Original Articles

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Pulsed radiofrequency for periorbital sagging: a comparative study

Radiofrequência pulsada para flacidez periorbitária: estudo comparativo

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ABSTRACT

Introduction: Wrinkles, sagging, changes in texture and skin pigmentation in the periorbital region are common complaints in dermatologic practices. Several treatment options, including fractional radiofrequency, which has been shown safe and effective, have been described.

Objective: To compare outcomes and side effects after the use of two types of electrodes coupled to a radiofrequency device, used for rejuvenating the eyelid region.

Methods: A comparative, randomized and blind clinical trial was carried out with patients bearing aging in the periorbital region. The patients were treated with two different electrodes (called standard tip and Lima 8 tip), which can be coupled to the same radioelectrosurgery device. The variables investigated were sagging, wrinkles, texture and firmness of the treated skin, in addition to the presence of adverse effects. Thirty days after the last session, patients answered to a satisfaction questionnaire, having been photographed for clinical assessment.

Results: The patients treated with both tips experienced considerable satisfaction with the improvement of sagging and wrinkles. The variable firmness presented worse satisfaction indices, with a disadvantage for the standard tip. Important edemas emerged after the use of both tips; nevertheless ecchymosis occurred most frequently and lasted longer with the Lima 8 tip. Hyperpigmentation was more frequent and longer lasting with the standard tip, however without statistically significant difference.

Conclusions: The two tips were equally effective for the treatment of sagginess, wrinkles and skin texture in the periorbital region. The patients treated with the Lima 8 tip had higher satisfaction indices regarding the skin's firmness, experiencing a higher incidence of ecchymosis, as well as a longer duration of that side effect.

Keywords: Eyelids; Pulsed radiofrequency Treatment; Skin aging

RESUMO

Introdução: *Rugas, flacidez, alterações da textura e da pigmentação da pele da região periorbitária são queixas comuns nos consultórios dermatológicos, para as quais têm sido descritas várias opções terapêuticas, entre elas a radiofrequência fracionada, que se tem mostrado segura e eficaz.*

Objetivo: *Comparar os resultados e efeitos colaterais após o uso de dois tipos de eletrodos acoplados a um aparelho de radiofrequência, para o rejuvenescimento da região palpebral.*

Métodos: *Trata-se de ensaio clínico comparativo, randomizado e cego com pacientes portadores de envelhecimento da região periorbitária, tratados com dois eletrodos diferentes, que podem ser acoplados a um mesmo aparelho de radioeletrocirurgia, denominados ponteira-padrão e ponteira Lima 8. Os aspectos investigados foram flacidez, rugas, textura e tonalidade da pele tratada, além da ocorrência de efeitos adversos. Trinta dias após a última sessão, os pacientes responderam a um questionário de satisfação e foram fotografados para julgamento clínico.*

Resultados: *Os pacientes tratados com ambas as ponteiras apresentaram expressiva satisfação com a melhora de flacidez e rugas. O item tonalidade apresentou piores índices de satisfação, com desvantagem para a ponteira-padrão. O edema foi importante após o uso de ambas as ponteiras, mas as equimoses ocorreram em maior frequência e por maior duração com a ponteira Lima 8. Houve maior ocorrência de hiperpigmentação e com maior duração com a ponteira-padrão, mas sem diferença estatisticamente significativa.*

Conclusões: *As duas ponteiras mostraram-se igualmente eficazes para o tratamento de flacidez, rugas e textura da pele da região periorbitária. Os pacientes tratados com a ponteira Lima 8 apresentaram maiores índices de satisfação com relação à tonalidade da pele, com maior ocorrência de equimoses, bem como maior duração do evento.*

Palavras-Chave: *Envelhecimento da pele; Pálpebras; Tratamento por radiofrequência Pulsada*

INTRODUCTION AND OBJECTIVE

Skin aging is a complex biological phenomenon that comprises intrinsic and extrinsic processes, producing visible manifestations such as wrinkles, sagginess, dryness and heterogeneous pigmentation of the skin. These changes are histologically associated with the quantitative and qualitative changes in the elastic and collagen fibers, atrophy and reduction of the dermoepidermal junction.[1]

The periorbital region is one of the first to show the signs of aging. Due to their delicate nature and safety concerns linked to the proximity of the eyeball, treatment options are limited.[2,3]

The currently available methods for the rejuvenation of the periorbital region include blepharoplasty, botulinum toxin, hyaluronic acid based cutaneous filling, dermabrasion, 88% phenol or 35% trichloroacetic acid chemical peels, microneedling, diverse radiofrequency modalities and ablative and non-ablative laser therapy. Despite the efficacy of these methods, their costs, potential side effects, long recovery periods and prolonged inactivity after the procedure correspond to limitations to their application.[4-6]

Radiofrequency uses electromagnetic radiation to generate heat and reach deeper tissues, keeping the skin's surface cool and protected. This energy causes immediate contraction and denaturation of the existing collagen fibers in the dermis, leading to the stimulation of new collagen and elastic fibers synthesis. This reorganization lends increased efficiency to them for supporting the periorbital skin.[7,8]

Fractional radiofrequency is a procedure that uses a random energy fractioning system that respects the tissue's thermal relaxation time, similarly to what happens with fractional CO laser, although with a different energy source.[9] This technique has allowed cost effective rejuvenation, with a low rate of complications, thus becoming more accessible as compared to lasers, yet with very similar outcomes.[10] More recently, a pulsed radiofrequency system has been created using electrodes with microneedles that penetrate the epidermis to provide radiofrequency pulses directly into the upper dermis. This technique was proven equally effective and with fewer side effects when compared to traditional fractional ablation procedures.[11]

The objective of the present study was to compare the results obtained in the treatment of wrinkles, sagginess, texture and skin tone of the periorbital region after the use of two different fractional radiofrequency tips coupled to a radiofrequency device, as well as the occurrence of adverse effects in both procedures.

METHODS

A randomized, blind, comparative, non-placebo clinical trial was performed, in which patients at the Dermatology Outpatient Clinic of the Hospital Universitário Lauro Wanderley, with aging in the periorbital region's skin and who wished to undergo rejuvenation treatment were selected (April to June 2017).

The sample of 92 patients had the following characteristics: mild to moderate periorbital sagginess, absence of indication for blepharoplasty, older than 18, absence of comorbidities that prevented the use of the device, such as the use of pacemakers or collagen diseases.

The softwares employed to determine sample size were the R and PS, available for download at http://www.r-project.org/ and biostat.mc.vanderbilt.edu, respectively.

All patients were adequately informed about the procedures and risks of the research project, having signed a Term of Free and Informed Consent and authorized the publication of photographs. The study was approved by the Research Ethics Committee of the institution.

The patients underwent three sessions with the FRAXX® radiofrequency device (Loktal Medical Eletronics Industria e Comércio Ltda, São Paulo (SP), Brazil), with intervals of 30 and 60 days, in April - September 2017. Photographic records were prepared before and one month after the third session.

All sessions were performed by the same applicator physician under topical anesthesia with 4% lidocaine cream (Dermomax® Aché, Guarulhos (SP), Brazil) and injection of 2% lidocaine with epinephrine, followed by aqueous chlorhexidine cleansing, and skin moisturizing with gauze and sterile saline solution. The FRAXX® radiofrequency device with Wavetronic 5000 was used in CUT mode in the following ways:

1) Megapulse, 60% power, sequence 2, active for 60ms, 60ms of delay, coupled to the standard tip with 64 microneedles (8x8) (half of the patients);

2) Single pulse, 30% power, active for 30ms, coupled to the 2.5mm Lima 8 tip (in the other half of the patients).

The limit of the application area was 2mm from the ciliary border in the lower eyelid and the palpebral fold in the upper eyelid. In the post-procedure, the patients used micropore tape for 24 hours, Cicaplast Baume® regenerator (La Roche Posay, Rio de Janeiro (RJ), Brazil) twice daily for five days, and SPF60 sunscreen. The first return visit took place five days after, aimed at evaluating side effects such as edema, echymoses and ulcerations. Thirty days after the last session, patients answered the satisfaction questionnaire and were photographed for clinical assessment. The questionnaire classified the degree of satisfaction into: dissatisfied, satisfied, and very satisfied. The authors of the present study also evaluated the occurrence of adverse effects, such as edema, ecchymosis, hyperchromia and others.

From that point on, classic descriptive statistics techniques were used. The database was built and analyzed by the statistical software R 3.3.1 for Windows. The sample was obtained using a probabilistic, simple random sampling method for estimation of a population proportion. A confidence level of 95% and an estimation error of 6% were considered.

RESULTS

The sample with 92 patients was subdivided into two groups of 46: one of the groups, consisting of patients who underwent treatment with the standard tip, was denominated *Standard Group*, and the other group, with patients who underwent treatment with a Lima 8 tip, was denominated *Lima 8 Group*.

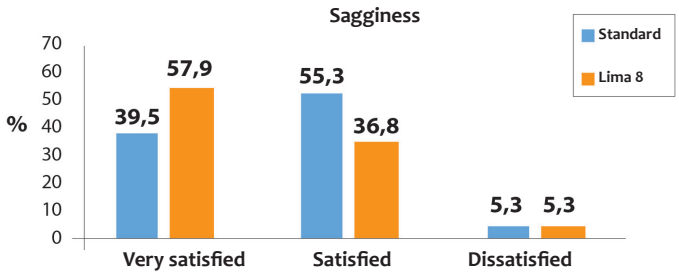
Of the 46 patients in the Standard Group, one dropped out of the study after the first session, while five followed suit after the second session. Of the 46 patients in the Lima 8 Group, four gave up after the first session, with three following suit after the second session. Three patients were excluded: two due to having been treated with botulinum toxin and one for having undergone cutaneous filling during the course of the study. After taking into account the exclusions, the final sample size was 76 patients – 38 in the Standard Group and 38 in the Lima 8 Group. The percentage of female patients was 92% in both groups. There was a higher prevalence of phototype III patients in both groups, with 60.5% in Standard Group and 47.4% in Lima 8 Group. Phototypes V and VI were found only in Lima 8 Group. Regarding the age, the groups had similar mean ages: 47.21 years in Standard Group, with a standard deviation of 9.19 years, and 47,55 years in Group Lima 8, with a slightly lower standard deviation (7.47 years).

Regarding the patient satisfaction results linked to the evaluated treatments, the investigated aspects were *sagginess*, *wrinkles*, *texture* and *tone* of the treated skin. The results are summarized in Graphs 1 to 4. For the aspect *sagginess*, 57.9% of the patients who underwent treatment with the Lima 8 tip reported being very satisfied, while in the Standard Group that ratio was 39.5%; 55.3% of the patients were satisfied with the outcomes of the treatment in Standard Group while 36.8% has the same opinion in Lima 8 Group. In general, both treatments presented expressive results regarding sagginess, since the aggregate percentages (very satisfied and satisfied) were 94.8% and 94.7% for the Standard Group and Lima 8 Group, respectively.

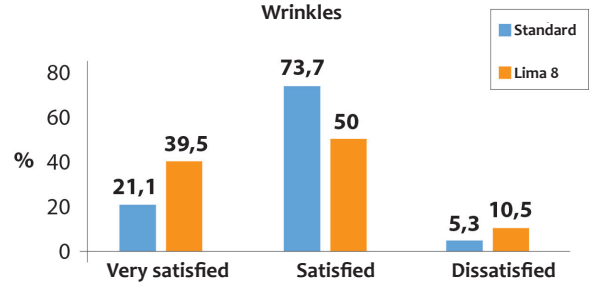
Regarding the aspect *wrinkles*, more than half of the patients were satisfied with both treatments, whose percentages were 73.7% for the Standard Group and 50% for Lima 8 Group. Evaluating the level of aggregate satisfaction, the percentages of very satisfied and satisfied patients were 94.8% (Standard Group) and 89.5% (Lima 8 Group).

Regarding the aspects *texture* and *tone*, the results indicated that the highest percentages of patients classified as very satisfied were found in Lima 8 Group – 50% and 44.7% for texture and tone, respectively. For the Standard Group, these percentages were 28.9% and 18.4%, respectively. In general, regarding texture and tone, the compared procedures yielded similar results, with the accumulated percentages for the category very satisfied and satisfied with the *texture* being 97.3% (Standard Group) and 97.4% (Lima 8 Group), and 65,8% (Standard Group) and 68.4% (Lima 8 Group) with the *tone*. The results also indicated that the item *tone* was associated with the worst satisfaction index when compared to the other items, for both treatments being compared.

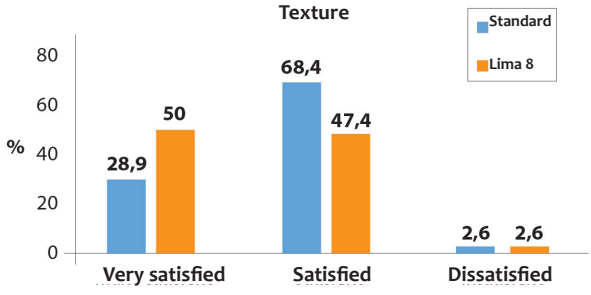
Comparison tests were applied using the chi-square homogeneity test aimed at comparing the patients satisfaction regarding the therapies being analyzed. The p-values of the tests for each investigated aspect were considered significant when $p < 0.05$. As shown in Table 1, the results showed that for the *sagginess*, *wrinkles* and *texture* there were no significant statistical differences (p-values > 0.05), meaning that both treatments yielded very similar results regarding the satisfaction with the results. Nevertheless, regarding the aspect *tone*, there was a significant difference between the treatment with the standard tip and that based on the tip Lima 8, at the specified significance level (p-value = 0.0272), according to Table 1.



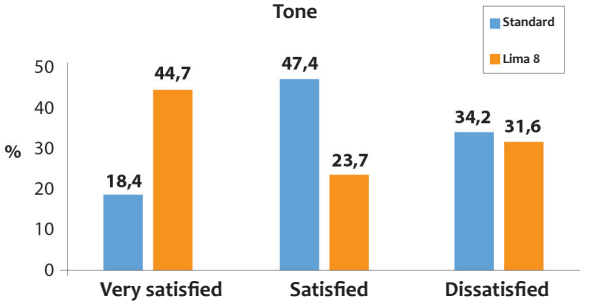
Graph 1: Percentage distribution of the patients' satisfaction regarding the aspect *sagginess*



Graph 2: Percentage distribution of the patients' satisfaction regarding the aspect *wrinkles*



Graph 3: Percentage distribution of the patients' satisfaction regarding the aspect *texture*



Graph 4: Percentage distribution of the patients' satisfaction regarding the aspect *tone*

Regarding the main side effects, edema, ecchymosis and darkening were evaluated (Table 2). Regarding the occurrence of edema, both treatments presented an equal and expressive percentage: 94.7%. Of the patients who underwent treatment with the Lima 8 tip, 86.8% had ecchymosis as an adverse effect – a higher frequency than that of the Standard Group (57.9%). Darkening was present in 63.2% of the patients in Standard Group and in less than half of those in Lima 8 Group.

Based on the evaluation of the significant differences between the treatments regarding adverse effects, it was possible to verify that only for ecchymosis there were significant differences between the treatments, with a p-value of 0.0094.

Considering the variable *days of edema*, it was possible to observe that the mean duration was 3.08 ± 1.05 days in the Standard Group and 3 ± 1.37 days in for Lima 8 Group. Regarding the *days of ecchymosis*, the mean value was 3.73 ± 1.7 days for the treatment with the standard tip, and longer with the Lima 8 tip, whose mean duration was 6.18 ± 3, 27 days. As for the *days of darkening*, it was longer for the standard tip than it was for the Lima 8 tip.

Aiming at observing the statistically significant differences between the duration of the adverse effects' persistence of the treatments, comparative tests were conducted. The non-parametric counterpart of the Student t-test and the U-Mann-Whitney test were used.

As can be seen in Table 3, it was possible to verify that at the specified level of significance for the variable *days of ecchymosis*, there were significant differences between the treatments being compared, indicating a longer duration of side effects for the Lima 8 tip. For the variables *days of edema* and *days of darkening*, the tests did not suggest significant differences (p-value > 0.05), although in the exploratory analysis it was evidenced that the treatment with the standard tip was associated with longer durations of side effects.

Figures 1 and 2 show some of the results obtained, while Figure 3 depicts some of the adverse events observed in this study.

Table 1: Frequency distribution regarding aspects and treatment

		Tip				
		Standard		Lima 8		*p-value*
Aspect		n	%	n	%	
Sagginess	Very satisfied	15	39.5	22	57.9	0.3187**
	Satisfied	21	55.2	14	36.8	
	Dissatisfied	2	5.3	2	5.3	
Wrinkles	Very satisfied	8	21.1	15	39.5	0.1199**
	Satisfied	28	73.6	19	50	
	Dissatisfied	2	5.3	4	10.5	
Texture	Very satisfied	11	28.9	19	50	0.1459**
	Satisfied	26	68.5	18	47.4	
	Dissatisfied	1	2.6	1	2.6	
Tone	Very satisfied	7	18.4	17	44.7	0.0272*
	Satisfied	18	47.4	9	23.7	
	Dissatisfied	13	34.2	12	31.6	

*** chi-square test value**
**** chi-square test permutation value**

Table 2: Percentage distribution of the occurrence of side effects for the Standard and Lima 8 treatments

		Tip				
Side effect		Standard		Lima 8		p-value
		n	%	n	%	
Edema	Yes	36	94.7	36	94.7	1**
	No	2	5.3	2	5.3	
Ecchymosis	Yes	22	57.9	33	86.8	0.0094*
	No	16	42.1	5	13.2	
Darkening	Yes	24	63.2	16	42.1	0.1072*
	No	14	36.8	22	57.9	

*** chi-square test value**
**** exact Fisher's test value**

Table 3: Descriptive measures for the variables days of edema, days of ecchymosis and days of darkening for the Standard and Lima 8 Groups

	Tip					
Statistics	Days of edema		Days of ecchymosis		Days of darkening	
	Standard	Lima 8	Standard	Lima 8	Standard	Lima 8
n	38	38	38	38	38	38
Nas	2	2	16	5	14	22
Mean	3.08	3	3.73	6.18	29.58	22.13
Median	3	3	3,5	7	30	30
Standard deviation	1.05	1.37	1.7	3.27	17.61	10.07
Minimum	1	1	1	2	2	3
Maximum	5	7	7	20	60	30
p-value	-	0.5837	-	0.0008	-	0.1640

DISCUSSION

Periorbital wrinkles mainly arise as a result of photoaging and repetitive muscle contraction over time. Treatment of the periorbital area is difficult due to its delicate nature and important function. To avoid eye lesions and complications, such as scars and ectropion, it is important to control the depth of treatment. A minimally invasive approach using microneedles is capable of accurately controlling the depth of treatment, meaning a lower risk is expected as compared to those of the other technologies. The positive therapeutic result is believed to result from a combination of the effects of radiofrequency and microneedling.[12]

Some studies on the thermal effects of fractional radiofrequency delivered by microneedles to *in vivo* skin have shown the formation of a confined zone of denatured collagen or radiofrequency thermal zone. The presence of superficial perivascular inflammatory cells infiltrates was described in these studies from the first day of the procedure, with a initial peak of neutrophils – that progress to lymphocytes – in 7 (and up to 30) days. The areas of denatured collagen were replaced by newly formed collagen fibers three months after a single session, which was evidenced by the increased presence of mucin in the treated area. There was also an increase in elastic fibers and a progressive

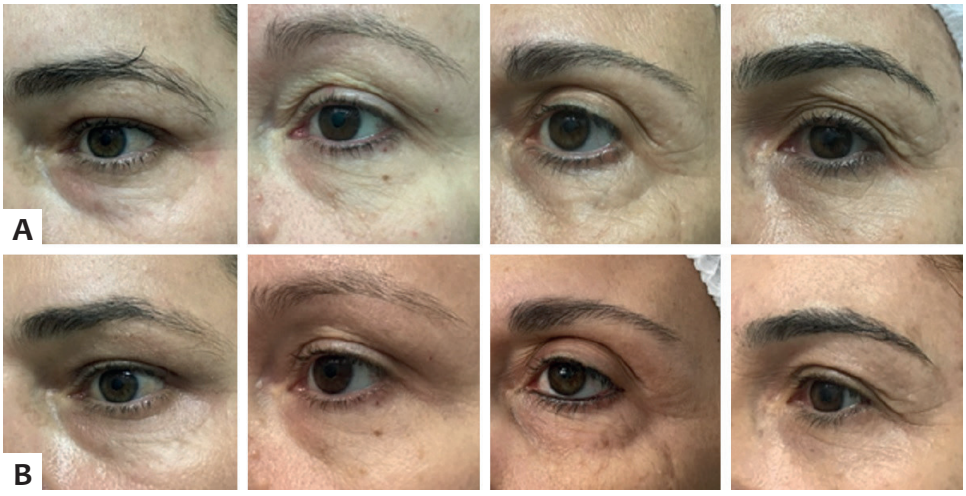


Figure 1: A - Pretreatment**; B -** Post treatment with Lima 8 tip

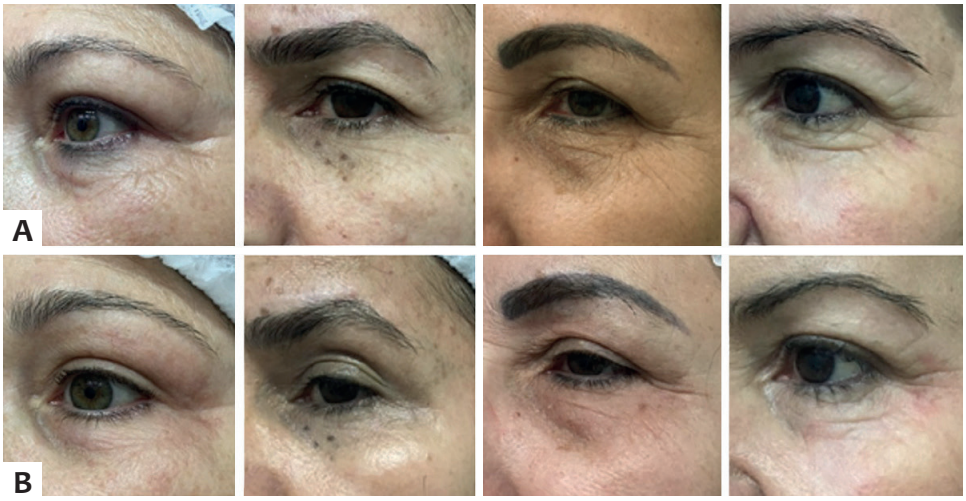


Figure 2: A - Pretreatment**; B -** Post-treatment with Standard tip

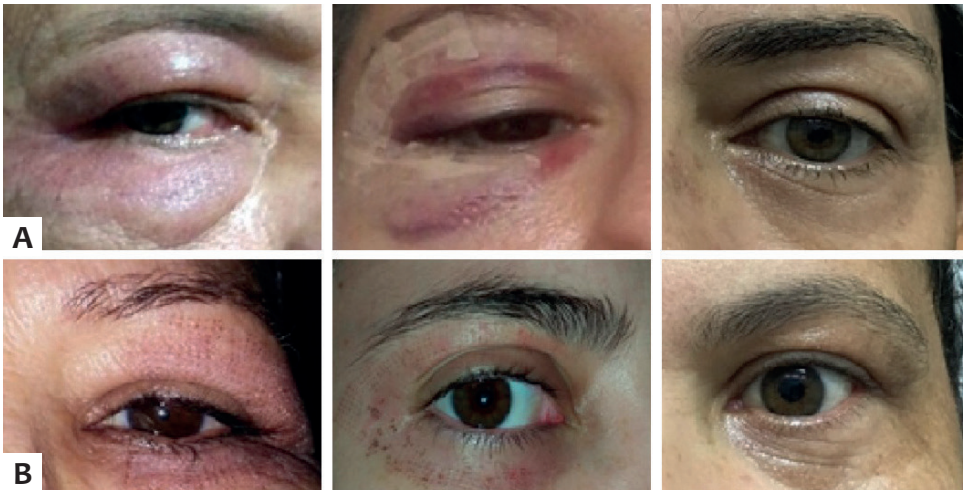


Figure 3: A - Adverse effects occurred with the use of the Lima 8 tip (edema, ecchymosis and post-inflammatory hyperchromia);
B - Adverse effects occurred with the use of the Standard tip (crusting, erythema, edema and post-inflammatory hyperchromia);

decrease in the density of melanin incontinence, with total disappearance after three months of follow-up.[13]

One study used fractional radiofrequency microneedling (RFXEL®) in the region of the eyes of 11 patients. The treatment's side effects were minimal as compared to those of conventional ablative and non-ablative lasers. Pain was minimal in almost all patients who used topical anesthetic creams, and bleeding was transient when compared to that of isolated microneedling or dermabrasion. The crusts disappeared within a week, and no patient reported post-inflammatory hypo or hyperpigmentation.[12]

In a comparative study between fractional radiofrequency with multineedles and botulinum toxin in the periorbital region, it has been demonstrated that radiofrequency treatment can better regenerate elastic and collagen fibers as compared with botulinum toxin, meaning that the first can be effective for the rejuvenation of static wrinkles. This study noticed prompt patient satisfaction with botulinum toxin type A, nonetheless the effect decreased in the 18-week follow-up. On the other hand, radiofrequency gradually and slowly improved the wrinkles, and provided greater satisfaction up until the 18th week of the follow-up.[14]

In the same study, fractional radiofrequency (INFINI®) was used with 49 microneedles, in three sessions (0, 3 and 6 weeks) in the periorbital area of 9 patients. In that study, three patients dropped out (25%) and the pain ranged from painless to intolerable. Hematomas improved within a week, and there was no crusting, hypopigmentation or infection. Two patients (22.2%) reported postinflammatory hyperpigmentation, which resolved spontaneously in two months.[14]

Another study used fractional radiofrequency (FRAXX®) with 64 microneedles (measuring 0.2mm in thickness and 0.8mm in length), in the megapulsed mode. Anatomopathological studies verified that epidermal (ablative) perforation measured 0.1mm and that the thermal effect on the dermis (non-ablative) was 0.1mm deep, meaning that it reached the papillary dermis, with negligible lateral thermal effect and total preservation of the tissue located between the perforations. In that study, a single session was performed with three passes in the lower eyelids of 20 patients, of which 18 were very satisfied (90%), and two (10%) were only satisfied with the outcomes. The edema lasted on average 3 days before disappearing; the erythema, 17 days; and the crusts, 10 days. Two patients (10%) had postinflammatory hyperpigmentation in the treated region, which was resolved after use of the topical combination of hydroquinone with tretinoin for 15 days.[15]

In the present study, three sessions were performed, with intervals of 30 and 60 days, in 38 of the 76 patients, using the same power, active and delay parameters, and methodology. A total of 39.5% of patients were very satisfied while 53.3% were satisfied with the outcomes obtained regarding the variable *sagginess*. Likewise, 21.1% were very satisfied and 73.7% were satisfied regarding the improvement in the variable *wrinkles*. Edemas lasted on average 3.1 days, while ecchymoses lasted 3.7 days, with postinflammatory hyperpigmentation occurring in 63.2% of the patients and lasting on average 29.6 days. Other side effects observed in the present study were: burning sensation (15.7%), pruritus (15.7%), crusting (13.1%), ulceration (5.2%), acneiform eruption (2.6%), and contact eczema (2.6%). On a diverse study, fractional radiofrequency (FRAXX®) was applied with 8 microneedles (Lima 8), this time in single pulsed mode. These needles are 0.1mm thick and 2.5mm long, and it is possible to reach the epidermis, dermis and, sometimes, the periorbital musculature, with them, causing contraction and intense stimulation of collagen. In that study, a single session was performed on the upper and lower eyelids of 19 patients, without overlap. The patients, who were between 42 and 67 years old, their Fitzpatrick's phototype ranging from II and IV, all reported satisfaction with the results (good and very good). The pain was considered tolerable, and the edemas and hematomas lasted between 5 and 7 days. Postinflammatory hyperpigmentation occurred in 11 patients (58%) and was resolved within 20 to 30 days with the use of whitening formulations. No infections, achromia, ectropion or unsightly scars were observed in this group.[16]

In the present study, 3 sessions were performed with intervals of 30 and 60 days, in 38 of the 76 patients included in the study, observing the same power and active parameters, and methodology. The ages in the sample varied between 30 and 61 years, with a mean value of 47.5 years, while the Fitzpatrick's phototypes ranged from II to VI, with phototype III being the statistical mode, with 47.4% of the patients. There was satisfaction with the results in *sagginess* among 94.7% of patients (aggregate satisfaction = very satisfied and satisfied), and 89.5% regarding *wrinkles*. Regarding the side effects, the authors of the present study obtained results in line with a study by Lima,[16] with a mean edema duration of 3 days, and mean ecchymosis duration of 6.2 days. Regarding postinflammatory hyperpigmentation, 42.1% of the patients had it – less than the 58% observed by Lima[16] – having experienced resolution in 22.2 days on average. There were no infections, hypochromia or scaring. Other side effects were pruritus (15.7%), increased local sensitivity (2.6%), acneiform eruption (2.6%), and contact eczema (2.6%).

When comparing the satisfaction with the results obtained with the standard tip and the Lima 8 tip regarding *sagginess*, *wrinkles*, *texture* and *skin tone*, there were significant differences between the treatments only in the variable *tone* (p-value = 0.0270), for a significance level of 5%, with an advantage in favor of the Lima 8 tip.

As for the occurrence of side effects, such as edema, ecchymosis and postinflammatory hyperpigmentation, there were significant differences between treatments only for ecchymosis, which was more frequently with the Lima 8 tip – a fact that can be justified by the different lengths of the needles (Lima 8 = 2.5mm and Standard = 0.8mm). As expected, there was also a significant difference in the duration of ecchymosis, with a mean value of 6.2 days for the Lima 8 tip, and 3.7 days for the Standard tip.

As is the case in other studies, the authors of the present study cannot state that the results obtained were the best possible. In addition, there is still no consensus on the ideal number of passes, or on the maximum or minimum number of sessions for an optimal outcome. There are also a large number of radiofrequency devices available worldwide operating in different pulse delivery modes, types of tips, and needle sizes, with variations in the used power level, making it difficult to compare the methodology, results and effects of radiofrequency devices.

In this way, this legitimates the comparison proposed by the authors of the present article, by analyzing the results obtained employing the 64 micro-needles tip and the Lima 8 tip, given that the same radiofrequency device (Wavetronic coupled to the FRAXX® fractional system) is used in both cases. ●

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