Effect of pan retinal photocoagulation on Macular and optic nerve capillary density and foveal avascular zone area in patients with diabetic retinopathy An OCT angiography study

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Short title: OCT angiography in diabetic retinopathy.

Abstract

Purpose: This study evaluated changes of macular and optic nerve capillary density, foveal avascular zone (FAZ) area and macular thickness following Panretinal photocoagulation (PRP) in eyes with severe non-proliferative diabetic retinopathy (NPDR) and early proliferative diabetic retinopathy (PDR) using optical coherence tomography angiography (OCTA).

Patients and methods: The study enrolled 40 eyes of 28 subjects with severe NPDR and early PDR and no significant macular edema who were candidates for panretinal photocoagulation. The outcome measures were the difference in macular superficial and deep capillary plexus vessel densities, radial peripapillary capillary plexus (RPCP) vessel density, FAZ area, central macular thickness and best-corrected visual acuity at the baseline vs. at 1 and 3 months post-PRP.

Results: The mean of macular VD at SCP and DCP showed a significant increase after PRP at 1- and 3-months. (All $p < 0.05$). The mean VD at RPCP decreased after PRP, this decrease wasn't statically significant neither at 1 month nor at 3 months after PRP. (All $p > 0.05$). The superficial and deep FAZ area constricted 3 months post-PRP. ($p < 0.05$). Central macular thickness (CMT) showed statistically significant increase after laser treatment versus the baseline thickness, but no significant alterations in BCVA were reported post-PRP at 1- and 3-months.

Conclusion: PRP supports the integrity of the macular and peripapillary microvasculature, the FAZ area constricts post-PRP, possibly because of the reflow of capillary plexus occlusion. After PRP, the CMT increased.

Key words: Diabetic retinopathy; Optical coherence tomography angiography; Panretinal photocoagulation; Vessel density.

INTRODUCTION

Diabetic retinopathy is the main cause of preventable visual loss, characterized by microaneurysms, capillary non-perfusion, and ischaemia, resulting in neo-vascularization and macular oedema. both of which can severely compromise visual function[1].

In spite of various novel therapeutic options, e.g., intravitreal anti vascular endothelial growth factor (Anti-VEGF), PRP remains an effective and beneficial option for severe NPDR and PDR, as demonstrated in numerous reports[2].

Although the mechanism of action of the laser treatment is unclear, it is hypothesized to reduce metabolic demand and facilitate oxygen diffusion from the choroid to the retina. Thereby, downregulation of angiogenic factors and VEGF production by retinal tissue[3]. Improved oxygenation occurs in two ways: First, the laser burns cause the retina to become thinner inducing the choriocapillaris to be closer to the inner retinal layers. Second, the highly metabolically active photoreceptors are destructed, reducing the total oxygen demand of the retina[4].

In spite of its efficacy and benefits in the treatment of PDR, laser photocoagulation of the retina has some adverse effects and complications. These include diminution of vision secondary to macular oedema, retinal detachment, and visual

field loss[5].

While the majority of earlier reports have described the large vessel effects related to PRP, the OCTA technology has enabled a detailed evaluation of microvascular retinal alterations. OCTA is a non-invasive depth-resolved modality which allows a high-quality vascular mapping and promotes visualization of vascular system in various capillary plexuses[6].

OCTA procedure can be carried out repeatedly at short intervals since the intra-procedural patient's discomfort is minimal[4]. Recently, OCT-A has been utilized to evaluate alterations that occur in FAZ features and macular and choroidal perfusion after PRP in DR eyes[7].

PATIENTS AND METHODS

This prospective, uncontrolled, interventional, non-comparative case series study aimed to assess changes of macular and optic nerve capillary density, FAZ area and macular thickness after PRP in cases with severe NPDR and early PDR using OCTA.

The study included 40 eyes of 28 cases with severe NPDR and early PDR who were candidates for pan retinal photocoagulation at Mansoura ophthalmic center, Mansoura University, Egypt. It was conducted for duration of one year from June 2021 to June 2022.

The Inclusion criteria were patients aged > 18 years, diagnosis of type 1 or type 2 diabetes without center involving diabetic macular oedema, severe NPDR or PDR confirmed by fluorescein angiography, the necessity for PRP because of ischaemia or neo-vascularization. The exclusion criteria included visual acuity < 20/200, previous laser therapy, history of intravitreal injection or intra-ocular operation, macular exudate and fibrovascular proliferation, history of ocular trauma, glaucoma, uveitis, axial length > 26.5 mm, and media opacity that could hinder fundus visualization.

The study was approved by the institutional research board (IRB) NO: MS.21.06.1540 of Mansoura Faculty of Medicine. Written consents were taken from the participants after explanation of the aims, methods, anticipated benefits, and potential risk of the procedures.

All patients were subjected to thorough ophthalmic evaluation including history taking, measurement of corrected distance visual acuity (CDVA) with Snellen chart (converted to LogMAR), refraction, anterior segment examination using slit-lamp biomicroscopy, measurement of intraocular pressure (IOP) with Goldman applanation tonometer, measurement of Axial length by IOL master, and fundus examination using indirect ophthalmoscope and slit lamp biomicroscopy with auxillary lens (volk 90), after dilatation of the pupil by mydriatic eye drops. Measurement of CMT using spectral-domain optical coherence tomography (version 6.16.7; Heidelberg Engineering, Heidelberg, Germany), Fundus photography (colored & fluorescein angiography) was carried out using (Canon CX-1 Digital Fundus Camera).

A spectral domain OCT system Spectralis HRA-OCTA (version 6.16.7; Heidelberg Engineering, Heidelberg, Germany) was utilized for OCTA image acquisition. This OCT-based system can image the structure and ocular microvasculature. Full-spectrum amplitude-decorrelation angiography (FSADA) with a probabilistic approach was used to produce high-contrast OCTA images. Macular and peripapillary scans were obtained with a 10-degree field of view, 3×3 mm^2, using pre-determined automatic real-time tracking, and a quality index of 25.

Superficial and deep FAZ were measured manually, Retinal perfusion in macular SCP and DCP and RPCP was assessed by assessing the vessel density (VD) which is the ratio of the area occupied by blood vessels over the total measured area and the results were calculated by The GNU Image Manipulation Program V.2.10.32 (GIMP) software at the superficial vascular complex (SVC), deep vascular complex (DVC) and Radial peripapillary capillary (RPC) segment.

Panretinal photocoagulation (PRP) was performed with Ocular mainster PRP 165 laser lens (Ocular Instruments, Bellevue, WA 98004, USA) and visulas green laser machine 532 nm (Carl Zeiss Meditec AG Geoschwitzer Str. 51-52,07745 Jena, Germany). After pupillary dilation with mydriatic eye drops under topical anesthesia, RPP was performed at two to three consecutive sessions (inferior and superior half, respectively), with 7 days between treatments. according to the guidelines of ETDRS Research Group. Laser burns were spaced one laser spot size apart. Treatment was applied posteriorly just outside the arcades and peripherally as far as possible. Laser settings were 200-micron spot size

(causing retinal burns of about 400 microns), pulse duration of 50 ms, and power of 130 - 180 milliwatts. Burns were 2000 burns in number and were greyish in colour. Follow up was at 1 and 3 months after baseline measurements. Patients did not receive any further therapy. Before and at the first and third months of follow-up post-PRP, ophthalmological evaluation and OCTA were done, and data were recorded.

Statistical analysis:

Data were analysed by the SPSS software V 24 for Windows. At first, normal distribution of data underwent testing using one-sample Kolmogorov-Smirnov test.

Qualitative data were expressed as frequencies and percents. Continuous variables were expressed as means ± SDs (standard deviations) for normally distributed data and medians (minimum, maximum) for non-parametric data. The two paired groups were compared with paired t test. A result was considered significant if the $p \leq 0.05$.

RESULTS

The mean age of cases was 48.25±7.26 years; (14.3% aged ≤ 40y & 60.7% aged from 40-50y & 25% aged >50y). According to sex, 53.6% of the participants were males and 46.4% were females. According to laterality shows that 57.1% of patients had unilateral disease, and 42.9% had bilateral disease. According to type of diabetes 78.6% of participants were IDDM. The mean HbA1c level was 7.55±0.72; and mean duration of diabetes mellitus was 17.10±5.47 years. Approximately 67.9% of patients were hypertensive, the mean duration of hypertension was 13.44±5.61 years, 35.7% had dyslipidemia, and 10.7 % had cardiac disease. **(table 1).**

Table (1): Demographic data among the studied cases (n=28):

Demographic data	(n=28)
Age (Years)	
Mean ± SD	48.25±7.26
Min-Max	35-62
Age categories	
≤40 y	4 (14.3%)
40-50 y	17 (60.7 %)
>50 y	7 (25.0 %)
Sex	
Male	15 (53.6%)
Female	13 (46.4%)
Laterality	
Unilateral disease	16 (57.1%)
Bilateral disease	12 (42.9%)
Type of diabetes	
IDDM	22 (78.6%)
NIDDM	6 (21.4%)
Duration of DM (years)	
Mean ± SD	17.10±5.47
HbA1C	
Mean ± SD	7.55±0.72
Dyslipidemia	
Yes	10 (35.7%)
No	18 (64.3%)
Hypertension	
Yes	19 (67.9%)
No	9 (32.1%)
Duration of HTN (years) Mean ± SD	13.44±5.61
Cardiac disease	
Yes	3 (10.7%)
No	25 (89.3%)

SD= Standard deviation; IDDM= Insulin dependent Diabetes mellitus; NIDDM= non-insulin dependent Diabetes mellitus; HBA1c= Glycosylated hemoglobin; HTN= Hypertension

As regard clinical examination of the patients, the mean corrected distance visual acuity of participants was 2.4 ±

1.02. The median refraction was -1.25, with a range of -2.75 to 2.25. The mean AL was 23.40±0.44 mm. The mean IOP was 14.28±1.79 mmHg.

According to anterior segment examination, 65% of participants were normal, and 35% had senile immature cataract. According to Posterior segment examination, the majority of patients 70% had early PDR, and 30% had severe NPDR. **(table 2).**

Table (2): Clinical data of studied eyes (n=40):

Clinical data	(n=40)
CDVA (inverted logMAR) Mean ± SD	2.4 ± 1.02
Refraction Median (Min-Max)	-1.25 (-2.75-2.25)
AL Mean ± SD (mm)	23.40 ± 0.44
IOP Mean ± SD (mmHg)	14.28 ± 1.79
Anterior segment	
Normal	26 (65.0%)
Senile immature cataract	14 (35.0%)
Posterior segment	
Early PDR	28 (70.0%)
Severe NPDR	12 (30.0%)

SD= Standard deviation; CDVA= Corrected distance visual acuity; logMAR= logarithm minimal angle of resolution; NPDR: Non-proliferative diabetic retinopathy; PDR: Proliferative diabetic retinopathy.

Macular vessel density (VD) at SCP and DCP showed significant increase. SCP was 32.55±3.66 at baseline and was increased to 34.02±3.81 and 35.23±3.54 after one month and three months of PRP treatment, respectively. DCP was 37.15±2.53 at baseline and was increased to 38.35±2.88 and 39.84±2.94 after one month and three months of PRP treatment, respectively. (All $p < 0.05$) **(table 3).**

VD at RPCP did not show significant difference between the mean values of radial peripapillary vessel density. RPCP was 46.95±2.93 at baseline and was decreased to 45.61±2.68 and 45.16±2.84 after one month and three months of PRP treatment, respectively. (All $p > 0.05$) **(table 3).**

Superficial FAZ area (mm^2) showed a significant reduction from 0.42±0.04 at baseline, to 0.39±0.03 after one month and to 0.38±0.03 after 3 months of PRP treatment. As well, deep FAZ area (mm^2) showed a significant reduction from 0.65±0.04 at baseline, to 0.64±0.05 after one month and to 0.62±0.04 after 3 months of PRP treatment. (All $p < 0.05$) **(table 3).**

Analysis of CMT (µm) demonstrated that the mean CMT was significantly increased. CMT was 266.85±21.16 at baseline and was increased to 285.70±18.69 and 320.35±36.09 after 1 month and after 3 months of PRP treatment, respectively. ($p < 0.05$) **(table 3).**

Table 3: The Optical coherence tomography angiography (OCT-A) parameters of macula and radial peripapillary area at baseline and during follow up periods after pan-retinal photocoagulation (PRP):

OCTA parameter	Baseline Mean ± SD	After 1 m Mean ± SD	After 3 ms Mean ± SD	Test of significance		
				P1	P2	P3
Macular SCP (%)	32.55±3.66	34.02±3.81	35.23±3.54	t=3.4 **P=.002**	t=6.7 **P=.004**	t=4.4 **P≤.001**
Macular DCP (%)	37.15 ± 2.53	38.35±2.88	39.84±2.94	t=3.9 **P=.001**	t=7.0 **P≤.001**	t=7.03 **P≤.001**
RPCP (%)	46.95±2.93	45.61±2.68	45.16±2.84	t=11.7 P=0.184	t=11.4 P=0.097	t=11.6 P=0.35
Superficial FAZ (mm^2)	0.42 ± 0.04	0.39 ± 0.03	0.38 ± 0.03	t=21.1 **P=.007**	t=10.8 **P≤.001**	t=4.55 **P≤.001**
Deep FAZ (mm^2)	0.65 ± 0.04	0.64± 0.05	0.62 ± 0.04	t=4.9 **P≤.001**	t=10.4 **P≤.001**	t=6.8 **P≤.001**
CMT (µm)	266.85±21.16	285.70±18.69	320.35±36.09	t=8.9 **P≤.001**	t=10.3 **P=.034**	t=6.8 **P≤.001**

SD= Standard deviation; SCP= Superficial capillary plexus; DCP= Deep capillary plexus; RPCP= Radial peripapillary capillary plexus; FAZ= Foveal avascular zone (superficial and deep); CMT=: Central macular thickness; P1: Baseline versus after 1m, P2: Baseline versus after 3m, P3: After 1m versus 3m, t: paired t test, Significant p≤0.05. written in **bold**

Analysis of CDVA (Inverted logMAR) showed no significant difference among the mean values of the mean CDVA. It was increased from 2.4 ± 1.02 at baseline to 2.7 ± 1.2 after 3 months. (p >0.05) **(table 4).**

Table (4): Comparison between Pre and post CDVA:

CDVA (Inverted logMAR)	Pre CDVA	Post CDVA	Paired t test	P value
Mean ± SD	2.4 ± 1.02	2.7 ± 1.2	t=2.19	0.082

SD= Standard deviation; CDVA= Corrected distance visual acuity; Significant p≤0.05.

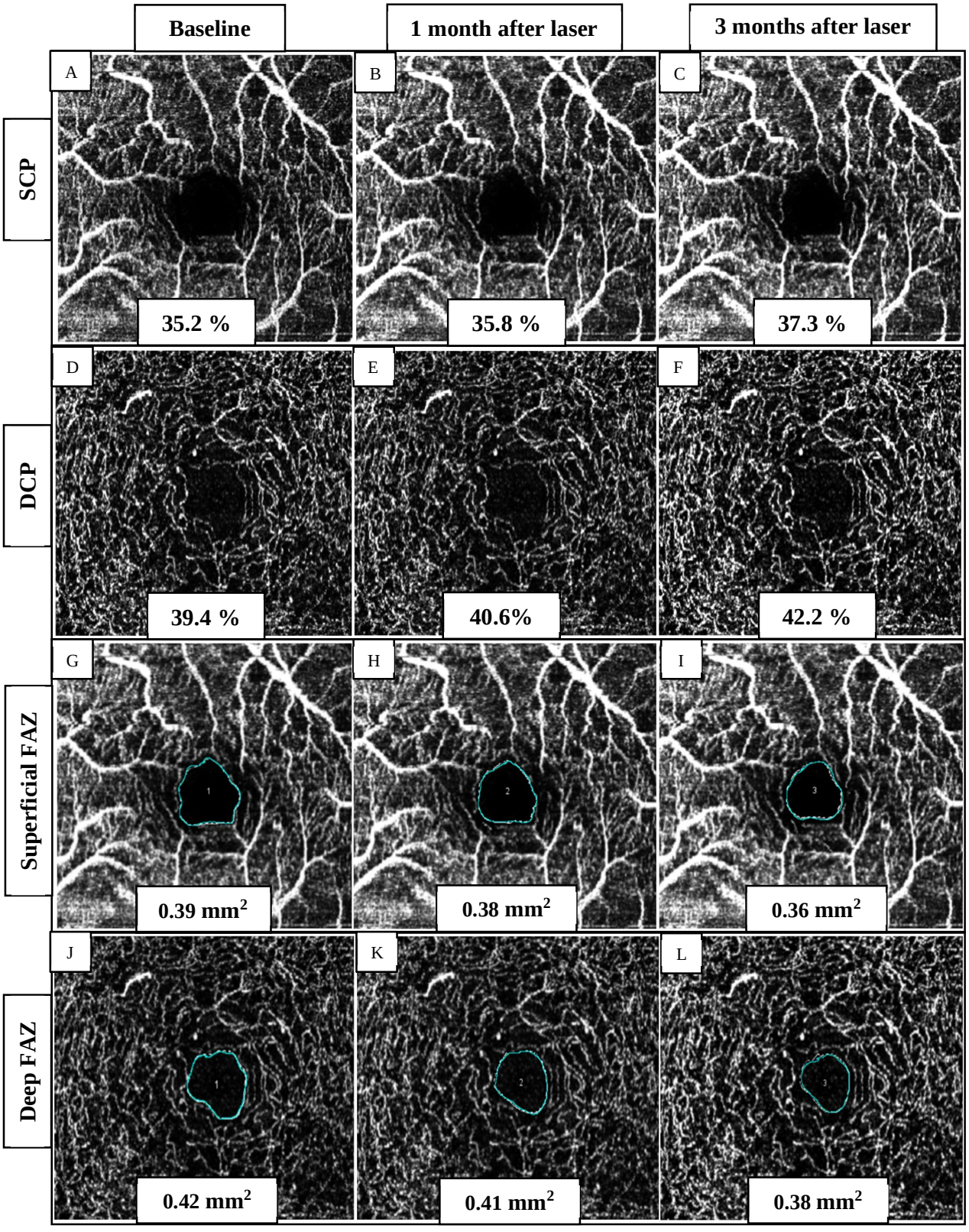

Fig. 1. Optical coherence tomography angiography (OCTA) parameters of a patient with proliferative diabetic retinopathy. The baseline and first- and third-month superficial capillary plexus density (A-B-C), deep capillary plexus density (D-E-F), superficial FAZ (G-H-I), deep FAZ (J-K-L) are shown.

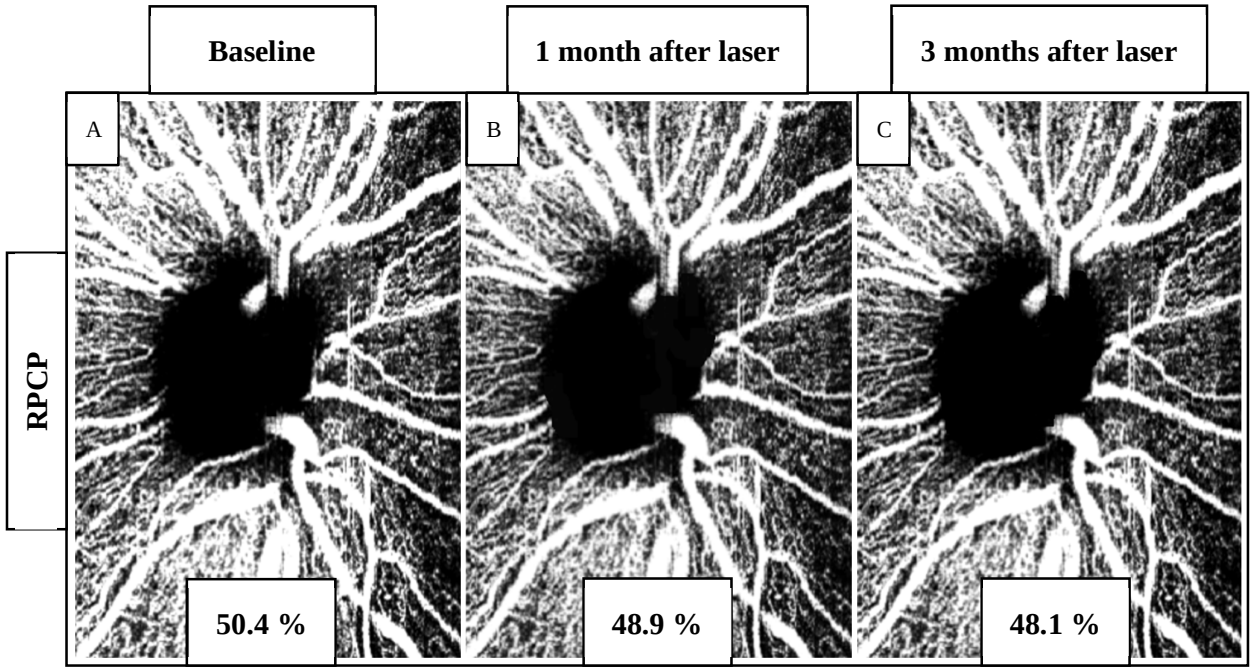

Fig. 2. Optical coherence tomography angiography (OCTA) parameters of a patient with proliferative diabetic retinopathy. The baseline and first- and third-month Radial peripapillary capillary plexus density (A-B-C) are shown.

Comparison between NPDR and PDR regarding OCTA parameters:

The mean values of macular vessel density at SCP and DCP were significantly higher among eyes with severe NPDR than that with PDR at all three time points ($p < 0.05$). The mean values of radial peripapillary vessel density were significantly higher in eyes with severe NPDR than that with PDR at all three time points ($p < 0.05$). As regards the mean values of superficial and deep FAZ, no significant difference existed between PDR and severe NPDR eyes. ($p > 0.05$). As regards mean values of CMT, no significant difference existed between PDR and severe NPDR eyes. ($p > 0.05$). **(table 5).**

Table 5: Comparison between NPDR and PDR regarding OCTA parameters:

	PDR (n=28)	NPDR (n=12)	Test of significance	P value
		SCP (%)		
Baseline	30.70± 4.12	33.34± 3.29	t= 4.80	**<0.001**
After 1 month	31.33± 3.89	33.73± 3.67	t= 4.52	**0.001**
After 3 months	32.94± 3.14	35.77± 3.66	t= 4.68	**<0.001**
		DCP (%)		
Baseline	36.28± 2.21	39.19±1.94	t= 3.57	**0.004**
After 1 month	37.65± 2.48	39.97± 3.08	t= 1.78	**0.041**
After 3 months	38.91± 2.09	42.0± 3.43	t= 2.16	**0.024**
		RPCP (%)		
Baseline	45.81± 2.61	49.63± 1.59	t= 3.30	**0.004**
After 1 month	44.16± 2.64	47.50± 1.76	t= 2.81	**0.012**
After 3 months	43.58± 2.42	47.01± 1.49	t= 3.18	**0.005**
		Superficial FAZ (mm^2)		
Baseline	0.42± 0.03	0.41± 0.04	t= 0.131	0.329
After 1 month	0.41± 0.04	0.39± 0.02	t= 0.027	0.352
After 3 months	0.39± 0.03	0.38± 0.04	t= 0.166	0.466
		Deep FAZ (mm^2)		
Baseline	0.66± 0.03	0.63± 0.06	t= 0.195	0.076
After 1 month	0.65± 0.02	0.62±0.05	t= 0.224	0.065
After 3 months	0.63±0.03	0.59±0.05	t=0 .173	0.084
		CMT (µm)		
baseline	262.29± 20.73	277.50± 19.76	t=1.52	0.145
After 1 month	283.14± 18.48	291.67± 19.44	t=0.931	0.364
After 3 months	318.57± 36.82	324.50± 37.34	t= 0.329	0.746

t: paired t test, Significant p≤0.05 written in **bold**

DISCUSSION

According to the recommendations of the ETDRS group, PRP should be considered in eyes with PDR, and in those with severe NPDR, particularly when regular follow-up is unavailable. PRP has been suggested to have many mechanisms such as blood flow autoregulation, improvement of retinal oxygen supply, and metabolic stimulation of retinal pigment epithelium. However, PRP still carries a high risk of macular injury, as retinal nerve fiber layer and ganglion cell complex thinning, loss of photoreceptors, or worsening of

diabetic macular oedema[2].

The effectiveness of PRP in PDR is thought to be related to improved inner retinal oxygen delivery which in turn reduce angiogenic drive and induces regression of neovascularization[8].

OCTA technique enables high quality mapping of retinal vessels at various capillary plexus levels[9].

In our study, we evaluated changes in OCTA parameters post- PRP in patients with severe N-PDR or early PDR. A significantly reduced FAZ area was reported three months post-PRP in comparison to baseline. Moreover, significant increases in the macular VD at SCP and DCP were found at 1st month and 3rd month of the follow-up period.

Similarly, recent reports assessed retinal microvascularization following PRP using OCT-A in patients with severe N-PDR or early PDR and revealed differences in the distribution of retinal blood flow. Very Similar result was found by, Abdelhalim et al. who found a significant improvement in retinal vascular density at 6 months post-PRP[6]. Also, Mirshahi and co-workers reported a significantly increased VD in SCP and DCP 3 months post-PRP in patients with PDR or severe N-PDR[10]. Chatziralli, et al. showed significant increases in the VD of SCP at 6th month and 12th month of follow-up, while no statistically significant differences were observed in the VD of DCP[11].

On the contrary, in the study by Sariyildiz C, et al.[4], no significant alterations in the VD of the SCP and DCP were found at the 3rd and 6th months post-PRP. Moreover, Zhao and his team found no changes in OCTA parameters following PRP in PDR or severe NPDR eyes[12]. As well, Faghihi et al., found no significant alterations in the foveal or parafoveal retinal vascular density parameters at 1 month and 6 months post-PRP in severe NPDR or early PDR eyes[7]. Fawzi et al. found no significant changes in VD parameters post-PRP[13]. Sabaner et al. reported non-significant changes in the parafoveal and perifoveal VD at 6 months post-PRP[14]. Kim and co-workers showed a reduction in VD 1-month post-PRP in patients with PDR or severe N-PDR, while a significant increase in VD was observed at SCP and DCP one-year post-PRP[15].

In this study, macular superficial and deep capillary densities statistically significant increased after PRP. Redistribution of the macular capillary circulation may be a reason for such phenomenon. Also, overproduction of nitric oxide because of PRP-induced inflammation might have a key role in vasodilation of retinal vessels, making them more noticeable with OCTA[16].

As regards FAZ changes post-PRP treatment, findings from previous studies are controversial. FAZ enlargement and irregularity is an important indicator of macular ischaemia in diabetes[17]. According to Salz et al., PDR eyes had a larger FAZ than healthy eyes. The progression of DR might be linked to a more irregular FAZ because of occluded capillaries[18]. Chatziralli, et al. showed significant reduction in FAZ area 6 months post-PRP in PDR eyes in comparison with baseline[11]. As well, Sabaner et al. showed a significant reduction in FAZ area post-PRP in NPDR patients[14]. Abdelhalim and colleagues reported a significant reduction in FAZ area 6 months post-PRP in PDR[6]. Additionally, Faghihi and his team demonstrated that FAZ area constricted and was significantly more circular 6-month post-PRP[7], as in this study at the 3 months follow up. This can be clarified by the fact that the improvement of blood flow in the residual macular capillaries could have resulted in a better posterior pole perfusion[7].

However, Misharhi et al., found no significant alteration in FAZ area 3 months post-PRP[10]. Lorusso and colleagues also reported no change in FAZ area 6 months post-PRP in PDR patients[19]. The study by Sariyildiz et al. revealed no significant change in FAZ area at the 3rd and 6th month after laser treatment[4].

The differences in OCTA devices and the utilized software, along with the variations in population and follow-up, might be the cause of the discrepancy in the results of various studies.

OCTA can effectively visualize the vessels in the peripapillary region. Radial Peripapillary capillary density showed no statistically significant differences at month 1 and 3 of the follow-up period. (Decreased from baseline to 1 month and 3 months after PRP). Similar findings were reported by, Huang T, et al. who found no significant changes in the whole peripapillary VD at 12 months post-PRP when compared with baseline[20]. Faghihi, et al. reported no significant alterations in the Peripapillary vascular density. (Decreased from baseline to 1 month after PRP and then increased after 3 months to the

amount less than baseline)[7].

In the present study and as compared to the baseline, there is mild but statistically significant increase in CMT post-PRP. However, no significant alteration in CDVA was found following PRP at any time point of the follow-up periods. Indeed, PRP can cause clinical or subclinical macular oedema[10]. An interruption of blood-retinal barrier might be the mechanism of such phenomenon[21]. Soman et al. showed, CMT increase does not influence the functional outcomes in more than 80 % of their cases after PRP[22].

In this study, there were 4 eyes with macular thickness > 350 micron and CDVA < 0.176 that required intravitreal injection after 3 months. Similarly, studies by Faghihi et al.[7] and Shimura et al. revealed increases in CMT post-PRP, which returned to normal later[23]. Also, Lee et al. observed an increased CMT at one-year post-PRP, which was persistent[21]. Acar and Onur also noticed a significantly increased CMT at 6 months post-PRP[24].

Other complications with successful management occurred throughout the follow up period. Three patients need additional laser and one patient complicated with vitreous hemorrhage.

The Limitations of the study include the absence of a control group which interfered with making a firm conclusion about the correlation between VD changes and PRP. However, it is unethical not to treat PDR cases, and hence the enrollment of control subjects is not viable. relatively small sample size is another concern, a larger sample size and longer follow-up periods are recommended to clarify the relationship between the different studied variables. Another limitation of our study is the lack of considerations of other foveal area haemodynamic parameters including fractal dimensions and subfoveal choroidal thickness.

Despite advances in OCTA technology, several artifacts cannot be easily fixed. Low-quality images were excluded, but projection, motion, and segmentation could have negatively influenced measurements.

CONCLUSION

In conclusion, this study demonstrated that PRP is a useful and reliable treatment option that supports the integrity of the macular and peripapillary microvasculature, After PRP, the FAZ area was significantly reduced and the CMT increased.

Disclosure

The author(s) report no conflicts of interest in this work.

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Data Availability: The authors declare that all data supporting the findings of this study are available within the article and its supplementary information file.

Competing interests: The authors declare no competing interests.

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Ethics declarations: All procedures performed in the study followed the 1964 Helsinki declaration and its later amendments, University Ethics Committee approved the project.

Conflict of interest

Mariam Aql, Tarek Mohsen, Abd El-Monem Elhessy, Dina Abd El-Fattah. All authors have no conflicts of interest that are directly relevant to the content of this review.

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