# Novel Nonablative Radio-Frequency Rejuvenation Device Applied to the Neck and Jowls: Clinical Evaluation and 3-Dimensional Image Analysis

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## ABSTRACT

**Objective:** To use 3D photography to evaluate the clinical efficacy of a novel radiofrequency delivery device used to improve the appearance of rhytids and laxity of the face and neck.

**Study Design:** Forty-nine subjects received a total of two radio-frequency treatments to the face and neck one-month apart. The novel radio-frequency delivery device was used to heat the dermis between 41-43°C for five heat cycles. Primary outcome measures were clinical efficacy quantified by the Global Assessment Improvement Scale (GAIS) and a patient survey that assessed treatment satisfaction.

**Results:** Assessments of 3D photographs revealed an overall improvement in 74% of study subjects. 85% of patients noted an overall improvement in the appearance of their skin. 81% of patients rated their post-treatment skin laxity as improved, 85% rated their skin smoothness as improved and 62% rated their skin brightness as improved.

**Conclusion:** Subjects in this study demonstrated an overall improvement in face and neck appearance with regard to skin tightening, wrinkles, and skin texture suggested by overall patient satisfaction (85%) and physician-rated GAIS improvement (74%). This study suggests that radiofrequency applied with a continuous thermal treatment device is a safe and efficacious way to improve the overall appearance of aging facial skin.

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## INTRODUCTION

There are multiple manifestations of the aging face, which are influenced by internal and external factors. Rhytids develop around the eyes, forehead, mouth, and lower jaw. Skin laxity increases noticeably in the jowls and neck. As a means to correct these changes, patients seek out various treatment options including surgical intervention, photorejuvenation, radio-frequency devices, chemical ablation, retinoids, fillers and neurotoxins. Non-invasive and non-ablative procedures have increased in popularity because they have little to no recovery time and minimal side effects. Of the non-ablative procedures, radio-frequency devices have been shown to decrease skin laxity and improve the appearance of rhytids.[1] It has been suggested that results are achieved by the thermal effect: electrically generated radiowaves produce heat in the skin as determined by the formula: Energy (J) = $I^2 \times R \times T$ (I = Current, R = Impedance of the tissue, T = time of application).[2] At the frequencies used by these devices, the greater impedance of the dermis relative to the epidermis leads to heat production in the dermis with sparing of the epidermis. Thus, dermal collagen fibrils are selectively targeted, resulting in collagen fibril shortening[3]. The heat produced also induces an inflammatory response leading to collagen neogenesis.[4] In this study we describe a novel application of monopolar radio-frequency (RF) to generate continuous heat in the dermis resulting in skin tightening and an overall improved cosmesis.[5] Clinical data evaluating the efficacy of this procedure was limited. To address this deficiency, we designed a prospective clinical study to evaluate overall patient satisfaction and investigator assessed clinical efficacy of this novel monopolar radio-frequency device.

**FIGURE 1.** Area of the face treated with the Pellevé™ Wrinkle Treatment System.

## METHODS

### Study Design

This prospective clinical study was conducted at two study sites using a protocol that was preapproved by an institutional review board. Subjects that fulfilled the eligibility criteria and provided written consent to study treatment and photography received two treatments, spaced at 30-day intervals.

The patients were treated with the Pellevé™ Wrinkle Treatment System (Ellman, International), which consists of the Pellevé™ S5 RF Generator with the Pellevé™ handpiece, IR thermometer (Fluke, Everett, WA) and treatment gel. The treatment area included the full face and neck, excluding the forehead and upper eyelids (Figure 1). The entire treated area received a minimum of five "passes" with the device. A "pass" is defined as the treatment region reaching the desired temperature of 41-43°C as determined by the IR thermometer.

Photographic images were taken in identical three-dimensional fixed positions with the Vectra 3M Imaging System (Canfield imaging systems, Fairfield, NJ) and analyzed using the system's Mirror software.

Efficacy and safety analyses were performed on the entire pooled population.

Results were reviewed at baseline and at 120 days post 2nd treatment. The degree of clinical improvement was then given a global aesthetic improvement scale (GAIS) (Table 1) for each patient by the investigator. The score was calculated based on comparative analysis of pre- and post-treatment 3D photographs. A score of -1 = the appearance is worse than the original condition; 0 = the appearance is essentially the same as the original condition; 1 = appreciable improvement in the appearance from the original condition; 2 = marked improvement in the appearance from the original condition; 3 = optimal cosmetic results in this patient.[1]

**TABLE 1.**

| Global Aesthetic Improvement Scale (GAIS) | |
|---|---|
| (3) Very Much Improved | Optimal cosmetic result from the implant in this patient |
| (2) Much Improved | Marked Improvement in appearance from the initial condition but not completely optimal |
| (1) Improved | Obvious improvement in appearance from the initial condition, but a touch-up is indicated |
| (0) No Change | The appearance is essentially the same as the original condition |
| (-1) Worse | The appearance is worse than the original condition |

Subjects satisfaction was assessed at 120 days after their second treatment by assigning an overall value for skin tightening, wrinkles, and skin texture where -1 = worse; 0 = no change; 1 = subtle improvement; 2 = mild improvement; 3 = moderate improvement; 4 = very good improvement.

### Study Population

Patients were recruited from a private dermatology practice in Los Angeles, California. All patients met the following inclusion criteria: 30-70 years of age; moderate to severe neck wrinkles corresponding to a 4-9 on the Fitzpatrick Wrinkle Assessment Scale;[6] willingness and ability to comply with protocol requirements, including returning for follow-up visits and abstaining from exclusionary procedures for the duration of the study; willingness and ability to provide written photo consent and adherence to photography procedures (ie, removal of jewelry and makeup); willingness and ability to provide written informed consent prior to performance of any study related procedure.

Patients were excluded from the study for the following reasons: Subjects who were pregnant, nursing, planning to become pregnant, and/or not using a reliable form of birth control; Subjects who had prior exposure to any hyaluronic acid, or any other filler, injection for any purpose in the 12 months preceding study enrollment through the duration of the study; Subjects who had prior exposure to any botulinum toxin for rhytids in the treatment area in the 6 months preceding study enrollment through the duration of the study; Subjects who had a prior cosmetic procedure to improve rhytids in the treatment area (ie, rhytidectomy, $CO_2$/erbium laser resurfacing, Thermage/Thermacool radio-frequency treatment) within 12 months or who have visible scars that may affect evaluation of response and/or quality of photography; Microdermabrasion, or prescription level glycolic acid treatments within 3 months prior to study participation or during the study; Active cut, wound, or infection on the skin; Oral isotretinoin within the past 12 months; Active HSV-1; History of keloids or hypertrophic scarring; Existing or history of skin malignancy in the treatment area during the past 12 months; Existing or history of skin dis-

**TABLE 2.**

| Patient Demographics | |
|---|---|
| Age | Mean: 58 (30-71) |
| Men<br>Women | N = 4 (8%)<br>N = 45 (92%) |
| Skin Type<br>I<br>II<br>II-III<br>III<br>IV<br>V | <br>N = 1<br>N = 8<br>N = 2<br>N = 12<br>N = 0<br>N = 1 |
| Rhytids Score | 3.2 ± 0.4 (N = 26) |
| Laxity Score | 3.2 ± 0.4 (N = 26) |

**TABLE 3.**

**Investigator Overall GAIS Scores and Patient Study Survey Overall Satisfaction Scores**

| GAIS Overall | | | Satisfaction Overall | | |
|---|---|---|---|---|---|
| Mean Score | | 0.88 | Mean Score | | 1.08 |
| SD | | 0.73 | SD | | 0.63 |
| Score | Frequency | % | Score | Frequency | % |
| -1 | 1 | 2.94 | 0 | 4 | 15.38 |
| 0 | 8 | 23.53 | 1 | 16 | 61.54 |
| 1 | 19 | 55.88 | | | |
| 2 | 6 | 17.65 | 2 | 6 | 23.08 |

-1 = Worse
0 = No change
1 = Subtle Improvement
2 = Mildly Improved

ease in the treatment area during the past 12 months; History of collagen or vascular disease; Subjects who have implantable pacemaker, automatic implantable defibrillator or cadioverter (AICD), or any other implantable electric device; Subjects who have used, within 30 days, any medication that can cause dermal hypersensitivity or affect skin characteristics; History of autoimmune disease; History of any disease that inhibits pain sensation; History of Diabetes I or II; Concurrent therapy that, in the investigator's opinion, would interfere with the evaluation of the safety or efficacy of the study device; Subjects who anticipate the need for surgery or overnight hospitalization during the study; Subjects who, in the Investigator's opinion, have a history of poor cooperation, noncompliance with medical treatment or unreliability; enrollment in any active study involving the use of investigational devices or drugs.

## Statistical Analyses

Statistics were calculated using Stata IC, Version 10 (College Station, TX).

**FIGURE 2.** 2D images of two different patients using the Vectra 3D system. (Patient 1) the neck pre **a)** and 120 days post **b)** therapy.

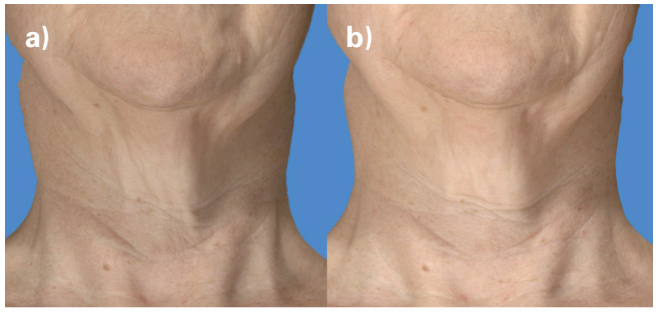
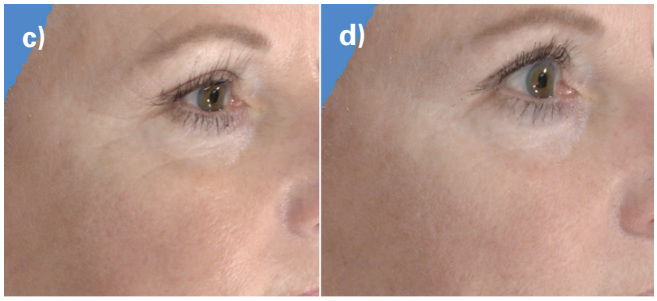



**FIGURE 3.** (Patient 2) crows feet pre **c)** and 120 days post **d)** treatment.




## RESULTS

Fifty patients were enrolled in the study however one was eventually excluded for receiving injectable filler during the study assessment period (Table 2). The median patient age was 59 (range 30-71years).

Investigator assessments were based on pre- and 120-day post-treatment 3D photographs (Figure 3). The 3D photographs included the entire face and neck from the frontal hairline to the clavicles. Baseline and 120-day post treatment photos were viewed side-by-side, and the investigator rotated and zoomed in and out of each image in order to compare the same anatomical areas at different time points. At the time of viewing, a GAIS score was assigned to each comparative image. This evaluation resulted in overall improvements of at least 1 point on the GAIS in 74.67% of study subjects (Table 3).

Patient satisfaction was assessed by use of a study subject survey. 84.62% of patients noted an overall improvement (Table 3) at 120 day post-treatment with no adverse effects reported. 80.77% of patients rated their post-treatment skin laxity having at least subtle improvement (score of 1 or higher); 84.61% and 61.54% of patients rated their post-treatment skin smoothness and brightness as having at least subtle improvement, respectively (Table 4). All subjects were able to return to normal activity immediately post-treatment. There were no reports of post-procedural pain or discomfort. No adverse events were reported.

**TABLE 4.**

**Patient Study Survey Skin Post-Treatment Skin Laxity, Smoothness, Brightness Scores**

| Laxity | | | Smoothness | | | Brightness | | |
|---|---|---|---|---|---|---|---|---|
| Mean Score | | 0.85 | Mean Score | | 1 | Mean Score | | 0.73 |
| SD | | 0.46 | SD | | 0.57 | SD | | 0.67 |
| Score | Freq | % | Score | Freq | % | Score | Freq | % |
| 0 | 5 | 19.23 | 0 | 4 | 15.38 | 0 | 10 | 38.46 |
| 1 | 20 | 76.92 | 1 | 18 | 69.23 | 1 | 13 | 50.00 |
| 2 | 1 | 3.85 | 2 | 4 | 15.38 | 2 | 3 | 11.54 |

-1 = Worse
0 = No change
1 = Subtle Improvement
2 = Mildly Improved

## DISCUSSION

Non-ablative facial skin rejuvenation with this monopolar radiofrequency device, Pellevé™ wrinkle treatment system, offers some advantages over other non-ablative procedures including little to no recovery time and few, if any, side effects. In this study, patients underwent two treatments separated by one month. 81% of patients rated their post-treatment skin laxity as having at least subtle improvement. 85% reported improved post-treatment skin smoothness and 62% reported improved post-treatment skin brightness. Data from this study also showed that both patient and investigator appreciated an overall improvement at the 120-day post-treatment end-point.

These results are in agreement with other studies done on different radio-frequency devices.[5,7,8,9] There were, however, confounding variables in this study that may have led to type I errors. Alignment of patient head and neck positioning for the 3D imaging system at follow-up may not have been identical to baseline photos. Hydration status of each patient at the time of photographic evaluation was not controlled for and may have influenced skin laxity and the appearance of rhytids. The photographs taken by the imaging system were electronically sampled and digitized, which can affect 3D investigator interpretation. Further studies using the Vectra 3D photography system to assess facial rejuvenation with radiofrequency delivery devices are needed to clarify this issue.

## CONCLUSION

After undergoing two treatments with a novel non-ablative radio-frequency rejuvenation device, subjects in this study demonstrated an overall improvement in face and neck appearance with regard to skin tightening, wrinkles, and texture. This was confirmed by both overall patient satisfaction (85%) and physician-rated GAIS improvement (76%). Patients reported no side effects, and there was no recovery time after each treatment. This study suggests that the Pellevé™ Wrinkle Treatment System is a safe and efficacious device to improve the overall appearance of aging facial skin.

## DISCLOSURES

This study was supported in part by an unrestricted educational grant provided by Ellman, International.

## REFERENCES

1. El-Domyati M et al. Radiofrequency facial rejuvenation: Evidence-based effect. *J Am Acad Dermatol* 2011;64:524-35.
2. Tunnel JW, Pham L, Stern RA, et al. Mathematical model of nonablative RF heating of skin. *Lasers Surg Med* 2002;14(Suppl):318.
3. Zelickson B, Kist D, Bernstein E, Brown DB, Ksenzenko S, Burns J, Kilmer S, Mehregan D, Pope K. Histological and ultrastructural evaluation of the effects of a radiofrequencybased nonablative dermal remodeling device: A pilot study. *Arch Dermatol* 2004;140:204–209.
4. Moetaz el-Domyati M, el-Ammawi TS, Medhat W, Moawad O, Brennan D, Mahoney MG, Uitto J. Radiofrequency facial rejuvenation: evidence-based effect. *J Am Acad Dermatol*. 2011 Mar;64(3):524-35.
5. Stamplar M. The pelleve procedure: an effective method for facial wrinkle reduction and skin tightening. *Facial Plast Surg Clin North AM*. 2011 May;19(2):335-45.
6. Weiss RA, Harrington AC, Pfau RC. et al. Periorbital skin resurfacing using high energy erbium:YAG laser: results in 50 patients. *Lasers Surg Med*. 1999;2481- 86
7. Hsu TS, Kaminer MS. The use of nonablative radiofrequency technology to tighten the lower face and neck. *Semin Cutan Med Surg* 2003;22:115–23.
8. Ruiz-Esparza J, Gomez JB. The medical face lift: a noninvasive, nonsurgical approach to tissue tightening in facial skin using nonablative radiofrequency. *Dermatol Surg* 2003;29:325–32.
9. Robert A. Weiss MD, Margaret A. Weiss MD, Girish Munavalli MD MHS, et al. Monopolar Radiofrequency Facial Tightening: A Retrospective Analysis Of Efficacy And Safety in Over 600 Treatments. *J Drugs Dermatol*. 2006;707-712

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