

# Patient satisfaction and efficacy of accent radiofrequency for facial skin wrinkle reduction

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**Background:** Radiofrequency (RF) is a new technique to treat facial wrinkles. This study was designed to assess the efficacy of Accent RF in wrinkle reduction of different areas of the face. **Materials and Methods:** Patients with mild to severe facial wrinkles were treated with Accent using RF energies of 35-145 W. The average energy used in this study was 83.11 W. Patients received four subsequent weekly RF sessions. Wrinkle improvement was rated by two physicians comparing 6-month post treatment photographs with pretreatment photos. Moreover, patient satisfaction was assessed at 1 and 6 months after the last session of the treatment. **Results:** A total of 45 women participated in this study. In terms of patient satisfaction one month after the last treatment, 8.9% of the patients declared their dissatisfaction, 53.3% were somehow satisfied, 33.3% were satisfied, and 4.4% were very satisfied. At 6 months, patient satisfaction was as follows: 4.4% dissatisfied, 31.1% somehow satisfied, 46.7% satisfied, and 17.8% very satisfied. Patient satisfaction 6 months after the last treatment was significantly higher than 1 month post treatment ( $P = 0.006$ ). At 6 months, patient satisfaction was not more than 75% in any treatment areas of the face. **Conclusion:** The results of this study suggest that Accent RF may be considered as a possible effective option for facial skin rejuvenation although its efficacy and safety needs to be evaluated further in randomized controlled trials.

**Key words:** Accent radiofrequency, facial wrinkles, patient satisfaction

**How to cite this article:** Jaffary F, Nilforoushzadeh MA, Zarkoob H. Patient satisfaction and efficacy of Accent radiofrequency for facial skin wrinkle reduction. *J Res Med Sci* 2013;18:970-5.

## INTRODUCTION

Wrinkle reduction has increasingly become a common cosmetic procedure. Several methods are available for skin rejuvenation including dermabrasion, chemical peeling, autologous cultured fibroblasts transplantation, and ablative and nonablative laser therapy.<sup>[1,2]</sup> Despite the proven efficacy of these methods, their potential side effects and pitfalls such as pain, long recovery, and posttreatment downtime period has limited their application.<sup>[1,3]</sup> Cosmetic plastic surgery is the first choice treatment for skin laxity. However, for patients who do not want to undergo surgery or do not have time off work, monopolar radiofrequency (RF) is the/one of the best noninvasive alternative for soft tissue augmentation.<sup>[4,5]</sup> RF is an electromagnetic energy of 3 kHz to 300 MHz, which is similar to the optical energy that interacts with the tissue and produce heat. Despite lasers that target selective chromophore to produce heat, tissue resistance to electron movement in RF field is the source of heat generation in nonablative RF.<sup>[6-8]</sup> Induced dermal heating to the critical point of 65°C result in collagen contraction and promotes wound

healing.<sup>[8]</sup> Selective dermal heating along with maintaining epidermal integrity could potentially decrease posttreatment side effects and minimize the recovery period.<sup>[9,10]</sup> Monopolar RF was approved by Food and Drug Administration (FDA) as a noninvasive treatment for periorbital wrinkles in 2002 and for removing facial wrinkles in 2004.<sup>[11]</sup> Accent is a RF system with both monopolar and bipolar devices and got FDA approval for treating wrinkles in 2007.<sup>[11]</sup> RF wave penetrate deeply up to 20 mm with monopolar headpiece and 2-4 mm by bipolar headpiece.<sup>[12,13]</sup> Local anesthesia is required with both hand pieces. The average treatment sessions were 1-2 for monopolar and 6-8 for bipolar mode.<sup>[14]</sup> Although previous studies have shown RF as a safe and effective method for reducing wrinkles it could not be considered as nonsurgical lifting for skin rejuvenation as presented in misleading promotions by some physicians.<sup>[13]</sup> Published clinical evidence documents monopolar RF for skin tightening and treating mild to moderate wrinkles<sup>[9]</sup> and similar to any other cosmetic procedure it has its specific indications, efficacy, problems, and limitations. Careful patient selection and real expectation are the key points in a successful treatment.<sup>[15,16]</sup>

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**Received:** 27-01-2013; **Revised:** 04-07-2013; **Accepted:** 28-07-2013

The optimum RF parameters is a controversial issue despite the considerable evidence of its efficacy and safety in removing periorbital, chin and neck wrinkles and eyebrow lifting.<sup>[17-20]</sup> Some authors have reported high patient satisfaction for RF treatment but the overall impression of available reports is that the results of nonablative RF are neither predictable nor significant.<sup>[5,21-25]</sup> Subjective nature of the major outcome measure of these studies questions the validity of their results.

The main objective of this study was further assessment of Accent RF and its parameters for treatment of skin laxity and reducing wrinkles in Iranian patients.

## MATERIALS AND METHODS

A total of 45 patients with facial wrinkles were recruited from Jordan dermatology Clinic in Tehran and Novin Laser, Isfahan for this study. All patients signed informed consent form after complete explanation of the study design. Patients that meet any of the following conditions were excluded from the study: History of taking oral isotretinoin, Botox injection, injection of any filling agent, laser, chemical peeling, dermabrasion or cosmetic surgery within last 12 months for perioral area and within last 6 months for the rest of the face, pregnancy, lactation, history of severe cardiac disease, collagen and vascular disease, immunosuppressive disease or taking immunosuppressive drugs, patients with history of a dermatologic disease or active dermatologic problem such as herpes, history of keloid, having pacemaker or any metal pieces in body.<sup>[11,26]</sup>

Baseline photographs were taken from all patients using Canon, Digital camera, 8.3 Mega pixels, 6015. All photos were taken by the same person using the same angle and distance of the light source.

Patients received Accent RF (Accent, Alma Lasers™ US 2007, monopolar or bipolar mode) for 4 weekly sessions in at least one anatomic area of the face (frontal, periorbital, perioral, laugh lines, cheeks, or chin). Each treatment area on the face was about 30 cm<sup>2</sup> and 3 × 2 cm in periorbital area.

For all areas of the face, 5-6 passes of 30 seconds were performed except for the periorbital area, which was limited to 4 passes. In each session, two initial passes of 30-60 seconds were made to heat the area to 40°C, and then another 2 passes of 30 seconds were applied to maintain the tissue temperature in 40-44°C. Energy level of initial passes was 80 W for monopolar handpiece, 100 W for bipolar handpiece, and 74 W for periorbital area. Five circular movements were made during each 30 second

pass of the handpiece. Follow up visits were done 1 and 6 months after the last session and all patients were asked and assessed for any adverse effects.

Follow up photography was taken 6 months after the last session. Wrinkle improvement was graded by three blinded assessor physicians comparing baseline and 6-month posttreatment photographs (0 = <25%, 1 = 25-50%, 2 = 51-75%, 3 = >75%).<sup>[26]</sup>

Patients satisfaction 1 and 6 months after the last treatment session was evaluated using a questionnaire with 4-point Likert scale (1 = Not satisfied, 2 = fairly satisfied, 3 = Satisfied, 4 = Very satisfied).<sup>[26,27]</sup>

Mean percentage agreement among the three physicians was assessed.<sup>[28]</sup> Data was analyzed by SPSS software version 12, SPSS Inc. using chi-square, Wilcoxon and Spearman correlation tests. This was a pilot clinical trial with SDRLC research project No. 8620.

## RESULTS

A total of 45 patients (42 women, 3 men) with age range of 31-65 years (mean = 45.62) participated in this study: 31-40 years, 28.9%; 41-49 years, 42.2%; 50-58 years, 24.4%, and 59-68 years, 4.4%. About 70% of the patients were aged over 50 years.

A total of 21 patients (46.7%) were Fitzpatrick skin type III and 24 had type IV. Other characteristics of the patients are summarized in [Table 1].

A total of 832 RF sessions were performed on 213 anatomical areas of the face in 45 treated patients.

The mean energy level was 35-57 W in 293 (34.4%), 58-79 W in 25.4% of the sessions, 80-101 W in 32.8%, 102-123 W in 6%, and only 0.5% of the sessions were performed with the range of 124-145 W.

**Table 1: Demographic characteristics of the skin of the patients treated with accent radiofrequency**

Parameter	Grade/type/place	Mean (%)
Skin fragility	Fragile	46.7
	Normal	53.3
Skin fat	Dry	51.1
	Normal	22.2
	Oily	26.7
Skin firmness	Firmly	38.6
	Flaccid	61.4
Skin sagging	With sagging	46.7
	Without sagging	53.3

Fourteen patients were treated in the frontal area for 176 sessions with the energy level of 44-124 W. RF with the rage of 35-56 W was done on periorbital area of 42 patients. There was a total of 156 sessions on laugh area of 39 patients, 172 sessions on cheek area of 43 patients, and 176 sessions on chin area of 44 patients with the energy level of 45-145 W in all these three areas [Table 2].

The applied mode of Accents RF is summarized in [Table 3].

[Table 4] shows assessment of facial wrinkles by blinded physicians. None of the treated facial areas achieved wrinkle improvement >75%.

**Table 2: Energy level and number of accent treatment sessions performed on different areas of the face**

Treatment area	Number of patients	Total number of treatment sessions	Total energy level (W)	Energy level (W)	Number of treatment sessions	Percent of treatment sessions (%)
Forehead	44	176	44-126	44-65	91	51.7
				66-85	57	32.4
				86-105	21	11.95
				106-126	7	4
Periorbital	42	168	35-56	35-45	75	43.6
				40-56	97	56.4
Nasolabial fold	39	156	45-145	45-70	47	30.1
				71-95	81	51.9
				96-120	26	16.7
				121-145	2	1.3
Chin	44	176	45-145	45-70	52	29.5
				71-95	70	39.8
				96-120	52	29.5
				121-145	2	1.1
Cheeks	43	172	45-145	45-70	53	30.8
				71-95	91	52.9
				96-120	26	15.1
				121-145	2	1.2

**Table 3: Mode of Accent radiofrequency and level of energy applied on different areas of the face**

Treatment area	Accent mode	Number of treated patients	Applied energy level (W)
Cheeks	Monopolar	15/172	60-106
	Bipolar	157/172	45-145
Forehead	Bipolar	176/176	44-126
Periorbital	Bipolar	168/168	35-56
Chin	Monopolar	5/176	75-95
	Bipolar	171/176	45-145
Nasolabial fold	Monopolar	49/156	55-121
	Bipolar	107/156	45-145

**Table 4: Physician assessment of clinical improvement at 6 moths posttreatment**

	No improvement	Clinical improvement (1225%)	Clinical improvement (26-50%)	Clinical improvement (51-75%)	Clinical improvement 75%
Forehead	17.1	71.4	11.4		
Periorbital	2.8	61.1	36.1		
Nasolabial folds	2.7	24.3	62.2	10.8	
Cheeks		80	20		
Chin		62.9	37.1		

**Table 5: Patient satisfaction 1 and 5 months after last accent treatment session**

	Not satisfied (1)	Fairly satisfied (2)	Satisfied (3)	Very satisfied (4)
1 month posttreatment	8.9	53.3	33.3	4.4
6 months posttreatment	4.4	31.3	46.7	17.8

1 = Not satisfied, 2 = Fairly satisfied, 3 = Satisfied, 4 = Very satisfied

Mean percentage agreement for physician assessment was 33.4%, 35.5%, 37.7%, 41.3%, 39.2%, and 38.4% for forehead, orbit, cheek, chin, nasolabial fold and full face respectively.

[Table 5] shows patient satisfaction 1 and 6 months posttreatment. Patients were significantly more satisfied of RF results at 6 months posttreatment than 1 month (Wilcoxon test,  $P = 0.006$ ). There was no relationship between patient satisfaction and physician clinical assessment at 6-month posttreatment (Spearman test,  $r = 0.05$ ,  $P = 0.73$ ).

Patients satisfaction for full face improvement at 6 months was more than the physician assessment with no significant relationship (Spearman test, correlation coefficient = 0.05,  $P = 0.73$ ). There was no significant relationship between physician's assessment of improvement and age and also there were no relationship between the energy level and patients or physicians opinion ( $P > 0.05$ ).

Adverse effects of Accent therapy one month after the treatment were erythema (11.1%), erythema and edema (86.7%), edema and ecchymosed (2.2%). There was no report of fat atrophy in patients of this study. There was no side effect 6 months after the last session.

## DISCUSSION

Skin rejuvenation has shifted from ablative methods toward fractional ablative and nonablative procedures during past 15 years. RF is a safe effective procedure for reducing skin wrinkles.<sup>[29]</sup> Collagen repair and realignment is a possible mechanism of tissue tightening followed by RF treatment. Assessment of RF treated skin shows that heat generated by tissue's natural resistance to RF waves induces changes in collagen fibrils and an increase in expression of messenger RNA (mRNA) for collagen type I.<sup>[30]</sup> Clinical results of tissue tightening by nonablative RF was first reported in periorbital area. Different results have been reported for its efficacy such as skin tightening in 14 out of 15 patients treated with RF in lower one-third of the face, and modest wrinkle improvement with high patient satisfaction in laugh lines and achieving significant improvement of skin laxity in 70% of the treated patients 3 months posttreatment.<sup>[19,31-33]</sup>

The results of this study were different in terms of wrinkle improvement and patient satisfaction from similar studies.

For physician assessment, Friedman *et al.*<sup>[5]</sup> reported 26-50% wrinkle improvement in 96% of the treated patient and >75% improvement in 19% of the patients. In cheek area, 42% of patients achieved 51-75% and 17% more than 75% improvement of wrinkles. In our study neither in the same area nor in periorbital and frontal areas the improvement was not more than 50%.

There was no wrinkle improvement of >75% in none of the treated areas of this study. Several factors such as energy level, number of passes, interval between treatment sessions and mode of RF could be involved in different achieved responses in the rate of wrinkle improvement and patient satisfaction. Applied energy level in the Friedman 2007 study for monopolar RF was similar to previous studies.<sup>[19,32-34]</sup> The range of applied energy in our study was 60-121 W for monopolar RF and 35-145 W for bipolar RF compared with 80-140 W and 50-70 W in the Friedman study, respectively. In our study both monopolar and bipolar RF were used at laugh lines while in the Friedman *et al.* study, only monopolar handpiece was used in this area. For cheek area, in 91.27% of patients (157/172) bipolar mode was used compared with monopolar RF applied in the Friedman *et al.* study, with a modest more range of energy (100-140 W versus 60-106 W in our study. In our study, the range of applied energy in periorbital and chin area was less than the Friedman *et al.* study for monopolar mode and more for bipolar mode. Most of the sessions in chin area and laugh lines in our study were bipolar (171-176 W and 107-156 W, respectively). In contrast to the results of our study, Hsu and Kaminer reported a significant relationship between energy level and clinical response.<sup>[35]</sup>

In the Friedman study, RF therapy was initiated with 20 seconds (per pass)  $\times$  120 W for monopolar and 20 seconds (per pass)  $\times$  60 W for bipolar mode and was continued with 20 seconds (per pass)  $\times$  100 W, and 20 seconds (per pass)  $\times$  50 W, respectively. In our study both modes were initiated with 80-100 W, 20 seconds and the maintenance energy level was selected based on the treatment area. Average number of passes in the Friedman study was 5 for all facial areas compared with 5.6 passes used in our study for all facial areas except for periorbital area (mean = 4 passes). Some studies have estimated 9-10 passes to achieve clinical improvement.<sup>[36,37]</sup> The most observed difference in clinical results of our study and the Friedman *et al.* study were in frontal, periorbital, and cheek areas. Possible explanations for this difference are higher energy level and application of monopolar mode in cheek area, higher energy level in periorbital area, application of both modes in frontal area, and different duration of outcome assessment (6 months versus 1 month posttreatment in the Friedman study). Previous studies have shown greater clinical results for RF in young patients. Alster and Tanzi reported less clinical improvement in patients >62 years compared with >46 years for the Friedman study.<sup>[6,18]</sup> However, the results of our study did not confirm this finding.

Greater patient satisfaction 6 months posttreatment versus 1 month in our study may be attributed to induction of fibroblast and continued collagen synthesis. Significant pain and fat atrophy is reported following

RF performance with a similar device.<sup>[38]</sup> No fat atrophy was observed in our patients similar to the Friedman results. Both RF modes in our study were performed without using local anesthetic and it was considered as a moderate, tolerable discomfort by the patients. Although the efficacy of RF for facial wrinkle improvement is confirmed by the recent published reviews, more careful scrutiny on the included trials of these reviews reveals that these reviews mostly have summarized company-sponsored trials.<sup>[39]</sup> Other studies have shown that a expected post-RF clinical improvement in 80-85% of the treated patients is a modest skin tightening and some patients may experience no benefit at all.<sup>[5,40,41]</sup>

Few experiences have examined RF-induced histological changes.<sup>[42]</sup> It is not clear how long heat-induced collagen changes will persist after RF treatment. Such histological changes may not be consistent in older patients with advanced photo aging skin problems. Currently, the clinical consensus on optimum RF parameters to achieve the best clinical results is not available.<sup>[37]</sup> The results of our study could be considered as one step in the chain of trials to achieve this objective.

As an overall conclusion several aspects needs to be included in initial RF consultation sessions. RF should be introduced to the patients as a technology to reduce — and not remove — fine facial wrinkles, with less efficacy and side effects than ablative procedures.<sup>[26,40,41]</sup> The best candidates for this procedure are young patients with modest facial skin sagging. The immediate results after RF are due to collagen contraction and edema which are temporary and there are modest final permanent results.<sup>[42,43]</sup> Adequate training programs for physicians and careful patient selection are recommended for perfect performance and minimizing the side effects.<sup>[36]</sup> Comprehensive consultation sessions, honest patient-physician relationship, and real expectations will further guarantee the successful results.

It should be emphasized that the efficacy of nonablative methods (including RF) cannot be compared with ablative procedures. Nonablative methods are good choices for the patients who want to minimize posttreatment pain and downtime period. Combination treatment of RF and other procedures such as Botox, filling agents and fractional laser is increasingly used for skin rejuvenation.<sup>[41,43]</sup>

This was a pilot clinical study of Accent efficacy and safety for facial skin wrinkles and all its limitations including small sample size and lack of standard group should be considered in any interpretation of the results. Randomized clinical trials comparing the effect of Accent RF with standard comparators for facial wrinkle reduction and evaluation of optimum contributing factors such as mode,

energy, pass and number of treatment sessions should be further designed following such pilot studies.

## ACKNOWLEDGMENT

This study was approved by SDLRC ethical committee, Isfahan University of Medical Sciences, Isfahan, Iran. The authors would like to thank all SDLRC affiliated physicians and staff including H. Heidari for data entry and Dr. M. Hosseini for his comments in data analysis. The authors do not have any conflict of interest.

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**Source of Support:** Skin Disease and Leishmaniasis Research Center, Isfahan University of Medical Sciences. **Conflict of Interest:** None declared.