



The use of radiofrequency-assisted lipolysis with radiofrequency microneedling in premature jowl and neck laxity following facialplasty

Daniel Demesh MD¹ | Robert T. Cristel MD¹ | Nimit D. Gandhi MD^{2,3} |
Eljona Kola MS^{2,3} | Steven H. Dayan MD, FACS^{1,2,3}

¹Department of Otolaryngology-Head & Neck Surgery, Division of Facial Plastic & Reconstructive Surgery, University of Illinois at Chicago, Chicago, IL, USA

²DeNova Research, Chicago, IL, USA

³Chicago Center for Facial Plastic Surgery, Chicago, IL, USA

Correspondence

Daniel Demesh, Department of Otolaryngology-Head & Neck Surgery, Division of Facial Plastic & Reconstructive Surgery, University of Illinois at Chicago, 1855 W. Taylor, Suite 2.42, Chicago, IL 60612, USA.

Email: ddemesh@gmail.com

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Abstract

Background: A subset of facelift patients have premature redevelopment of skin laxity in the lower face and neck. Many patients seek alternatives to revision facelifts to avoid high risks and costs. Radiofrequency-assisted lipolysis (RFAL) with Radiofrequency (RF) microneedling may be alternative minimally invasive options.

Objective/Aim: To evaluate the efficacy of radiofrequency energy devices for treatment of premature jowl and neck skin laxity following facialplasty.

Methods: This is a single-center, prospective study of patients seeking treatment for jowl and neck skin laxity 1-5 years following facialplasty. Treatment was performed with the InMode radiofrequency AccuTite[®] and Morpheus8[®] systems. Study duration was 12 months with 6 months of follow-up. Endpoints included improvement in skin tightening assessed by blinded investigators, and investigator and subject assessment of skin appearance. Subjects also rated satisfaction with treatment and pain levels.

Results: The study protocol was completed by nine patients. Based on investigator evaluations, 33% had marked improvement at 3 months, which increased to 55% at 6-month postprocedure. Patient-reported improvement was “markedly improved” in 67%, “moderate improvement” in 11%, and “slight improvement” in 22% at 3 months. Overall patient satisfaction was rated as “very satisfied” by 33% and “satisfied” by 67% at 3 months. There were no adverse events reported.

Conclusion: The results of this study provide supporting evidence that RFAL technology can provide a safe, minimally invasive, and effective treatment for skin laxity in the jowls and neck in patients who desire further correction after undergoing primary facelift.

KEYWORDS

face and neck contouring, facelift failure, minimally invasive body shaping, radiofrequency-assisted lipolysis, revision facelift, secondary facelift

1 | INTRODUCTION

The average results after facelift surgery last for many years. Results can range from 5 to 15 years, but generally can be expected to last 10 years on average.^{1,2} However, some patients experience premature skin laxity in the face and neck postprocedure when results no longer meet their appearance goals. Early skin laxity following facelift can be particularly bothersome in patients over the age of 50 and can be seen within the first 5 years postoperatively.² Skin laxity can be most pronounced in the lower face and neck.^{1,2} For these patients, a revision facelift is often their only choice. Secondary facelift procedures can be associated with increased risks and complications and increased the costs for the patient. Revision facelifts have increased risks due to excess scar tissue, a thinned superficial musculoaponeurotic system, and increasing concerns for poor wound healing after additional manipulation of the skin.³ These can all increase the risk of facial nerve injury, poor wound healing, and poor outcomes. Furthermore, patients may be seeking surgery from another surgeon, and therefore, it may not be fully known reliably how the first procedure was performed. With this, the desire for a minimally invasive, safe, and less traumatic rejuvenation treatment has grown substantially in recent years.

Minimally invasive, temperature-controlled radiofrequency (RF) technology offers an optimal energy-based, nonsurgical alternative to surgery. This particular study will focus on radiofrequency-assisted lipolysis (RFAL) technology through InMode MD Ltd.⁴ RF energy is applied to the treatment area using an AccuTite[®] handpiece with two electrodes. An internal active electrode emitting coagulative thermal energy targets the deep soft tissues, while a larger external electrode with low energy density creates nonablative RF heating. RF energy flows between the internal and the external electrode placed on the skin, heating the tissue in between the electrodes and causing a thermocoagulative effect. The treatment stimulates contraction and collagen formation while simultaneously coagulates and liquefies adipose tissue with profound contraction of the fibroseptal network.⁵⁻⁸ The RFAL technology became a well-established alternative for body,^{7,8} face, and neck^{6,9-11} rejuvenation treatments using RFAL-based handpieces.

An additional delivery treatment for skin tightening in the jowl and neck utilizes the InMode system with the Morpheus8[®] handpiece (K180189).¹² It is designed for delivering radiofrequency energy to the skin in a nonhomogeneous fractional manner, via an array of 24-electrode pins. The energy is delivered to the skin through bipolar arrays of 24 insulated pins and results in localized heating and ablation of the skin that is in direct contact with the pins' noninsulated tip.¹² Ablation of the skin promotes skin renewal while untreated skin between the pins enables faster healing of the tissue. This maintains the integrity of the treated skin and serves as a reservoir of cells that accelerate and promote the healing process. There is also the contribution of nonablative, noncoagulating dermal matrix heating that occurs in the skin that is not subject to fractional ablation.

The objective of this clinical study was to evaluate the efficacy of using these two radio frequency delivery systems to treat premature jowl and neck laxity following facialplasty.

2 | METHODS

This is a single-center, prospective, open label, IRB approved clinical study which consisted of a single arm of subjects. From 2018 to 2020, these patients presented with premature jowl and neck laxity 1-5 years following previous facialplasty seeking skin tightening treatments. Exclusion criteria included pregnancy, previous facelift complications (history of nerve injury or hematoma), active electrical implant, significant comorbidity, history of bleeding coagulopathies or the use of anticoagulants, any active dermatologic pathology in the treatment area, history of abnormal wound healing, use of Isotretinoin within 6 months, and any surgical or skin resurfacing treatment such as laser or chemicals in treated area within 6 months. Patients signed informed consent and were not financially incentivized.

The study duration was approximately 12 months, including screening, one treatment, and four follow-up visits at 1-week, 3-month, and 6-month post-treatment. Study endpoints included improvement in skin tightening as assessed by blinded investigators, as well as investigator and subject assessment of the skin appearance improvement. Subjects were also asked to assess satisfaction with the treatment and to rate pain levels throughout the process. Success was defined by correct identification of the pre- and post-treatment photographs by blinded investigators as demonstrated in at least 70% or greater of patients completed the treatment at 3-, and 6-month post-treatment. Investigator and subject assessment of the skin appearance improvement was performed using a 0 - 4 -points Likert scale at 3-month, and 6-month follow-up visits: 4 = Significantly marked improvement; 3 = Marked improvement; 2 = Moderate improvement; 1 = Slight improvement; 0 = No difference. Subject assessment of overall treatment satisfaction was recorded using a 5-point Likert scale at 3-month and 6-month follow-up visits: +2 = Very satisfied; +1 = Satisfied; 0 = Indifferent; -1 = Disappointed; -2 = Very disappointed. Subjects were also asked to rate pain during the procedure, immediately after treatment, and at each follow-up visit based on the numerical scale response. The subjects were presented a scale with both words and numbers along a horizontal line and asked to make a mark along the scale. They were then asked to rate pain from 0 to 10, with 0 equaling no pain and 10 equaling the worst possible pain.

All subjects underwent treatment performed using the InMode RF[™] System (InMode MD Ltd., Yokneam, Israel). The treatment session included a subcutaneous application of the bipolar RFAL AccuTite handpiece (HP060906), which was then followed by treatment with the transcutaneous Morpheus8 24-pin handpiece which only had an external application. Treatment areas included the lower third of the face to address the jowl skin laxity and/or neck as determined by the primary investigator. Prior to the procedure, subjects

were sedated with nitrous oxide, 50% NO₂ and 50% O₂, and then local anesthesia was injected to the treatment area using tumescent solution. The tumescent solution was composed of 50 mL 1% lidocaine HCl, 6 mL 8.4% sodium bicarbonate, and 0.5 mL 1:100 000 epinephrine in 250 mL 0.9% normal saline. All subjects received 150 mL of tumescent solution prior to the procedure. Subjects also were given two 500 mg cephalexin tablets on the day prior to the procedure, and on the day of procedure. Small incisions were created postauricularly or submentally depending on the treatment area for internal electrode insertion. Sterile water-based gel was then applied to the skin surface to insure good contact of external electrode. Treatment parameters were set at as external temperature 40.5°C, and Internal temperature 65°C. Loose closing of the port incisions with a suture provided drainage of treated areas after the treatment. After the RFAL treatment, Morpheus8 treatment was performed with recommended treatment parameters according to skin response and manufacturer guidelines. Subjects then completed two 500 mg cephalexin tablets on postprocedure days 1 and 2.

Follow-up visits were conducted at 1-week, 3-month, and 6-month post-treatment, and photographs were taken to document progression. Data from the surveys were entered using a double-entry method and controlled by periodic and random validation check programming. The study coordinator obtained all the data and performed all statistical analyses to avoid potential bias that could be created by the treating physician participating in the analysis.

3 | RESULTS

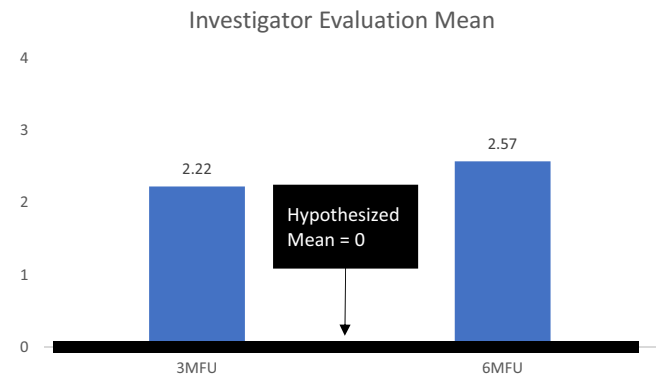
The study enrolled nine subjects aged from 51-79 with a mean age of 61. All patients were female, Caucasian, with a Fitzpatrick skin type 2 except for one patient with type 4 and another with type 3. All enrolled subjects completed the single treatment session and participated until the 3-month follow-up, and two subjects were lost to follow-up for the remaining visits. Seven subjects (78%) completed the 6-month follow-up visits including satisfaction assessments. There were no adverse events in the study.

The average amount of energy provided during treatment with the initial AccuTite RFAL handpiece was 1.4 kilojoules on the right side of the face and neck, and 1.3 kilojoules on the left side. For the second part of the treatment, the Morpheus8 24pin handpiece was used to deliver energy at a 3-mm depth, over 1-2 passes, and at a 25-30 energy level. On the right side of the face/neck, there was an average of 110 pulses delivered, and 116 on the left side. The treatments were well tolerated by all subjects, and there were no adverse events recorded. The pain scale assessments demonstrated an average pain level of 3 at 1 week, 1 at 3 months, and 0 thereafter.

Based on the investigator's blinded evaluation, there was correct identification of pre- and postphotographs for all the subjects. Results demonstrated from the investigator evaluation that three subjects (33%) had "marked improvement" at 3 months, which increased to five subjects (56%) at the 6-month follow-up. One patient with "moderate improvement" and another with "mild improvement"

TABLE 1 Follow-up visit one-sample *t* test results: Investigator evaluations

Measure	<i>t</i>	<i>df</i>	<i>P</i> -value	Mean	Mean difference
Test Value = 0					
3MFU	10.00	8	<0.001	2.22	2.22
6MFU	8.65	6	<0.001	2.57	2.57



GRAPH 1 The following graph displays the results compared with the hypothesized mean value

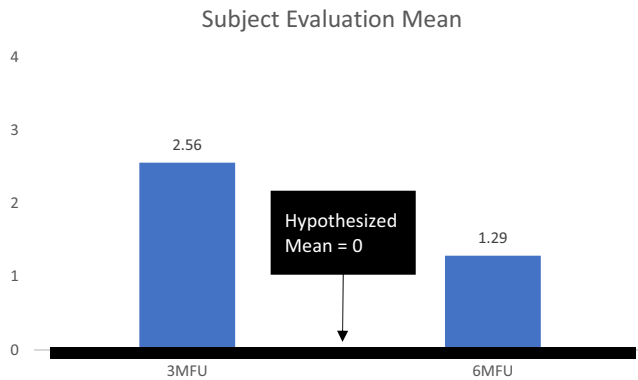
at 3 months both advanced to "marked improvement" at the 6-month mark. Two patients who had "mild improvement" at the 3-month mark were lost to follow-up.

Anecdotally, there is sufficient evidence to suggest the procedure resulted in subject improvement. As an added step, a series of one-sample *t* tests against hypothesized means were conducted. This inferential statistical test determines if the observed or sample mean is different, statistically, from a hypothesized population mean. Given the 5-point scale was anchored by 0, which represented no difference, this value (0) was selected as the hypothesized mean by which to compare the sample results. After all, if the procedure truly had no benefit, all investigator evaluations would support the null hypothesis—the pre- and postprocedure photographs did not differ. Not surprisingly, the investigator evaluations at the 3-month and 6-month follow-up were statistically significant, indicating improvement compared with the hypothesized mean. The relevant statistics are reported in Table 1 and Graph 1.

On the subject-rated improvement, questionnaire 6 (67%) responses were "markedly improved," 1 (11%) "moderate improvement," and 2 (22%) noted "slight improvement" at the 3-month visits. Again, as an added step, a series of one-sample *t* tests against hypothesized means were conducted for the subject evaluations of improvement. Given the 5-point scale was anchored by 0, which represented no difference, this value (0) was again selected as the hypothesized mean by which to compare the sample results. Not surprisingly, the subject evaluations at the 3- and 6-month follow-up were statistically significant, which indicates improvement compared to the hypothesized mean; the relevant statistics are reported in Table 2 and Graph 2.

TABLE 2 Follow-up visit one-sample t test results: subject evaluations

Measure	t	df	P-value	Mean	Mean difference
Test Value = 0					
3MFU	7.56	8	< 0.001	2.56	2.56
6MFU	3.06	6	0.02	1.29	1.29

**GRAPH 2** The following graph displays the results compared with the hypothesized mean value**TABLE 3** Follow-up visit one-sample t test results: subject satisfaction

Measure	t	df	P-value	Mean	Mean difference
Test value = 0					
3MFU	8.00	8	<0.001	1.33	1.33
6MFU	1.92	6	0.10	0.57	0.57

On the satisfaction rating at the 3-month follow-up, all patients rated themselves at the level of "satisfied" or above. Patient satisfaction at this time point was rated at "very satisfied" by 3 (33%) and "satisfied" by 6 (67%) patients. By the 6-month follow-up, the satisfaction tempered a bit, though was still relatively strong. That is, 14% (1 respondent) was dissatisfied, 14% (1 respondent) was neither satisfied nor dissatisfied, and 71% (5 respondents) were satisfied. The single patient who was "unsatisfied" at 6 months, previously recorded a "very satisfied" rating at the 3-month visit. At the final follow-up visit over 70% (five out of seven respondents) of patients who recorded an answer rated "satisfied" or higher.

Again, a series of one-sample t tests against hypothesized means were conducted. Given the 5-point scale had a midpoint of 0 (neither unsatisfied nor satisfied), this value (0) was selected as the hypothesized mean by which to compare the sample results. The subject satisfaction ratings at the 3-month follow-up were statistically significant; the relevant statistics are reported in the following table. The 6-month follow-up was nearing significance ($P = 0.10$). However, given the small sample size at the 6-month mark, this finding is not surprising. Had the two patients from the 3-month

follow-up not exited the study by the 6-month mark, it is likely the difference would have been statistically significant. The information is displayed in Table 3 and Graph 3.

Finally, as it relates to patient pain ratings, there was a significant decrease in pain evaluations from the 1-week follow-up to the 3-month and 6-month follow-up. At the 1-week follow-up, 67% ($n = 6$) registered pain < 5 , the midpoint of the scale, while 33% ($n = 3$) registered pain levels at or > 5 , with the highest pain registered at an 8. At the 3-month follow-up, 67% ($n = 6$) had zero pain, and the rest had pain at or below 5 ($n = 3$). By the 6-month follow-up mark, no one indicated they had any pain ($n = 7$), as all patients registered a 0 on the scale.

Again, one-sample t tests against a hypothesized value were computed. For this series of tests, it was determined to compare all follow-up visits against a decreasing pain threshold across time. That is, the 1-week follow-up was compared with a hypothesized mean of 5, the 1-month follow-up was compared with a mean of 3, and the 6-month follow-up was compared to a mean of 1. After all, it is logical that pain evaluations would decrease over time; therefore, the hypothesized mean by which patient evaluations are compared against should also decrease. For the first follow-up visit (1-week, compared with a hypothesized mean of 5), the difference was approaching statistical significance; $t(8) = -1.84$, $P = 0.10$. However, by the 3-month follow-up (and compared with the mean of 3, the decrease was significant; $t(8) = -3.33$, $P = 0.01$. Finally, compared with the hypothesized mean of 1, for the 6-month follow-up, the t test can not be computed, as all patients registered a value of 0, and thus, there was no variance by which to calculate the test. Thus, we can be confident that by the 6-month mark, no pain from the procedure remained. The following Table 4 and Graph 4 present the relevant statistics.

In sum, anecdotally and inferentially, the procedure resulted in improved subject and investigator evaluations, subject satisfaction, and subject pain evaluations across time, compared with hypothesized mean values. In other words, based on the scales employed, evaluators and subjects, in general, indicated they noticed improvement, subjects were satisfied, and subjects registered decreasing levels of pain across time after the procedure.

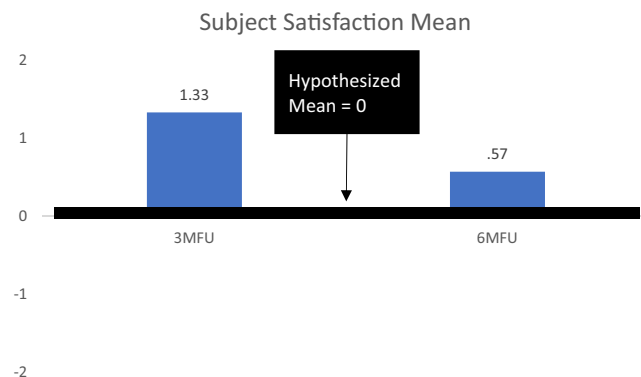
**GRAPH 3** The following graph displays the results compared with the hypothesized mean value

TABLE 4 Follow-up visit one-sample *t* test results: subject pain

Measure	<i>t</i>	<i>df</i>	<i>P</i> -value	Mean	Mean difference
Test value = 5					
1WFU	-1.84	8	0.10	3.22	-1.78
Test value = 3					
3MFU	-3.33	8	0.01	1.00	-2.00
Test value = 1					
6MFU	n/a	6	n/a	0.00	-1.00

4 | DISCUSSION

There is an increasing body of evidence suggesting that patients are looking toward minimally invasive procedures for results in the aesthetic field. We surmise that this is especially true for patients who have already underwent surgical treatments with unsatisfactory results. Radiofrequency-based skin tightening procedures can offer an opportunity for patients to receive treatment for skin laxity in the face and neck with minimal downtime, lower cost, and decreased risk of complications as compared to surgical treatment. While we agree that current nonsurgical methods do not yet yield results with the highest potential of change as compared to full surgical treatments, we suggest that a compromise can be met with minimally invasive techniques such as RFAL and RF microneedling to meet patient expectations. The results of this study suggest that minimally invasive treatment of skin laxity in the face and neck with radio frequency technology can provide repeatable, satisfactory results, with minimal downtime and risk.

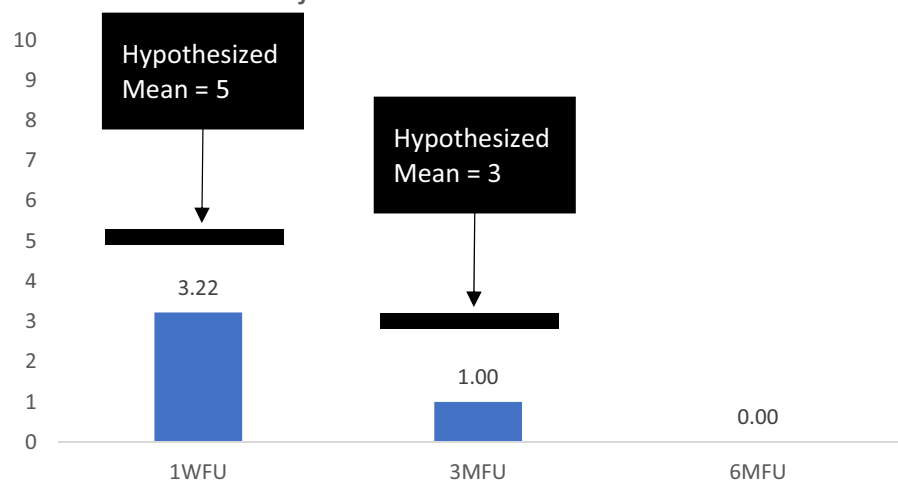
The survey results show that at the 3-month follow-up, all enrolled patients had an improvement in skin appearance in the treatment area based on both the investigator and patients' responses. The two patients who were lost to follow-up at the 6-month visit recorded "satisfied" and "very satisfied" responses at the 3-month follow-up. Both were considered to have "mild improvement" by investigator evaluation at that visit. Surveys were obtained from both

the investigators and subjects in an attempt to demonstrate that degrees of improvement were shared by both the provider and patient. In examining the results of the follow-up questionnaires, there was complete congruency on ratings of improvement between the investigator and subjects for 5 out of 9 (55%) patients at 3 months. Of the ratings that did not match, 2 patients had rated themselves 2 levels higher, and 1 patient rated themselves 1 level higher on the improvement scale vs the investigator rating. Only 1 patient's ratings were lower than the investigator's at the 3-month mark. The data show that even though 100% of subjects rated at least 1 level of improvement at the 3-month mark, 30% rated the improvement even higher than what the investigator had determined. This suggests that providers rate improvements more conservatively as compared to patients.

An important difference between results following surgery vs minimally invasive procedures with radiofrequency is the time it takes to visualize results. During surgery, skin, fascia, and muscles are mechanically repositioned over the facial skeleton and provide an immediate change to the shape of the face and neck. With RFAL and RF microneedling technology, it can take longer to see the changes while the skin and subcutaneous tissues undergo remodeling. This becomes an important factor when counseling patients before the procedure. In our survey results, this can be demonstrated by the fact that three out of the seven patients recorded at least one level higher in improvement rating between the 3- and 6-month follow-up visits. The pain surveys also provide evidence that the procedure was very well tolerated by the subjects. At the 1-week follow-up, the average pain rating was 3 and a median of 2. During the 3-month follow-up, there were only three patients that were experiencing any residual pain with an average of 1 for the cohort.

The results from this study are limited by the small size of the patient cohort, and a larger sample size would be needed to demonstrate the effects more robustly. Future studies with a larger sample size and longer period of follow-up would be needed to strengthen our results and provide more information regarding the longevity of effect.

Subject Pain Evaluation Mean



GRAPH 4 The following graph displays the results compared with the hypothesized mean value for the three tests

In conclusion, the results of this study complement the existing body of literature demonstrating the efficacy of radiofrequency treatment of skin laxity in the lower face and neck. These results provide supporting evidence that RFAL and RF microneedling technology can particularly provide a safe, minimally invasive, and effective treatment for skin laxity in the jowls and neck in patients who desire further correction after undergoing primary facelift.

AUTHORS' CONTRIBUTIONS

DD, RC, NG, EK, and SD performed the research. NG, EK, and SD designed the research study. DD, RC, NG, EK, and SD analyzed the data. DD, RC, NG, EK, and SD wrote the paper. All authors have read and approved the final manuscript.

ORCID

Daniel Demesh  <https://orcid.org/0000-0002-6969-9548>

Nimit D. Gandhi  <https://orcid.org/0000-0002-5088-7995>

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BEFORE AND AFTER

