Effectiveness and Safety of Hands-Free Bipolar Radiofrequency Treatment for Lower Face Contouring: A Clinical Study

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Abstract

The most popular non-invasive treatment that people seek out for facial contouring is bipolar radio frequency (RF). Unlike other radiofrequency treatments, hands-free bipolar radiofrequency is a novel device designed to minimize doctor-patient interaction. It uses pre-set settings to deliver controlled energy concentration at optimal temperatures, eliminating the need for manual application. Twenty-one patients with lower face laxity were treated with hands-free bipolar radiofrequency on both sides of the lower cheek area. The patients went through once a week for four consecutive weeks. Three blinded dermatologists evaluated the pre-treatment and post-treatment results at each follow-up visit. The 3D photographs were recorded by a Vectra camera and analyzed for association. The reduction in fat volume over three months showed significant changes in both the right and left sides. After one month, the right side showed a mean change of -2.0 ± 1.2 and the left side -1.7 ± 1.2, both statistically significant. After two months, the mean reductions were -1.5 ± 0.8 on the right and -1.5 ± 1.2 on the left, with both changes also significant. By the third month, the mean reductions continued at -1.2 ± 0.6 on the right and -1.1 ± 0.7 on the left, remaining statistically significant. Only a few candidates experienced mild erythema and pain, which resolved quickly over time. Overall, hands-free bipolar RF offers non-invasive fat reduction, skin tightening, and comfort for contouring, though results are gradual and require multiple sessions.

Keywords: *Bipolar radiofrequency, non-invasive, hands-free, face contouring, adverse effect*

1. Introduction

Skin aging is a natural phenomenon in human beings. The clinical signs often include degradation of skin texture, such as deep wrinkles and folds, dullness, loss of skin elasticity, and sagging skin (Kligman, 1989). Wrinkles appear due to the loss of collagen fibers, especially type 4 and 7, as we age (Watson et al., 2001) Similarly, the degradation of elastic fibers results in skin laxity (Escoffier et al., 1989). Advancing age is associated with the loss of subcutaneous fat volume, skin flaccidity, and bone resorption, leading to sagging skin (Faria et al., 2022). Sagging in the lower face and double chin are clinically examined by palpation. The condition presents as a change in facial contour due to overhanging, atrophic, and flaccid skin, without increased adipose tissue volume (Faria et al., 2022).

Anti-aging is the most common aesthetic goal sought by individuals undergoing aesthetic treatments. Several innovative technologies—both invasive and non-invasive—have been developed to address facial wrinkles, laxity, and uneven contours of the lower face. Recently, FDA-approved non-invasive methods for skin facial remodeling include non-ablative radiofrequency therapy, light and laser therapies, cryolipolysis, high-intensity focused ultrasound (HIFU), and high-intensity focused electromagnetic field (HIFEM) treatments. In aesthetic dermatology, radiofrequency (RF) technology has been significantly used for body contouring, cellulite reduction, and facial tightening. RF energy could be delivered into different tissues such as skin, fat, and muscle. The purpose of the device is to use electromagnetic radiation to cause the fast movement of charged particles in the tissues to produce heat. When a critical temperature is reached, which is between 65 and 75 degrees Celsius,

collagen denatures, causing tissue to shrink or contract. After collagen fibril contraction by heat, the results demonstrated the effectiveness of trans-epidermal remodeling. Additionally, neo-collagenases and clinical improvement are evident in periorbital, mid and lower face areas, and the neck.

Likewise, bipolar radiofrequency devices have two electrodes **(**positive and negative poles**)** that are often incorporated on a single handpiece, allowing precise control of energy penetration with minimal discomfort (Levy et al., 2016)**.** Bipolar RF devices give an extra layer of control over energy penetration and, as compared to monopolar devices, may cause less discomfort to the patient during treatment (Alessa, & Bloom, 2020)**.** In addition to bipolar radiofrequency, the hands-free RF devices have pre-set settings to deliver controlled energy concentration at optimal temperatures (Hendricks, & Farhang, 2022)**.** Thus, these hands-free devices can be used on any skin type with the safety profile**.** However, the high energy exposure may increase the risk of burns, edema, and other adverse events, which lead to skin dyspigmentation and scarring (Chawvavanich et al., 2022a)**.** Due to its interesting profile, we decided to capture its efficacy and safety in the treatment of the lower face**.**

2. Objectives

1. To evaluate the fat volume reduction in the lower face, using a 3D-stimulated camera to compare baseline data and data after the follow-up at months 1, 2, and 3.

2. To assess the clinical outcomes with the Global Aesthetic Improvement Scale (GAIS) and the 5-Point photonumeric scales for the assessment of jaw.

3. To monitor safety and adverse complications associated with hands-free bipolar radiofrequency.

3. Materials and Methods

The study protocol was reviewed and approved by the Ethics Committee of the Institute of Dermatology, Bangkok, Thailand, with the study code of IRB/IEC 001/2567. We recruited 22 male and female patients, who were willing to receive four weeks of therapy using hands-free bipolar radiofrequency and had lower cheek sagging. The Fitzpatrick skin type between I to VI was presented to the participants between 35-55 years old, with specific BMI not exceeding 27 kg/m^2 during and after the study period. Before the research started, each participant was made sure to have understood and signed an informed consent form. The exclusion criteria for the study included pregnancy during the study period, breastfeeding, a history of botulinum toxin injections within the past six months, soft tissue augmentation within a year prior to the therapy, and agreement not to receive additional aesthetic treatments, such as ablative or non-ablative laser rejuvenation, within the previous year.

The study was conducted once a week for 4 consecutive weeks (weeks 1, 2, 3, and 4), and then follow-up sessions were held three times at 1-month, 2-month, and 3- month after the last treatment. The individuals were screened and were taken photos prior to the start of the therapy. The treatment zones on both sides of the lower cheek area. The treatment parameters was set as follows: a cut-off temperature of 40°C-42°C and an energy of 20- 30 J. Each of the treatments involved heating the treated region to 42°C and then maintaining that temperature for 20-45 minutes on either side of the cheek.

All clinical photographs that have been recorded by the Vectra camera from baseline were used to evaluate fat volume reduction at the end of the follow-up visit (1-month, 2-month and 3-month). Investigators used 3D stimulated camera 'Vectra' to determine lower facial volumetric measurable data and demonstrated in "cc" and "cm". The three-blinded investigators evaluated the overall of the facial contouring during the baseline and follow-up (1,2 and 3 month) after the last treatment by photographs to determine whether there were improvements in clinical outcomes. This clinical improvement was assessed using two different scales including Global Aesthetic Improvement Scale (GAIS), and the 5-point photonumeric scales for jaw assessment. Before the research project began, inter-rater reliability among the experts was measured using the calculation of Intraclass Correlation Coefficient (ICC), which should have a value of 0.75 or higher to be able to proceed with the evaluations (Koo, & Li, 2016).

The demographic data were analyzed and expressed as frequency for categorical data. Mean values and standard deviations were calculated for quantitative variables. The reported side effects were also expressed as frequency. Fat volume reduction, changes in Global Aesthetic Improvement Score (GAIS) over time, and changes in 5-point photonumeric scales for jaw assessment over time were analyzed using repeated-measures ANOVA and paired t-test for pairwise comparisons. A p-value < 0.05 was considered statistically significant.

4. Results and Discussion

Overall, 22 eligible candidates were successfully recruited. Unfortunately, one male candidate dropped out due to the loss of follow-up. As a result, 21 candidates continued the treatment process, and successfully completed the procedure. The study included 21 patients with an average age of 43.4 years (±6.3). The majority were female (19 out of 21), with only 2 males. The average weight was 64.1 kg (±7.6), and the average height was 160.1 cm (±7.6). The mean BMI was 25.0 (±2.0) (Table 1).

Table 1 The characteristic of the patients recruited in the study

Characteristics	Mean ± SD
Age (years)	43.4 ± 6.3
Gender, N (%)	
Female	19 (90.5)
Male	2 (9.5)
Weight (kg)	64.1 ± 7.6
Height (cm)	160.1 ± 7.6
BMI	25.0 ± 2.0

The fat volume reduction over three months showed significant changes in both the right and left sides. After one month, the right side reduced by -2.0 ± 1.2 and the left side by -1.7 ± 1.2, both statistically significant. After two months, reductions were -1.5 ± 0.8 on the right and -1.5 ± 1.2 on the left, with both changes also significant. By the third month, reductions continued with -1.2 ± 0.6 on the right and -1.1 ± 0.7 on the left, remaining statistically significant (Table 2).

Table 2 Fat volume reduction over time

Time	Right		Left		P-Value
	Mean change (± SD)	95% CI	Mean change (± SD)	95% CI	
One month from baseline	-2.0 ± 1.2	(-2.5,-1.4)*	-1.7 ± 1.2	(-2.2,-1.1)*	0.125
Second months from baseline	-1.5 ± 0.8	(-1.8,-1.1)*	-1.5 ± 1.2	(-2.1,-1.0)*	0.873
Third months from baseline	-1.2 ± 0.6	(-1.5,-0.9)*	-1.1 ± 0.7	(-1.4,-0.8)*	0.474

Note: *Statistical for significant. p-value calculated using Paired t-test

The error bar plot was used to display the presentation of the fat volume over time by months for two groups with left represented by the colour red, while right represented by the colour blue. The y-axis represented the mean fat volume with a 95% confidence internal (CI), and the axis represents time in months (Figure 1A). The overall trend showed that the fat volume appears to decrease over time with a negative value indicating a significant reduction in the fat volume. This plot was further illustrated that at month 1, the mean fat volume reduction is more pronounced in the right group compared to the left. Moreover, there was a trend of stabilization or slight increase in fat volume reduction by month 2 and 3 in both groups (Figure 1B). Interestingly, both sides had similarity, suggesting consistency in the treatment effect. To sum up, the procedure does appear to cause fat reduction over time, yet it is not permanent, and there is a possibility to partially regain over time.

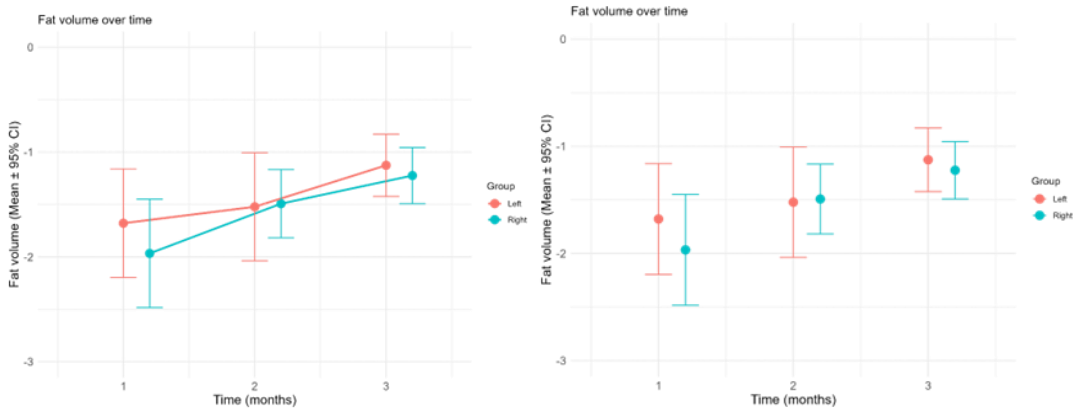

Figure 1 Error bar plot showing the fat volume reduction over time. The y-axis represents fat volume (mean ± 95% CI), and the x-axis represents time (months).

The Global Aesthetic Improvement Score (GAIS) showed a significant improvement over three months. At one month, the mean score was 2.2 ± 0.5, with 71.4% reporting slightly improved, 23.8% good improved, and 4.8% reporting no change results. By two months, the mean score increased to 2.7 ± 0.6, with 52.4% seeing good improved and 9.5% reporting very good improved. At three months, the mean GAIS reached 3.0 ± 0.7, with nearly half (47.6%) reporting good improved and 28.6% experiencing very good improved. No participants reported change of results after the first month, indicating progressive aesthetic enhancement over time (Table 3).

Furthermore, the illustration of the GAIS score through a line plot showed an upward trend without major fluctuations over time, indicating a positive progression in the measured outcome. Notably, the error bars were not excessively large, meaning the measurements were relatively stable across the participants (Figure 2).

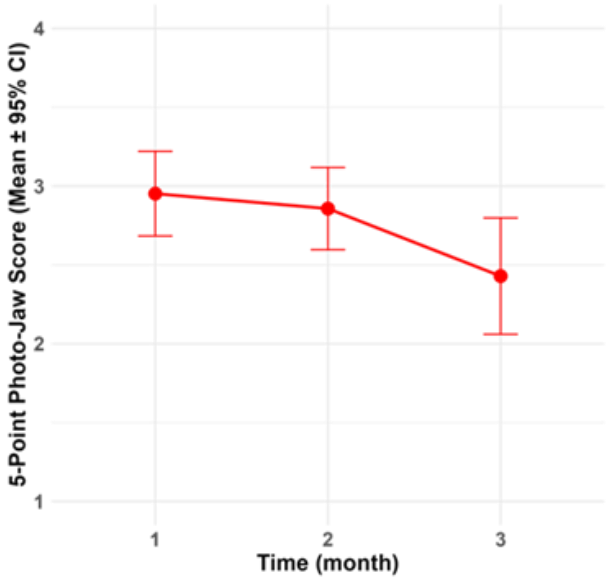

Figure 2 Bar plot showing the changes in GAIS score over time.

Table 3 Changes in GAIS over time

Time	Global aesthetic improvement score (GAIS) N (%)
One month (Mean ± SD)	2.2 ± 0.5
5=Excellent improved	-
4=Very good improved	-
3=Good improved	5 (23.8)
2=Slightly improved	15 (71.4)
1=No change	1 (4.8)
0=Worse	-
Second months (Mean ± SD)	2.7 ± 0.6
5=Excellent improved	-
4=Very good improved	2 (9.5)
3=Good improved	11 (52.4)
2=Slightly improved	8 (38.1)
1=No change	-
0=Worse	-
Third months (Mean ± SD)	3.0 ± 0.7
5=Excellent improved	-
4=Very good improved	6 (28.6)
3=Good improved	10 (47.6)
2=Slightly improved	5 (23.8)
1=No change	-
0=Worse	-

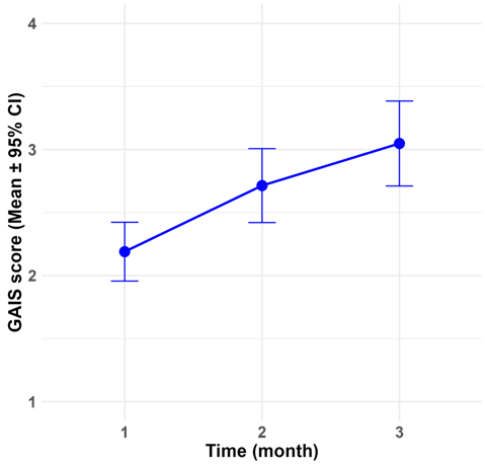

Figure 3 Change of 5-Point number scales assessment jaw score over time

The 5-point photonumeric scales for jaw assessment scores showed a significant improvement over three months, the jaw contour was assessed using a 5-point photonumeric scale, where 1 = None, 2 = Mild, 3 = Moderate, 4 = Severe, and 5 = Very severe. At one month, the mean score was 3.0 ± 0.6, with most participants rating their jaw contour as moderate (66.7%) or severe (14.3%), while 19% rated it as mild. No participants reported a none and very severe rating. At two months, the mean score slightly decreased to 2.9 ± 0.6, with 66.7% still rating their jaw contour as moderate, but the proportion rating it as severe declined to 9.5%, and 23.8% report a mild rating. At three months, the mean score further declined to 2.5 ± 0.8, with fewer participants rating their jaw contour as moderate (33.3%) or severe (9.5%), while 47.6% rated it as mild, and 9.5% as none. The results [207]

indicate a mild to severe in jaw score at one month (Table 4). However, the scores significantly declined over time, with a higher percentage of participants rating their jaw as mild or moderate by the third month (Figure 3).

Regarding side effects during the four weeks, mild erythema was reported by 3 participants in week 1, decreasing to one participant in week 2, with no further cases in weeks 3 and 4. Pain was observed in 2 participants during week 2, but no case was reported in other weeks. No participants experienced swelling, erythema, burning, hyperpigmentation, hypopigmentation, mild blistering, rash fever, infection, or required medical intervention at any point. Additionally, there were no reports of effects on daily activities, required assistance, or hospitalization throughout the four weeks (Table 5).

Table 4 Change of 5-point photo numeric scales assessment jaw score over time

Time	5-Point Photo numeric Scales Assessment Jaw Score
	N (%)
One month (Mean ± SD)	3.0 ± 0.6
1=None	-
2=Mild	4 (19.0)
3=Moderate	14 (66.7)
4=Severe	3 (14.3)
5=Very severe	-
Second months (Mean ± SD)	2.9 ± 0.6
1=None	-
2=Mild	5 (23.8)
3=Moderate	14 (66.7)
4=Severe	2 (9.5)
5=Very severe	-
Third months (Mean ± SD)	2.5 ± 0.8
1=None	2 (9.5)
2=Mild	10 (47.6)
3=Moderate	7 (33.3)
4=Severe	2 (9.5)
5=Very severe	-

Table 5 A description of side effect at week 1 2 3 and 4.

Side effect	Week 1	Week 2	Week 3	Week 4
Slightly erythema	3	1	0	0
Pain	0	2	0	0
Swelling	0	0	0	0
Erythema	0	0	0	0
Burning	0	0	0	0
Hyperpigmentation	0	0	0	0
Hypopigmentation	0	0	0	0
Mild blistering	0	0	0	0
Rash fever	0	0	0	0
Infection	0	0	0	0
Required medical intervention	0	0	0	0
Effect to the daily activity	0	0	0	0
Required assistance	0	0	0	0
Required hospitalization	0	0	0	0

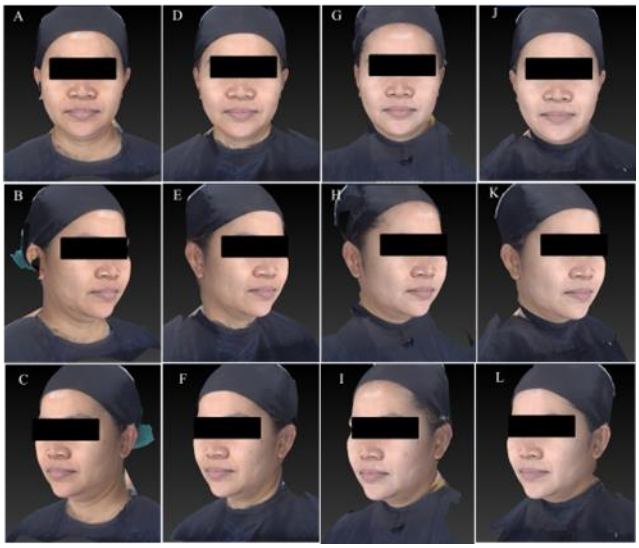

Figure 4 Participant representation of significance changes in fat reduction from different angles from 1st, 2nd, and 3rd month. A, B, C represented baseline pictures. D, E, F represented 1st month follow-up. G, H, I represented 2nd month follow-up. J, K, L represented 3rd month follow-up.

Interestingly, we observed that hand-free RF has remarkably reduced fat volume at the cheeks and chin area at the first, second, and third month compared with the baseline (Figure 4). There was almost no noticeable erythema seen immediately after the procedure. Most importantly, the participants mostly reported the mild satisfaction during the first month of the procedure, yet the overall satisfaction increased in the third month.

Since the introduction of RF devices two decades ago, RF devices have immensely been upgraded for efficacy, efficiency, and precaution (Hodgkinson, 2009). Favorable outcomes, along with less undesired effects, have made this device a standout for skin tightening and body contouring (Labadie et al., 2023). Our study found that there was a significant effect on the fat volume reduction over three months. At the same time, the study by Labadie and her colleagues found that 70% of the 64 participants had significant improvement as well (Labadie et al., 2023). Histologically, no scar formation was observed, yet a great amount of collagen remodeling was noticed (Chawvavanich et al., 2022b; Labadie et al., 2023). To further elaborate, our study mainly focused on fat volume reduction, changes in Global Aesthetic Improvement Score, jaw score assessment through photonumeric scale, and side effects, yet other studies seemed to focus more on post-treatment satisfaction and pain score (Dayan et al., 2022). 52.4% of our participants stated there is a good improvement in their fat reduction, which is in concordance with the study of Labadie et al., 2023. The only difference was that their studies had more participants (n=67), in which they could yield better significant results. Interestingly, one study by Park et al., (2016) where they used bulk/external monopolar RF found that there was 82% mild improvement in the first month, while our study found 71.4% slight improvement. This result indicated that even though theoretically monopolar RF is more effective, our bipolar hand-free RF could obtain almost the same result of fat reduction within the same time period (Park et al., 2016).

Considering the side effects, our study found that 3 participants among 21 experienced slight erythema at week 1, and only one experienced mild erythema at week 2. In contrast, one study about the effectiveness and side effects of bipolar radiofrequency treatment for submental laxity by Chawvavanich et al., (2022a) found that all of their participants immediately developed erythema post-treatment from 10 to 15 minutes (Chawvavanich et al., 2022 b). The limitation of this study is that our study has a small sample size (21 participants), and lacks long-term follow-up. A multicenter trial with a larger number of participants is required in order to obtain more

statistically significant results, especially on the treatment side effects, pain score, and participant satisfaction. Another limitation is that we could not perform the histology of the patients' skin response before and after treatment due to the constraint of financial funding. Further investigation is also needed regarding the cutaneous histology features in the context of Thai people's skin response to the bipolar RF procedure.

As a recommendation, bipolar hands-free RF devices are strongly recommended due to their efficacy, efficiency, time-saving nature, and convenience for both operators and patients undergoing the procedure. With proven effectiveness supported by clinical evidence, it assesses fat volume reduction, aesthetic improvement, and side effects. Results show significant fat reduction and improved jawline aesthetics with minimal adverse effects, highlighting its potential as a non-invasive contouring treatment.

5. Conclusion

In conclusion, the non-invasive, RF technology consists of bipolar, mono polar and multiple bipolar. Commonly, the bipolar RF equipped without hands-free device and consisted only a traditional manual method to transfer the energy to the target tissues. Unlike previous RF devices, our current bipolar RF device offers a hands-free therapy mode for the first time. This implies that the devices could currently be put on the patient and pre-set to target temperatures and stimulated, without requiring a manual application by the provider. The bipolar hands-free RF is a promising non-invasive method for localized fat reduction, particularly for individuals seeking mild to moderate contouring with added skin tightening benefits. While it offers advantages such as comfort, safety, and collagen stimulation, results are gradual and require multiple sessions. Compared to other fat reduction modalities, RF is best suited for those prioritizing skin firmness alongside fat loss rather than significant volume reduction. For optimal results, it may be combined with other body-contouring treatments or a healthy lifestyle.

6. Acknowledgment

There is no conflict of interest.

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