus Concepts. He has performed research studies for Venus and speaks on their behalf. For purposes of this paper, Dr. Gold has not received any financial benefits relating to this project. Dr. Wichai is a consultant, investigator, and speaker for Venus Concept. Dr. Wichai did not receive any payment for conducting the study.

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