A Retrospective Study of Patient Satisfaction Following a Trial of Nano-fractional RF Treatment

Martin Ray MD[a] and Michael Gold MD[b]
[a]View Laser Skin Rejuvenation, Delta British Columbia, Canada
[b]Gold Skin Care Center and Tennessee Clinical Research Center, Nashville, TN

ABSTRACT

Traditional techniques used to treat dermatological conditions have typically involved surgery or full ablation of tissue. With the emergence of fractional radiofrequency (RF) technology, treatment for various skin conditions no longer requires surgery or full ablation. Instead, these treatment techniques deliver thermal energy, derived from fractional RF energy, in a highly targeted manner through multiple micro-needles, referred to as pins. This technique hastens recovery time and leads to less reported side effects associated with traditional methods of tissue augmentation. While the efficacy of this treatment has been demonstrated, patient satisfaction has not been assessed and documented thoroughly. The current study examined patient-reported satisfaction following treatment with the Venus Viva™ as assessed across five separate domains of self-reported satisfaction; degree of comfort during treatment procedures, recovery time following treatment, convenience and efficiency of treatment appointments, treatment results, and whether the patient would recommend the treatment to a friend. Participants included 43 healthy adult volunteers who reported varying degrees of facial dermatological conditions, such as rhytides, hyperpigmentation, or the redness associated with acne vulgaris. Participants received between one and three treatments with the Venus Viva™ device. Patient satisfaction was assessed three months following the last treatment. Results indicated that patients are highly satisfied with treatments received from the Venus VivaTM device and are highly likely to recommend the procedure to a friend.

J Drugs Dermatol. 2015;14(11):611-614.

INTRODUCTION

As individuals age, collagen, which comprises the majority of dermal proteins, can become disorganized leading to atrophy of the epidermis.[1] Evidence of this degeneration includes flattening of the dermal-epidermal junction; loss of rete processes; reduced number of fibroblasts; and decreased levels of overall collagen. Regardless of the underlying etiology, most aesthetic skin complaints related to aging have traditionally been treated with plastic surgery.[2]

Within the last decade, interest in minimally invasive or non-invasive techniques for cosmetic facial rejuvenation, with little to no down time for recovery, has grown substantially. Historically, dermatological concerns of the face, such as rhytides, striae, skin laxity or texture irregularities, have been treated with either surgical intervention or ablative dermal resurfacing techniques.[3] The majority of these procedures work by destroying the epidermis and inducing dermal injury. As the skin heals, dermal collagen is then reorganized, leading to several desired secondary effects, such as skin tightening and improvement in rhytides.[4] Examples of these techniques include chemical peels, dermabrasion, char-free pulsed carbon dioxide (CO_2), and erbium-doped yttrium aluminum garnet (Er:YAG) lasers.[5,6]

More recently, efforts have increased to develop a technique that provides effective treatment for dermatological conditions affecting the face, while also minimizing both post-treatment recovery time and the potential risk for infection, scarring, and hyperpigmentation. As such, attention has been given to the use of thermal energy for inducing dermal injury while preserving the integrity of the epidermal layer. Several techniques have been developed that utilize thermal energy, including both light-based systems and noninvasive lasers. Evidence from clinical evaluations of these procedures has provided support for their effectiveness in treating facial rhytides.[7,8]

Unlike techniques developed from light-based non-ablative resurfacing, treatment using radiofrequency (RF) energy causes thermal energy in the skin, initiating dermal injury. The thermal energy generated from RF is created by an oscillating electrical current, which causes charged molecules and ions to collide against one another to generate heat energy in the tissue. Depending on the intensity, this thermal energy can be used to stimulate or ablate targeted tissue within the body.[9]

The potential clinical applications of RF energy are widely varied and depend on the depth of the targeted tissue, the specific frequency used during treatment and the method which the energy is delivered to the tissue,[10] though RF energy is most

FIGURE 1. Venus Viva device with diamond polar and viva nano-fractional applicators.

commonly used in cosmetic dermatology as a non-invasive method of skin tightening and facial rejuvenation. The effects of treatment with RF energy are produced within the heated area by 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.[9,10]

"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."

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.[11-12] This fractional technology, piloted in 2009 uses pins as electrodes to deliver the RF energy to the targeted tissue and have been regarded as successful in treating a variety of dermatological conditions.[12] These new fractional RF devices have been shown to improve facial brightness, tightness, and skin pigmentation.[13-15] More work is necessary, however, to evaluate the safety and effectiveness of using RF to treat various skin conditions such as melasma.

While the technology behind fractional RF has received some support for its efficacy in treating a variety of skin conditions, the patient's degree of satisfaction with the procedure has not been fully assessed. As such, the current study examined patient-reported satisfaction following treatment with the Venus Viva™.

MATERIALS AND METHODS

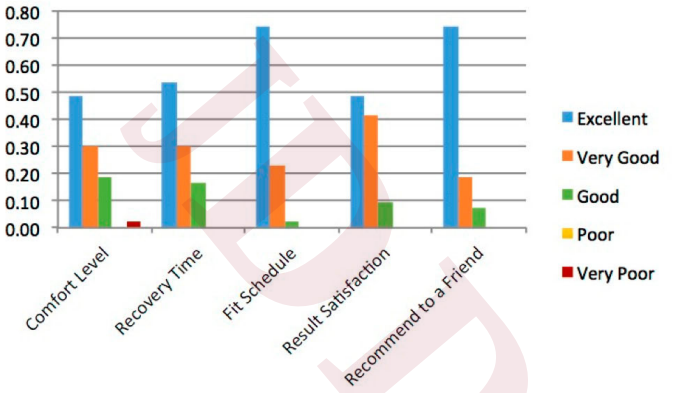
Participants included 43 healthy volunteers, over the age of 18 years, reporting varying degrees of facial rhytides, hyperpigmentation, skin laxity, or texture irregularity. Study participants were enrolled in the study after meeting all inclusion and exclusion criteria, as well as providing informed consent. Participants who were pregnant or nursing, had an implanted pacemaker or defibrillator, or exhibited symptoms of an acute systemic or local infection, such as herpes simplex, were excluded from participating in the study.

Participants received up to three treatments of non-ablative RF technology. This study utilized the Venus Viva™ device, whose exclusive design operates using both SmartScan™ and Nano-Fractional RF™ technology (Venus Concept, Toronto, Canada), for treatment delivery. More specifically, Nano-Fractional RF™ technology provides targeted density control of the heated zone by delivering the RF energy individually through 160 pins per tip, with 62mj per pin and a small footprint per pin (150X20 microns). This unique design allows for more control over the ablation/coagulation ratio; thereby reducing patient discomfort during the procedure and resulting in minimal downtime following the procedure for recovery. Further, the Venus Viva™ device uses patented SmartScan™ tip technology, which provides over 1000 pulses of energy, penetration depths of up to 500 microns, and multiple options for pattern selections (Figures 1 and 2).

Ratings of patient satisfaction were obtained three months following the last treatment and evaluated using a 5-item questionnaire. Each item was rated on a 5-point Likert-type scale

FIGURE 2. Venus Viva nano-fractional smart scan tip.

FIGURE 3.



(1="very poor"; 2="poor"; 3="good"; 4="very good"; 5="excellent"). This questionnaire assessed five separate domains of self-reported satisfaction, including degree of comfort during treatment procedures, recovery time following treatment, convenience and efficiency of treatment appointments, treatment results, and whether the patient would recommend the treatment to a friend.

RESULTS

All study participants completed between one and three treatments with Venus Viva™ using both SmartScan™ and Nano-Fractional RF™ technology. There were no unexpected adverse side effects from the treatment reported or detected during the study. A portion of the study participants reported moderate skin erythema and edema within the treated area, which resolved within several days without further treatment or sequela. During the initial healing phase following treatment, tiny pin-point epidermal crusts were noted to appear at each micro-ablated spot. These crusts were no more than 250 microns in diameter and were naturally exfoliated within several days of the procedure, resulting in epidermal resurfacing. None of the study participants reported experiencing additional severe side effects from the treatment, such as burns, skin irritation, or scarring.

Overall, results from the patient satisfaction questionnaires three months after treatment were positive. See Figure 3 for the full results from the questionnaire. On average, 60% of study participants reported "excellent" satisfaction across each of the five domains of patient satisfaction. Moreover, only one participant reported "very poor" in the domain of comfort during treatment procedures. No other ratings of "poor" or "very poor" satisfaction were reported across the five domains.

DISCUSSION

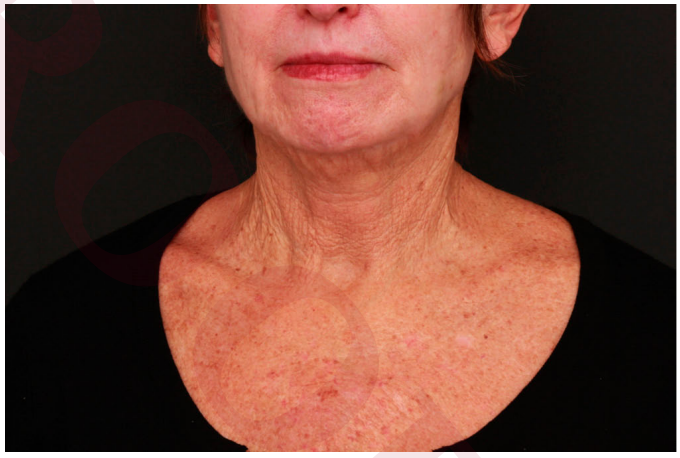
Findings from this study lend additional support for the use of fractional RF for treating various age-related skin conditions. Specifically, findings demonstrate positive patient satisfaction with regard to the Venus Viva™ device. It is encouraging to note that patients reported satisfaction with both the comfort level of the treatment as well as the recovery time following the treatment procedures. The sample size included in the current study is relatively limited in skin typing and conditions and as such, it is necessary for this study to be replicated on other populations who present with a variety of skin conditions, to assess for the generalizability of these findings.

Given these promising findings, the Venus Viva™ device may be regarded as the ideal treatment modality for providing skin rejuvenation to patients suffering from symptoms of natural aging and other skin conditions.

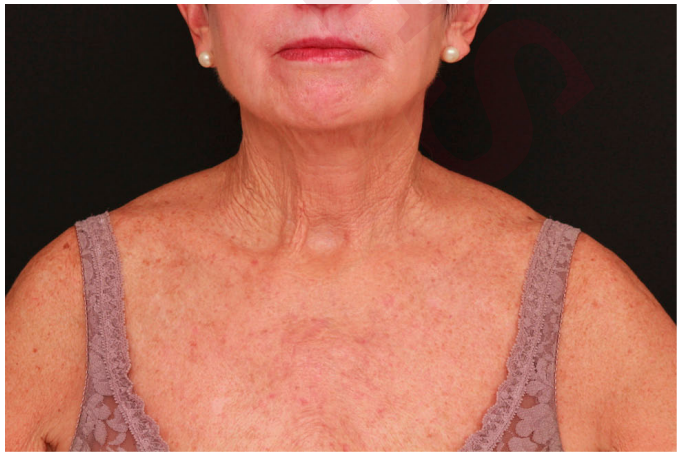
Limitations

The current study is not without limitations, which likely impact the interpretation of the findings. Of note, the questionnaire utilized for this study was limited in terms of the number of items assessing the various domains of patient satisfaction.

FIGURE 4. (A) Before neck and décolleté;



(B) After neck and décolleté; 3 treatments.



This restricted the potential range of responses, thereby affecting the variability of the data. As such, conclusions from these data should be interpreted with caution. Future studies are necessary utilizing a more in depth assessment of patient-reported satisfaction following treatment with the Venus Viva™ device. These concomitant studies may also consider including open-ended questions in order to achieve a fuller investigation into the patient's perceptions of the treatment procedure.

CONCLUSION

Overall, participants receiving treatment for their facial dermatological concerns with the Venus Viva™ device, indicated that they were generally very satisfied with the procedure. In fact, 60% of participants reported "excellent" satisfaction across all domains of patient satisfaction assessed by the current study. In terms of the domains of patient satisfaction individually, patients also reported very high degrees of satisfaction with regard to degree of comfort during treatment procedures, recovery time following treatment, convenience and efficiency of treatment appointments, treatment results, and whether they would recommend the treatment to a friend. Only one participant reported "very poor" satisfaction within the domain of comfort during treatment procedures. No other ratings of "poor" or "very poor" satisfaction were reported across the five domains.

Previous clinical studies have demonstrated the efficacy of the Venus Viva™ device for treating various skin conditions, including striae, acne scarring, irregular texture, rhytides, hyperpigmentation, and skin laxity. An example is shown in Figure 4. Treatment using SmartScan™ and Nano-Fractional RF™ technology has also resulted in aesthetic improvements for each subject, as measured by visually comparing images taken at follow-up to those taken prior treatment. These studies suggest that fractional RF is an effective treatment for abnormal collagen formation and promotes the formation of new dermal proteins to give the appearance of smoother, clearer skin.

Moreover, this study provides additional support for the Venus Viva™ device is a preferred treatment for rejuvenating facial skin. Results from patient satisfaction surveys indicate that RF is safe and that the treatment is well tolerated among patients with a variety of cosmetic skin complaints. This device is believed to offer increased efficacy, due to the operator ability to control both power and pulse duration, which results in improved control of tissue ablation or coagulation ratio. The reduced pin footprint is also believed to be associated with decreases in reported side effects from the treatment. This study also demonstrates that SmartScan™ and Nano-Fractional RF™ technology provides homogenous RF treatment with increased density control, which leads to a greater frequency of painless radiofrequency exposure. Indeed, it may be that SmartScan™ with Nano-Fractional RF™ technology is an appropriate tool for treating other skin conditions, though additional work is necessary to explore the efficacy of this treatment on a variety of skin conditions.

DISCLOSURES

Dr. Michael H. Gold is a consultant for Venus Concept. Dr. Martin Ray received an honorarium for the study from Venus Concept and is on the Allergan Advisory Board.

REFERENCES

1. Helfrich YR, Sachs DL, Voorhees JJ. Overview of skin aging and photoaging. *Dermatol Nurs* 2008;20:177-183.
2. Finzi E, Spangler A. Multipass vector (Mpave) technique with nonablative radiofrequency to treat facial and neck laxity. *Dermatol Surg* 2005;31:916-922.
3. Sadick NS. Update on non-ablative light therapy for rejuvenation: A review. *Lasers Surg Med* 2003;3:2120-2128.
4. Goldberg DJ, Cutler KB. Nonablative treatment of rhytids with intense pulsed light. *Lasers Surg Med* 2000;26:196-200.
5. Hruza GJ. Laser skin resurfacing. *Arch Dermatol* 1996;132:451-455.
6. Goldberg DJ. Er:YAG laser resurfacing: What is its role? *Aesth Surg J* 1998;18:255-260.
7. Narins RS, Narins DJ. Nonablative skin resurfacing. *Aesth Surg J.* 2004;24:281-284.
8. Zelickson BD, Kist D, Bernstein E et al. Histological and ultrastructural evaluation of the effects of a radiofrequency-based nonablative derumal remodeling device: A pilot study. *Arch Dermatol* 2004;140:204-209.
9. Alster TS, Lupton JR. Nonablative cutaneous remodeling using radiofrequency devices. *Clin Dermatol* 2007;25:487-91.
10. Beasley, KL, Weiss RA. Radiofrequency in cosmetic dermatology. *Dermatol Clin* 2014;32:79-90.
11. Zelickson BD, Kist D, Bernstein E, et al. Histological and ultrastructural evaluation of the effects of a radiofrequency-based nonablative dermal remodeling device: A pilot study. *Arch Dermatol* 2004;140:204-9.
12. Hantash BM, Ubeid AA, Chang H, Kafi R, Renton B. Bipolar fractional radiofrequency treatment induces neoelastogenesis and neocollagenesis. *Lasers Surg Med* 2009;41:1-9.
13. Kim JE, Lee HW, Kim JK, et al. Objective evaluation of the clinical efficacy of fractional radiofrequency treatment for acne scars and enlarged pores in Asian skin. *Dermatol Surg* 2014;40:988-95.
14. Gold MH, Biron JA. Treatment of acne scars by fractional bipolar radiofrequency energy. *J Cosmetic Laser Therapy* 2012;14:172-8.
15. Ong MWS, Bashir SJ. Fractional laser resurfacing for acne scars: a review. *British Journal of Dermatology* 2012;166:1160-1169.

AUTHOR CORRESPONDENCE

Michael H. Gold MD

E-mail:..... drgold@goldskincare.com