

NON-ABLATIVE CAPACITIVE RESISTIVE 448 kHz RADIOFREQUENCY FOR WRINKLE REDUCTION PILOT STUDY

PABLO NARANJO MD, PhD¹ / JOSÉ LUIS LÓPEZ-ESTEBARANZ MD, PhD² / TAIMUR SHOAIB MD, FRCSEd (Plast)³

¹ Medical Director of "Clínica Elite Laser de Madrid"; Specialist in Laser and Aesthetic Medicine; Coordinator of the Master in Aesthetic Medicine at the Universidad Rey Juan Carlos de Madrid; Laser professor in the Masters in Aesthetic Medicine at the Complutense University of Madrid and the University of Alcalá de Henares. ² Heads the Department of Dermatology at University Hospital Foundation Alcorcón in Madrid; Professor of Dermatology at the Rey Juan Carlos University; Director of DermoMedic (Madrid). ³ Consultant plastic surgeon. Medical Director of La Belle Forme (UK).

ABSTRACT

Background: Anti-aging non invasive cosmetic procedures are a common way of addressing cosmetic concerns raised by patients. Radiofrequency treatment is a well established form of non surgical cosmetic improvement, which is used particularly for wrinkle reduction.

Objective: The aim of this study was to determine the effectiveness of repeated treatments of 448 kHz monopolar capacitive/resistive radiofrequency in facial wrinkle reduction.

Methods: We recruited 32 healthy volunteers to undergo six radiofrequency treatments over a four week treatment period. No other treatment for facial wrinkles was performed during the study period. Treatment was performed with temperature control of the skin to prevent skin burns (40-42°C). The results were evaluated after two months and three months following completion of treatment, using the Fitzpatrick facial wrinkle scale on standardized photographs. A skin digital analyser was used to objectively assess the evolution of wrinkles. Subjective questionnaires were also used for patients and professionals to rate improvement, effectiveness and friend recommendation. Statistical significance was determined by the Paired student's *t*-test (*p*<0.05).

Results: There was a significant reduction of wrinkle size and depth with an improvement of at least one point in the Fitzpatrick wrinkle scale in 80% of participants. No undesirable side effects were reported.

Conclusions: The use of a 448 kHz monopolar capacitive/resistive radiofrequency with Temperature Monitoring Control has proven to be safe and effective in the improvement of wrinkle appearance up to three months after treatment.

INTRODUCTION

Antiaging treatments and skin care in general are becoming very popular. The concern for safety and to avoid down time and the risk associated to surgery, non-invasive procedures, such as non-ablative radiofrequency (RF) and different types of laser and light sources are increasing their presence in the market, being used to promote facial rejuvenation (1-4).

In spite of the popularity of laser and pulsed lights, their use have many limitations such as skin colour, depth of

action as well as many side effects and posttreatment down time in ablative lasers (2, 4-7), whilst other techniques such as radiofrequency are not affected by such limitations (8).

The aim of RF is to rise up tissues temperature (hyperthermia). The effects of hyperthermia are directly related with the type of tissue, the temperature reached as well as the time of exposition (9-11). Among its different effects are the induction of fibroblast proliferation (12-14) and activation of neocollagenesis (12, 13).

The use of radiofrequency (RF) in antiaging treatments is well established for its action on collagen remodelling, skin tightening and wrinkle attenuation (15, 16).

In order to optimise working parameters of a 448 kHz monopolar capacitive / resistive radiofrequency (448 kHz CRET) device in Facial Treatment Methodology for Wrinkles, a pilot multicentre evaluation with a thermal control application protocol has been undertaken.

The aim of the study was to determine the effect of RF treatment on the skin following multiple treatments.

MATERIALS AND METHODS

Study Design

This has been a Spanish and United Kingdom multicentre prospective study. The study population has included 32 healthy volunteers (30 women and two men), suffering of wrinkles with ages ranging from 31 to 83 years old and skin photo type from II to IV (Fitzpatrick scale) (17), population inclusion criteria can be seen at Table 1.

Volunteers' wrinkles were classified following Fitzpatrick Wrinkle Classification and Degree of Elastosis criteria (18) (Table 2).

Volunteers received 6 treatment sessions (30 minutes per session) over a 4-week treatment period. Sessions were done under temperature control to ensure that the local temperature achieved and maintained was $\geq 40^{\circ}\text{C}$ (40-42°C) in each area.

Results were evaluated after the treatment, at two and three months after the completion of the treatment.

RF Device and accessories

As RF source, an INDIBA® device (INDIBA S.A., Barcelona, Spain) was used. To assess that the desired temperature (40°C) was achieved an IR Thermometer (Fluke 62

Include	Exclude / Avoid	Contraindicated for IDC treatment
Male or female surgical > 18 with a Fitzpatrick Skin Type I-IV Presenting wrinkle score (Fitzpatrick Wrinkle Classification System or similar) of 4 - 9	Blepharoplasty, surgical face lift (12 months) or chemical peel treatment within the last 6 months Hyaluronic facial filler or botulinum toxin injection within the last 6 months (Or Collagen - Spain) Current wrinkle reduction treatment Future facial treatment with any of the above until 3 months post final IDC TCM session Know hypersensitivity to • Radiofrequency • TheraCream™ (including active ingredients) • Nickel, chromium	Pacemaker or any electronic implant Pregnancy Areas of broken skin on facial region (recent burns, abscesses, open wounds) Thrombophlebitis Removable dentures (in resistive mode)

Table 1. Inclusion criteria for the enrolment of volunteers in the study.

Class	Wrinkling	Score	Degree of Elastosis
I	Fine wrinkles	1 - 3	Mild (fine textural changes with subtly accentuated skin lines)
II	Fine to moderate depth wrinkles. Moderate number of lines	4 - 6	Moderate (distinct papular elastosis-distinct papules with yellow translucency under direct lightening- and dyschromia)
III	Fine to deep wrinkles. Numerous lines. With or without redundant skin folds	7 - 9	Severe (multipapular and confluent elastosis-thickened yellow and pallid- approaching or consistent with cutis rhomboidalis)

Table 2. Fitzpatrick wrinkle scale and elastosis degree (18).

MAX+) was used. Finally to measure wrinkles (total size, depth, width and maximum depth) a skin analyser was used (Antera 3D®).

Effectiveness evaluation

Effectiveness was assessed by standardized facial photographs. Images were taken before starting the treatment, at the end of the treatment and at two and three months as follow up pictures after the last session.

Treatment results were evaluated with subjective questionnaires for both, patients and professionals, to rate: *improvement, effectiveness and friend recommendation*. To assess in an objective manner, by means of a skin analyser digital measure of wrinkles was done to get data of: total size, depth, width and maximum depth.

Statistical significance was determined by Paired student's *t*-test.

Safety evaluation

Safety was assessed by subjective questionnaires (pleasantness, tolerance and erythema) filled out by the professionals and the volunteers as well as a record of undesirable side effects. Output power was to be reduced when erythema was ≥ 4 (scale from 0 to 5 as maximum erythema), or when pain/tolerability was ≥ 9 (scale from 0 to 10 as maximum pain). Therapists were asked to maintain a subjective dialogue with the volunteers throughout the session to confirm their comfort.

Treatment protocol

In all volunteers, whole face was treated and temperature was monitored to ensure 40° C was achieved during the treatment. Precise parameters, such as treatment

time, initial power guide and final power guide was provided for each area in the face.

RESULTS

Study Population

All 32 subjects enrolled into the study completed all 6 RF sessions, although three cases were excluded for not fitting the inclusion criteria. The age of those patients finally included in the study ranged from 37 to 83 years old with an average age of 56 $\pm$ 11 y.o. Skin Fitzpatrick photo types distribution was: 2.4% Type I, 61.0% Type II, 24.4% Type III and 12.2% Type IV. Fitzpatrick wrinkle score distribution of patients before the treatment is shown in Table 3.

Class	Score	Basal	3 months after treatment
I	1		
	2		2 (7,1%)
	3	1 (3,6%)	5 (17,9%)
II	4	2 (7,1%)	4 (14,3%)
	5	5 (17,9%)	8 (28,6%)
	6	6 (21,4%)	4 (14,3%)
III	7	8 (28,6%)	2 (7,1%)
	8	5 (17,9%)	3 (10,7%)
	9	1 (3,6%)	

Table 3. Fitzpatrick Wrinkle Classification assessment at baseline and 3 months after the last treatment

Fitzpatrick Wrinkle Evaluation

Overall the mean basal wrinkle degree was Fitzpatrick 6.5 (± 1.5), at the end of the treatment, the mean degree decreased to 5.8 (± 1.6) and at three months follow up, after the end of treatment, it had decreased to 5.3 (± 1.4), percentage distribution can be seen at Table 3. Paired student's t-test showed statistical significance in Fitzpatrick Wrinkle degree reduction at the end of the treatment ($p=0.002$), at two months follow up ($p=0.000$) and at three months follow up ($p=0.000$).

Images showing the basal state (before treatment) and the outcome at three months of completing the treatment can be seen from Figure 1 to Figure 4.

Effectiveness

Not all the patients that undertook 448 kHz CRET treatment were tested with the skin analyser, just the data of eleven patients could be collected after the end of treatment.

Paired student's t-test showed a significant total size reduction ($p=0.000$) of wrinkles as depth reduction ($p=0.001$), maximum depth reduction was not significant as neither was the slight increase in width after the treatment was concluded (Table 4). Examples of the Skin analyser images are shown in Figures 5 to 8.

Subjective questionnaires say that Professionals saw *no change* in 11% of the patients, 58% *improved*, 21% showed *much improvement* and 11% *improved very much* (Table 5). Among patients answers, 26% didn't see *any improvement* at all, 42% *improved somewhat*, 11% *moderately* and 21% *strongly*. The treatment was felt as moderately or strongly pleasant by 95% of the patients (Table 6). Erythema questionnaire showed a mean value of 3, where 0 was no erythema and 5 intense erythema.

Safety

The treatment proved to be safe, no undesirable side effects were reported. Regarding tolerability, therapist evaluation gave punctuation of 2 being 0 no pain and 10 worst possible pain. In general it has been a treatment well tolerated by most of the patients (Table 6).

There were no withdrawals.

	Total size	Depth mm	Width mm	Max. depth
Mean loss	4.93	0.02	-0.001	0.03
% loss	16.10	2 (7,1%)	4 (14,3%)	4 (14,3%)

Table 4. Wrinkle mean loss and percentage of loss one month after starting the treatment. After a Paired student's t-test, total size reduction was statically significant ($p=0.000$) as depth reduction ($p=0.001$) (N=11).

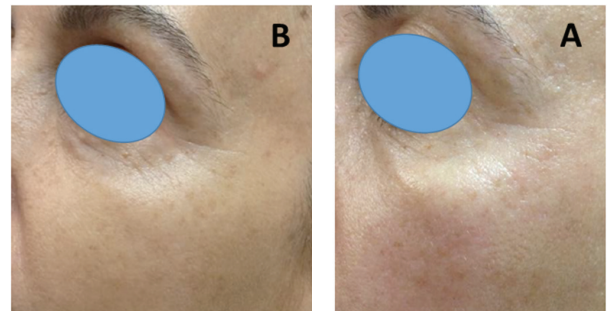


Figure 1. 63-year old patient before (B) and 3 months after (A) the last tx.

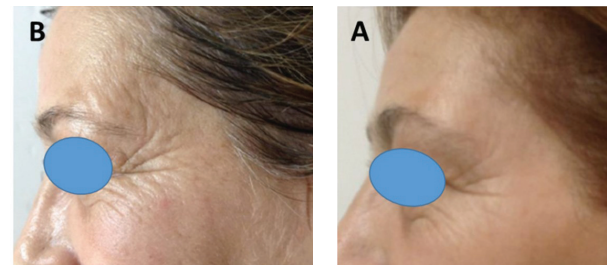


Figure 2. 55-year old patient before (B) and 3 months after (A) the last tx.

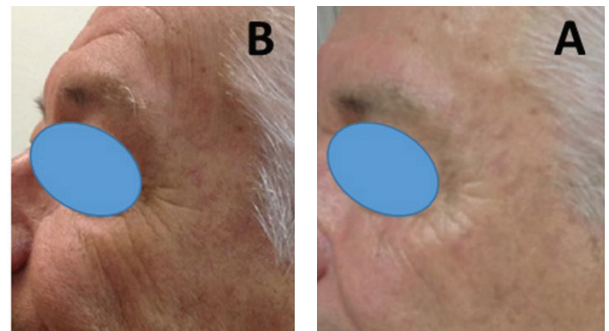


Figure 3. 74-year old patient before (B) and 3 months after (A) the last tx.

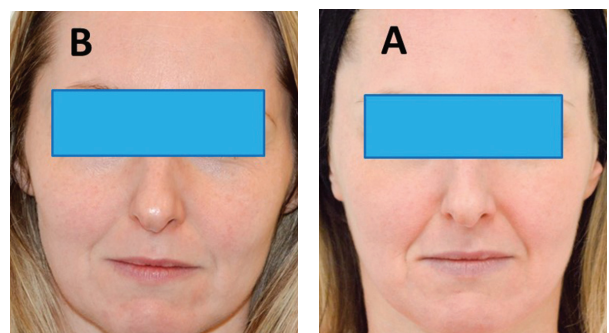


Figure 4. 74-year old patient before (B) and 3 months after (A) the last tx.

THERAPIST EVAL.	Worst	No change	Improved	Much improved	Very much improved
Improvement	0	2 (8,7%)	11 (47,8%)	8 (34,8%)	2 (8,7%)

Table 5. Results of the subjective therapist questioner to evaluate the efficiency of INDIBA® treatment on wrinkles per treated patient (N=23).

SELF EVALUATION	No improvement	Some	Moderate	Much
Improvement	5 (17,9%)	11 (39,3%)	4 (47,8%)	8 (28,6%)
Attractive	14 (14,3%)	12 (42,9%)	5 (47,8%)	7 (25,0%)
Pleasant	1 (3,6%)	1 (3,6%)	8 (47,8%)	18 (64,3%)
Recommend to friends	1 (3,6%)	3 (10,7%)	8 (47,8%)	16 (57,1%)

Table 6. Results of the patients' subjective perception questioner (N=28).

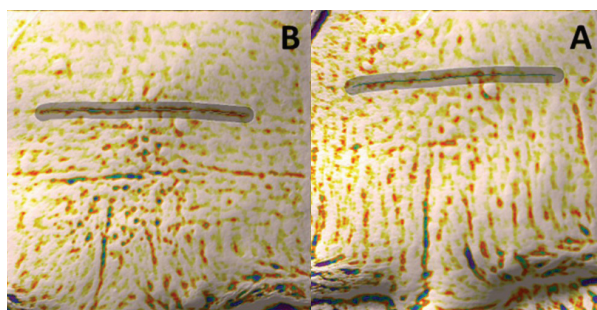


Figure 5. 45 y.o. Wrinkle measures before the treatment (B): total size 15.4 / depth 0.0517 mm / width 1.65 mm / maximum depth 0.080. Measures after the treatment (A): total size 12.6 / depth 0.0356 mm / width 1.83 mm / maximum depth 0.059

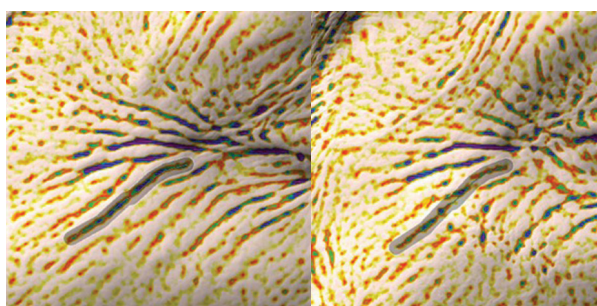


Figure 7. 69 y.o. Wrinkle measures before the treatment (B): total size 25.8 / depth 0.0803 mm / width 1.5 mm / maximum depth 0.112. Measures after the treatment (A): total size 18.7 / depth 0.0674 mm / width 1.45 mm / maximum depth 0.116

DISCUSSION

The treatment with a 448 kHz CRET for wrinkles has proven to be a safe technology, stated by all questionnaires to both professionals and patients.

Although pictures in many patients could not translate the relevant improvement, all evaluations showed an improvement of wrinkles appearance. Skin analysis showed a decrease of wrinkles total size by a 16%, decrease of depth by a 15% and decrease of maximum depth by 18%, only width showed an increase by 0.6%. Subjective assessment by therapist claim improvement of wrinkles in 89% of patients, as well as self-evaluation where 74% of patients said to have experienced some degree of improvement.

What looks contradictory at first glance is the increase of the mean wrinkles width (0.57 %) whilst the rest of measures showed a decrease (total size, depth and maximum depth). This could be a result of the relaxation of the depth, that would track the tissue and get both sides of the wrinkle closer, with this relaxation and its resurfacing would relax the sides and make them spread away from the centre of the wrinkle giving a false appearance of wrinkle widening.

The present results are to be attributed to the effect of hyperthermia on tissues, as it has been reported that collagen denaturation starts at 40° C, collagen coagulation leads to skin shrinkage, in this process there is a microinflammatory stimulation of fibroblasts which stimulates neocollagenesis and neolastinogenesis that will cause an eventual skin tightening (19).

CONCLUSIONS

The use of 448 kHz CRET with Temperature Monitoring Control has shown to be safe and effective in the improvement of wrinkles appearance up to three months after the end of treatment.

Further studies would help to evaluate the risks and benefits of different temperature ranges as well as the sessions regime protocol.

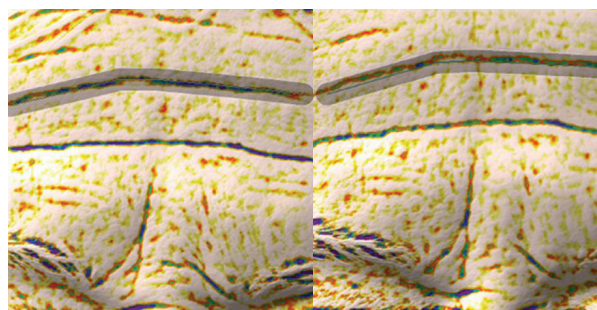


Figure 6. 54 y.o. Wrinkle measures before the treatment (B): total size 26.1 / depth 0.0859 mm / width 1.9 mm / Maximum depth 0.202. Measures after the treatment (A): total size 22.3 / depth 0.0651 mm / width 2.13 mm / maximum depth 0.089

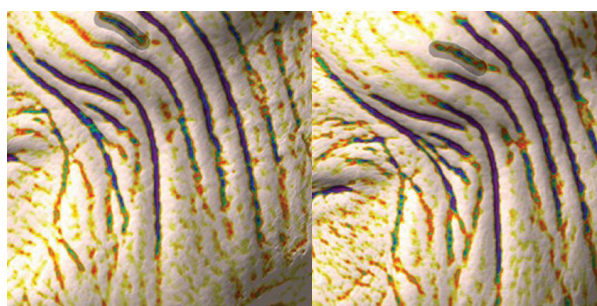


Figure 8. 83 y.o. Wrinkle measures before the treatment (B): total size 48.9 / depth 0.144 mm / width 1.8 mm / maximum depth 0.191. Measures after the treatment (A): total size 39.7 / depth 0.11 mm / width 1.81 mm / maximum depth 0.143.

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