

# A Prospective Study on the Efficacy and Safety of the Bipolar Radiofrequency with Multi-Channel and Vacuum-Assisted for Rejuvenation in Periorbital Area

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**Introduction:** The periorbital region is highly susceptible to aging, manifesting as wrinkles, skin laxity, and under-eye bags due to collagen loss and fat displacement. Vacuum-assisted multi-frequency bipolar radiofrequency (RF) offers precise energy delivery, effectively stimulating collagen remodeling while ensuring safety and patient comfort.

**Objective:** This study aimed to evaluate the efficacy and safety of a bipolar RF device with channeling optimized RF energy (CORE™) technology and vacuum assistance for periorbital rejuvenation.

**Patients and Methods:** A prospective, single-center trial enrolled 28 participants (18–60 years), receiving four treatments at three-week intervals. Efficacy was assessed through Fitzpatrick Wrinkle Scale (FWS), Investigator Global Assessment (IGA) scores, and objective skin parameters (hydration, elasticity, gloss), alongside participant self-assessments. Safety was evaluated via adverse events (AEs) and pain scores (VAS).

**Results:** Among 22 participants who completed the study, 95.46% achieved  $\geq 25\%$  improvement in FWS scores (mean reduction:  $-1.55 \pm 0.50$ ), with significant wrinkle reduction from the second treatment ( $p < 0.001$ ). IGA scores showed visible improvement in under-eye bags, while skin hydration and elasticity increased. About 90.91% of participants reported high satisfaction, and 91.3% rated pain  $\leq 1$ , with no AEs reported. The total observation period was approximately 12 weeks, including four treatment sessions and a three-week follow-up after the final session.

**Conclusion:** Bipolar RF treatment with CORE technology and vacuum assistance is a safe and effective non-invasive modality for improving periorbital wrinkles and under-eye bags. By promoting collagen remodeling and skin tightening, this technology offers significant clinical and aesthetic benefits with minimal discomfort and no adverse events.

**Keywords:** radiofrequency, periorbital wrinkles, under-eye bags, vacuum assisted, CORE technology

## Introduction

The eye region is located in the center region of human face and serves as the primary focus in visual and social interactions. Research on visual attention consistently identifies the face, particularly the periorbital region, as the most informative area of a person. Studies show that the majority of visual hot spots are concentrated on the face, with a significant emphasis on the eyes.<sup>1</sup> Gender-specific gaze patterns further reveal that men primarily focus on women's eyes, while women tend to direct their attention slightly below men's eyes. These findings underscore the pivotal role of the eyes, including skin quality and tightness in perceptions of attractiveness.

Wrinkles around the eye and lower eyelid bags are common manifestations of aging, primarily resulting from the decline in collagen and elastin production, which leads to reduced skin elasticity.<sup>2</sup> Given that the periorbital skin is the thinnest in the human body, these age-related changes become particularly pronounced.<sup>3</sup> Wrinkles develop due to progressive skin laxity, whereas under-eye bags are largely attributed to the displacement or hypertrophy of infraorbital

fat pads.<sup>4</sup> These structural alterations contribute to a fatigued or aged appearance. In addition to aging, genetic predisposition plays a significant role in the early onset of these features.<sup>5</sup> In addition, anatomical and functional changes have a substantial impact on the periocular region. Periocular aging is a multifactorial process influenced by various age-related alterations. With advancing age, the loss of subcutaneous tissue beneath the periocular skin, facial skeleton remodeling, and fat pad atrophy or repositioning contribute to eyelid descent and an aged appearance.<sup>6</sup>

The appearance of periorbital wrinkles and under-eye bags can negatively impact self-perception, social interactions, and mental health. People often associate under-eye bags with fatigue, aging, or stress, leading to perceptions of reduced confidence, hindered professional and personal relationships, and diminished vitality or success. In severe cases, such concerns can lead to anxiety or stress, significantly affecting quality of life. Consequently, aesthetic medicine has emerged as a thriving industry, leveraging groundbreaking technologies to provide innovative anti-aging solutions. Among advanced aesthetic treatments, non-invasive and minimally invasive interventions, including botulinum toxin injections, dermal fillers, laser resurfacing, radiofrequency (RF) treatments, and platelet-rich plasma therapies, are rapidly outpacing traditional invasive surgical procedures in market revenue and patient preference.

Amongst the interventions, RF-based devices have emerged as a novel non-invasive modality for rejuvenation treatments, with the potential benefits of decreased recovery duration and less post-operative complications.<sup>7</sup> Ever since the US Food and Drug Administration approved the first RF device for facial wrinkle reduction, the RF technology is now widely used in aesthetic applications in promoting skin tightening and rejuvenation. Compared to monopolar RF, bipolar RF offers higher safety, lower discomfort, and better patient acceptance.<sup>8</sup> While traditional bipolar RF had limitations in penetration depth, modern multi-frequency bipolar RF with vacuum technology overcomes this by enabling adjustable energy penetration to target different skin layers effectively. In addition to stimulating collagen remodeling, triggering neocollagenesis and ne elastogenesis, the thermal stimulatory effect of RF also contributes to lipolysis,<sup>9–13</sup> collectively contributing to rejuvenation.

The effectiveness and applications of bipolar RF combined with vacuum technology in aesthetic medicine have been well-established. However, its specific application in addressing under-eye wrinkles, bags and related skin quality issues has not been explored extensively. This clinical trial aims to evaluate the efficacy and safety of a bipolar RF device with channeling optimized RF energy (CORE™) technology and vacuum-assisted for improving wrinkles, under-eye bags and enhancing the skin quality of the periorbital region.

## Methods

### Trial Design

This study is a prospective, single-center clinical trial with a self-controlled before-and-after design.

### Participants

Eligible male or female participants between 18 and 60 years old with a facial wrinkle scale  $\leq$  Class III on the Fitzpatrick Wrinkle Scale were eligible to participate. Participants were excluded if they were pregnant, breastfeeding, planning to conceive, or had skin conditions (eg, herpes, eczema, rashes), heat-triggered disorders, or contraindications listed in the device manual. Exclusion criteria also included prior treatments such as synthetic fillers, facial chemical peels, laser treatment, or botulinum toxin without meeting required waiting periods, as well as severe photoaging, excessive skin laxity, keloids, or significant scarring at the treatment site. Current smokers, nicotine users, recent clinical trial participants, and those with conditions or behaviors that may interfere with the study's safety or efficacy assessments were also excluded.

### Description of Treatment

Skin in the treatment area was cleansed prior to radiofrequency treatment. Treatments were performed using the skin tightening (ST) and Face-Contouring (FC) applicators of the bipolar multi-channel radiofrequency device (Reaction, Sinclair Co., Ltd., Israel) with CORE Technology combining RF and vacuum therapy. The CORE Technology also provides different RF frequency channel models: Mode I at 0.8 MHz, Mode II at 1.7 MHz, and Mode III at 2.45 MHz, targeting specific layers of the skin to heat all skin layers of collagen and elastin fibers and increasing the metabolic rate of subcutaneous tissue.

A multi-channel Mode IV (including 0.8/1.7/2.45MHz) enables the heating of all skin layers simultaneously. Considering the collagen neosynthesis cycle and the cumulative benefits of multiple treatments.<sup>14,15</sup> This study involved four consecutive treatment sessions on both sides of the face at three-week intervals. There were two steps for treatments using two applicators: Step I, FC applicator with Mode III, Vacuum level 1 (30kPa), RF energy level 2 (8W) or level 3 (14W) for 3–4 minute in each side; Step II, ST applicator with 6°C contact cooling, Mode III, 50–80 J/cm<sup>3</sup> for 6–8 pass in each side, endpoint is Slight edema and erythema. For step I, the temperature was monitored by an infrared thermometer and maintained between 39°C and 42°C. Subjects were followed-up for 3 weeks after their last treatment.

## Outcome Measures

All evaluations were conducted before each treatment and three weeks after the fourth treatment. Photographs were taken at each visit using VISIA™ (Canfield Scientific Inc., Fairfield NJ, USA).

The severity of wrinkles in the areas beneath the lower eyelids among participants were evaluated using the Fitzpatrick Wrinkle and Elastosis Scale (FWS)<sup>16</sup> by the investigators. The primary endpoint was the proportion of participants achieving a  $\geq 25\%$  improvement on the FWS compared with the baseline FWS 3 weeks after completing the fourth RF treatment. The severity of under-eye bags were assigned by the investigators using an Investigator's Global Assessment (IGA) score (0 = none, 1 = very mild, 2 = mild, 3 = moderate, 4 = severe, 5 = very severe).<sup>17</sup> The skin physiological parameters were assessed as follow: Stratum Corneum Hydration (SCH) was measured by the Corneometer® CM 825 (Courage + Khazaka Electronic) through the changes in capacitance of the skin surface; skin elasticity was assessed by the Cutometer® Dual MPA 580 (Courage + Khazaka Electronic) and the glossary of skin was measured by the Skin Glossimeter GL 200 (Courage + Khazaka electronic).<sup>18</sup> All participants were requested to complete a modified Global Aesthetic Improvement Scale (GAIS) to evaluate the improvement in their facial appearance (1 = very much improved, 2 = much improved, 3 = improved, 4 = no change, 5 = worse). The safety parameters included all reports of adverse events (AEs) up to the 3-week post-treatment visit. Participants were also requested to complete a visual analog scale (VAS) pain assessment after each treatment procedure.<sup>19</sup>

## Statistical Analysis

Data were expressed as mean (standard deviation, SD) for continuous variables and number (percentage) for categorical variables. The primary and secondary efficacy endpoints were modeled with the generalized estimating equation (GEE), which suitably matches the data of repeated measurements over time in a longitudinal study and considers the correlation between individual observations. Multivariable GEE analyses were adjusted for a prespecified set of confounders and estimates for the effect of treatment on the efficacy endpoints. The GEE model also examined the odds ratio (OR) and 95% confidence intervals (CIs) of having moderate to severe under-eye wrinkles. A two-sided P-value of  $<0.05$  was regarded as statistically significant. Data management and statistical analyses were conducted using SAS version 9.4 software (SAS Institute, Inc).

## Ethics

Each participant provided signed informed consent prior to participating in any trial-related activities. This protocol was approved by Biomedical Research Ethics Committee, Peking University First Hospital. Registration number ChiCTR2400088260.

## Results

### Patient Demographics

Twenty-eight participants underwent the study procedure with the RF device treatment for at least three times. The study included 27 females (96.43%) and 1 male (3.57%) with an overall group average age of 43.28 years ( $\pm 6.72$  standard deviation) and a range of 33 to 56. The mean body mass index (BMI) of the participants was 22.17 ( $\pm 2.91$ ). Fitzpatrick Wrinkle Scale Class I–III were enrolled; 6 (21.43%) Class I (FWS 1–3), 16 (57.14%) Class II (FWS 4–6), and 6 (21.43%) Class III (FWS 7–9). The demographics and clinical characteristics of treated subjects are summarized in Table 1.

**Table 1** Baseline Characteristics of Study Population

| Characteristics                                      | All Patients (N = 28) |
|------------------------------------------------------|-----------------------|
| Age, mean (SD) (years)                               | 43.28 (6.72)          |
| Age, range (years)                                   | 33.43–56.47           |
| Gender, n (%)                                        |                       |
| Female                                               | 27 (96.43%)           |
| Male                                                 | 1 (3.57%)             |
| Ethnicity                                            | Asian                 |
| BMI, mean (SD)                                       | 22.17 (2.91)          |
| Fitzpatrick Wrinkle Scale, n (%)                     |                       |
| I                                                    | 6 (21.43%)            |
| II                                                   | 16 (57.14%)           |
| III                                                  | 6 (21.43%)            |
| Baseline FWS Score, mean (SD)                        | 5.14 (1.71)           |
| Baseline IGA Score, mean (SD)                        | 2.68 (1.32)           |
| Baseline stratum corneum hydration, mean (SD) (a.u.) | 68.07 (16.17)         |
| Baseline skin elasticity, mean (SD) (%)              | 63.51 (9.8)           |
| Baseline skin gloss, mean (SD) (a.u.)                | 5.13 (1.15)           |

## Efficacy Endpoints

Twenty-eight participants received at least three RF treatments during this trial; however, six participants did not return for the last visit after the fourth treatment. Among the 22 participants who completed the study, the mean ( $\pm$  SD) change of FWS was  $-1.55 \pm 0.50$ , with 21 participants (95.46%) achieved the primary efficacy endpoint of a  $\geq 25\%$  improvement in the FWS score compared to baseline at three weeks after the fourth RF treatment. Comparison of the above outcome measures over the five time points was done using a generalized estimating equation, resulting the values presented in Table 2. Adjusted by demographic data including age, gender, and BMI, the likelihood of moderate to severe under-eye wrinkles (FWS scores 4–9) significantly decreased starting from the second treatment (OR, 0.84; 95% CI, 0.73–0.97;  $p = 0.016$ ) and continued to decrease further with an increasing number of treatments (post third treatment: OR, 0.83; 95% CI, 0.72–0.96;  $p = 0.012$ ; post fourth treatment: OR, 0.72; 95% CI, 0.60–0.87;  $p < 0.001$ ).

A generalized estimating equation was applied to assess variations in the IGA outcome measures across the five time points, and the corresponding results are presented in Table 3. After adjusting for demographic factors, including age, gender, and BMI, the estimated change in IGA showed a significant decrease beginning with the third treatment (post-third treatment: estimated in IGA change from baseline,  $-0.20$ ; 95% CI:  $-0.35$  to  $-0.04$ ;  $p = 0.013$ ; post-fourth treatment: estimated in IGA change from baseline,  $-0.25$ ; 95% CI:  $-0.42$  to  $-0.08$ ;  $p = 0.004$ ).

**Table 2** Generalized Estimating Equations (GEE) Estimate the Odds Ratio of Moderate or Severe Wrinkles at Different Time Points and Groups

| Variable                           | Odds Ratio | 95% Confidence Interval | P Value  |
|------------------------------------|------------|-------------------------|----------|
| Post-1st treatment (ref=baseline)  | 0.93       | (0.85–1.03)             | 0.174    |
| Post-2nd treatment (ref=baseline)  | 0.84       | (0.73–0.97)             | 0.016*   |
| Post-3rd treatment (ref=baseline)  | 0.83       | (0.72–0.96)             | 0.012*   |
| Post-4th treatment (ref =baseline) | 0.72       | (0.60–0.87)             | <0.001*  |
| Gender (ref = female)              | 0.78       | (0.60–1.01)             | 0.055    |
| Age                                | 1.03       | (1.01–1.04)             | < 0.001* |
| BMI                                | 1.00       | (0.96–1.05)             | 0.971    |

Notes: \* $p < 0.05$ ; Severe wrinkles are defined as FWS scores of 7–9 points. Moderate wrinkles are defined as FWS scores of 4–6 points.

**Table 3** Generalized Estimating Equations (GEE) Estimate the Change of IGA at Different Time Points and Groups

| Variable                           | Estimated IGA Change | 95% Confidence Interval | P Value  |
|------------------------------------|----------------------|-------------------------|----------|
| Post-1st treatment (ref= baseline) | -0.09                | (-0.19–0.01)            | 0.085    |
| Post-2nd treatment (ref=baseline)  | -0.03                | (-0.16–0.10)            | 0.673    |
| Post-3rd treatment (ref=baseline)  | -0.20                | (-0.35 – -0.04)         | 0.013*   |
| Post-4th treatment (ref=baseline)  | -0.25                | (-0.42 – -0.08)         | 0.004*   |
| Gender (ref = female)              | -0.18                | (-0.80–0.45)            | 0.579    |
| Age                                | 0.08                 | (0.03–0.13)             | < 0.001* |
| BMI                                | -0.01                | (-0.15–0.12)            | 0.849    |

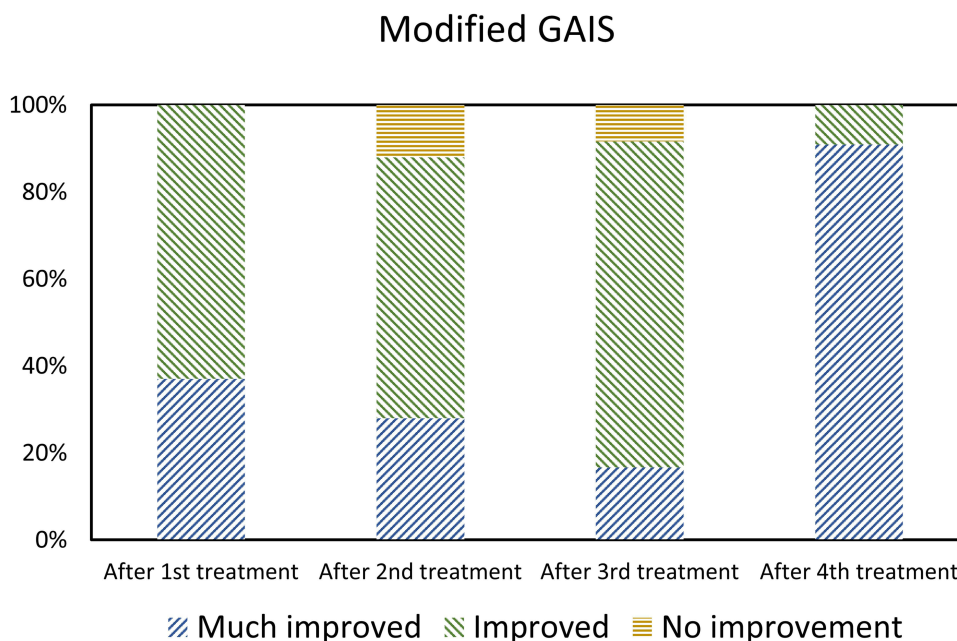
Notes: \*p < 0.05; IGA, Investigator's Global Assessment.

A generalized estimating equation used to compare the stratum corneum hydration (SCH), elasticity, and gloss outcome measures over the time points, and the corresponding results are presented in Table 4. After adjusting for gender, age, and BMI, the estimated skin hydration showed a significant increase after the fourth treatment (estimated change in skin hydration from baseline, 8.28 a.u.; 95% CI: 2.95 to 13.62;  $p = 0.002$ ). The change in skin elasticity from baseline, adjusted for age, gender, and BMI, demonstrated a significant improvement from the second treatment (post-second treatment: 3.95%; 95% CI: 0.15 to 7.74;  $p = 0.042$ ), and continued to improve in accordance with increased number of treatments (post-third treatment: 4.23%; 95% CI: 0.57 to 7.89;  $p = 0.024$ ; post-fourth treatment: 5.23%; 95% CI: 1.27 to 9.18;  $p = 0.010$ ). For the degree of skin gloss, there's no significant change through the evaluation period based on the obtained  $p$ -values.

**Table 4** Generalized Estimating Equations (GEE) Estimate the Change of Skin Physiological Conditions at Different Time Points and Groups

| Stratum Corneum Hydration (SCH) | Variable                            | Estimated SCH Change        | 95% Confidence Interval | P Value  |
|---------------------------------|-------------------------------------|-----------------------------|-------------------------|----------|
|                                 | Post-1st treatment (ref = baseline) | -1.35                       | (-8.53–5.83)            | 0.712    |
|                                 | Post-2nd treatment (ref = baseline) | -6.49                       | (-13.23–0.25)           | 0.059    |
|                                 | Post-3rd treatment (ref = baseline) | 0.58                        | (-6.47–7.63)            | 0.872    |
|                                 | Post-4th treatment (ref = baseline) | 8.28                        | (2.95–13.62)            | 0.002*   |
|                                 | Gender (ref = female)               | -14.19                      | (-19.69 – -8.70)        | < 0.001* |
|                                 | Age                                 | -0.25                       | (-0.72–0.21)            | 0.287    |
|                                 | BMI                                 | -1.07                       | (-2.05 – -0.08)         | 0.033    |
| Skin Elasticity                 | Variable                            | Estimated elasticity change | 95% Confidence Interval | P value  |
|                                 | Post-1st treatment (ref = baseline) | 2.33                        | (-1.96–6.62)            | 0.287    |
|                                 | Post-2nd treatment (ref = baseline) | 3.95                        | (0.15–7.74)             | 0.042*   |
|                                 | Post-3rd treatment (ref = baseline) | 4.23                        | (0.57–7.89)             | 0.024*   |
|                                 | Post-4th treatment (ref = baseline) | 5.23                        | (1.27–9.18)             | 0.010*   |
|                                 | Gender (ref = female)               | -14.87                      | (-17.77 – -11.96)       | < 0.001* |
|                                 | Age                                 | -0.49                       | (-0.74 – -0.24)         | < 0.001* |
|                                 | BMI                                 | -0.05                       | (-0.66–0.56)            | 0.873    |
| Skin Gloss                      | Variable                            | Estimated gloss change      | 95% Confidence Interval | P value  |
|                                 | Post-1st treatment (ref = baseline) | 0.22                        | (-0.22–0.67)            | 0.332    |
|                                 | Post-2nd treatment (ref = baseline) | -0.14                       | (-0.60–0.31)            | 0.540    |
|                                 | Post-3rd treatment (ref = baseline) | 0.26                        | (-0.27–0.79)            | 0.332    |
|                                 | Post-4th treatment (ref = baseline) | 0.13                        | (-0.37–0.63)            | 0.605    |
|                                 | Gender (ref = female)               | -1.16                       | (-1.87 – -0.45)         | 0.001    |
|                                 | Age                                 | -0.04                       | (-0.10–0.02)            | 0.160    |
|                                 | BMI                                 | 0.04                        | (-0.09–0.17)            | 0.556    |

Note: \*p < 0.05.



**Figure 1** Results of participant evaluated modified GAIS after each treatment.

**Notes:** The stacked bars show the proportion of participants reporting “Very Much Improved”, “Much Improved”, “Improved”, “No Change”, or “Worse” at each treatment visit and at 3-week follow-up after the fourth treatment.

Using the modified GAIS, most participants self-reported improvement since the first treatment, as shown in Figure 1. Throughout the trial, 22 participants (88%) after the second and the third treatment rated themselves as Improved or Much Improved. Specifically, 3 weeks after completing the fourth treatment, 20 participants (90.91%) rated themselves as Much Improved, and the rest 2 participants (9.09%) Improved.

## Safety Endpoints

The VAS pain scores over the treatment and the three-week follow up period were evaluated. All participants reported VAS scores  $\leq 3$ . Three weeks after the fourth treatment, 91.3% of participants (21/23) reported a VAS pain score of  $\leq 1$ . In addition, no adverse events were reported during the trial.

## Discussion

Periorbital wrinkles and under-eye bags result from thin skin, collagen loss, and repetitive muscle movement, leading to skin laxity and fat displacement. RF technology addresses these concerns by delivering controlled thermal energy, stimulating collagen production and skin tightening, making it a safe and effective non-invasive solution for periorbital rejuvenation.

RF-based skin rejuvenation operates through controlled thermal effects on deep tissue layers, particularly targeting collagen in loose connective tissue.<sup>20–23</sup> The thermal impact induces two primary mechanisms: immediate collagen denaturation leading to tissue contraction, and a subsequent wound-healing response that stimulates new collagen formation and remodeling. While higher temperatures (67–85°C) can cause structural collagen changes, research indicates that moderate heating (43–45°C) is sufficient to trigger beneficial metabolic responses and fibroblast proliferation without tissue damage.<sup>23,24</sup> Contemporary evidence suggests that thermal stimulation, rather than thermal damage, achieves optimal rejuvenation outcomes, with treatment parameters maintained below 43°C to preserve epidermal integrity while promoting collagen regeneration.<sup>11,25</sup>

In contrast to monopolar systems, which delivers energy diffusely to untargeted connective tissues rather than treating the desired epidermis, bipolar RF delivers energy in a confined path between positive and negative electrodes, resulting in more focused tissue penetration through adjusting the frequency. This controlled energy distribution not only reduces pain during treatment but also enhances safety.<sup>26,27</sup> Bai et al reported the CORE technology Bipolar RF can reach a depth



of 0.9 cm in ex vivo swine skin with three different frequencies: 0.8 MHz, 1.7 MHz, and 2.45 MHz.<sup>11</sup> The integration of vacuum technology further optimizes treatment delivery by securing the target tissue between electrodes, enabling effective outcomes through a higher energy density at lower energy settings. It is estimated that bipolar RF combined with CORE technology enables heating deeper tissue ranging from 3.9 to 18.6 mm depth at the different RF frequencies, different vacuum intensity levels applied and different applicators available with the system.<sup>28</sup> This combination of precise energy delivery and tissue manipulation through vacuum assistance also contributes to a favorable safety profile with minimal adverse events.<sup>29,30</sup> In summary, the CORE technology Bipolar RF provides better controlled energy distribution, enabling precise and adjustable energy penetration for skin rejuvenation, improved safety profile with less side effects, and greater patient comfort.

The periorbital skin is the thinnest in the body, measuring approximately 1.5 mm (including the epidermis and dermis), compared to the 2–4 mm thickness of typical skin tissue.<sup>31</sup> With adjustable RF frequency combined with vacuum technology, the CORE technology Bipolar RF is well-suited for periorbital wrinkle treatment due to its precise and controlled energy delivery, targeting the dermis tissue without affecting other tissues. For treating under-eye bags, which involve displaced fat tissue along with the loss of elastic fibers, deeper energy penetration is necessary. When combined with vacuum technology and an appropriate frequency, the CORE technology bipolar RF can effectively target fat deposits while also stimulating collagen remodeling, contributing to both skin tightening and a lipolytic effect. The CORE technology bipolar RF enhances energy efficiency between electrodes, providing adjustable penetration depth and ensuring broader tissue coverage—a capability beyond traditional monopolar or bipolar RF. This precise energy control makes it ideal for periorbital rejuvenation, offering targeted collagen stimulation for wrinkle reduction and deeper fat remodeling for under-eye bags, while ensuring greater safety, comfort, and treatment effectiveness. In our study, skin elasticity significantly improved after RF treatment. About 95.46% subjects achieved a  $\geq 25\%$  improvement in the Fitzpatrick Wrinkle Scale (FWS) score three weeks after the fourth treatment, with a mean reduction of  $-1.55 \pm 0.50$ . Skin elasticity, measured by the Cutometer<sup>®</sup> Dual MPA 580, also demonstrated significant improvement starting with the second treatment and continued to enhance with additional treatment sessions. Similarly, under-eye bags, assessed using the Investigator Global Assessment (IGA) score, showed significant improvement starting from the third treatment. Skin hydration and elasticity significantly improved after RF treatment. Participants' self-assessment using the modified GAIS revealed high satisfaction, with 90.91% reporting "Much Improved" after the fourth treatment. These improvements align with the established mechanism of RF technology, which promotes neocollagenesis and neoelastogenesis through controlled thermal energy delivery.<sup>11,32</sup> Compared with prior trials utilizing other RF devices, including fractional RF and infrared bipolar RF, the results in mitigating periorbital wrinkles have shown either insignificant improvements in FWS scores or lower responder rates for participant satisfaction (44%, compared with over 90% in our trial).<sup>33,34</sup> For instance, a trial in Korea using fractional RF for periorbital wrinkles reported that all 11 participants exhibited some wrinkle improvement, but only 2 showed improvement in the lower eyelid area, a rate notably lower than our findings.<sup>35</sup> A study utilizing a vacuum-assisted bipolar RF device demonstrated significant improvements in periorbital skin appearance and texture, highlighting the advantages of vacuum-assisted bipolar RF in addressing wrinkles in sensitive facial areas.<sup>30</sup> The findings of this study align with previous research demonstrating the efficacy of vacuum-assisted multi-frequency bipolar RF devices in promoting collagen remodeling and improving skin laxity.<sup>20</sup> Our study confirms that vacuum-assisted multi-frequency bipolar RF provides sufficient penetration depth and intensity to effectively improve periorbital wrinkles and under-eye bags, achieving superior skin tightening and high patient satisfaction. As highlighted in the prior study, in addition to the energy-confinement effect of vacuum, the adjustable RF frequencies also enable controlled energy delivery to targeted depths, enhancing treatment precision and outcomes.

In analyzing skin physiological parameters including skin hydration, elasticity, and gloss, we utilized gender, age, and BMI as parameters to adjust the GEE. Researches had reported that skin elasticity was higher in female than in male.<sup>36</sup> The results indicated that the female skin has a higher ability to recover after stretching in comparison with male skin. The researches done by Xin et al confirmed that with aging, skin elasticity decreases on the hand, forehead, and periorbital region.<sup>37</sup> Li et al enrolled 86 patients in Chengdu, China for an observational study to characterize the skin physiology in Chinese population.<sup>38</sup> They found that the skin of female participants was significantly more hydrated than that of male participants. Ma et al enrolled 198 females in Shanghai, China, to investigate the correlations between BMI

and facial skin physiological parameters, and the results demonstrated that skin hydration in the stratum corneum decreased with increased BMI.<sup>39</sup> A similar conclusion was also displayed by Ye et al, collecting data from 1405 Chinese,<sup>40</sup> stressing the concept that BMI is negatively correlated with stratum corneum hydration. The abovementioned studies further strengthened the findings in our study.

In addition to the promising effects in mitigating wrinkles and under-eye bags, treatments with CORE technology Bipolar RF also proved to be safe, with no adverse events reported throughout this trial and 91.3% of participants rating VAS pain scores  $\leq 1$ . The low level of discomfort associated with the treatment makes it suitable for all individuals experiencing periorbital aging issues. Most importantly, the treatment was well-tolerated, with no adverse events reported and at follow-up, providing sufficient evidence that CORE technology Bipolar RF is efficient and safe to treat periorbital wrinkles and under-eye bags.

Finally, the synergistic action of vacuum and electromagnetic fields may underlie the observed clinical improvements. Evidence indicates that this combined approach enhances microcirculation and lymphatic drainage, modulates ion exchange across cell membranes, and stimulates fibroblast activity, promoting collagen and elastin regeneration.<sup>41,42</sup> These mechanisms contribute to improved tissue oxygenation, reduced fibrosis, and restoration of melanocyte activity, resulting in better skin elasticity, tone, and color consistency, which together support the clinical efficacy observed in our study.

While the study provides strong evidence for the efficacy of Reactive Bipolar RF treatment, the relatively small sample size, single-centered trial, and short follow-up period limit the generalization and long-term assessment of the results. These factors may have introduced potential selection bias and limited the representativeness of the patient population. Future studies with larger cohorts in multiple centers and extended follow-up duration are necessary to confirm the durability of these effects. Such designs would also allow more robust statistical analyses and subgroup evaluations to identify predictors of better treatment response. Additionally, direct comparisons with other treatment modalities, such as laser- or ultrasound-based therapies, could provide further insight into the relative efficacy of the CORE technology Bipolar RF device for periorbital rejuvenation. This would enable clinicians to better tailor treatment options to the specific needs and aesthetic goals of individual patients.

In conclusion, this study suggests that CORE technology bipolar RF treatment may be an effective and well-tolerated approach for improving periorbital wrinkles and under-eye bags. By promoting collagen production and dermal remodeling, this technology appears to offer meaningful clinical and aesthetic benefits for individuals seeking non-invasive rejuvenation of the periocular area.

## Abbreviations

AE, adverse event; CI, confidence interval; FC, Face-Contouring; FWS, Fitzpatrick Wrinkle Scale; GAIS, Global Aesthetic Improvement Scale; GEE, generalized estimating equation; IGA, Investigator Global Assessment; OR, odds ratio; RF, radiofrequency; SD, standard deviation; SCH, Stratum Corneum Hydration; ST, skin tightening; VAS, visual analog scale.

## Data Sharing Statement

The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding author.

## Ethics Statement

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Biomedical Research Ethics Committee of Peking University First Hospital (Approval No.: 2023Yan-515-002; “Yan” stands for “research” in Mandarin). Approval date: January 4, 2023. Registration number at [chictr.org.cn](http://chictr.org.cn): ChiCTR2400088260. Animal studies were not applicable.

## Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.



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## Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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## Disclosure

Authors declare no conflicts of interest for this article.

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