

NOVEL NONABLATIVE RADIOFREQUENCY REJUVENATION DEVICE: CLINICAL EVALUATION AND PATIENT SATISFACTION

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Provided for educational purposes

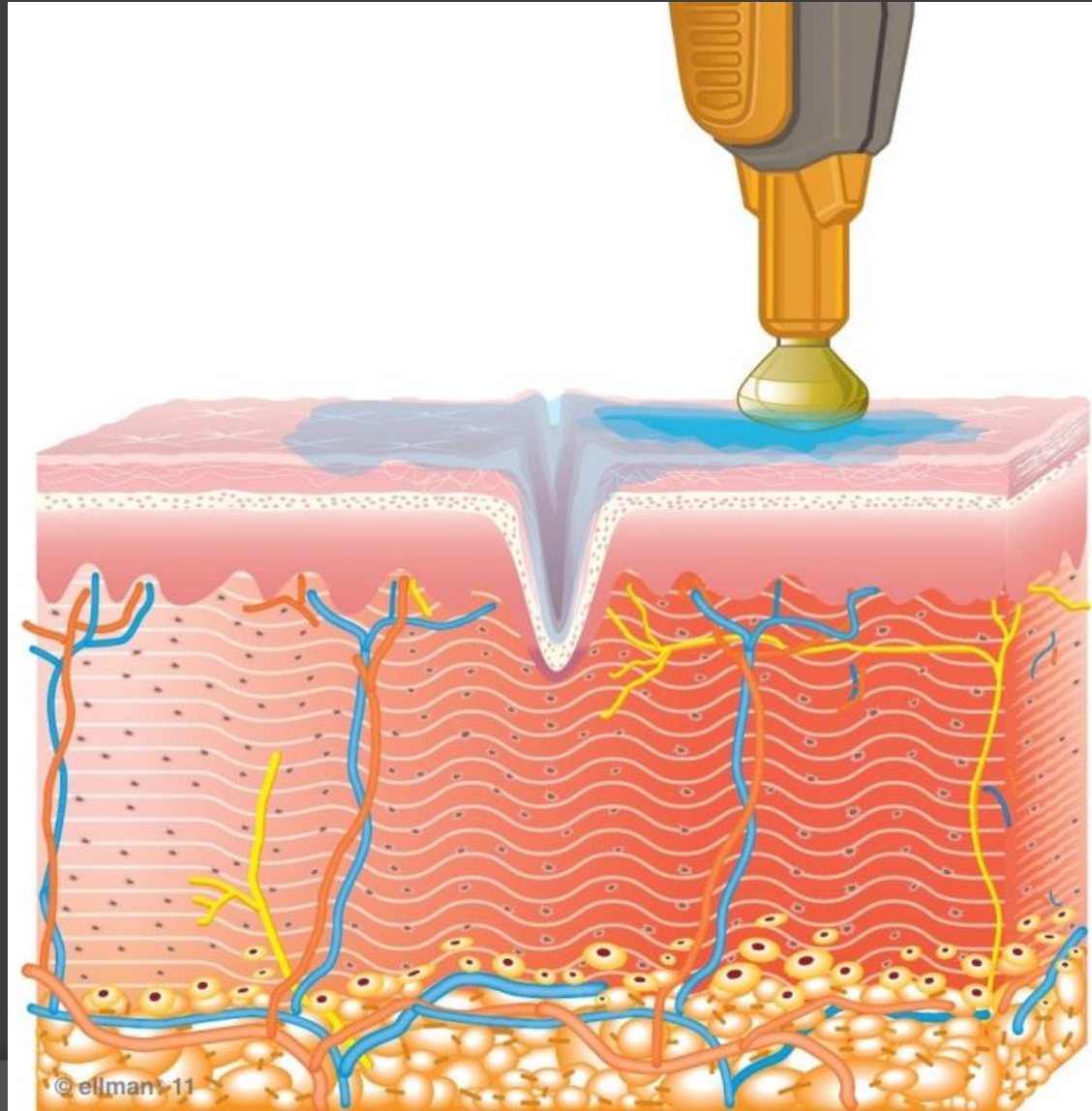
Disclosures

- Ellman International, Inc.
 - Investigator

Introduction

- ⦿ Non-ablative radiofrequency devices
 - Decrease skin laxity, tighten skin
 - Improve the appearance of rhytids
 - No recovery time
- ⦿ Thermal effect:
 - 4Mhz RF –to- current flow –to- deep tissue heating
 - Dermal collagen fibril shortening
 - Dermal collagen synthesis

Novel handpiece



Surgitron® RF™ S5 with Pellevé™ handpiece



Subjects

- ⦿ 49 subjects
- ⦿ Men and women, ages 30-71
- ⦿ Moderate to severe neck wrinkles
 - 4-9 on Fitzpatrick Wrinkle Assessment Scale
- ⦿ No other cosmetic procedures (fillers, neurotoxins, lasers) to treated area for 12 months prior and throughout study
- ⦿ Excluded for implanted electrical devices, pregnancy, inability to complete study

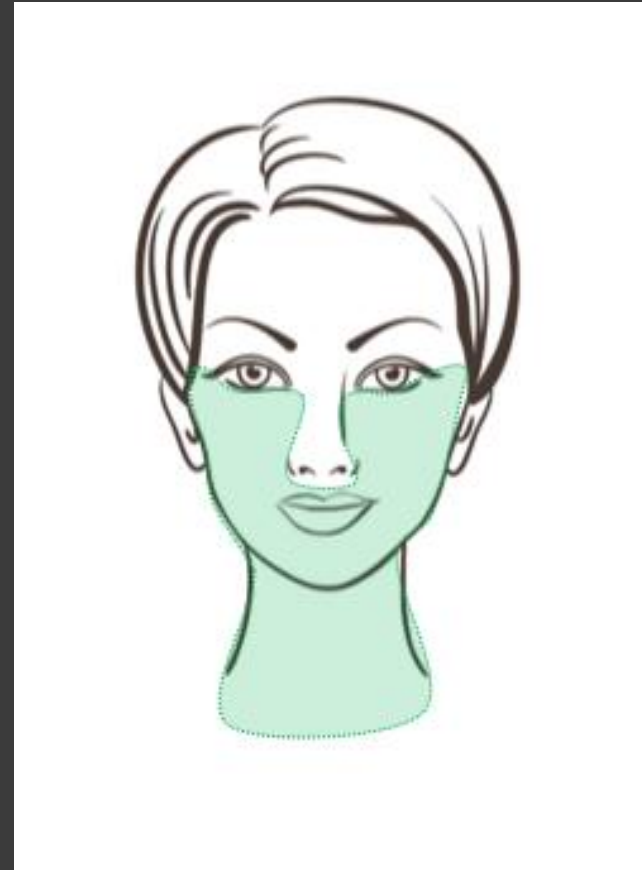
Subject Characteristics (Enrolled)

Sex	Men	N=4 (8%)
	Women	N=45 (90%)
Age	Average 58	Median 59 (Min 30, Max 71)
Skin Type	I	N=1
	II	N=8
	II-III	N=2
	III	N=12
	IV	N=0
	V	N=1
Rhytids Score	3.2 ± 0.364	
Laxity Score	3.4 ± 0.53	

Interesting to note older than typical age range & median

Study design

- Two treatments, one month apart
- Treatment area from crows feet to clavicles
- 3D photographs at baseline and 120 days after 2nd treatment



Treatment parameters

- 5 passes (heat cycles)
- Crows feet to clavicles
- Surface temperature target range:
41-42°C
 - IR thermometer
- Second treatment 30 days later

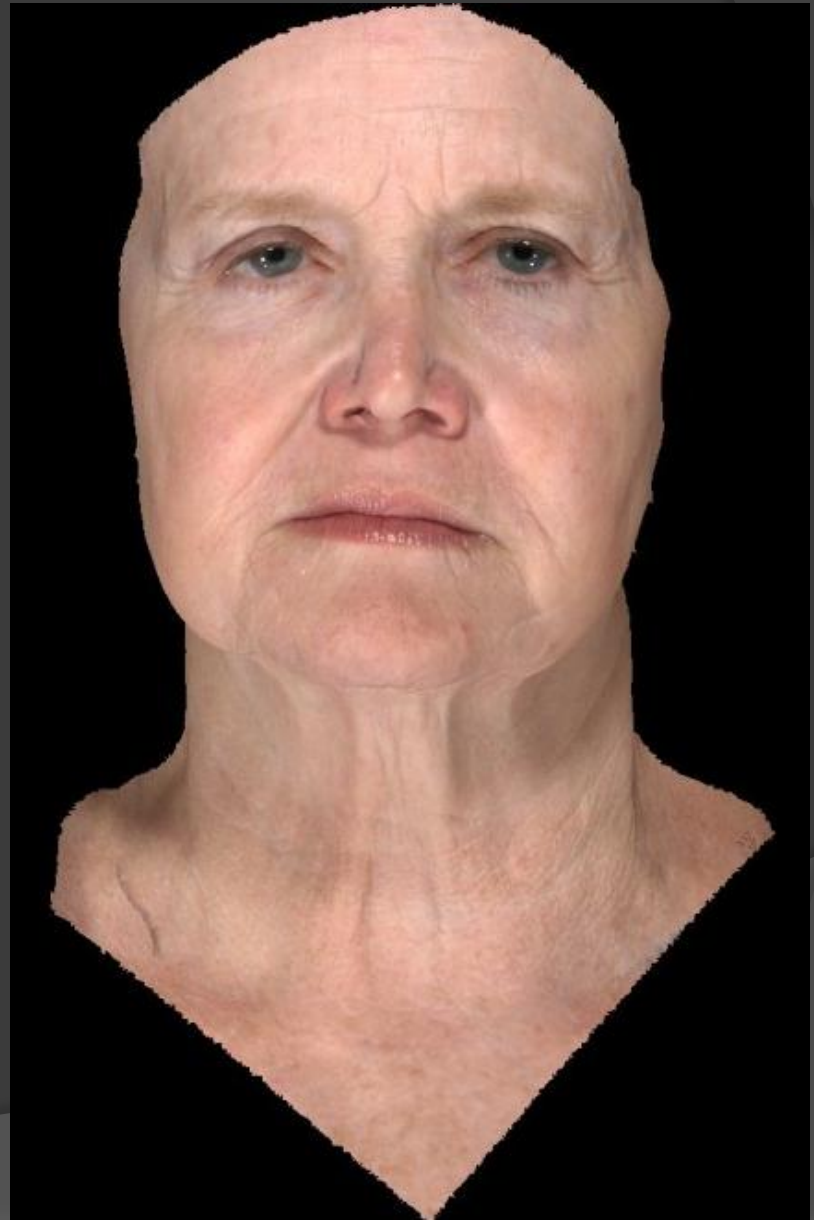


3D Photography





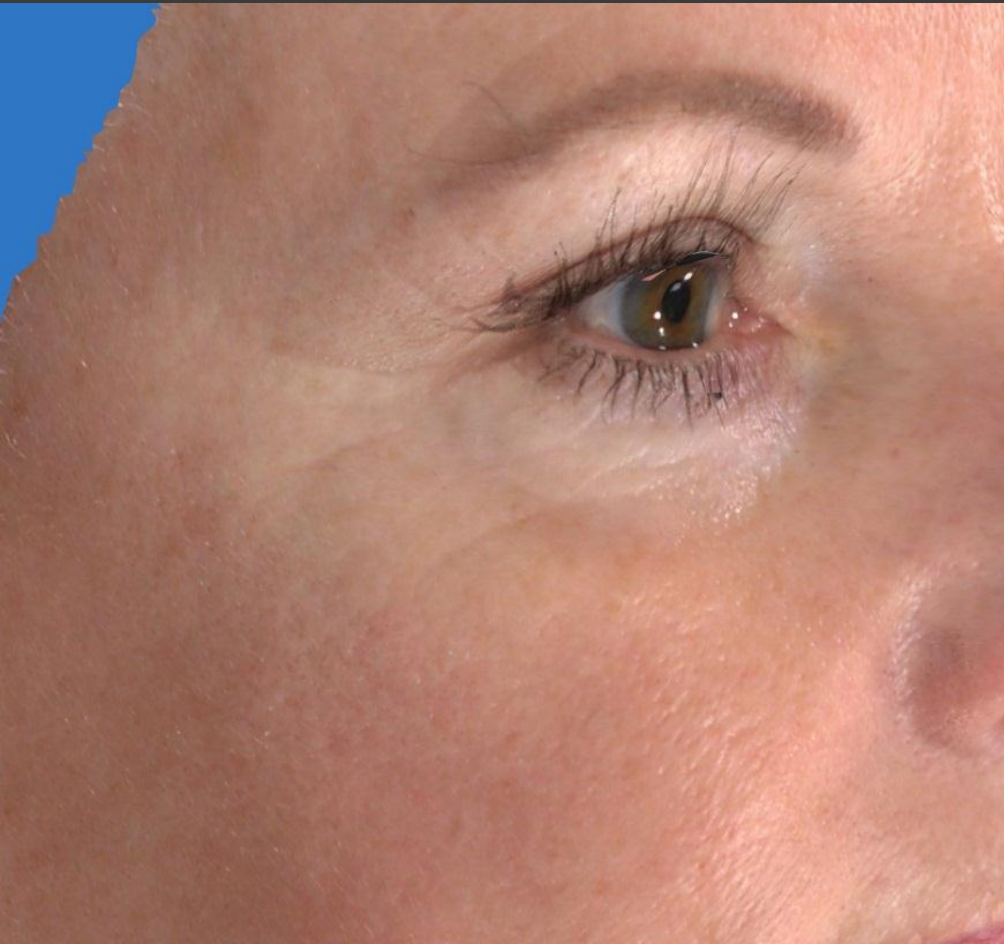
Before and After photos



Before and After photos

Pre treatment

120 day



Before and After photos

Pre treatment

120 day

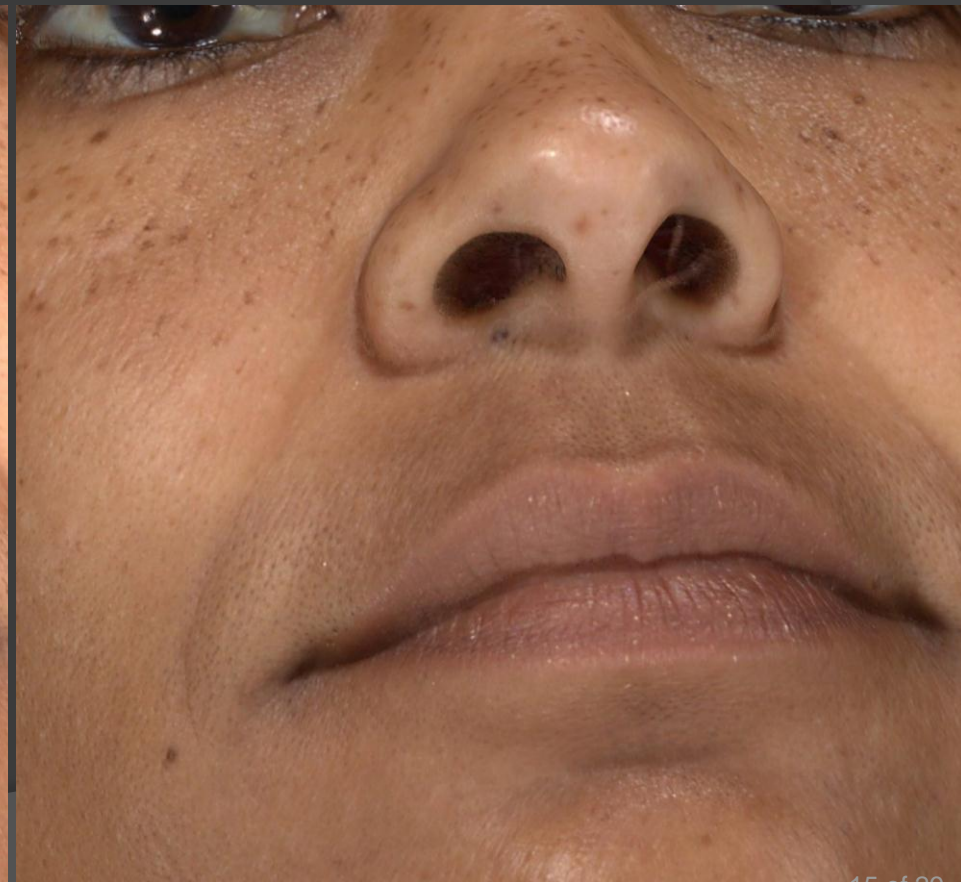
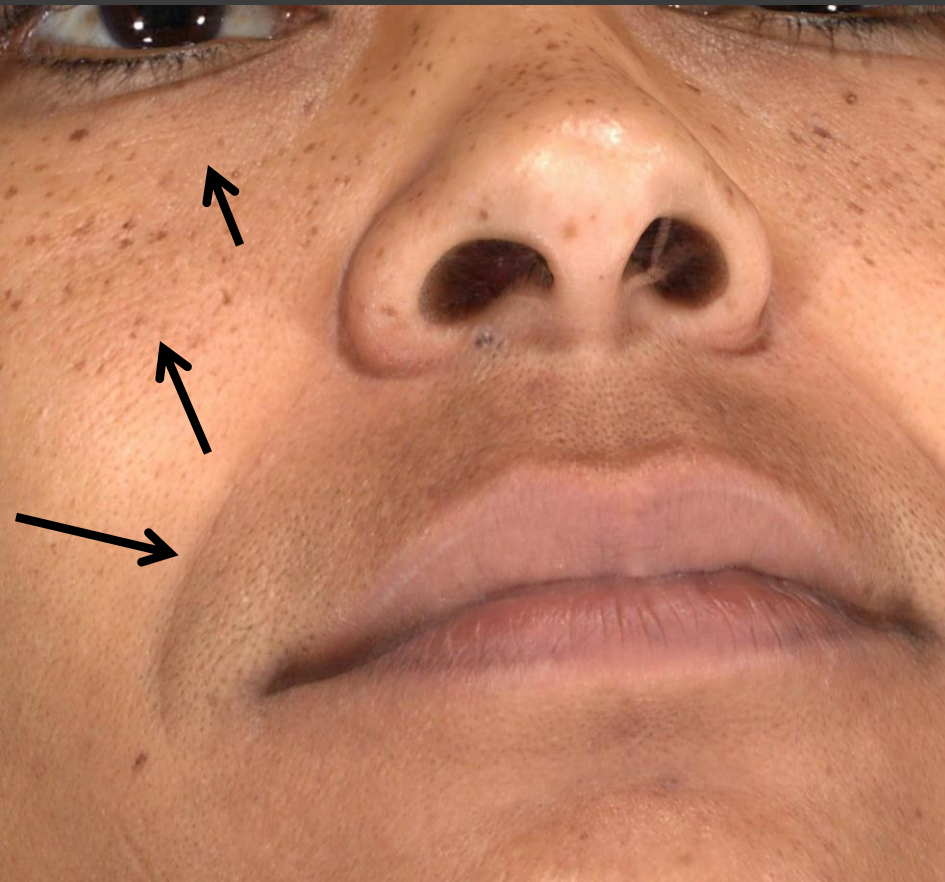


Before and after photos

Right Nasal Labial Fold is less pronounced at 120 days than pretreatment

Pre treatment

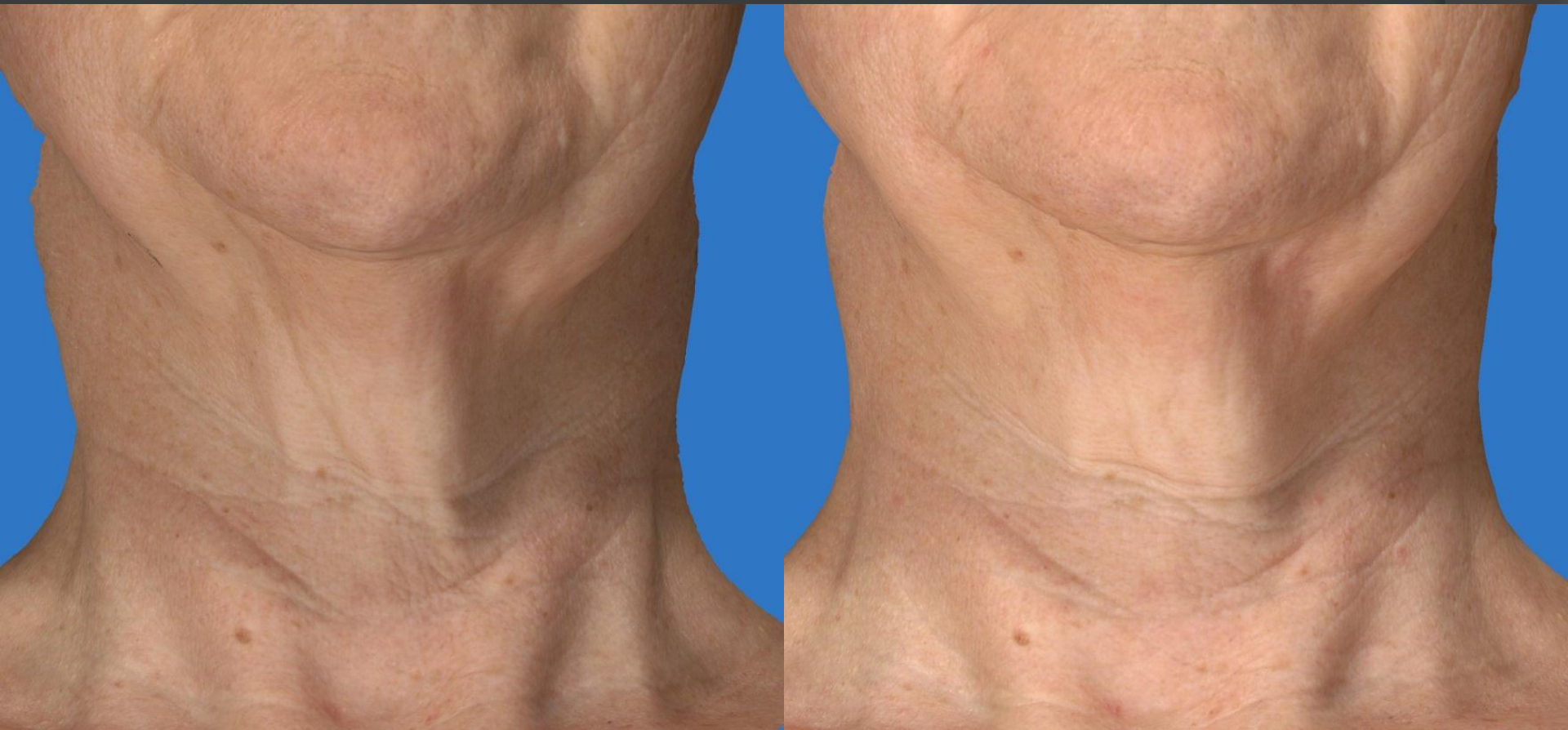
120 day



Before and After photos

Pre treatment

120 day



Pre treatment

120 day



Results

- ⦿ Global Aesthetic Improvement Scale (GAIS)
 - -1 worse
 - 0 no change
 - 1 improved
 - 2 much improved
 - 3 very much improved

Adapted from Narins R et al, Dermatol Surg 2003; 29: 588-95

GAIS Overall

120 days	Frequency	Percent
-1	1	2.94
0	7	20.58
1	20	58.82
2	6	17.65
Total	34	

76.47% of patients demonstrated improvement based on GAIS comparisons of 3D images at 120 days.

Patient Satisfaction Surveys

⦿ Laxity	-1	Worse
⦿ Smoothness	0	No change
⦿ Brightness	1	Subtle improvement
	2	Mildly improved
	3	Moderately improved
	4	Very good improvement

Subject Satisfaction: Overall

Overall Satisfaction	Frequency	Percent
0	4	15.38
1	16	61.54
2	6	23.08
Total	26	

Mean overall satisfaction: 1.08 ± 0.63

84.62% Overall patient satisfaction

Subject Satisfaction: Laxity

Laxity	Frequency	Percent
0	5	19.23
1	20	76.92
2	1	3.85
Total	26	

Mean satisfaction laxity: 0.85 ± 0.46

Subject Satisfaction: Smoothness

Smoothness	Frequency	Percent
0	4	15.38
1	18	69.23
2	4	15.38
Total	26	

Mean satisfaction smoothness: 1.00 ± 0.57

Subject Satisfaction: Brightness

Brightness	Frequency	Percent
0	10	38.46
1	13	50.00
2	3	11.54
Total	26	

Mean satisfaction brightness: 0.73 ± 0.67

Results (120 days)

Overall Physician GAIS

- 76% of subjects improved, based on 3D image assessment

Subject Satisfaction

- 85% of subjects noted overall improvement in skin laxity, brightness and smoothness

Discussion

- ⦿ Non-ablative monopolar radiofrequency tightening
 - Painless
 - No adverse effects
 - No down time
 - Improvement in rhytids, skin texture, and skin tightness

Our Team

- ⦿ Heidi B. Prather, MD (U. Pittsburgh)
- ⦿ Jeffrey J. So, MS, PA-C
- ⦿ Jonathan Schouest, BS
- ⦿ Jason Bentow, MD (Harbor-UCLA)
- ⦿ Ronald L. Moy, MD, FAAD (UCLA)

References

1. Narins R et al. A randomized, double-blind, multicenter comparison of the efficacy and tolerability of Restylane versus Zyplast for the correction of nasolabial folds. *Dermatol Surg* 2003; 29: 588-95
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. 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.
7. 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.

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