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The Removal of Post-sclerotherapy Pigmentation following Sclerotherapy Alone or in Combination with Crossectomy

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ABSTRACT

Background: Sclerotherapy is a widely used method for the obliteration of blood vessels. Hyperpigmentation is a frequent complication that results from haemosiderin (FeO) accumulation. Hyperpigmentation and changes in the skin can be observed with ultrasound.
Objective: The aim of this study was to evaluate the efficacy of hyperpigmentation elimination using an intense pulse light generator (IPL) equipped with radio waves (RF) under ultrasonography (US) control.
Methods: Twenty-one women with permanent hyperpigmentation (after sclerotherapy or crossectomy combined with sclerotherapy) underwent a hyperpigmentation eliminating therapy with the use of IPL + RF and were monitored by using US. The thicknesses of the dermis and the subcutaneous tissue as well as the echogenicities of each layer were assessed.
Results: As a result of the therapy, a complete regression of hyperpigmentation was achieved in 90.48% of the women, and in 9.52% of the women, the therapy led to a reduction in hyperpigmentation but did not cause its complete disappearance. An increase in dermal echogenicity and a decrease in subcutaneous tissue echogenicity were observed, but there was no change in their thicknesses. After the therapy, the ultrasound images of areas of previous hyperpigmentation corresponded with images that were characteristic of healthy skin.
Conclusion: IPL + RF therapy is effective for eliminating permanent skin hyperpigmentation after sclerotherapy. US is also useful in this therapeutic method.

Sclerotherapy is a widely used method for the treatment of teleangiectasia and reticular veins (below 3 mm in diameter) as well as large veins (above 3 mm in diameter).[1] Recently, sclerotherapy has been effectively used to treat chronic venous insufficiency alone or in combination with classical surgery or endovascular methods.[2] Despite numerous advantages, such as the ease of operation, high efficiency and low cost, this method presents some possible complications. One of the most common complications is the hyperpigmentation of the skin that can appear at the site at which a sclerosing agent was administered or along a vein treated by sclerotherapy.[1,3] Hyperpigmentation occurs in approximately 15–20% of patients who have been subjected to sclerotherapy.[4,5] In most cases, the hyperpigmentation disappears spontaneously within several months after the procedure.[1] Unfortunately, the hyperpigmentation that appears within a short time after the sclerotherapy is permanent in approximately 10% of patients.[4,6] The aetiology of post-sclerotherapy hyperpigmentation still causes a lot of controversy.[7–9] Various methods have been used to remove post-sclerotherapy hyperpigmentation.[7,10,11] Good results were reported in cases in which a Q-switched ruby laser[12] and a flash lamp-excited laser were used, with wavelengths of 694 and 510 nm, respectively.[13] However, these studies were conducted on a very small group of subjects.

One of the latest pieces of equipment used for eliminating hyperpigmentation is an intense pulse light generator (IPL). An IPL is based on a high-energy lamp filled with gas, which is the source of a non-coherent light beam, with a wavelength between 500 and 1300 nm.[14,15] To obtain an adequate wavelength, filters are used to block out the shorter wavelengths.[14] In recent years, some IPL generators have also been equipped with bipolar radio frequency waves (RF). The combination of IPL + RF in one device provides the operator with the sophisticated synergistic action of the two different energy types.[16] IPL + RF damages cells that contain chromophores according the selective thermolysis rule[15] and

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Table 1
The parameters used to remove hyperpigmentation using IPL + RF therapy.

Parameters	Skin phototype (Fitzpatrick scale)						Average in all patients
	I	II	III	IV	V	VI	
Number of patients [*n*]	8	11	2	0	0	0	21
Average minimum dose of IPL [J/cm^2]	27.75	22	17.5	0	0	0	23.76
Average minimum dose of RF [W]	18.75	19.45	16.5	0	0	0	18.90
Average maximum dose of IPL [J/cm^2]	37.25	30.09	24.5	0	0	0	32.29
Average maximum dose of RF [W]	28.88	28.88	27.5	0	0	0	28.33
Average number of treatments	7.375	6.645	8.5	0	0	0	7

stimulates fibroblasts to synthesise collagen, a key factor for providing skin with elasticity and a normal appearance.[17,18]

Until now, no one has monitored the course of hyperpigmentation elimination therapy using ultrasound, which is useful for the evaluation of skin and subcutaneous tissue.[19–21]

The purpose of this study was to evaluate the effectiveness of eliminating hyperpigmentation using an IPL that was additionally equipped with RF. Our study did not involve teleangiectasia removal.

Material and Methods

Study sample

The study sample consisted of 21 women aged 25–68 years; the mean age was 48.95 years. All of the women included in the study sample manifested permanent, that is, persisting for more than 18 months, hyperpigmentation located on their lower limbs. The decision on whether to include a patient inducted into the IPL + RF-assisted therapy was made based on the visual assessment of the hyperpigmented skin area, the analysis of the disease history and elimination due to contraindications to the therapy. When the clinical progression of venous insufficiency according to Classification of Chronic Venous Insufficiency (CEAP) was considered, the C1, C2 and C3 categories were ascribed to 7, 10 and 4 women, respectively. Hyperpigmentation occurred in four, three and six women who underwent sclerotherapy for teleangiectasia (spider veins), reticular veins and collateral varicose veins, respectively. It also occurred in eight cases of trunk obliteration – six patients underwent sclerotherapy for the great saphenous vein (GSV) and two patients for the small saphenous vein (SSV). The obliteration of teleangiectasia, reticular veins and collateral varicose veins was conducted using the Tournay method. This method is based on injecting a sclerosing agent into a patient staying in a decubitus. The obliteration is performed from the proximal to the distal direction because the closure of peripheral varicose veins is easier after the elimination of large varicose veins.[3] In the case of teleangiectasia, a 0.5% polidocanol solution was administered, whereas reticular veins were obliterated with a 0.5% or 1% polidocanol solution and varicose veins with a 2% polidocanol solution. The polidocanol solution was injected using a 1-ml syringe with a 29G × 1/2″ needle. The Section Ambulatoire des Varices avec Sclérothérapie (SAVAS) method,[2] which is a combination of surgery and sclerotherapy, was used to obliterate the trunks of GSVs and SSVs. A classical crossectomy, that is, the ligation and section of a saphenofemoral junction (SFJ) or a saphenopopliteal junction (SPJ) without the removal of the trunk of a GSV or SSV, was performed in our study. Perforating veins were ligated and cut. A 3% polidocanol foam was administered into the left trunk of the vein. The foam was prepared earlier by Tessari's method.[3] The polidocanol foam was injected through a thin latex catheter inserted into the GSV by making a skin incision two-thirds of the way up the shin. The injection of the foam into an SSV was preceded by making an incision in the region of the lateral ankle. Postprocedurally, all of the patients wore II class compression stockings (23–32 mmHg) for an 8-week period. The diameters of the teleangiectasias, reticular veins and collateral varicose veins were less than 1 mm, equal to 2–3 and 3–5 mm, respectively. The greatest diameters of a GSV and an SSV were 12 and 10 mm, respectively.

Ultrasonography

For ultrasound exams, a Toshiba Aplio device equipped with an 18-MHz linear head was used. Ultrasound examinations were performed before the treatment, at each subsequent procedure and after completing the therapy with constant settings. The following parameters were assessed: the thickness of the dermis, the thickness of the subcutaneous tissue, the echogenicity of the dermis and the echogenicity of the subcutaneous tissue. The measurements of the dermis and subcutaneous tissue thicknesses were obtained based on the standard device software settings.

The dermis and subcutaneous tissue echogenicity values were calculated by the summation of the pixel numbers in a defined range of brightness within the borders of the region of interest (ROI).

Monitoring the therapy with the use of an ultrasound was aimed at observing whether the veins subjected to sclerotherapy did or did not undergo recanalisation, that is, if patency restoration did or did not occur in the lumen.

IPL + RF and dose adjustment

To eliminate the hyperpigmentation of the study subjects, we used an IPL + RF instrument, model S-E 3200, SUS Photon Technology CO., China, with a head with a wavelength spectrum of 530–1200 nm. The planned therapy covered up to 10 single

Table 2
The results of the therapy used to remove hyperpigmentation.

Parameters	Before therapy [mm]					After therapy [mm]					*t*	*p*
	Min	Max	Me	$\bar{x}$	IQR	Min	Max	Me	$\bar{x}$	IQR		
Thickness of the dermis	1.03	1.92	1.48	1.49	0.340	1.29	1.87	1.48	1.52	0.330	−0.66	.519
Thickness of the subcutaneous tissue	5.70	16.46	11.11	11.42	5670	6.47	16.30	11.69	11.53	5590	0.29	.778
Dermis echogenicity	10517	12811	11931	11766.29	631	11204	12965	12243	12192.90	327	−3.79	<.001
Subcutaneous tissue echogenicity	47398	53568	51517	51424.67	1037	46835	50930	49710	49389.48	1063	6.78	<.001

Min - minimum value, Max - maximum value, Me - median, $\bar{x}$ - arithmetic mean, *p* - statistically significant level for Student's *t*-test, IQR - interquartile range.

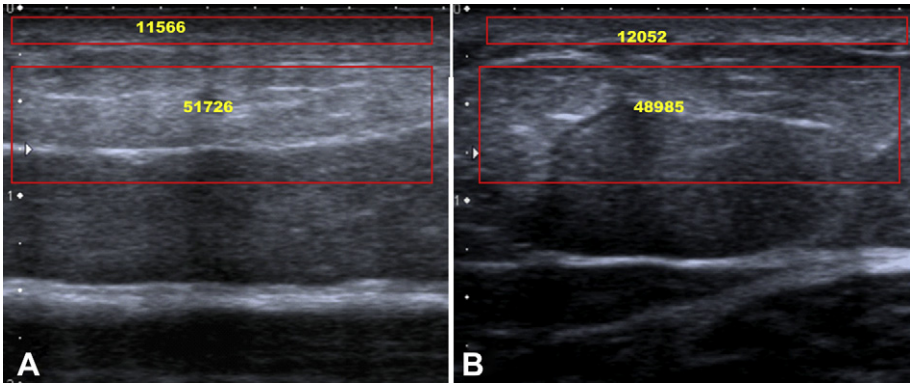

Figure 1. Echogenicity of the dermis and the subcutaneous tissue: A-before treatment, B-after treatment.

procedures that were performed within 30–40-day intervals. The number of procedures was dependent on the characteristics of the changes occurring in the skin (the average was seven treatments) (Table 1). If hyperpigmentation regressed earlier, the therapy was terminated accordingly (Table 1). Initial therapeutic parameters were established based on the skin phototypes (according to the Fitzpatrick's scale)[22] and the parameters recommended by the manufacturer of the device for the elimination of hyperpigmentation after sun exposure. To verify that the initial parameter settings were not too high (did not cause skin burns), a 'trial' was conducted. This trial involved the application of IPL + RF to a small hyperpigmented skin area; if during a 24-h period, no lesions appeared on the skin surface, that is, a burn and/or severe erythema, the series of procedures was started. The basis for an elevation of the dose was a lack of change in the ultrasonography (US) image and in pictures (the area of hyperpigmentation did not change in its dimensions, and it did not get lighter or darker) that had been taken before the therapy and approximately 30 days after the start of the IPL + RF procedure. Dermis echogenicity, which is considered to be a useful parameter for analysing changes in the skin, the appearance of respective skin layers and the borderline that separated them were carefully analysed.[23,24] According to the literature, we assumed that if the use of IPL + RF caused collagen restoration in the dermis,[17–19,25,27] then provided that the dose was adequately adjusted, an increase in dermis echogenicity should have taken place. In turn, these changes should be reflected in the ultrasound images in terms of dermis growth (Table 1).

The ultrasonographic assessment of the performance of the IPL + RF procedure was initiated by the application of a thin gel layer onto the hyperpigmented area. The gel provided a better adherence of the applicator to the skin and normal light beam transmission. Next, the IPL + RF applicators were applied side by side onto the overcoloured area, emitting light and radio waves. During the procedure, the eyes of the patients and the staff were protected by wearing special goggles.

In addition, photographic documentation was made using a camera, a Canon 550D with a Canon EF 50 mm f/2.5 lens, with the macro on. After finishing the therapy, all of the patients were asked to fill in a questionnaire regarding the level of their satisfaction with the therapy.

The data collected were analysed by three independent researchers.

All of the women had been informed about the type and the aim of the study and signed an informed consent form.

Statistical analysis

Statistical analyses were performed using the *Statistica 8* software. The Shapiro–Wilk test was applied, and the study sample was found to have a normal distribution. Then, Student's *t*-test and a univariate analysis of variance (ANOVA) for dependent groups were used. A statistically significant level was assumed to be $\alpha = 0.05$.

Results

The detailed analysis of the ultrasonographic images demonstrates that the pictures of hyperpigmented skin are different from the pictures of healthy skin. A characteristic feature of an US hyperpigmentation image was a blurred boundary between the dermis and the subcutaneous tissue. Before beginning the therapy, such an US hyperpigmentation image was present in 17 out of the 21 women studied, which represented 80.95% of the study sample. The US examinations that were performed during the treatment revealed the gradual differentiation of the dermis and the subcutaneous tissue. Moreover, a border between them started to become visible while the US skin image gradually began to resemble the image of the healthy skin. Once the IPL + RF therapy was finished, a blurred border between the subcutaneous tissue and the dermis was still observed in only two individuals. The changes in the US images occurred concomitantly with perceptible changes on the skin surface. According to the analysis of the ultrasound images conducted by the three independent investigators, the changes due to hyperpigmentation became less visible in the US images (regressed) and a visible borderline developed between the dermis and the subcutaneous tissue. In two individuals, after the end of the IPL + RF treatment, a clear separation of the dermis from the subcutaneous tissue was not visible in their US images; the hyperpigmentation became lighter but did not regress completely.

Changes occurring in the skin were also revealed by the analysis of the data describing the two studied parameters, that is, the echogenicity of the dermis and the echogenicity of the subcutaneous tissue (Table 2). Due to the therapy that was used, increases in dermis echogenicities were recorded. Fig. 1 shows an example of this where the mean echogenicity of the dermis increased from 11766.76 pixels to 12192.90 pixels following treatment. This difference was statistically significant at the level of $p < 0.001$ (Table 2). Prior to the start of the IPL + RF therapy, the subcutaneous tissue in hyperpigmented areas was characterised by a higher echogenicity in all of the studied females. The mean echogenicities of the subcutaneous tissue before and after the IPL + RF therapy were significantly reduced ($p < 0.001$; Table 2). In addition, this tissue became more and more hypoechogenous in the US images as well (Fig. 1). In agreement with our study results, no statistically significant changes were found in terms of the dermis and subcutaneous tissue thicknesses prior to and following the

Table 3
Comparison of the results for different patient groups distinguished on the basis of the CEAP classification.

Parameters	Before therapy [$\bar{x}$]					After therapy [$\bar{x}$]				
	C1 $n = 7$	C2 $n = 10$	C3 $n = 4$	F	p	C1 $n = 7$	C2 $n = 10$	C3 $n = 4$	F	p
Thickness of the dermis	1474	1430	1643	1118	0.349	1541	1469	1598	0.729	0.496
Thickness of the subcutaneous tissue	11.207	11.591	11.385	0.0267	0.974	10.36	11.882	12.705	0.887	0.429
Dermis echogenicity	11899.143	11702.100	11694.250	0.317	0.732	12308	12045.4	12360.25	1700	0.211
Subcutaneous tissue echogenicity	50925.143	51369.6	52436.5	1867	0.183	49078.714	49519.7	49607.75	0.409	0.670

C1, C2 and C3 - groups of patients according to the CEAP classification, n - abundance, $\bar{x}$ - arithmetic mean, F - ANOVA (analysis of variance) result, p - level of statistical significance.

IPL + RF treatment (Table 2). No veins regained patency during the therapy.

Due to the fact that the research sample was diverse and hyperpigmentation arose after the closing of the blood vessels of different diameters, the sample was divided into smaller groups according to the CEAP classification to determine whether there were statistically significant differences among the groups for each parameter before the start of treatment and after its completion (Table 3). The analysis showed no statistically significant differences among the groups. This is not surprising given the small numbers and the finding requires confirmation in a larger study.

The majority of individuals declared that the appearance of their legs was important to them. Before starting the IPL + RF therapy, 85.71% declared that their legs were ugly, but only one person (4.67%) made the same declaration after the treatment. The average level of patient satisfaction (scale 0–10; 0 = not very satisfied, 10 = very satisfied) was 8.71.

In summary, from the obtained results, we conclude that a reduction in hyperpigmentation has taken place in all of the women studied as a result of the therapy used. In 90.48% of the patients, a complete regression of hyperpigmentation occurred because of IPL + RF treatment (Fig. 2). After the end of the therapy, the skin areas formerly affected by hyperpigmentation did not differ from the hyperpigmentation-free areas of the neighbouring skin. In the case of 9.52% women, the hyperpigmentation became lighter, and its area diminished; however, it did not regress completely (Fig. 3). No IPL + RF post-therapeutic complications were discovered in the sample of women treated.

Discussion

The value of sclerotherapy as a therapeutic method for removing unwanted blood vessels is unquestionable.[1–6] Unfortunately, it is very difficult to remove the permanent post-sclerotherapy hyperpigmentation that may arise as a result of the procedure.[11,13] Haemosiderin plays a key role in the formation of hyperpigmentation. It is a water insoluble, crystalline protein–iron complex that accumulates in cells and extracellular matrices.[26] Therefore, to

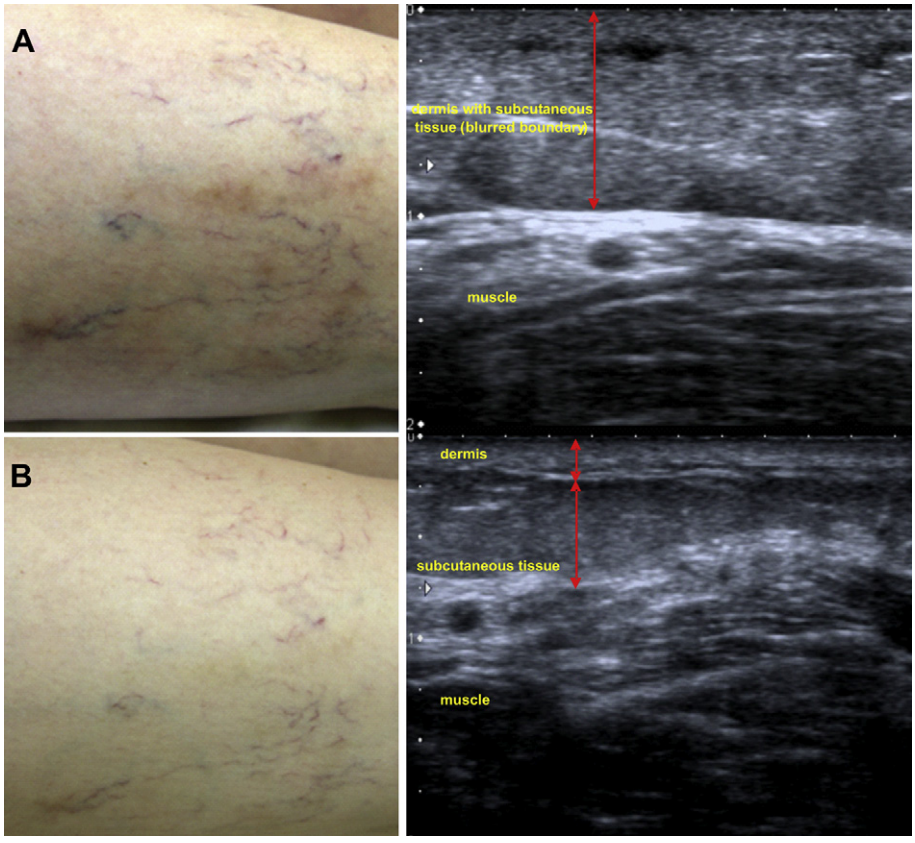

Figure 2. Permanent post-sclerotherapy hyperpigmentation: A-before treatment, B-complete regression of hyperpigmentation after 5 treatments.

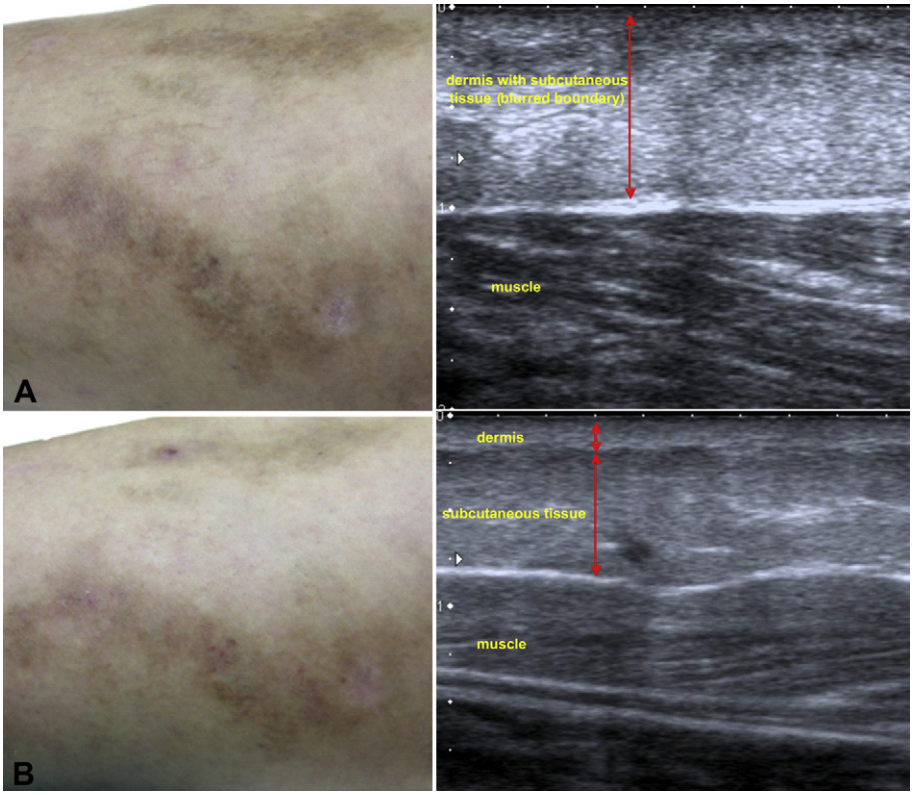

Figure 3. Permanent post-sclerotherapy hyperpigmentation: A-before treatment, B-partial regression of hyperpigmentation after 10 treatments.

remove this hyperpigmentation, it is crucial to eliminate haemosiderin to provide an improved appearance of the skin, which is dependent on the presence of collagen.[17] Such a therapeutic approach will bring a satisfactory aesthetic outcome to patients. As shown in our studies, a therapy composed of a series of IPL + RF procedures can achieve the reduction or even total elimination of hyperpigmentation.

The results of the tests conducted by Goldman[8] showed that haemosiderin accumulates up to 2.8 mm below the granular layer. Therefore, the use of an IPL, which emits waves from 530 to 1200 nm to eliminate hyperpigmentation, can access the accumulated haemosiderin, and the light waves that are generated may penetrate up to 5 mm into the skin.[27] In addition, haemosiderin absorbs light of 694 nm wavelength particularly well.[11] The concomitant use of IPL + RF may also have a beneficial impact on the obtained results. With their use in combination, the effectiveness of the procedure may increase,[17] in addition to using lower parameter settings, compared with the effectiveness when using only one energy type. Concomitant use of IPL + RF causes the procedure to be safer and reduces the number of potential complications (burnings and erythema).[16,17] In addition, in favour of the use of the combined IPL + RF technology, it is more effective than the use of IPL alone in improving skin appearance.[17] Bitter and Mulholland[19] demonstrated that IPL + RF therapy was effective for the removal of solar lentigo and other forms of hyperpigmentation in 78% of their patients. The authors also reported that 97% of subjects, in whom both therapeutic alternatives were tried, that is, IPL + RF and IPL alone, found that the IPL + RF therapy was more effective than the use of IPL alone. The results of the combined therapy are seen more rapidly, and it is more comfortable for a patient.[17]

An extremely useful tool for the monitoring of the therapy described herein was the application of US to the skin. This was an important use of this tool because nobody had previously removed post-sclerotherapy hyperpigmentation by means of IPL + RF therapy. Owing to the use of US, we were able to monitor changes occurring in the skin, and thus, we were not confined to a solely photography-based skin evaluation. Moreover, the use of US enabled us to manage the dose of IPL + RF applied. Dermis echogenicity was the most useful parameter in the US studies. We believe that the increase in dermal echogenicity is the result of collagen synthesis. Collagen restoration was promoted by the application of light pulses and radio waves. The dermis layer, stimulated for reconstruction, likely exerted a positive reparative effect on the appearance of the hyperpigmented skin area. Our results are consistent with the findings of other authors.[23,24] Our study also found some variability in the echogenicities of the subcutaneous tissue. The echogenicity of this layer decreased after the termination of therapy. According to other authors' works, an elevated echogenicity of the subcutaneous tissue can be observed during inflammation.[28] Unfortunately, the cases described in the literature cover inflammatory states of different aetiologies. Thus, we are currently unable to make an unambiguous interpretation of this result. We presume that, perhaps, as in the case of chronic venous insufficiency, a chronic inflammation that is stimulated and sustained by haemosiderin occurs in the subcutaneous tissue.[26] As a result of the changes triggered by a series of IPL + RF procedures, three layers may be distinguished in the US skin images, that is, the epidermis, the dermis and the subcutaneous tissue, which correspond to the images of healthy skin.[19–21] Consistent with the obtained results, after a series of 10 procedures, we failed to achieve total regression of hyperpigmentation in only 2 of the 21 cases. One can presume that the following factors may have influenced the persistence of the *status quo*: the hyperpigmentation dimensions linked to the type of sclerosing agent used for the sclerotherapy, the concentration of the

sclerosing agent and the method of administration,[3] the diameters of the obliterated vessels, the skin phototype, the settings of the procedural parameters and the number of procedures. In one of the patients who had phototype III skin, the hyperpigmentation did not regress; therefore, the IPL + RF doses were low. In another patient, an overcolouring appeared after GSV sclerotherapy (9 mm in diameter). In that case, for the initial four procedures, we found it difficult to adjust the IPL + RF dose because no changes were recorded either in the USs image or on the surface of the skin. A gradual regression of the hyperpigmentation was witnessed only after the next few procedures.

This paper describes our experiences connected to the elimination of post-sclerotherapy hyperpigmentation by means of IPL + RF therapy. Considering the results, further studies on the issue are necessary to determine the best possible parameter settings for the use of IPL + RF to eliminate haemosiderin hyperpigmentation. An in-depth understanding of the usefulness of US in terms of skin studies also deserves additional scientific attention.

Conflict of Interest/Funding

None.

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