ORIGINAL ARTICLE



Lower face lifting and contouring with a novel internal real-time thermosensing monopolar radiofrequency

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Abstract As demand for a youthful appearance has increased, various techniques for face lifting and contouring have been used to reduce excess fat deposition and improve skin laxity. Recently, radiofrequency (RF)-assisted lipolysis and liposuction (RFAL) has been introduced for body and face contouring. This study aimed to evaluate the clinical improvement and safety of a new RFAL device for face lifting and contouring. A prospective study was conducted in 20 Korean patients who underwent an internal real-time thermosensing monopolar RFAL procedure. Prior to treatment and 12 and 24 weeks after treatment, digital photographs were taken, and the degree of improvement as measured by investigators and patients was recorded. Skin elasticity was measured using a Cutometer (CT575, Courage and Khazaka®, Cologne, Germany). Safety profiles were also evaluated at each visit. Results showed favorable improvement in skin laxity and fat deposition. Both investigators' evaluations and patients' evaluation showed significant improvement between 12 and 24 weeks. Although the changes in skin elasticity measured by the Cutometer were not statistically significant, all three treated regions showed a trend toward improvement. No major side effects such as infection or burn were observed. The internal, real-time thermosensing monopolar RFAL device showed clinical efficacy and safety. After further studies with more patients and longer follow-up periods, internal real-time

thermosensing monopolar RF devices might become one of the popular treatment options for face lifting and contouring.

Keywords Face contouring · Lifting · Liposuction · Radiofrequency · Skin laxity

Introduction

Facial soft tissue undergoes age-related changes in terms of volume, shape, position, and consistency. Aging can also lead to changes in facial expression, creating an unattractive appearance that gives a negative impression. As demand for a youthful appearance has increased, face lifting and contouring have received attention as promising procedures in the fields of dermatology and plastic surgery. Face lifting and contouring procedures have become one of the fastest-growing medical aesthetic techniques worldwide.

Excisional facial surgery, called rhytidectomy or facelift, was introduced in the early 1900s as the first face lifting procedure. With advances in technology, subfascial dissection of the anatomical superficial musculoaponeurotic system (SMAS), called SMASectomy, became widespread [1]. Despite the marked efficacy of this procedure, concerns regarding the excisional nature of this surgery and visible scars limited its popularity, especially among Asians with dark skin [2]. In response to this trend, various nonsurgical face lifting and tightening procedures were introduced including injection of materials such as tissue fillers and botulinum toxin. Soft tissue fillers are designed to address fat atrophy. With aging, fat atrophy becomes clinically apparent in multiple areas of the face including temple and cheek areas, resulting in excessive skin in proportion to diminished volume [3]. Fillers occupy these concave spaces, leading to a younger appearance. Neurotoxin injection is also a simple and effective treatment



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for the aging face. It transiently paralyzes the treated muscles and reduces wrinkles created by muscle movement [4]. Soft tissue fillers and neurotoxin injection produced a paradigm shift toward office-based, easy-to-perform techniques [5, 6]. Although these injection procedures are easy to perform and moderately effective in treating skin aging, they are not suitable for skin laxity and do not remove abnormal fat deposits. For removal of excess fat, liposuction was presented as a solution. Mechanical liposuction, first introduced by Illouz in 1982, is well-established and frequently used to remove excess fat from body parts such as the abdomen and thighs [7]. Since their introduction, mechanical liposuction techniques have undergone many refinements. However, liposuction only removes the fat, not the excess and lax skin. In an effort to achieve face lifting and simultaneous removal of excess fat, newer technologies including power-assisted liposuction, ultrasound-assisted liposuction, and laser-assisted liposuction (LAL) were developed for body contouring [8–10]. LAL is effective for both skin tightening and lipolysis/liposuction. However, the relatively slow treatment speed, difficulty in achieving uniform heating, and risk of burns have limited its use [11]. In 2009, the FDA approved a cryolipolytic device (CoolSculpting®; ZELTIQ Aesthetics, Inc., Pleasanton, CA, USA) for reduction of flank and abdominal fat. Cryolipolysis uses the principle that adipocytes are more susceptible to cold temperatures. Cold temperatures trigger adipocytes to undergo lysis and be engulfed by macrophages [12]. However, cryolipolysis is not able to restore skin flexibility. The ideal treatment for simultaneous fat removal and skin tightening remains elusive.

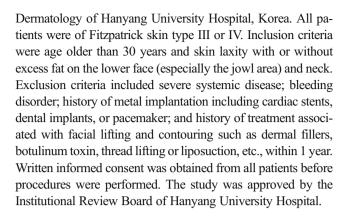
Recently, another promising technique, radiofrequency (RF)-assisted lipolysis and liposuction (RFAL), has been developed for body and face contouring [13, 14]. The first RFAL device used internal bipolar RF combined with an aspiratory cannula and an epidermal-thermosensing electrode. Internal RF can induce more efficient lipolysis with simultaneous liposuction compared to external RF devices. However, bipolar RF cannot produce uniform volumetric heating compared to monopolar RF. As bipolar RF energy only travels between two closely positioned electrodes, bipolar RF is relatively shallow.

In the present study, we evaluated the clinical improvement and safety profiles achieved with a new internal real-time thermosensing monopolar RFAL device (APOLEX®, Chung Woo Medical, Seoul, Korea) for face lifting and contouring.

Materials and methods

Subjects

We prospectively included 20 patients undergoing an internal real-time thermosensing monopolar RFAL procedure between January 2014 and November 2014 in the Department of



Methods

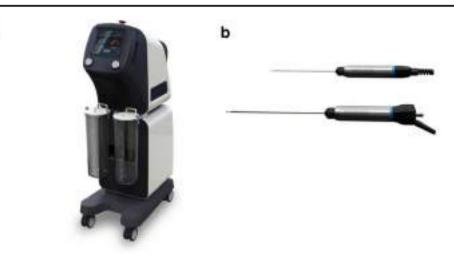
The face and neck areas were treated with an internal real-time thermosensing monopolar device equipped with RFAL technology (Fig. 1).

Procedure

The treatment areas included two or three parts of the lower face and neck, the left and right lower face, and the midline area of the neck below the chin (Fig. 2). Standard preparation and draping techniques with an iodine-based antimicrobial solution were performed. The ports of entry for the cannula were preauricular and submental areas. Incision site anesthesia was done with 1 % lidocaine and a 25-gauge needle. A stab incision using a no. 11 blade scalpel was made as an entrance for a 1-mm blunt cannula to deliver the tumescent solution and an internal RF cannula. The modified tumescent solution was a mixture of 1 % lidocaine, triamcinolone acetonide (5 mg/L), and 0.9 % normal saline at a ratio of 2:1:7. After modified tumescent anesthesia, an internal RF cannula was inserted and moved back and forth using fanning technique. The plane of the treatment was determined by palpation of internal cannula moving 5–10 mm below the skin surface, which is equal to the upper subcutaneous plane. A 1.0-mm diameter cannula was mainly used for the face and submentum. For three patients, a 2.5-mm-diameter cannula with two holes was used for liposuction of submental fat. The APOLEX® study device can control the maximum probe temperature between 0 and 100 °C. We set a treatment temperature of 60 °C, which was measured by a micro-thermosensor located inside the tip of the cannula. The device offers a suction pressure that ranges from 0 to 100 kPa, and we set the pressure to a maximum of 80 kPa. The energy delivered was planned at 2000 J on each side and 1000 J on the submentum. Energy levels of each treatment area were adjusted depending on the size of treatment areas, the amount of individual fat deposition, and skin laxity from 500 to 2000 J. The treatment end point was between 40 and 42 °C of skin surface temperature of the whole treatment area. The skin surface temperature was measured



Fig. 1 The RFAL device, APOLEX®. a Main body of the APOLEX® with control screen and two suction bottles. b Hand pieces of the APOLEX® with and without holes for simultaneous suction. c The output power depending on the diameter of cannula



| Diameter (mm) | 1 | 2 | 2.5 | 3 | 3.5 | 4 |
|---------------------|----|----|-----|----|-----|-----|
| Output power (Watt) | 20 | 32 | 57 | 95 | 108 | 120 |

using a standard device, noncontact thermometer (Digitech, Jaycar, Rydalmere, NSW, Australia). The port sites were left open and covered with Steri-StripsTM (3M Surgical Products, St. Paul, MN, USA).

C

Evaluation of clinical efficacy

1. Investigator global assessment

Three independent dermatologists compared the baseline and 12- and 24-week photographs to evaluate clinical improvement. They were totally blinded, and they also had no information if the arranged photographs are at baseline, 12 weeks, or 24 weeks. All digital photographs were taken under identical lighting conditions in the same room. They were obtained from the front of the face and at 45° and 90° angles on each side prior to treatment and 12 and 24 weeks after treatment. A five-point grading scale was used (1 = no improvement, $2 = \sim 25$ % improvement,

 $3 = \sim 50$ % improvement, $4 = \sim 75$ % improvement, $5 = \sim 100$ % improvement).

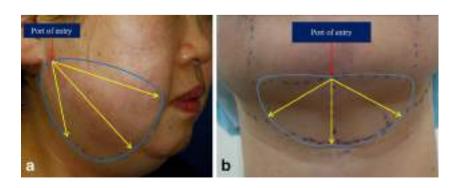
2. Patient global assessment

Each patient also evaluated clinical improvement at 12 and 24 weeks after treatment. The same five-point grading scale as was used with the IGA was used here.

3. Measurement of skin laxity

Skin elasticity was measured with a noninvasive, in vivo suction skin viscoelasticity meter (Cutometer CT575, Courage and Khazaka®, Cologne, Germany) [15]. The viscoelasticity meter performs measurements based on the principle of negative pressure suction and elongation. The closer each value is to 1, the more elastic is the skin. Skin elasticity was measured at four sites on the face and one site on the submental area. Two points on the malar area served as controls. The measurement points were as follows: 2 cm lateral and 0.5 cm inferior to the corner of the lip along the nasolabial fold and at the center of the submentum (Fig. 2a). For accuracy, elasticity was

Fig. 2 The ports of entry for the cannula, the vectors, and the borders of the areas treated. a Right side of lower face. b Submental area





measured three times at each point by the same evaluator, and mean values were calculated.

Side effects

Patients were questioned about the following side effects: duration of postprocedural pain, bruising, erythema, tingling sensations, numbness and paresthesia, burns, infections, and other side effects. Major complications were defined as infection, seroma, burns, and skin necrosis.

Statistical analysis

Statistical analyses were conducted using IBM SPSS statistics (Version 22, NY, USA). Change in skin laxity was analyzed using the Friedman test or Mann-Whitney test. A *p* value of 0.05 or lower was considered statistically significant.

Results

delivered

Demographic information

A total of 20 Korean patients (19 females and 1 male) aged 34–60 years (mean 46.4 ± 7.8) were enrolled. The amounts of

Table 1 Demographic information on the 20 patients, with amounts of tumescent solution and total energy

| Number Sex Age | | Age | Tumescent (co | c) | Energy (J) | | | |
|----------------|---|-----|---------------|-----------|------------|-------------|-----------|---------------|
| | | | Right cheek | Submentum | Left cheek | Right cheek | Submentum | Left cheek |
| 1 | F | 49 | 20 | 10 | 20 | 900 | 500 | 900 |
| 2 | M | 34 | 40 | 15 | 40 | 2000 | 700 | 2000 |
| 3 | F | 50 | 40 | | 50 | 2000 | | 2000 |
| 4 | F | 36 | 30 | | 30 | 1500 | | 1600 |
| 5 | F | 45 | 40 | | 40 | 1500 | | 1500 |
| 6 | F | 52 | 40 | | 40 | 1500 | | 1500 |
| 7 | F | 39 | 30 | | 30 | 1600 | | 1600 |
| 8 | F | 46 | 30 | 20 | 30 | 1500 | 1500 | 1500 |
| 9 | F | 58 | 50 | 10 | 45 | 1500 | 500 | 1500 |
| 10 | F | 51 | 30 | 20 | 30 | 1500 | 800 | 1500 |
| 11 | F | 40 | 60 | 10 | 50 | 1800 | 800 | 1800 |
| 12 | F | 60 | 40 | 15 | 40 | 1500 | 600 | 1500 |
| 13 | F | 52 | 40 | 20 | 40 | 1500 | 500 | 1500 |
| 14 | F | 60 | 50 | 20 | 50 | 1800 | 800 | 1800 |
| 15 | F | 49 | 40 | 20 | 40 | 2000 | 1000 | 2000 |
| 16 | F | 47 | 40 | 20 | 40 | 2000 | 800 | 2000 |
| 17 | F | 43 | 20 | | 20 | 1000 | | 1000 |
| 18 | F | 40 | 30 | | 30 | 1500 | | 1500 |
| 19 | F | 38 | 20 | | 20 | 1500 | | 1500 |
| 20 | F | 39 | 40 | 20 | 40 | 1500 | 1000 | 1500 |

tumescent solution and energy delivered are shown in Table 1. In all patients, total RF delivery time was within 30 min.

Of the 20 patients, 14 completed the follow-up schedule of 24 weeks. The other six patients were unable to visit the hospital because of the distance from their homes. They responded to questions regarding their satisfactions and side effects by telephone or e-mail.

Efficacy

Investigator global assessment

The investigators evaluated clinical improvement via photographs of the 14 patients who completed the follow-up schedule. The rest six patients who did not have their 24-week photographs taken were excluded in physicians' evaluation. Skin tightening and loss of fat were observed in all patients. Tightening of the jowl line was clinically apparent at 12 weeks and maintained at 24 weeks (Figs. 3, 4, and 5). The mean grade of clinical improvement from baseline to 12 weeks was 2.71 ± 0.57 , and that from baseline to 24 weeks was 3.00 ± 0.63 (Table 2).

Patient global assessment

At every visit, patients were asked to assess their satisfaction. After 12 weeks, the mean patient satisfaction score was $3.9\,\pm$



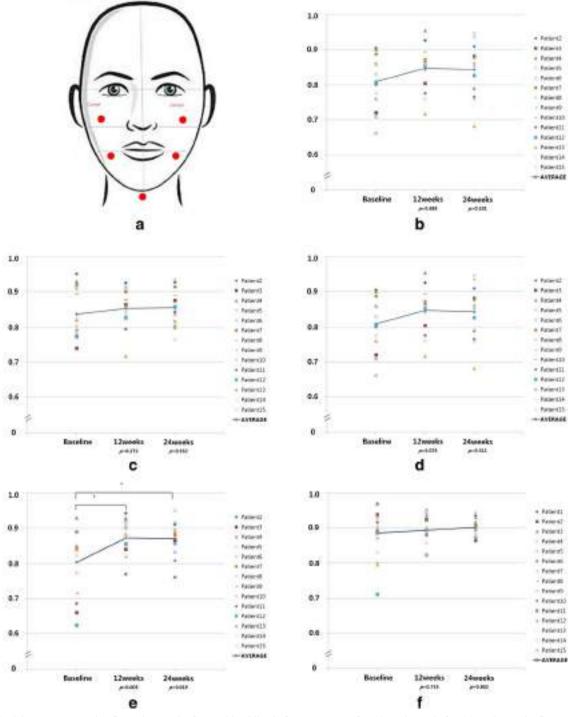


Fig. 3 Elasticity was measured at five points on the face and jowl line before treatment, after 12 weeks, and after 24 weeks. a The five measurement points on face and neck. b right malar area (control), c left malar area (control), d right buccal area, e left buccal area, and f submentum

0.79, and that after 24 weeks increased to 4.3 ± 0.98 (Table 3) (Fig. 6).

Skin laxity

The elasticity of the right malar area, used as a control, increased from 0.82 ± 0.06 to 0.83 ± 0.06 after 12 weeks and to

 0.85 ± 0.04 after 24 weeks (p = 0.683 and 0.101, respectively). In the left malar area (control), elasticity was 0.84 ± 0.07 at baseline, 0.85 ± 0.04 after 12 weeks, and 0.86 ± 0.05 after 24 weeks (p = 0.272 and 0.552, respectively). At the right buccal area, elasticity also increased from 0.81 ± 0.08 to 0.85 ± 0.06 after 12 weeks (p = 0.074) and to 0.84 ± 0.08 after 24 weeks (p = 0.311). In the left buccal area, elasticity



Fig. 4 Patient 1: A 49-year-old female with a heavy neck who showed significant improvement in the jowl line over baseline at 12 weeks after treatment; the effect was maintained for the 24 weeks of follow-up. Note the decreased fat deposition and sharpened jowl line. a Frontal view at baseline, b after 12 weeks, and c after 24 weeks; d oblique view at baseline, e after 12 weeks, and f after 24 weeks



measured 0.80 ± 0.10 at baseline, 0.87 ± 0.05 after 12 weeks, and 0.86 ± 0.05 after 24 weeks (p=0.005 and 0.019, respectively). In the submental area, elasticity increased from 0.88 ± 0.07 to 0.90 ± 0.04 after 12 weeks (p=0.733) and to 0.90 ± 0.03 after 24 weeks (p=0.802) (Fig. 2b–f).

Safety

Minimal to moderate postoperative facial edema was noted by all patients but resolved spontaneously within 1 week. Of the 20 patients, 17 had mild to moderate bruising that resolved spontaneously within 1–2 weeks. Three patients with excess fat deposition who received aspiration by negative pressure suffered more pronounced bruising. Two patients complained of paresthesia, which resolved within 2 weeks. There were no major complications such as burns, necrosis, or infection.

Discussion

In accordance with aging, skin laxity and abnormal fat accumulation are highlighted in the face and neck such as the submental area, jowls, lateral nasolabial folds, lateral labiomental folds, and lateral malar areas [16]. These changes lead to morphological disruption, resulting in an older appearance. RFAL is a new technique for lipolysis and contouring that can cause

neocollagenesis and simultaneously suction the lysed fat cells through a cannula using negative pressure [17]. Unlike LAL, which uses a bare glass laser fiber as a free beam, volumetric heating of RF with simultaneous liquefaction and aspiration has a shorter procedure time [18]. Skin laxity is largely caused by changes in connective tissue including collagen, elastin, and ground substances. Collagen is a triple helix with chains held together by hydrogen bonds. Collagen molecules are organized as fibrils, whose tensile properties are caused by intermolecular cross-links [19]. When collagen is denatured by heat, the hydrogen bonds rupture, and the triple helices unwind, resulting in randomly coiled molecules. Although collagen fibers contract, certain heat-stable cross-links are maintained, and the elastic properties of the collagen increase. This heat-modified collagen undergoes remodeling associated with fibroplasia and new collagen synthesis [20]. Lin et al. noted that collagen fibers began to curve at 52–55 °C [19]. On the basis of these theories, we set a maximum temperature of 60 °C, which was measured by a micro-thermosensor located inside the tip of the cannula. When the internal temperature was close to 60 °C, the epidermal temperature measured with an external infrared thermometer was 38–42 °C. Therefore, the temperature at the mid to lower dermis was estimated to be between 50 and 55 °C.

RF energy is an alternating current that flows from the tip of the electrode to the tissue. When the current enters the tissue, ions in the tissue follow the high-frequency alternation



Fig. 5 Patient 10: A 60-year-old female with excess fat deposition and wrinkles on the jowl line due to skin laxity. After 12 weeks, the wrinkles on the jowl line were less apparent, and the effect was maintained for the 24 weeks of follow-up. a Oblique view at baseline, b after 12 weeks, and c after 24 weeks; d side view at baseline, e after 12 weeks, and f after 24 weeks



Table 2 Investigator global assessment (IGA) scores at 12 versus 24 weeks after treatment

| IGA | | 12 weeks | | | | 24 weeks | | | | |
|-------|-----|----------|------|------|------|--------------------|------|------|------|-------------------|
| No. | Sex | Age | A | В | С | Mean (range) | A | В | С | Mean (range) |
| 1 | F | 49 | 3 | 4 | 4 | 3.33 | 2 | 5 | 4 | 3.00 |
| 2 | M | 34 | 4 | 2 | 4 | 4.00 | 3 | 3 | 4 | 3.33 |
| 3 | F | 50 | 2 | 3 | 3 | 2.67 | 3 | 3 | 3 | 2.67 |
| 4 | F | 36 | 3 | 3 | 3 | 2.67 | 3 | 4 | 3 | 3.00 |
| 5 | F | 45 | 2 | 3 | 2 | 1.67 | 2 | 3 | 2 | 2.00 |
| 6 | F | 52 | 3 | 3 | 3 | 3.00 | 4 | 4 | 4 | 3.67 |
| 7 | F | 39 | 1 | 3 | 2 | 1.67 | 1 | 4 | 2 | 1.67 |
| 8 | F | 46 | 3 | 4 | 3 | 3.33 | 3 | 5 | 3 | 3.00 |
| 9 | F | 40 | 2 | 2 | 2 | 2.00 | 3 | 2 | 3 | 2.67 |
| 10 | F | 60 | 2 | 4 | 4 | 3.00 | 2 | 5 | 4 | 3.00 |
| 11 | F | 52 | 2 | 3 | 2 | 1.67 | 2 | 4 | 2 | 2.00 |
| 12 | F | 60 | 2 | 3 | 3 | 2.33 | 2 | 3 | 2 | 2.00 |
| 13 | F | 49 | 3 | 2 | 2 | 2.33 | 3 | 3 | 3 | 2.67 |
| 14 | F | 47 | 2 | 2 | 2 | 2.00 | 2 | 2 | 2 | 1.67 |
| Avera | age | | 2.43 | 2.93 | 2.79 | 2.71 (2.00 ~ 3.67) | 2.50 | 3.57 | 2.93 | 3.00 (2.00 ~ 4.00 |

A, B, C: three different dermatologists

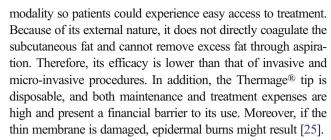


 Table 3
 Patients' evaluations at 12 versus 24 weeks after treatment

| Number | Sex | Age | 12 weeks | 24 weeks |
|---------|-----|-----|----------|----------|
| 1 | F | 49 | 4 | 5 |
| 2 | M | 34 | 2 | 3 |
| 3 | F | 50 | 4 | 5 |
| 4 | F | 36 | 3 | 2 |
| 5 | F | 45 | 4 | 4 |
| 6 | F | 52 | 5 | 5 |
| 7 | F | 39 | 4 | 5 |
| 8 | F | 46 | 5 | 5 |
| 9 | F | 40 | 3 | 3 |
| 10 | F | 60 | 5 | 5 |
| 11 | F | 52 | 4 | 5 |
| 12 | F | 60 | 4 | 5 |
| 13 | F | 49 | 3 | 3 |
| 14 | F | 47 | 4 | 3 |
| 15 | F | 58 | 5 | 5 |
| 16 | F | 51 | 3 | 4 |
| 17 | F | 43 | 4 | 5 |
| 18 | F | 40 | 4 | 5 |
| 19 | F | 38 | 4 | 4 |
| 20 | F | 39 | 4 | 5 |
| Average | | | 3.9 | 4.3 |

in the direction of the current. The resulting ionic agitation opposes the flow of alternating current and produces heat [11]. The amount of heat generated increases with impedance. Soft tissue is made up of several layers, including the dermis, fat, muscle, and fibrous tissue. Subcutaneous fat has a resistance of 2180 Ω , which is 10 times higher than that of the skin (289Ω) , and so produces a larger amount of heat energy than the skin. RF devices are either monopolar or bipolar and either internal or external. In monopolar systems, current flows from an electrode placed in contact with the tissue to a grounding electrode positioned on the skin far from the other electrode [21]. Therefore, monopolar RF energy delivers heat deep enough to involve the fibrous septae of the fat layer. In contrast, bipolar RF devices use two electrodes positioned at fixed distances, both of which are in contact with the treatment area. In bipolar devices, alternating current flows from the active electrode to the other electrode, passing only through the tissues between them. The depth of penetration corresponds to only half the distance between the electrodes [21].

The first external monopolar RF device for face lifting and contouring, approved in 2002, was the noninvasive Thermage® (Thermage Inc., Hayward, CA, USA) [20], composed of a generator, a handheld tip, and a cryogen unit. The tip has a capacitive membrane that disperses energy uniformly across the surface area. The depth of heating depends on the tip size and geometry. The efficacy of the Thermage® has been reported in a variety of studies [22–24]. It was developed as a noninvasive



To overcome the weaknesses of the noninvasive RF device, an internal, bipolar RF device was introduced in 2008 for body contouring [26]. The internal RF energy results in direct liquefaction of the adipose tissue and simultaneous coagulation of blood vessels. The skin tightening and tissue contraction induced by the RFAL are thought to be caused by its effect on the fibroseptal network. In vivo studies have shown that application of RFAL to the septofascial network results in a mean 33 % contraction. Mulholland and Paul also reported that RFAL significantly reduced the volume of tissue due to tissue contraction and retraction of adipose tissue and dermis [11]. Blugerman et al. reported the safety and feasibility of an RFAL device in 23 patients treated in the hip and lower abdomen [13]. The first device introduced, the BodyTiteTM RFAL device (Invasix, Yokneam, Israel), consisted of a cannula-type probe with a heated tip plus a hollow bipolar tube for aspiration [26]. Three years later, newer cannulas for use on the face and neck were developed. The FaceTiteTM has a 1.6-mm-diameter, 10-cm-long cannula, and the NeckTiteTM uses a 2.4-mm-diameter, 12-cmlong cannula that also has holes for aspiration [2]. The siliconecoated internal cannula tip emits RF energy toward an external electrode that reflects heat back to the epidermis. As the external electrode requires direct contact with the skin surface, the face and neck are hard-to-treat areas due to their irregular contours. Also, the external electrode is relatively large and heavy, and the procedure can be time-consuming and labor-intensive.

Recently, the internal and monopolar RF device named ThermiTightTM (ThermiHealth Co, Texas, USA) was introduced. It provides precise and controlled subdermal heating that is thermistor-controlled for subdermal skin tightening using a percutaneous RF treatment probe. Key retrospectively analyzed 35 patients for submental skin tightening, showing that the combined mean change between baseline and postprocedure skin laxity scores was significantly decreased, and no adverse events were reported. However, this device has no ability to suction fat [27].

The new RFAL device, the APOLEX®, deploys a hand piece to deliver monopolar RF energy to adipose tissue and dermis (Fig. 1a). The internal cannula consists of a coated arm with a high-intensity, heat- and chemical-resistant material and a conductive tip that emits monopolar RF energy (Fig. 1b). The cannula also has a real-time micro-thermosensor that recognizes internal temperature and regulates the electric current. The diameter of the cannula used in this study was 1.0 or 2.5 mm. A 2.5-mm cannula with two holes for suction was used in three patients. The cannula emits monopolar RF energy either



Fig. 6 Patient 12: A 60-year-old female with fine wrinkles on the jowl line due to skin laxity. After 12 weeks, the wrinkles on the jowl line were less apparent, and the effect was maintained for the 24 weeks of follow-up. a Oblique view at baseline, b after 12 weeks, and c after 24 weeks; d side view at baseline, e after 12 weeks, and f after 24 weeks



continuously or in a pulsed mode. When set in pulsed mode, the triggering frequency is 40 Hz, and the on/off time is automatically regulated depending on the diameter of the cannula and the set temperature within the range of 1–10 ms of on time and 15– 24 ms of off time. Period wave (T) is defined as 1/frequency. In case of 40 Hz, T is 1/40 Hz and on time + off time would be 25 ms. When on time is 1 ms, off time is 24 ms and when on time is 10 ms, off time is 15 ms. The output power, depending on the diameter of cannula, is shown in Table 4. In this study, we used pulsed mode because continuous mode reached the maximum temperature too fast, resulting in frequent shutdown, inhomogeneous tissue temperature, and side effects. The maximum temperature was set at 60 °C based on previous reports. When the internal temperature reached the set point, the device automatically shuts down. The aspiration port is connected to an aspirator and suction bottle for simultaneous aspiration of liquefied fat when needed.

In the present study, the result of patients treated with APOLEX® revealed that there was a 25–50 % improvement

Table 4 The output power depending on the diameter of cannula

| Diameter (mm) | 1 | 2 | 2.5 | 3 | 3.5 | 4 |
|---------------------|----|----|-----|----|-----|-----|
| Output power (Watt) | 20 | 32 | 57 | 95 | 108 | 120 |

of IGA without any significant side effect. Moreover, the PGA scores were higher than the IGA scores that may mean better patients' satisfaction beyond physicians' evaluation. Although the effects on skin elasticity measured with the Cutometer® were not statistically significant, there was a trend of improvement in all three treated regions. However, we only used the Cutometer as a summative method because it is very sensitive to small variations, for example, a subtle change in the facial expression or placement with the tester's more/less pressure. Moreover, using this new device, we were able to break down fat more quickly than with LAL. Total RF delivery time was within 30 min in all patients. The access port was invisible despite being left open, and patients were able to return to their daily lives the day after treatment. Bruises were mainly observed side events, but they were yellow-greenish, not purple, and simple make-up was able to cover them. In addition, three of the patients requested fat aspiration on their jowl line. A two-holed, 2.5-mm-sized cannula was used in these three patients, and the total aspirate volume was 10 cc in two patients and 20 cc in the third. All three patients with aspiration showed more severe bruises than the other patients did. Unfortunately, as the patient number was small, it was not possible to statistically analyze the effect of aspiration.



In our experience, the use of internal real-time thermosensing monopolar RFAL produced significant improvement for lower face and neck contouring with a lower risk of side effects. Theoretically, an ideal lipolysis and liposuction system should (1) remove fat without compromising the viability of the overlying skin envelope; (2) cause soft tissue envelope contraction around the area of aspirated adipose tissue; (3) be safe and usable on patients under local tumescent anesthesia; and (4) lead to minimal bruising and swelling, thereby permitting shorter postoperative recovery periods [20]. The RFAL with APOLEX® almost fulfilled all four requirements. In addition, this new machine enables faster treatment and results in less physician fatigue. Therefore, we suggest this RFAL device as one of the alternative methods for lower face lifting and contouring. However, the study was limited because of no control group such as standard liposuction and small number of patients. Studies with longer follow-up periods are needed to assess the longterm effects of RFAL to meet patients' real needs.

Conclusion

In this study, we evaluated the clinical efficacy and safety of a new internal real-time thermosensing monopolar RFAL in 20 patients with facial skin laxity. A total of 16 of those patients were followed for 12 weeks after the procedure, and 14 completed a follow-up schedule of 24 weeks. Patients and physicians were satisfied with the clinical efficacy of the procedure, and no serious side effects were observed.

Although the previous bipolar RFAL device has a built-in protection system, it is limited due to a difference between the external and internal temperatures. Because our RF device can sense the internal temperature, the effect of RF will be maximized. Also, the hand piece of the device is lighter than those of earlier devices because it requires no external electrode, which significantly reduces the burden of the practitioner.

After verification through further studies with larger numbers of patients and longer follow-up periods, this internal real-time thermosensing monopolar equipment could be used effectively and safely to treat other delicate facial parts with excess fat deposition.

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Compliance with ethical standards Written informed consent was obtained from all patients before procedures were performed. The study was approved by the Institutional Review Board of Hanyang University Hospital.

Conflicts of interest The authors declare that there are no conflicts of interest.



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