

## **Results of studying the diabetic retinopathy course in potential kidney and pancreatic recipients while on hemodialysis**

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### **Abstract**

**Introduction.** *Kidney and pancreas transplantation is a surgical method for the treatment of patients with diabetes mellitus and terminal diabetic nephropathy. While waiting for surgical treatment, potential recipients receive maintenance hemodialysis. Dialysis initiates the loss of body fluid,*

*which in turn can affect the state of the intraocular structures.*

***Aim.*** *To study the effect of long-term hemodialysis therapy on ophthalmic parameters in patients with terminal diabetic nephropathy.*

***Material and methods.*** *Sixty patients (120 eyes) were examined: group A included 30 patients with end-stage renal failure as a result of diabetic nephropathy, group B included 30 people without systemic and ocular pathologies. The ophthalmological status of group A was assessed at the stage of planned preparation for renal replacement therapy, at 3 and 6 months after the initiation of dialysis. Ophthalmological examination consisted of the use of traditional and special diagnostic methods (microperimetry, photorecording of the fundus, optical coherence tomography angiography).*

***Results.*** *Within 6 months of hemodialysis courses, the following was recorded: a decrease in the thickness of the retina (Me: from 348.5 to 306.1  $\mu\text{m}$ ;  $p < 0.05$ ) and choroid (Me: from 330.3 to 294.9  $\mu\text{m}$ ;  $p < 0.05$ ), the improvement of retinal perfusion in eyes with diabetic macular edema (Me in the superficial capillary plexus: from 10.6 to 15.8% in the fovea, from 19.7 to 25.4% in the parafovea; in the deep capillary plexus: from 15.4 to 20.9% in the fovea, from 27.5 to 33.5% in the parafovea;  $p < 0.05$ ), a decrease in choroidal hemoperfusion (Me in the layer of choriocapillaries: from 59.0 to 54.2% in the fovea, from 59.3 to 54.7% in the parafovea; in the deep layer of the choroids: from 55.5 to 50.7% in the fovea, from 55.3 to 50.7% in the parafovea;  $p < 0.05$ ), an improvement in retinal photosensitivity (Me: from 16.7 to 20.3 dB in eyes with diabetic macular edema; from 21.1 to 24.2 dB in eyes without diabetic macular edema;  $p < 0.05$ ) and increased visual acuity in eyes with macular edema (Me: 0.1 to 0.3;  $p < 0.05$ ).*

**Conclusions.** *Against the background of maintenance hemodialysis hemodialysis in patients with terminal diabetic nephropathy, along with a decrease in hyperazotemia, there is an improvement in architectonics, hemodynamics of the retina and visual functions.*

**Keywords:** type 1 diabetes mellitus, diabetic nephropathy, diabetic retinopathy, hemodialysis, microperimetry, optical coherence tomography angiography

**Conflict of interests** Authors declare no conflict of interest

**Financing** The study was performed without external funding

**For citation:** Vorobyeva IV, Bulava EV, Balkarov AG, Dmitriev IV. Results of studying the diabetic retinopathy course in potential kidney and pancreatic recipients while on hemodialysis. *Transplantologiya. The Russian Journal of Transplantation.* 2023;15(2):188–199. (In Russ.). <https://doi.org/10.23873/2074-0506-2023-15-2-188-199>

BCVA, best corrected visual acuity

CDL, choroid deep layer

ChC, choriocapillaris

CRT, central retinal thickness

DM, diabetes mellitus

DME, diabetic macular edema

DMP, diabetic maculopathy

DN, diabetic nephropathy

DR, diabetic retinopathy

DRCP, deep retinal capillary plexus

ESRD, end-stage (chronic) renal disease

FAZ, foveal avascular zone

GFR, glomerular filtration rate

MHD, maintenance hemodialysis

MLS, macular light-sensitivity

OCT, optical coherence tomography

SRCP, superficial retinal capillary plexus

## **Introduction**

In recent decades, there has been a steady global trend towards an increase in the prevalence of type 1 diabetes mellitus (DM) [1]. According to I.I. Dedova et al., by the beginning of 2021, the prevalence of type 1 DM in the Russian Federation had increased from 168.7 to 180.9 cases per 100 thousand population of the country compared to the data of 2016 [2].

Diabetic nephropathy (DN) is one of the most significant chronic microvascular complications of type 1 DM. Initially, it is manifested as microalbuminuria with subsequent progression to proteinuria. The outcome of DN is end-stage (chronic) renal disease (ESRD) characterized by a pronounced decrease in the glomerular filtration rate ( $\text{GFR} < 15 \text{ ml/min/1.73 m}^2$ ) [3]. For eliminating the uremic syndrome and achieving the physiological regulation of carbohydrate metabolism with further prevention of the progression of diabetic complications, the patients with ESRD in the DN outcome undergo simultaneous pancreas-kidney allotransplantation [4]. While waiting for organ transplantation, potential recipients are given renal replacement therapy in the form of hemodialysis or peritoneal dialysis to maintain vital functions [5].

Dialysis initiates the loss of a large amount of fluid by the body due to the excretion of high-osmolar substances, which, in turn, can affect the status of the intraocular structures.

Previously, a number of authors have conducted studies to investigate ophthalmic parameters in patients receiving hemodialysis. Thus, it was found that while on dialysis therapy, the patients display changes in the level

of intraocular pressure [6], the thickness of retina [7] and choroid [8], choriocapillary perfusion [9], and visual acuity [10, 11]. However, these studies included patients with ESRD of various etiologies, including of non-diabetic genesis, without diabetic retinopathy (DR). In most of these studies, the ophthalmological status of patients was assessed on the basis of a single hemodialysis session.

In this regard, the purpose of this study was to investigate the effect of long-term hemodialysis therapy on ophthalmic clinical and morphofunctional parameters in patients with type 1 diabetes mellitus and DR.

### **Material and methods**

On the base of the Department of Ophthalmology, Russian Medical Academy of Continuous Professional Education of the RF Ministry of Health at the City Clinical Hospital named after S.P. Botkin, 60 patients (120 eyes) were examined. Of these, 30 patients (60 eyes) suffered from type 1 DM and ESRD in the DN outcome (group A). These patients started receiving the maintenance hemodialysis (MHD) therapy and met the criteria for potential kidney and pancreas recipients. The selection of recipients for the waiting list for organ transplantation was made by surgeons of the Kidney and Pancreas Transplantation Department of the N.V. Sklifosovsky Research Institute for Emergency Medicine. Along with MHD therapy, group A patients received intensive insulin therapy in the form of multiple injections or continuous subcutaneous infusion. Thirty examined patients (60 eyes) without systemic and ocular pathology constituted the control group (Group B) (Table No. 1).

**Table 1. Patient demographics**

Parameter		Group			
		A		B	
Number of patients, n	Men, % (n)	30	53 (16)	30	50 (15)
	Women, %(n)		47 (14)		50 (15)
Number of eyes, n		60		60	
Age, years		39 [31;45]		37 [29;48]	
Diabetes history, years		27 [19;31]		—	

*Note:* Data are presented as median (Me) and lower/upper quartiles [Q1;Q3].

Criteria for patient inclusion in group A were the following: presence type 1 DM, ESRD in the DN outcome and replacement renal therapy in the form of MHD. For group B, the inclusion criteria for patients to be enrolled in the study were the absence of ocular and systemic pathologies. The criteria for exclusion from the study were the presence of type 2 DM, ESRD of non-diabetic origin and renal replacement therapy in the form of peritoneal dialysis for patients of group A, the presence of a high degree of refractive error and any ophthalmic pathology and concomitant chronic systemic conditions for patients of group B.

On the day of the ophthalmological examination, patients underwent venous blood sampling with subsequent laboratory analysis to determine the levels of glucose, glycated hemoglobin, serum urea and creatinine concentrations.

The ophthalmological status of patients in group A was assessed at the stage of the planned preparation for renal replacement therapy, at 3 and 6 months after the initiation of dialysis therapy. Ophthalmological examination consisted of the use of traditional diagnostic techniques (measurements of the best corrected visual acuity (BCVA), biomicroscopy, gonioscopy, ophthalmoscopy) and special investigations, including the measurement of the macular light-sensitivity (MLS) by using a fundus Macular Integrity Assessment (MAIA) microperimetry (CenterVue Spa,

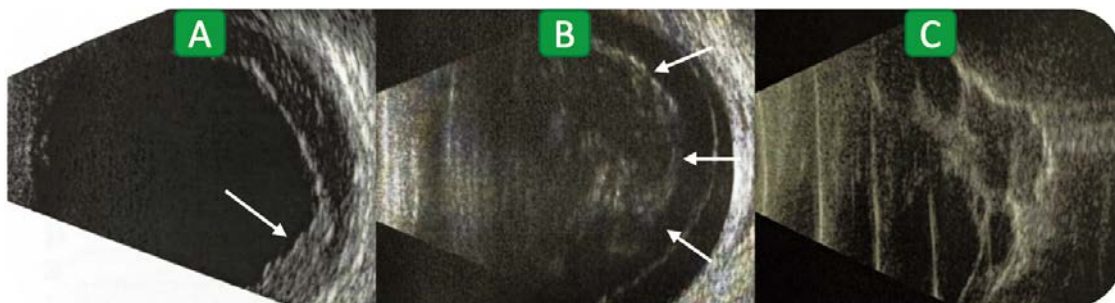
Italy), the fundus image acquisition by using a TRC-NW8 color fundus camera (Topcon, Japan), ultrasound examination using AVISO ultrasound system (Quantel Medical, France), the measurements of the central retinal thickness (CRT) and subfoveal choroid thickness, foveal avascular zone (FAZ) parameters and capillary perfusion density of the macular area in 4 vascular plexuses (superficial and deep retinal capillary plexuses [SRCP and DRCP], choriocapillaris [ChC] layer, and choroid deep layer [CD]) on the RS-3000 Advance 2 optical coherence tomograph (Nidek, Japan).

Statistical processing of the obtained results was performed using parametric and nonparametric criteria in the StatTech v.3.0.9 software and Microsoft Office Excel 2019.

## **Results**

According to ophthalmological findings available in patients, most of the patients from group A had DR before the ESRD development and had certain time to receive treatment for the disease (52 eyes, 86%) in the form of laser coagulation of the retina (14 eyes, 23%), intravitreal injection of an angiogenesis inhibitor (3 eyes, 5%), vitrectomy (3 eyes, 5%) or combination treatment (32 eyes, 53%).

The study of the hemodialysis effect on the morphological and functional status of 7 eyes of 7 patients from group A was impossible due to the existing gross proliferative changes in the vitreoretinal interface (extensive preretinal hemorrhages, subtotal and total hemophthalmos, traction retinal detachment) detected by ophthalmic echography (B-scan) (Fig. 1).



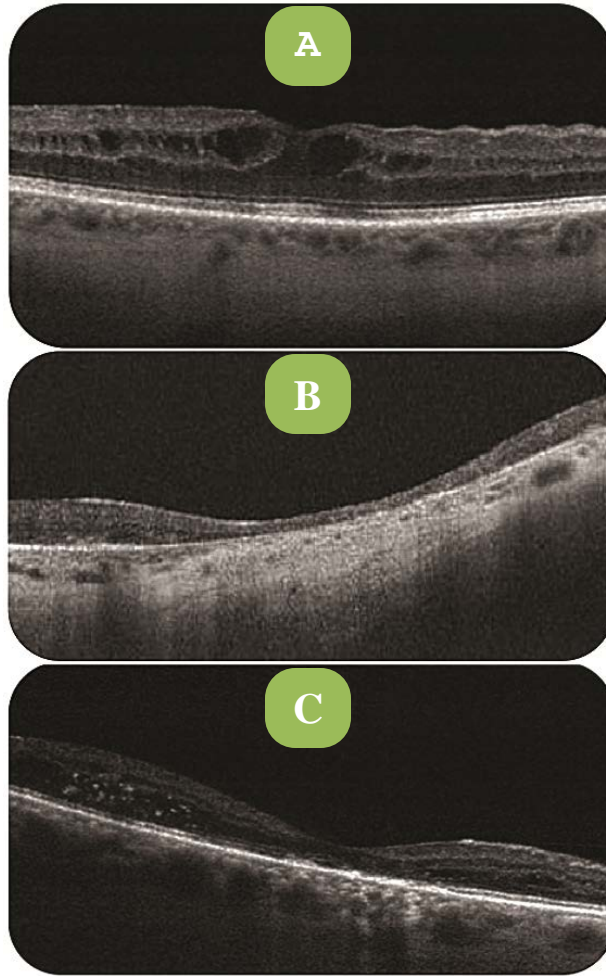
**Fig. 1. B-scan: A, preretinal hemorrhage; B, total hemophthalmos; C, old traction detachment with subatrophic deformity of the eyeball**

Patients with such ophthalmic abnormalities in the fundus were referred for consultation and possible further treatment to the Vitreoretinal Surgery Department.

The biomicrophthalmoscopy of 53 eyes in 30 patients available to this examination in group A, identified the signs of the proliferative stage of DR in the fundus in 69.8% of cases (37 eyes), the signs of preproliferative DR stage in 30.2 % (16 eyes) as per the World Health Organization classification [12].

In accordance with diabetic maculopathy classification by M.V. Gatsu and Ya.V. Bayborodov [13], OCT analysis in group A patients revealed the following forms of morphological and histological changes in the retina: signs of diabetic macular edema (DME) were present in 28.3% of cases (15 eyes), dry maculopathy in 3.8% (2 eyes), mixed maculopathy in 3.8% (2 eyes) (Fig. 2).

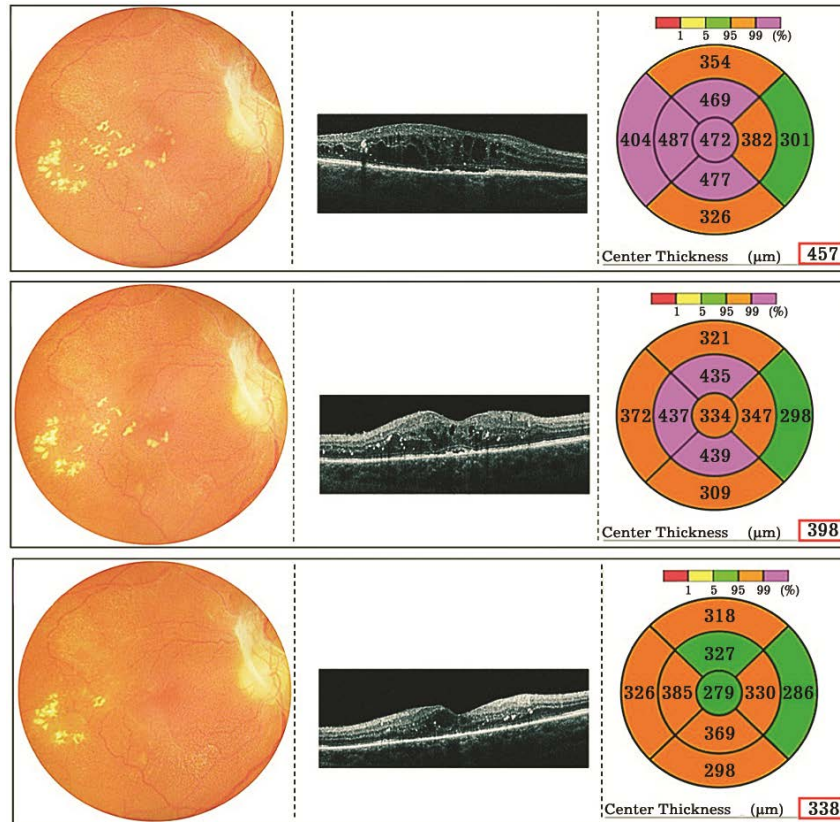




**Fig. 2. Linear optical coherence tomography scans of patients with diabetic maculopathy (DMP): A, wet form of DMP (diabetic macular edema); B, dry form of DMP; C, mixed form of DMP**

The CRT of patients with type 1 DM and ESRD was statistically significantly higher than that in the control group (Me: 348.5  $\mu\text{m}$  vs. 262.1  $\mu\text{m}$ ,  $p < 0.05$ ). Intragroup comparison of retinal thickness among patients of group A revealed the highest value of CRT in the eyes of patients with DME than in the eyes without macular edema (Me: 467.2  $\mu\text{m}$  vs. 328.5  $\mu\text{m}$ ,  $p < 0.05$ ). At 6 months of receiving MHD therapy, the retinal thickness decreased statistically significantly in all patients (Me: from 348.5  $\mu\text{m}$  to 306.1  $\mu\text{m}$ ,  $p < 0.05$ ). The most pronounced decrease in CRT was recorded in

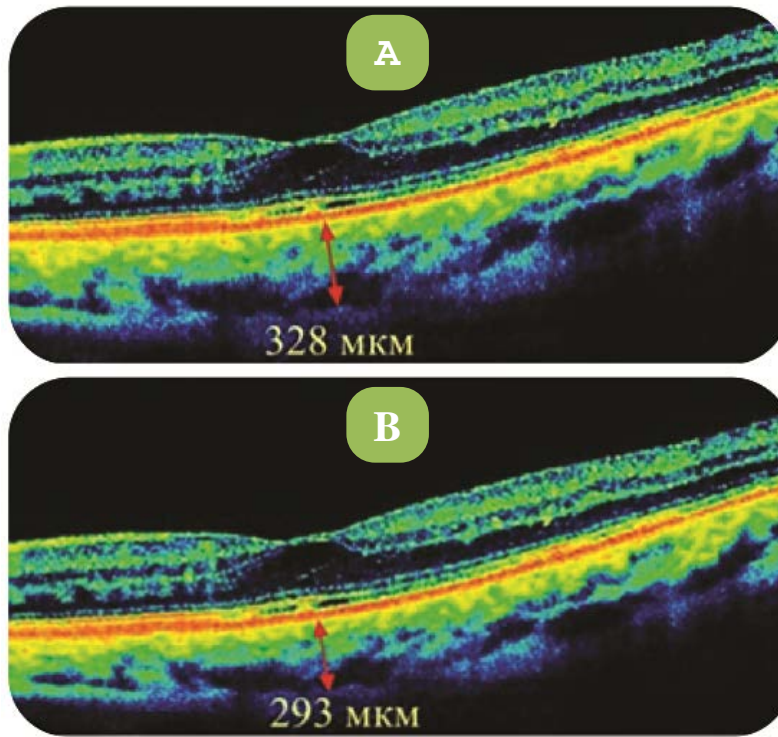
the eyes of patients with DME, whose retinal thickness had statistically significantly decreased as soon as by the 3rd month of treatment for ESRD (Me: up to 369.9  $\mu\text{m}$ ) and continued to decrease during half a year of renal replacement therapy (Me: up to 316.1  $\mu\text{m}$  at 6 months of MHD course) (Fig. 3).



**Fig. 3. Clinical example: results of examination of patient K. (36 years old) with type 1 diabetes mellitus and terminal diabetic nephropathy before the start of hemodialysis (A), at 3 (B) and 6 months (C) of renal replacement therapy (a, fundus photograph, c, linear optical coherence tomography scan of the macular area, c, retinal thickness)**

Subfoveal choroidal thickness in group A (Me: 330.3  $\mu\text{m}$ ) was larger than in group B (Me: 313.3  $\mu\text{m}$ ) ( $p < 0.05$ ). As compared to baseline pre-

dialysis values, choroidal thickness had statistically significantly decreased (Me: to 294.9  $\mu\text{m}$ ,  $p < 0.05$ ) by the 3rd month of treatment for ESRD and remained at the same level according to the results of the examination at month 6 of hemodialysis course (Me: 296.7  $\mu\text{m}$ ) (Fig. 4).



**Fig. 4. Clinical example: the thickness of the subfoveal choroid in patient V (38 years old) with type 1 diabetes mellitus and terminal diabetic nephropathy was 328  $\mu\text{m}$  (A) before the start of hemodialysis and 293  $\mu\text{m}$  during hemodialysis therapy (B)**

To assess the microvasculature of the macular area, 42 eyes of patients with type 1 DM and ESRD were selected, in which the architectonics of the retina and choroid were preserved and segmentation of the capillary plexuses could be traced. An intergroup comparison of retinal and choroidal perfusion showed the highest FAZ area values and the lowest perfusion density in

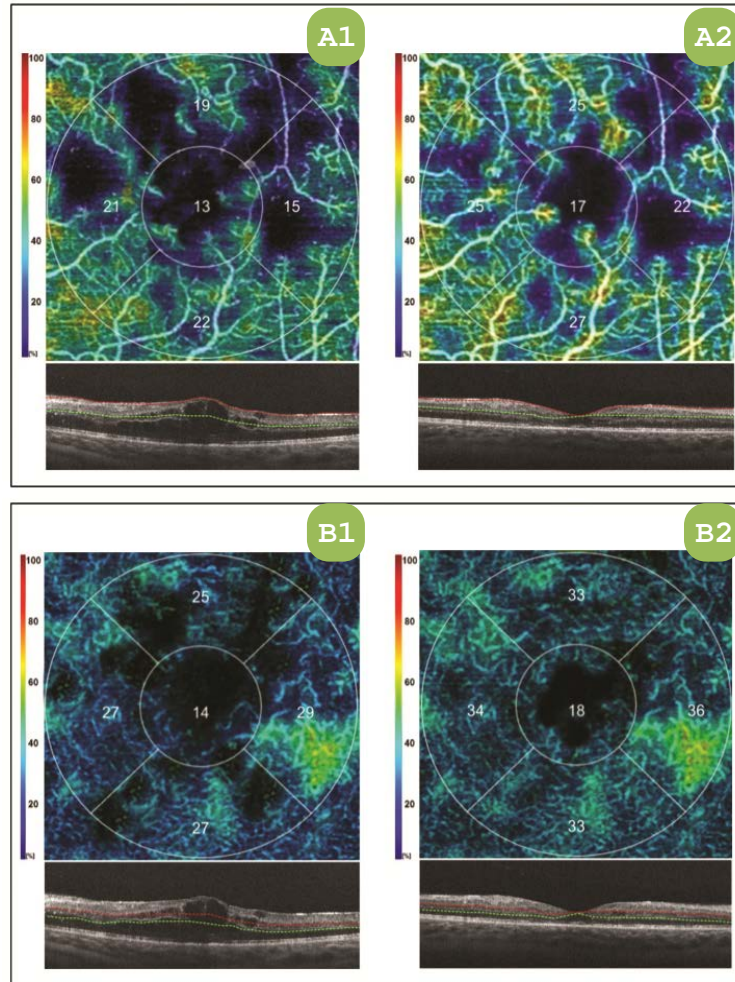
group A compared to group B (Me: FAZ being 0.42 mm<sup>2</sup> vs. 0.23 mm<sup>2</sup>, p<0.05; SRCP perfusion density making 15.7% vs. 27.3% in the fovea, 24.2% vs. 51.3% in the parafovea, p<0.05; DRCP perfusion density making 20.8% vs. 39.5% in the fovea, 33.9% vs. 61.4%, in the parafovea, p<0.05; ChC perfusion density making 59.0% vs. 65.4% in the fovea, 59.3% vs. 65.2%, in the parafovea, p <0.05; CDL perfusion density being 55.5% vs. 62.3% in the fovea, 55.3% vs. 62.3% in the parafovea, p<0.05).

The observed retinal perfusion in the eyes without DME was greater than in the eyes with macular edema. By the 3rd and 6th months of MHD, retinal perfusion had significantly improved in the eyes with DME, while it did not change statistically significantly in the eyes without DME (Table 2) (Fig. 5).

**Table 2. Dynamics of retinal perfusion in patients while on hemodialysis therapy**

Perfusion density, %	DME (15 eyes)			Without DME (27 eyes)		
	Before HD	3 mth of HD	6 mth of HD	Before HD	3 mth of HD	6 mth of HD
Superficial capillary plexus						
Fovea	10.6 [9.7;13.4]	13.7 <sup>#</sup> [11.8;15.7]	15.8 <sup>#</sup> [13.9;17.2]	17.4 [16.9;18.5]	17.5 [16.3;18.2]	17.5 [16.8;18.3]
Parafovea	19.7 [17.1;21.7]	21.8 <sup>#</sup> [19.6;23.7]	25.4 <sup>#</sup> [25.2;28.6]	28.0 [27.2;29.5]	28.0 [27.0;29.6]	28.2 [27.1;29.4]
Deep capillary plexus						
Fovea	15.4 [14.1;17.0]	18.7 <sup>#</sup> [16.3;20.4]	20.9 <sup>#</sup> [19.1;22.3]	24.0 [23.0;24.8]	24.3 [23.4;25.1]	24.6 [23.1;24.9]
Parafovea	27.5 [25.1;31.5]	30.6 <sup>#</sup> [29.1;34.4]	33.5 <sup>#</sup> [31.1;36.6]	36.3 [34.2;37.5]	36.5 [33.9;37.3]	36.8 [34.4;37.6]

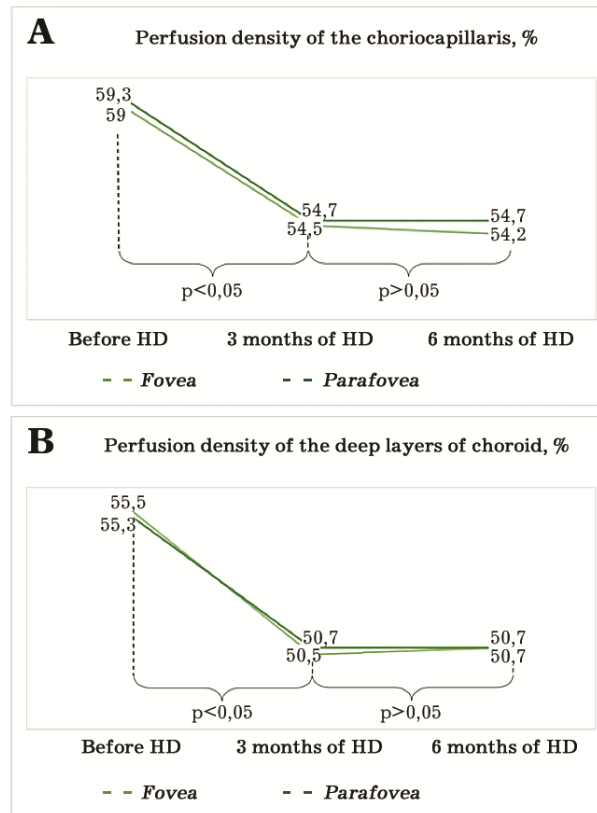
*Note:* perfusion values are given as median (Me) and lower/upper quartile [Q1;Q3]; # – statistically significant differences (p<0.05) compared with data before hemodialysis (HD).



**Fig. 5. Clinical example: the results of the perfusion density of the superficial capillary plexus of the retina (A1, before the start of hemodialysis, A2, while on hemodialysis therapy) and deep superficial capillary plexus of the retina (B1, before the start of hemodialysis, B2, while on hemodialysis therapy) in patient A. (40 years old) with type 1 diabetes and terminal diabetic nephropathy**

There was no difference in the ChC and CDL perfusion densities between the eyes with and without DME ( $p>0.05$ ). The choroidal perfusion density in patients of group A had statistically significantly decreased by the 3rd month of treatment for ESRD and remained at the same level according to the examination results at 6 months of MHD (Fig. 6).





Note: HD, hemodialysis

**Fig. 6. Dynamics of choroidal perfusion in patients while on hemodialysis therapy: choriocapillaries (A), deep layer of the choroid (B)**

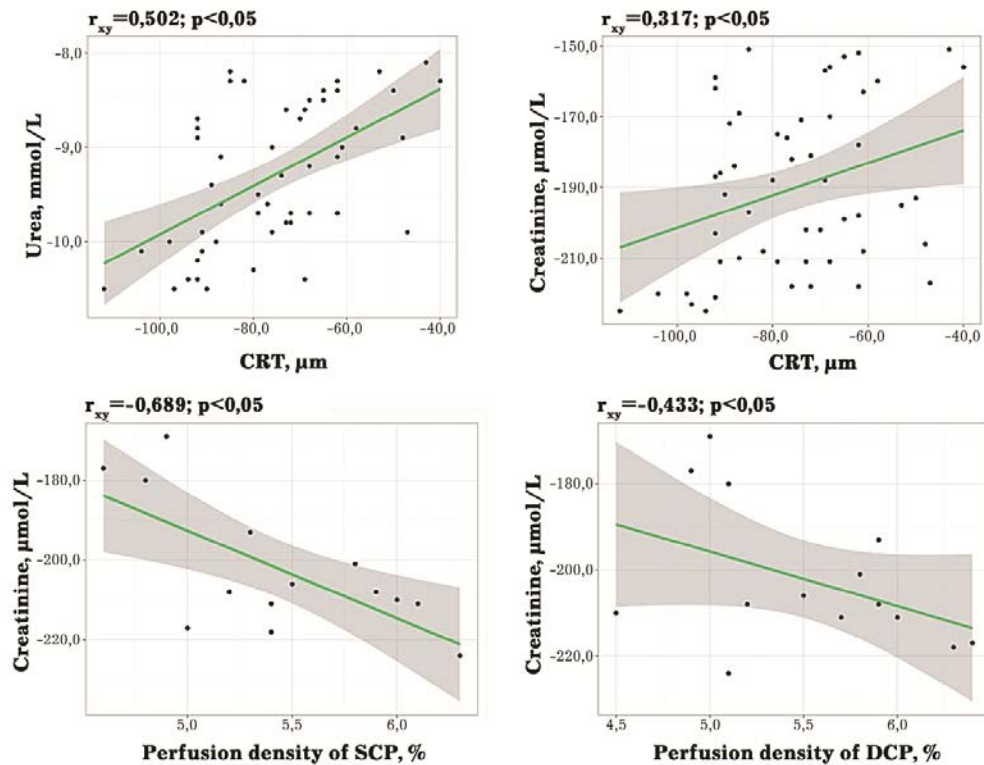
By the 6th month of dialysis therapy during the ongoing treatment for ESRD, there was an improvement in MLS among all patients of group A and an increase in BCVA in the eyes of patients with DME ( $p < 0.05$ ) (Table 3).

**Table 3. Dynamics of visual functions in patients on hemodialysis**

Parameter	Group A			
	DME (15 eyes)		Without DME (27 eyes)	
	Before HD	6 mth of HD	Before HD	6 mth of HD
BCVA	0.1 [0.05;0.3]	0.3 <sup>#</sup> [0.1;0.5]	0.5 [0.3;0.8]	0.6 [0.3;0.8]
MLS, dB	16.7 [13.8;19.3]	20.3 <sup>#</sup> [19.2;22.1]	21.1 [20.1;24.3]	24.2 <sup>#</sup> [22.4;25.9]

Note: the value of the best corrected visual acuity (BCVA) and macular light-sensitivity (MLS) are given as median (Me) and lower/upper quartile [Q1;Q3]; # – statistically significant differences ( $p < 0.05$ ) compared with data before hemodialysis (HD).

When comparing the systemic (urea, creatinine) and ophthalmological patients parameters that had changed during the treatment for ESRD, we revealed significant correlations: between the dynamics of the creatinine level and CRT ( $r_{xy}=0.317$ ;  $p<0.05$ ), urea and CRT ( $r_{xy}=0.502$ ;  $p<0.05$ ), creatinine and mean SRCP perfusion density ( $r_{xy}=-0.689$ ;  $p<0.05$ ), creatinine and mean DRCP perfusion density ( $r_{xy}=-0.433$ ;  $p<0.05$ ) (Fig. 7).



Note: DCP, deep capillary plexus; SCP, superficial capillary plexus; CRT, central retinal thickness

**Fig. 7. Correlations between dynamic changes in laboratory markers of diabetic nephropathy (urea, creatinine) and ophthalmological parameters (central retinal thickness, perfusion density of the superficial and deep retinal capillary plexus)**

## Discussion

It was previously reported that hemodialysis leads to a decrease in retinal thickness and an improvement in BCVA within 1–12 months of

therapy for ESRD [10, 11]. We have obtained the results that are consistent with the above. Thus, the thickness of the retina in our patients during 6 months of hemodialysis decreased from 348.5  $\mu\text{m}$  to 306.1  $\mu\text{m}$  ( $p<0.05$ ). The most pronounced decrease in CRT was noted in the eyes with DME, in which the positive effect of ESRD treatment was recorded on the 3rd month of hemodialysis (change in CRT Me: from 467.2  $\mu\text{m}$  to 369.9  $\mu\text{m}$ ,  $p<0.05$ ) and that effect increased over half a year of renal replacement therapy (on the 6th month of dialysis CRT was Me 316.1  $\mu\text{m}$ ). Against such a pronounced decrease in the retinal thickness, the patients with DME showed an improvement in BCVA (Me: from 0.1 to 0.3,  $p<0.05$ ). An improvement in visual functions was also recorded in investigating the MLS that increased statistically significantly among hemodialysis patients (the MLS dynamics in eyes with DME: Me from 16.7 dB to 20.3 dB; the MLS dynamics in eyes without DME: Me from 21.1 dB to 24.2 dB;  $p<0.05$ ).

Y.U. Shin et al. [9] reported a decrease in the choroid thickness and the ChC perfusion density. According to their results, the retinal perfusion density underwent no significant changes. We should note that the design of their study was to assess the ophthalmological parameters of patients with diabetic-originated renal failure and ESRD of other etiologies during a single session of hemodialysis. Their study did not include patients with DME. In our study, during 6 months of MHD, all patients showed a decrease in the choroidal thickness (Me: from 330.3  $\mu\text{m}$  to 296.7  $\mu\text{m}$ ,  $p<0.05$ ), a decrease in perfusion of both ChC (Me: from 59.0 to 54.2% in the fovea; from 59.3% to 54.7% in the parafovea;  $p<0.05$ ), and CDL (Me: from 55.5% to 50.7% in the fovea; from 55.3% to 50.7% in the parafovea;  $p<0.05$ ); there was no change in retinal perfusion among patients with DR without DME ( $p>0.05$ ), which is consistent with the results of the above mentioned



study. However, SRCP and DRCP perfusion increased in the eyes with DME (SRCP Me: from 10.6 to 15.8% in the fovea, from 19.7 to 25.4% in the parafovea; DRCP Me: from 15.4 to 20.9% in the fovea; from 27.5 to 33.5% in the parafovea;  $p < 0.05$ ).

Patients showed statistically significant correlations between changes in ophthalmic parameters (CRT, SRCP and DRCP perfusion densities) and changes in laboratory ESRD markers (urea, creatinine) during dialysis therapy.

The hematoretinal barrier has an autoregulatory function that maintains the fluid and electrolyte balance between the intravascular and intercellular retinal spaces [14]. In DR, in the presence of the inflammation triggered by cytokines, the blood-retinal barrier becomes damaged due to disrupted links between endotheliocytes, and due to the loss of pericytes, which in turn causes excessive accumulation of fluid in the retina intercellular space [15]. Unlike the retina, the choroid vessels have weak autoregulation and are mainly innervated by the autonomic nervous system [16].

Therefore, it can be assumed that a decrease in hyperazotemia during dialysis therapy leads to a decrease in the intercellular fluid in the retina, which is manifested in the decrease of retinal thickness. Reducing the retinal thickness in the eyes with DME leads to a secondary increase in capillary perfusion due to the elimination of vascular compression. A decrease in the thickness and perfusion of the choroid may be a manifestation of a reactive sympathetic vasoconstriction in response to the fluid loss by the body and, as a consequence, a decrease in arterial and perfusion pressure.

## **Conclusions**

1. Potential kidney and pancreas recipients with type 1 diabetes

mellitus and terminal diabetic nephropathy have pathological alterations in the ocular fundus, and low visual functions compared to similar patients without type 1 diabetes mellitus and renal function impairments.

2. Patients with diabetic retinopathy being on a long-term renal replacement therapy with hemodialysis display, along a decrease in hyperazotemia, improved retinal architectonics and hemodynamics and visual functions.

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*The article was received on March 6, 2023;  
approved after reviewing March 15, 2023;  
accepted for publication March 29, 2023*