

Long-Pulsed Dye Laser Versus Intense Pulsed Light for Photodamaged Skin: A Randomized Split-Face Trial With Blinded Response Evaluation

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Objective: In a randomized controlled split-face trial to evaluate efficacy and adverse effects from rejuvenation with long-pulsed dye laser (LPDL) versus intense pulsed light (IPL).

Materials and Methods: Twenty female volunteers with Fitzpatrick skin types I–III, classes I–II rhytids, and symmetrical split-face photodamage were included in the study. Subjects received a series of three treatments at 3-week intervals with half-face LPDL (V-beam Perfecta, 595 nm, Candela Laser Corporation) and half-face IPL (Ellipse Flex, Danish Dermatologic Development); the interventions being randomly assigned to left and right sides. Primary end-points were telangiectasias, irregular pigmentation and preferred treatment. Secondary end-points were skin texture, rhytids, pain, and adverse effects. Efficacy was evaluated by patient self-assessments and by blinded clinical on-site and photographic evaluations at 1, 3, and 6 months postoperatively. Adverse effects were evaluated by blinded clinical on-site evaluations.

Results: Telangiectasia improved from LPDL and IPL treatments with superior vessel clearance from LPDL treatments (postoperative side-to-side evaluations, patient self-assessments, $P < 0.031$, 3, 6 months). Irregular pigmentation and skin texture improved from both treatments with no significant side-to-side differences. No reduction was seen of rhytides on LPDL- or IPL-treated sides. Treatment-related pain scores were significantly higher after IPL (medians 7–8) than LPDL (4.75–5.5) treatments ($P < 0.001$). Adverse effects included erythema, oedema, and transient hyperpigmentation. Patients preferred LPDL- to IPL treatments ($P < 0.031$).

Conclusion: This study was based on two specific laser and IPL equipments, which found LPDL rejuvenation advantageous to IPL rejuvenation due to superior vessel clearance and less pain. *Lasers Surg. Med.* 40:293–299, 2008. © 2008 Wiley-Liss, Inc.

Key words: adverse effects; irregular pigmentation; pain; rhytids; skin texture; telangiectasia

INTRODUCTION

Non-ablative skin rejuvenation is used for the treatment of photodamaged skin, which clinically presents with telangiectasias, dyschromia, rhytides, rough skin texture, and enlarged skin pores [1–3]. Several types of non-ablative lasers and light sources have been shown effective

to treat photodamaged skin, including lasers in the visible part of the electromagnetic spectrum [potassium-titanyl-phosphate laser (KTP, 532 nm), pulsed dye lasers (PDL, 585 nm), long-pulsed dye lasers (LPDL, 585, 595 nm)], lasers in the near- and mid-infrared part of the electromagnetic spectrum [diode lasers (810, 1,450 nm), erbrium:glass laser (1,540 nm), Nd:YAG laser (1,064, 1,320 nm)] and intense pulsed light (IPL) systems (500–1,200 nm) [4–11]. The procedures are well established and associated with little or no downtime, acceptable pain and minimal postoperative inconvenience [12–18].

Photo-rejuvenation is thought to increase the formation of collagen by inducing a wound healing response important for the dermal remodelling process [17,18]. LPDL and IPL systems target the endogenous chromophores haemoglobin and melanin, which results in vessel clearance and reduction of dyschromia due to the concept of selective photothermolysis [4,7,8,17,19,20]. The efficacy of PDL and IPL for the treatment of sundamaged skin has previously been documented in controlled trials, showing substantial efficacy on vessel clearance and reduction of pigmentation [4–11]. However, so far this is the first trial that compares efficacy and adverse effects of IPL and LPDL rejuvenation in a homogeneous group of patients by a direct side-to-side comparison.

The aim of this randomized split-face trial was to compare efficacy, adverse effects, and patient acceptance with two widely used LPDL and IPL techniques for facial rejuvenation.

MATERIALS AND METHODS

Participants

Twenty healthy female volunteers participated in the study. The age of subjects ranged from 42 to 63 years

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(mean age 54 years) and constitution included Fitzpatrick skin types I ($n = 0$), II ($n = 12$), and III ($n = 8$) with class I ($n = 0$) and II ($n = 20$) rhytides. Inclusion criteria were split-face symmetry of telangiectasias, irregular pigmentation, skin texture, and rhytides. Exclusion criteria were age younger than 40 years, asymmetry of photodamaged skin, scarring, skin infection or inflammatory skin diseases, immunodeficiency or photosensitivity, pregnancy or lactation, current use of anticoagulants, aspirins or anti-inflammatory drugs, oral retinoid drugs within the past 6 months, medication known to induce photosensitivity within the past 3 months, rejuvenation procedures or collagen injection in the facial area within the past 12 months, and the presence of a suntan prior to treatment.

Patients were recruited from the community via advertisements in local newspapers and posters at the University of Copenhagen. All patients gave informed consent and the Committee on Biomedical Research Ethics of Copenhagen and Frederiksberg approved the protocol (KF 01 316279). The study was conducted from October 2006 to May 2007.

Randomization and Blinding

Initially patients underwent a clinical assessment by a blinded, independent physician (GJ) and patients were randomly allocated to three LPDL treatments on one side of the face and three IPL treatments on the other side of the face at 3-week intervals. Randomization was carried out by patients drawing lots between 20 opaque sealed envelopes, containing cards with subject number and split side treatment code (LPDL on the left side and IPL on the right side or vice versa). Eighteen of 20 patients received the allocated treatments and completed the study while two patients, both allocated to LPDL treatment on the right side and IPL treatment on the left side, withdraw from the study before finishing the scheduled treatments (one patient because of periorbital haematoma caused by pressure from the eye shield and one because of post-inflammatory hyperpigmentation on cheeks and forehead).

Interventions

Patients were treated to improve skin structure, irregular pigmentation and vascular signs of photodamage, including telangiectasias and background erythema (Table 1). The number of passes and settings for IPL- and LPDL treatments were approved by the companies, which included individual settings based on the preoperative skin appearance (Table 1). A single physician performed all IPL- and LPDL treatments (MH).

IPL treatments were performed with the Ellipse Flex (Danish Dermatologic Development A/S, Hørsholm, Denmark), which is a second generation IPL system. Dual mode filters restricted the emitted light to a wavelength band from 530 to 750 nm (PR applicator) and from 555 to 950 nm (VL applicator). As longer wavelengths from 750 nm/950 nm to 1,200 nm were removed, the emitted fluence levels were significantly lower than in comparable IPL systems. Before IPL treatment the area to be treated was covered with a colorless gel to optimize optical coupling

between light guide and skin. Pulses were placed without overlap. No cooling was applied with the treatments. Each treatment session included one pass of different settings, depending on the preoperative appearance of photodamage (Table 1).

Laser treatments were performed with a LPDL (V-beam Perfecta, 595 nm, Candela Laser Corporation, Wayland, MA) at non-purpuric settings with slightly overlapping pulses. Vascular lesions were treated with 10 mm and 3 mm \times 10 mm hand pieces with dynamic cooling device (DCD), pigmented lesions with 7 or 10 mm compression hand pieces without cooling.

Each treatment session included two full passes, except for pigmented lesions that were treated with only one pass. Different settings were used, depending on the preoperative appearance of photodamage (Table 1).

Efficacy Assessment

Clinical efficacy was evaluated by patient self-assessments and by one blinded trained physician (GJ) from on-site and photographic evaluations at 1, 3, and 6 months after the final treatment.

Patient self-assessments included bilateral estimates of improvement on the overall treatment outcome and on telangiectasias, irregular pigmentation, skin texture, and rhytides (5-point scales: worsening of appearance, no change in appearance, mild, moderate or significant improvement in appearance). Patients scored the intensity of treatment-related pain on a numerical scale from 0 (no pain) to 10 (worst imaginable pain). At each follow-up patients reported which treatment they preferred based on clinical efficacy and treatment-related inconvenience.

The blinded physician graded the side-to-side appearance of telangiectasias, irregular pigmentation, skin texture, and rhytides of left versus right sides of the face by on-site and photographic evaluations (5-point scales: no side-to-side difference in intensity, barely any difference, mild, moderate or marked differences in appearance of disease intensity between sides). Pre- and postoperatively the severity of telangiectasias, irregular pigmentation, skin texture, and rhytides was bilaterally graded into 4-point categorical scales (0: no visible disease, 1: mild, 2: moderate, and 3: marked disease intensity). Rhytides were assessed by Fitzpatrick 9-point scale [21]. Potential adverse effects such as oedema, erythema, purpura, blistering, hyperpigmentation, hypopigmentation, and scars were evaluated on 4-point scales (absent, mild, moderate, severe) prior to each treatment session and at follow-up visits.

Facial Photographs were taken with a Canon Digital Camera (EOS D30) equipped with a lens mounted ring flash (Canon Macro Lens EF 100 mm 1:2.8 USM). All photographs were taken in j-peg format and standardized in magnification, lighting and positioning (en face and 45 oblique). A single laboratory processed all photographs.

Statistical Analysis

Non-parametric statistical methods were used. The Friedman test and Wilcoxon matched pairs test were used

TABLE 1. Treatment Settings for Skin Rejuvenation With Long-Pulsed-Dye-Laser (LPDL) and Intense Pulsed Light (IPL)

Long-pulsed dye laser	Intense pulsed light		
At each Tx session (1–3), two full passes were given to all skin areas except pigmented lesions that were treated with only one pass: 1. Pass: Settings for telangiectasias or irregular pigmentation as needed. Remaining skin areas treated with skin structure settings 2. Pass: Skin structure settings	At each Tx session (1–3), one pass was given to all skin areas 1. Tx session: Rejuvenation settings 2. and 3. Tx sessions: Localized telangiectatic areas treated as stated below. Remaining skin areas treated with rejuvenation settings		
Preoperative parameters to determine settings	LPDL—specific settings	IPL—specific settings	Clinical end-points
Diffuse redness ± visible telangiectasia	10 mm spot 3 ms 5.5–8.5 J/cm ² DCD 30/20	PR applicator No visible vessels: 2.5 ms × 2 6–9 J/cm ² +visible vessels: 8 ms 7–15 J/cm ²	Erythema
Thin telangiectasia	10 mm 6 ms 7–9 J/cm ² DCD 30/20	Superficial, thin telangiectasias PR applicator 10 ms 8–16 J/cm ² Deep, thin telangiectasias VL-2 applicator 10 ms 10–18 J/cm ²	Erythema Vessel blanching or transient intravascular darkening
Medium size telangiectasia	10 mm 10 ms 7–10 J/cm ² DCD 30/20	Superficial, medium telangiectasias PR applicator 14 ms 9–15 J/cm ² Deep, medium telangiectasias VL-2 applicator 14 ms 11–18 J/cm ²	Erythema Vessel blanching or transient intravascular darkening
Thick vessels	10 mm 20 ms 10–12 J/cm ² DCD 30/20	VL-2 applicator 20 ms 12–20 J/cm ²	Erythema Vessel blanching or transient intravascular darkening
Linear thick vessels	3 × 10 mm, 40 ms 15–17 J/cm ² DCD 30/20	VL-2 applicator 20 ms 12–20 J/cm ²	Erythema Vessel blanching or transient intravascular darkening
Irregular pigmentation	Compression HP 7 or 10 mm 1.5 ms 7–10 J/cm ² No DCD	—	Pigment darkening

(Continued)

TABLE 1. (Continued)

Preoperative parameters to determine settings	LPDL—specific settings	IPL—specific settings	Clinical end-points
Skin structure	10 mm 6 ms 5–7 J/cm ² DCD 30/20	—	Erythema
Rejuvenation	—	PR applicator 2.5 ms × 2 7.5–8.5 J/cm ²	Erythema Pigment darkening

Patients were allocated to three split-face treatment sessions with both LPDL and IPL at 3-week intervals. Fluences on the nose generally 1 J/cm² higher than other parts of the face.

DCD, dynamic cooling device; HP, hand piece; Tx, treatment.

for paired comparisons. Proportions were compared using a sign test (binomial test). Descriptive data are presented as medians with interquartile ranges (IQR). *P* values less than 0.05 were considered significant.

RESULTS

LPDL- and IPL-treatments resulted in substantial improvement of telangiectasias with median improvements of one category for LPDL and 0.5 category for IPL (4-point categorical scale, *P* = ns), indicating that LPDL-treated sides improved from moderate to mild intensities of telangiectasias (Fig. 1). By postoperative direct side-to-side comparisons, the vessel clearance was superior on the LPDL- versus the IPL-treated sides (3, 6 months, *P* ≤ 0.004) (Table 2). Clinical on-site evaluations documented the greatest side-to-side difference at 6 months postoperatively where 14 patients (78%) scored better appearance of LPDL- versus IPL-treated sides with 8/14 patients (57%) obtaining marked differences and 3/14 patients (21%), 2/14 patients (14%), and 1/14 patient (7%) having moderate, mild, and barely visible differences, respectively. Blinded photographic evaluations established significantly greater reductions of telangiectasias on the LPDL- versus the IPL-treated sides as well, and confirmed the greatest side-to-side difference at 6 months postoperatively where 12 patients (67%) scored better appearances on LPDL- versus IPL-treated sides with 6/12 patients (50%), 5/12 patients (42%), and 1/12 patients (8%) obtaining moderate, mild, and barely visible differences, respectively (Table 2). By patient self-assessments, telangiectasias reduced significantly more on LPDL- versus IPL-treated sides (3, 6 months, *P* = 0.031; *P* = 0.008) (Fig. 2).

LPDL- and IPL-treatments improved irregular pigmentation and skin texture with similar median improvements of one category (4-point categorical scale, *P* = ns) from overall moderate to mild intensities. No postoperative side-to-side differences were seen in terms of irregular pigmentation and skin texture by blinded physician assessments or by patient self-evaluations (*P* = ns). No postoperative improvements were found of rhytides when evaluated by blinded clinical and photographic evaluations and by patient self-assessments (*P* = ns).

Adverse effects included mild, transient erythema and oedema in most patients and one patient experienced prolonged erythema on both sides of her face for 1 month after first treatment. Transient postinflammatory hyperpigmentation was observed in two patients up to 3 months after first treatment (IPL *n* = 2, LPDL *n* = 1). No patients experienced purpura, blistering, hypopigmentation, or scars. Pain scores in relation to first, second and third treatments were significantly higher after IPL- (medians 7–8) versus LPDL-treatments (medians 4.75–5.5) (*P* < 0.001) (Fig. 3). At 1, 3, and 6 months postoperatively,



Fig. 1. Clinical photographs before treatment and 6 months postoperatively showing substantial improvement of telangiectasias from LPDL and IPL treatments. The LPDL treated side obtained marked improvement and the IPL treated side obtained moderate improvement with residual vessels especially on the nose.

TABLE 2. Blinded Clinical and Photographic Side-to-Side Evaluations of Long-Pulsed-Dye-Laser (LPDL) Versus Intense Pulsed Light (IPL) Treated Sides at 1, 3, and 6 Months Postoperatively

Parameter	M	Clinical evaluations				Photographic evaluations				P	Patients with best appearance of LPDL tx side	Patients with best appearance of IPL tx side	Patients with best appearance of LPDL tx side	P		
		Patients with no difference, total	Patients with best appearance of IPL tx side	Degree of difference, Barely/mild/moderate/ marked	Total	Patients with best appearance of LPDL tx side	Degree of difference, Barely/mild/moderate/ marked	Total	Patients with best appearance of IPL tx side						Degree of difference, Barely/mild/moderate/ marked	Total
Telangiectasias	1	9	2	(0/2/0/0)	7	(1/3/2/1)	0.18	10	0	(0/0/0/0)	8	(1/3/4/0)	0.008			
	3	4	1	(0/1/0/0)	13	(5/5/0/3)	0.0018	9	0	(0/0/0/0)	9	(3/3/3/0)	0.004			
	6	4	0	(0/0/0/0)	14	(1/2/3/8)	0.0005	6	0	(0/0/0/0)	12	(1/5/6/0)	0.000			
Pigmentation	1	15	3	(0/2/1/0)	0	(0/0/0/0)	0.25	15	3	(0/1/2/0)	0	(0/0/0/0)	0.25			
	3	13	2	(1/1/0/0)	3	(1/1/1/0)	> 0.99	14	4	(0/2/2/0)	0	(0/0/0/0)	0.13			
	6	8	3	(0/0/3/0)	7	(1/2/4/0)	0.34	14	3	(1/0/2/0)	1	(0/1/0/0)	0.63			
Skin texture	1	16	1	(0/1/0/0)	1	(1/0/0/0)	> 0.99	18	0	(0/0/0/0)	0	(0/0/0/0)	> 0.99			
	3	14	0	(0/0/0/0)	4	(2/2/0/0)	0.13	18	0	(0/0/0/0)	0	(0/0/0/0)	> 0.99			
	6	17	0	(0/0/0/0)	1	(1/0/0/0)	> 0.99	18	0	(0/0/0/0)	0	(0/0/0/0)	> 0.99			
Rhytids	1	17	1	(0/0/0/1)	0	(0/0/0/0)	> 0.99	18	0	(0/0/0/0)	0	(0/0/0/0)	> 0.99			
	3	18	0	(0/0/0/0)	0	(0/0/0/0)	> 0.99	18	0	(0/0/0/0)	0	(0/0/0/0)	> 0.99			
	6	18	0	(0/0/0/0)	0	(0/0/0/0)	> 0.99	18	0	(0/0/0/0)	0	(0/0/0/0)	> 0.99			

P values less than 0.05 show significant differences between the proportion of patients with best appearance of the LPDL treated sides versus the IPL treated sides. M, months; Tx, treated.

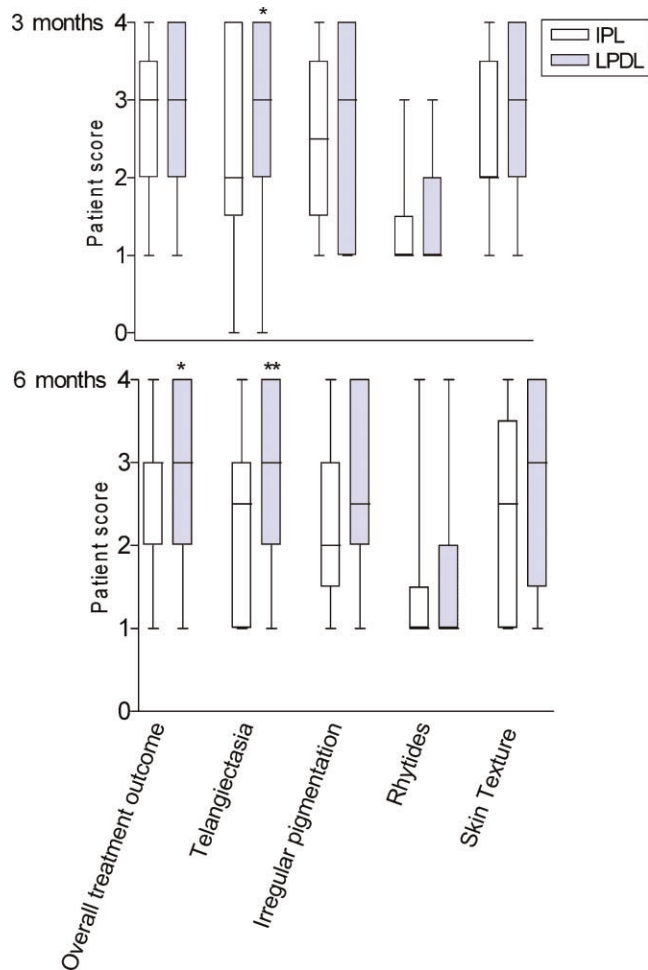


Fig. 2. Patient self-assessments of improvement on the overall treatment outcome and on telangiectasias, irregular pigmentation, skin texture, and rhytides (5-point scale: 0 = worsening of appearance, 1 = no change, 2 = mild, 3 = moderate, or 4 = significant improvement in appearance). The boxes extend from the 25th to the 75th percentiles (interquartile range) with a horizontal line at the median (50th percentile). Whiskers show the range of the data. * $P = 0.031$, ** $P = 0.008$.

15/18 (83%, $P = 0.008$), 14/18 (77%, $P = 0.031$), and 17/18 patients (94%, $P < 0.001$) preferred LPDL-treatments to IPL-treatments for future treatments due to less treatment-related pain and due to superior vessel clearance.

DISCUSSION

In this randomized controlled trial (RCT) we have found that rejuvenation with LPDL and IPL is similarly effective to clear irregular pigmentation and to improve skin texture whereas the LPDL is superior for vessel clearance. The superiority of LPDL for vessel clearance was detected by postoperative direct side-to-side comparisons, which was the preferred design to compare efficacies from two related topical treatments as patients were selected for inclusion to have preoperatively symmetrical facial photodamage and since possible minor discrepancies in split-face

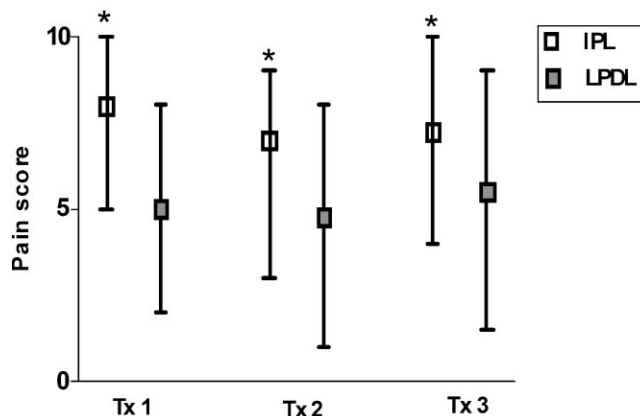


Fig. 3. Treatment-related pain immediately after first, second, and third treatments. The whiskers represent the data range with a marked box at the median (50th percentile). * $P < 0.001$. Tx = treatment.

symmetry were compensated for by the randomized design of this trial. Moreover, by choosing the split-face design the relatively small sample size was taken into account. Comparing the efficacies of LPDL versus IPL by before-and after reductions in vessel intensity, a trend was seen for LPDL superiority, however not significant, which indicates that a 4-point categorical scale is too rough to discriminate differences between the two treatments. Due to the better vessel clearance and due to less treatment-related pain, the majority of patients preferred LPDL to IPL treatments.

Non-ablative rejuvenation with LPDL and IPL is widely used to clear telangiectasias and irregular pigmentation and to improve skin-texture [4–8,20,22]. Randomized and non-RCTs have previously evaluated the efficacy of PDL and IPL rejuvenation showing significant improvements of telangiectasias and irregular pigmentation in up to 89% and 77% of patients, respectively, a couple of months after 2–3 IPL or PDL treatments [4,7,8]. In a recent RCT with a direct split-face side-to-side comparison on the efficacy of IPL rejuvenation versus untreated control skin, it was found that skin texture improved significantly whereas no efficacy was seen on rhytides [7]. These results are in accordance with the results from our study, in which no improvement was seen of rhytides from neither LPDL nor IPL, whereas skin texture improved from both treatments. Other controlled split-face trials have compared the efficacy of the 532-nm KTP laser versus the 595-nm PDL [4] and IPL [9] showing better results on telangiectasias after treatment with the KTP laser versus the PDL laser, whereas comparative results on telangiectasias and irregular pigmentation were found after treatment with the KTP laser versus IPL. In our study LPDL was superior to IPL for teleangiectatic lesions. A possible explanation might be the monochromaticity of 595 nm emitted light close to the oxyhemoglobin extinction coefficient, as well as the fact that the Vbeam Perfecta uses of a series of eight equivalent micropulses delivered within each macropulse, which increases the purpura threshold and allows the use

of higher fluences [20]. Moreover, the use of a compression handpiece with the LPDL, which removes blood from the treatment area, thereby eliminating hemoglobin as a competing chromophore, explains the effectiveness of LPDL and the comparable results of LPDL to broadband IPL for the treatment of pigmented lesions.

Today many non-ablative devices are used with cooling techniques in order to minimize treatment-related pain and to diminish unspecific thermal damage and thereby, to reduce the risk of inducing adverse effects [20,23–25]. In our study the LPDL was equipped with an integrated DCD whereas the IPL system did not use cooling, thus explaining the significantly higher pain scores on the IPL-treated sides compared to the LPDL treated sides. Moreover, absence of cooling during IPL rejuvenation may have negatively impacted IPL efficacy by the use of lower, more tolerable, treatment parameters.

To our knowledge this is the first RCT with a direct side-by-side comparison that examines efficacy and adverse effects of LPDL and IPL rejuvenation in a homogeneous group of patients. The experience of lower pain intensities and superior vessel clearance from the LPDL determined that the majority of patients preferred the LPDL to the IPL for rejuvenation procedures. We, therefore, conclude that with this study set-up, LPDL rejuvenation is advantageous to IPL rejuvenation. However, it might be possible that using an IPL-system with a cooling device, the results may have come out somewhat different. Therefore, the results from this study cannot be extended to other IPL-systems.

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