

EVALUATION OF THE CLINICAL RESULTS OF IMPLANTATION OF THE HYDROPHOBIC INTRAOCULAR LENS CT LUCIA 601P

Stepanov A., Jirásková N., Rozsival P.

Department of Ophthalmology, University Hospital Hradec Králové
Head prof. MUDr. Pavel Rozsival, CSc., FEBO

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MUDr. A. Stepanov
Oční klinika
Fakultní nemocnice
Sokolská 581
500 05 Hradec Králové
e-mail: stepanov.doctor@gmail.com

SUMMARY

Purpose: To evaluate the properties and clinical outcomes after implantation the new hydrophobic intraocular lens CT LUCIA 601P in patients undergoing routine cataract surgery.

Material and Methods: The study included 38 patients (43 eyes), mean age 70 ± 8 years (range 56–91 years) with senile cataract. After phacoemulsification intraocular lens CT LUCIA 601P was implanted. Patients were evaluated at 4 months after surgery. We assessed uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), refraction, keratometry and the incidence of posterior capsule opacification (PCO – Posterior capsule opacification).

Results: Before surgery the mean UCVA was 0.3 ± 0.18 and four months after surgery was 0.7 ± 0.15 . The mean BCVA before surgery was 0.58 ± 0.21 and after surgery was 0.94 ± 0.08 . PCO value was 0.199 ± 0.05 , that means minimal incidence of PCO.

Conclusion: The new hydrophobic intraocular lens CT LUCIA 601P could be easily implanted and after surgery shows a high degree of biocompatibility in patients undergoing routine cataract surgery.

Key words: intraocular lens CT LUCIA 601P, posterior capsule opacification, OSCA

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INTRODUCTION

The single-piece monofocal intraocular aspherical lens C-Loop Haptic CT LUCIA 601P is produced from special hydrophobic acrylate, the surface of the lens is covered with heparin, which provides better resistance against the occurrence and development of posterior capsule opacification (4). The material is also resistant against glistening (6). The patented aspherical optics Zeiss compensates for the physiological ocular aberration and preserves the depth of acuity. Thanks to the construction of the haptic “C-loop” with special curvature, an optimal stable position in the sac is guaranteed, and contact with the iris tissue is also eliminated. In this paper we present the postoperative results of patients in whom this intraocular lens has been implanted.

COHORT AND METHOD

The study included 38 patients (43 eyes) with senile cataract, who were operated on at the Department of Ophthalmology in Hradec Králové during the period from June until October 2014. Informed consent was obtained from each patient. Table 1 summarises the information about the patients and the preoperative data. All patients were operated on by a single surgeon (P.R.), and the operation was performed using the same surgical technique: installation anaesthesia, corneal incision of a size of 2.2 mm, creation of lateral incisions, capsulorhexis with diameter of 5 mm, hydrosection, phacoemulsification of the nucleus, irrigation and aspiration of the cortex and implantation of an intraocular lens (IOL) CT LUCIA 601P into the lens capsule.

Preoperatively we examined the patients' uncorrected

visual acuity (UCVA) and best corrected visual acuity (BCVA) on Snellen's optotypes, and we measured the axial length of the eyeball. IOL Master Carl Zeiss Meditec AG was used for calculation of the optical density of the IOL, we examined the patients on a slit lamp.

Postoperatively the patients were examined 4 months after the operation. At this follow-up examination we determined refraction, UCVA, BCVA, we examined the incidence of posterior capsule opacification (PCO) on a slit lamp and took digital photographs of the posterior capsule of the lens in retroillumination. We performed our own evaluation of PCO using the OSCA software (Open-Access Systematic Capsule Assessment) (1). The PCO index was calculated for the entire area of the optical part of the lens. An excluding criterion was Nd:YAG laser capsulotomy breaching the posterior capsule of the lens and preventing evaluation by the OSCA method. The preoperative and postoperative data (refractive and keratometric) was saved in an Excel document. SPSS Windows software (version 18.0) was used for the statistical analysis. A Kolmogorov-Smirnov test for normality was performed, a pair t-test for comparison of the parameters between the preoperative and postoperative examinations, a P value of 0.05 or less was considered statistically significant.

RESULTS

38 patients were examined (43 eyes), of whom 27 were women and 11 men. The average age of the patients at the time of the operation was 71 ± 8 years (range 56 to 91 years). No complications were recorded either perioperatively or postoperatively. Table 2 summarises the preoperative and postoperative refraction data,

Table 1 Patients and preoperative data

Characteristic	Value
Patients (number)	38
Eyes (number)	43
Age (years)	70,63 ± 7,5
Average ± SD	56 až 91
Range	
Sex, number (%)	11 (29)
Men	27 (71)
Women	
Preoperative UCVA ± SD	0,3 ± 0,18
Range	0,01 až 0,8
Preoperative refraction sphere (D)	-0,1 ± 2,6
Average ± SD	-6,25 až +4,0
Range	
Preoperative refraction cylinder (D)	-1,02 ± 0,66
Average ± SD	0 až -3,5
Range	
Axial length of eye (mm)	23,12 ± 0,81
Average ± SD	22,25 až 24,68
Range	
Average IOL values (D) ± SD	21.5 ± 0.85
IOL = intraocular lens	
UCVA = uncorrected visual acuity	

UCVA, BCVA, spherical equivalent (SE) and incidence of posterior capsule opacification (PCO). Postoperative BCVA was 0.8 or better in 40 eyes (100%) and 1.0 or better in 19 eyes (44.19%). Refraction was evaluated preoperatively, in which the average spherical equivalent was within the range of -0.6 ± 2.5 D, range -6.75 to +3.5. Four months after surgery the average spherical equivalent was $+0.17 \pm 0.39$, range -0.875 to +1.0. The mean value of the PCO index for CT LUCIA 601P = 0.199 ± 0.05 (min. 0.07; max. 0.29), which indicates an entirely minimal incidence of PCO. Centration of the IOL in the capsule was correct in all eyes. Before surgery BCVA was 0.58 ± 0.21 , after surgery BCVA improved to 0.94 ± 0.08 . The patients did not state any subjective complaints with visual phenomena.

DISCUSSION

The material of intraocular lenses plays a large role in the occurrence of secondary cataract (3, 5, 7, 8). The single-piece lens CT LUCIA 601P(Y) is produced from special hydrophobic acrylate of ultra-high purity. The main advantages of hydrophobic IOLs include good mechanical stability and biocompatibility. The edge of the CT LUCIA 601P lens has a 360° “square-edge” design, the surface of the IOL is covered with heparin, which prevents the occurrence and development of posterior capsule opacification and provides better resistance

Table 2 Preoperative and postoperative visual acuity and refractive data.

Characteristic	Preoperative	4 months after operation	P value
Average UCVA (Decimal) ± SD	0,3 ± 0,18	0,7 ± 0,15	<,001*
Range	0,01 až 0,8	0,5 až 1,2	
Average BCVA (Decimal) ± SD	0,58 ± 0,21	0,94 ± 0,08	<,001*
Range	0,05 až 0,8	0,8 až 1,2	
Diameter of refraction sphere (D) ± SD	-0,1 ± 2,6	+0,45 ± 0,41	,763
Range	-6,25 až +4,0	-0,25 až +1,5	
Average SE (D) ± SD	-0,6 ± 2,58	+0,17 ± 0,39	,02*
Range	-6,75 až +3,5	-0,87 až +1,0	
Refraction cylinder (D)	-1,02 ± 0,66	-0,9 ± 0,59	,21
Average ± SD	0 až -3,5	0,0 až -2,75	
Incidence of posterior capsule opacification (PCO) ± SD	-	0,199 ± 0,05	-
Range		0,07 až 0,29	

UCVA = uncorrected visual acuity

BCVA = best corrected visual acuity

SE = spherical equivalent

PCO = Posterior Capsule Opacification

*P value signals significant difference on 5% level of significance

against glistening (2, 6). The Design of the haptic “C-loop” guarantees better stabilisation and fixation of the lens in the sac. In our cohort we also demonstrated its good stability in the capsule. The intraocular lens we observed has neutral asphericity, which eliminates the existing spherical aberration of the lens, compensates for physical ocular asymmetry (angle kappa), does not alter the physiological corneal aberration, and preserves the depth of acuity. No complications were observed in connection with the use of new intraocular lenses. A wide range of dioptries are available from +4.0 to +30.0D. The shape of the lens meets the most stringent demands: total size 13 mm, the optical part has a parameter of 6 mm, aspherical patent optics Zeiss, 360° square edge (fig. 1). There is also a variant of the lens with a “natural” yellow filter, which preserves maximum contrast sensitivity and provides maximum protection of the macula – CT LUCIA 601P (Y). A large advantage of the CT LUCIA 601P lens is its packaging, wherein the IOL is supplied with an injector into which the cartridge with the IOL is inserted, and the IOL is implanted into the capsule of the actual lens without any further manipulation and contact with the surface of the eye. The value of the PCO index for the CT LUCIA 601P four months after surgery is 0.199 ± 0.05 , which indicates entirely minimal incidence of PCO. In 2013 we evaluated the incidence of posterior capsule opacifications at our clinic in the case of the hydrophobic



Fig. 1 The intraocular lens CT LUCIA 601P(Y)

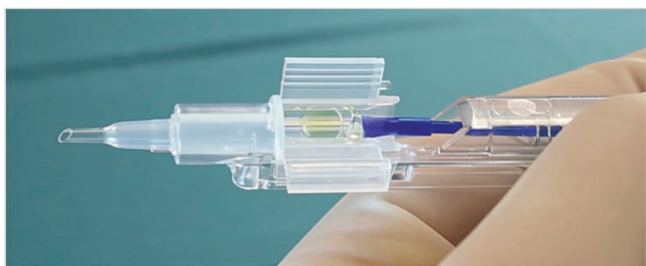


Fig. 2 The intraocular lens injector CT LUCIA 601P

-hydrophilic intraocular lens EriFlex 877 FAB, in which the PCO index three months after surgery was 0.15 ± 0.09 (7). The PCO index for the IOL CT LUCIA 601P is entirely comparable with the PCO index of IOLs produced from hydrophobic-hydrophilic material, and shows minimal values within a short postoperative period.

This study is the first study in the Czech Republic to describe the results of short-term evaluation following the application of the hydrophobic intraocular lenses CT LUCIA 601P in a group of patients undergoing routine cataract surgery.

CONCLUSION

The intraocular lens CT LUCIA 601P is easily implanted, and after surgery shows a high degree of biocompatibility in patients undergoing routine cataract surgery. On the basis of our experiences it is possible to state that the intraocular lens CT LUCIA 601P from the Zeiss company demonstrates good and stable postoperative results.

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TREATMENT OF MACULAR OEDEMA DUE TO RETINAL VEIN OCCLUSION WITH OZURDEX

Studnička J.¹, Dusová J.¹, Skoupá J.², Řehák J.³

¹Department of Ophthalmology, University Hospital and Charles University Faculty of Medicine, Hradec Králové

²PHARMA PROJECTS s.r.o. (Ltd.), Brno

³Department of Ophthalmology, University Hospital and Palacký University Faculty of Medicine, Olomouc

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Doc. MUDr. Jan Studnička, Ph.D.

Oční klinika FN a LF UK

Sokolská 581

500 05 Hradec Králové

e-mail: jan.studnicka@fnhk.cz

SUMMARY

Macular edema due to retinal vein occlusion is the second most common cause of vascular vision impairment. The authors refer two case reports that describe different response to treatment with OZURDEX, biodegradable injectable implant slowly releasing 700 µg dexamethasone. Treatment with corticosteroids is effective also in the case of cystic retinal edema, but its effect can be temporary. The most common adverse events are elevation of intraocular pressure and cataract development.

Key words: dexamethasone, macular edema, retinal vein occlusion, OZURDEX

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INTRODUCTION

After diabetic retinopathy, retinal vein occlusion is the second most common vascular pathology of the retina (5). Whereas branch retinal vein occlusion has an overall good prognosis, in the case of affliction of the main trunk the situation is far worse. In recent years we have had relatively powerful therapeutic tools available in the form of anti-VEGF substances and the depot preparation dexamethasone (OZURDEX®, Allergan Inc., Irvine, USA). Clinical practice has demonstrated that the use of these preparations significantly improves the patient's prospects of obtaining satisfactory resulting visual acuity (VA). Nevertheless, it has been demonstrated that the use of these substances in monotherapy is frequently not sufficient. In the BRAVO study (Ranibizumab for the Treatment of Macular Oedema following Branch Retinal Vein Occlusion Study: Evaluation of Efficacy and Safety), 31% of patients required salvage laser therapy (2). In the CRUISE study (Ranibizumab for the Treatment of Macular Oedema after Central Retinal Vein Occlusion Study: Evaluation of Efficacy and Safety) there was an improvement of VA by at least 3 rows (15 letters) from the beginning of the study up to the 6th month in 46–48% of eyes in comparison with the sham group – in 17% (1). The average gain was 14.9 letters, and the improvement of VA was maintained also in the extension – HORIZON study. However, there was a certain loss of letters in the second year, probably in connection with less frequent follow-up examinations. It is also stated that in the second year also a significant percentage of eyes remain with chronic macular oedema (ME), which requires treatment and whose prognosis is uncertain. Where resorption of ME took place the VA result was excellent, whereas the persistence of ME was connected with worse final VA (7). The GENEVA study evaluated the effectiveness and safety of the OZURDEX preparation (0.7 mg dexamethasone in biodegradable depot form) applied by injection into the vitreous area in 421 patients with retinal vein occlusion. However, the study does not

differentiate between the branch and main trunk of the central retinal vein, which with regard to the different prognoses for sight in the case of the two pathologies could have influenced the results (6). A promising alternative appears to be repeated injection of this drug.

CASE REPORT

The first case report relates to a 64 year old man with deterioration of sight in the right eye (RE) persisting for one month, who was first examined at the Department of Ophthalmology at the University Hospital in Hradec Králové in September 2012. It ensued from the patient's personal anamnesis that he had been treated since 2010 for type 2 DM by peroral antidiabetics and diet. For a number of years he had been treated for arterial hypertension. In 2008 he underwent cataract surgery in both eyes.

Upon the initial examination, best corrected visual acuity (BCVA) was determined at RE 20/25 and left eye (LE) 20/16. Intraocular pressure in both eyes was within the norm. On a colour digital photograph of the fundus of the RE retinal haemorrhages were visible in the area of the upper temporal branch of the central retinal vein, which was dilated and tortuous. Two cotton-wool spots were also visible along the vein, and incipient oedema in the macula (fig. 1). Pronounced arteriovenous crossing was evident on the retina of the LE, with compression on the venous branch of the upper temporal branch of the central retinal vein, and accompanying haemorrhage into the retina, without affliction of the macula. The performed fluorescence angiography showed a blockade of fluorescence by retinal haemorrhage and progressively grading hyperfluorescence of macular oedema in the RE (fig. 2). On the basis of the performed examinations, the finding was concluded as closure of the upper temporal branch of the central retinal vein in both eyes, in the RE complicated by swelling of the macula.

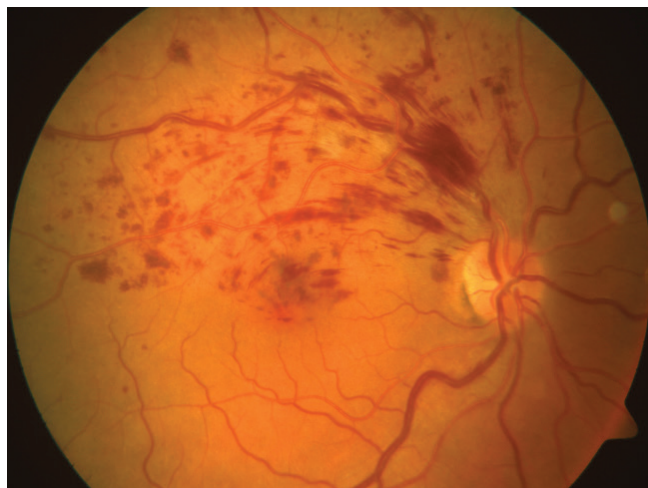


Fig. 1 Signs of occlusion of the upper temporal branch of the central retinal vein of the RE at the beginning of the pathology

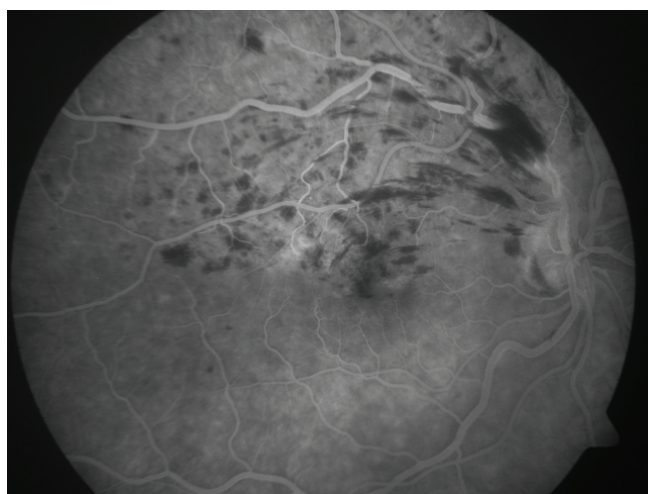


Fig. 2 Incipient macular oedema upon occlusion of the upper temporal branch of the central retinal vein of the RE demonstrable on FAG

With regard to the presence of risk factors, it was recommended to add an examination of the overall internal condition and compensation of DM, blood pressure and levels of cholesterol and triacylglycerol in the blood. The patient was indicated for the performance of laser barrage of the central region and upper temporal quadrant of the retina in the right eye. Vessel Due F (sulodexide) in tablet form was applied generally.

In April 2013 the patient came for an examination due to deterioration of vision in the RE and metamorphopsia persisting for three months. The patient had not reported for laser treatment of the retina of the RE, which had been indicated in September the previous year. The conducted internal examination concluded unstable arterial hypertension with blood pressure value of 150/90 mmHg. Upon a basic eye examination, BCVA was determined at RE 20/160, LE 20/20. The patient could not read Jaeger tables close up with the right eye, with the left eye he read J. no. 1 with + 2.0 sf. The finding on the retina of the RE showed pronouncedly worse closure of the upper temporal branch of the central retinal vein with massive intraretinal and preretinal haemorrhage, swelling of the macula and further development of retinal

ischemia (fig. 3). On optical coherence tomography (OCT) microcysts and macrocysts of the neuroretina were evident, with thickening of the neuroretina mainly in the upper part of the central retinal region (fig. 4). In the left eye the finding in the left eye was rectified, whilst pronounced atherosclerotic vascular changes persisted. With regard to the progression of the finding and deterioration of BCVA in RE, intravitreal application of OZURDEX was indicated. Before this laser treatment of the centre of the retina in the RE was performed. The general therapy was changed, Vessel Due F tablet was discontinued and therapy with Anopyrin (acetylsalicylic acid) 100 mg tablet and Ascorutin (ascorbic acid, rutoside trihydrate) tablet was recommended.

Three months after application of OZURDEX intravitreally in the right eye, the patient reported improvement of vision in the RE and regression of metamorphopsia. BCVA in the RE improved to 20/80, close up J no. 11 with + 3.0 sf. In the left eye vision remained within the norm. On the retina of the right eye retinal haemorrhage was absorbed, the vascular wall of the afflicted vein showed signs of fibrous reconstruction, the greater part of the retinal oedema was absorbed, cotton-wool spots remained as a manifestation of retinal ischemia, with lines of hard exudates in the lower part of the macula. We documented an improvement also upon performed OCT with a regression of the cyst of the neuroretina from the macula and a reduction of CRT. In the upper temporal quadrant of the retina we performed laser treatment of the retina afflicted by ischemia, and also added grid coagulation of the centre of the retina in areas of residual swelling of the retina, which was evident on the performed OCT. Ten months after the application of OZURDEX, YAG capsulotomy of the posterior capsule of the lens was performed due to a newly formed secondary cataract.

One year after application, in June 2014, the patient is without metamorphopsia, vision in the RE continued to improve after the laser procedure. BCVA in the RE is 20/50, close up the patient sees J. no. 8 with + 3.5 sf. In the left eye visual acuity remains within the norm. Intraocular pressure of both eyes is normal. Retinal haemorrhage and hard exudates on



Fig. 3 Progression of finding on the retina of the RE with extensive intraretinal and preretinal haemorrhage

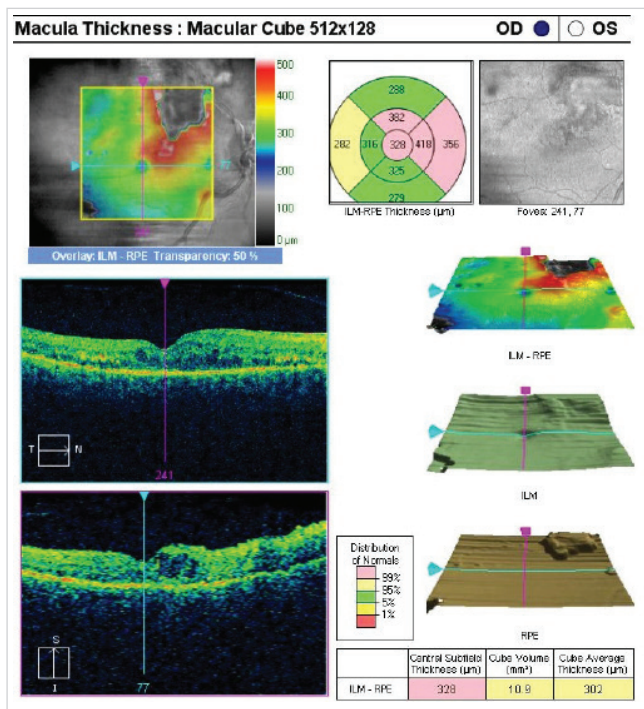


Fig. 4 Macular oedema and upper half of central retinal region of RE demonstrable on OCT (Cirrus, Zeiss)

the retina of the RE have been entirely absorbed. Cotton-wool spots and retinal oedema are no longer perceptible. In the macula there has been a reactive pigment shift, fine laser traces are visible in the central region, and in the upper temporal quadrant of the retina. The venous wall of the upper temporal branch of the central retinal vein manifests signs of fibrous reconstruction, partial atrophy of the disc of the optic nerve is evident (fig. 5). On OCT complete disappearance of macular swelling is perceptible, as well as formation of foveal depression and slight atrophy of the neuroretina (fig. 6).

In the second case report we refer to a 69 year old female patient, who reported to the Department of Ophthalmology at



Fig. 5 Improvement of finding on retina of RE one year after combined therapy with OZURDEX and laser treatment of the retina

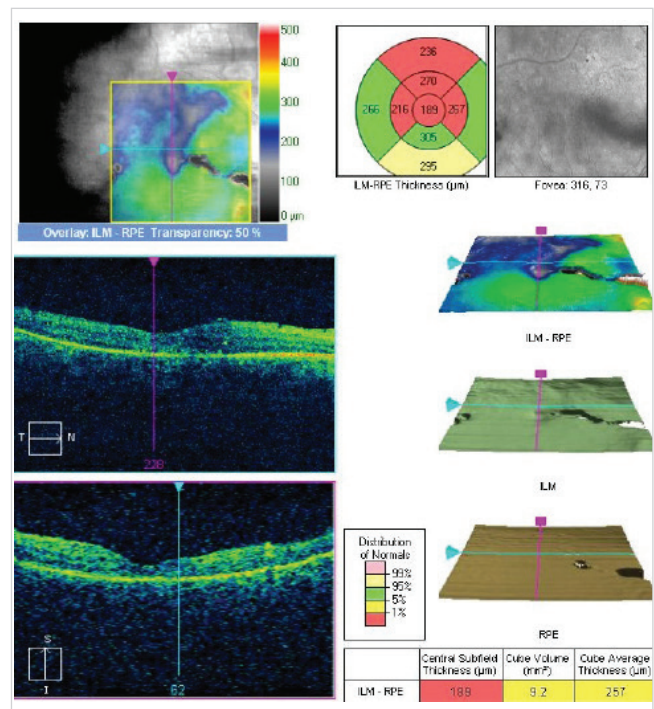


Fig. 6 Disappearance of welling of central region following combined therapy with OZURDEX and laser treatment of the retina. Subsequent thinning of the neuroretina in the place of affliction of the retina demonstrable on OCT (Cirrus, Zeiss)

the University Hospital in Hradec Králové with deterioration of vision in the left eye persisting for one month. At an examination conducted in February 2014, BCVA was determined at RE 20/16, LE 20/25. The finding in the anterior segment of the eye was within the norm, as was intraocular tension in both eyes. Upon examination of the posterior segment of the eye, signs of occlusion of the lower temporal branch of the central retinal vein were determined, complicated by macular oedema. In the area of the lower temporal branch of the retinal vein there are numerous intraretinal haemorrhages, in the surrounding area

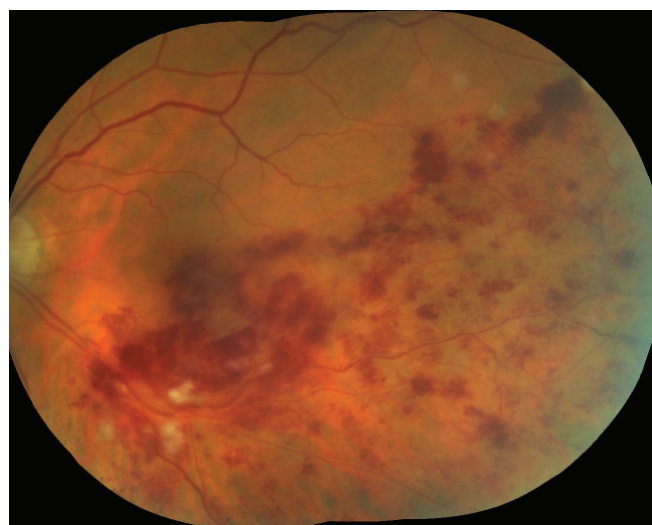


Fig. 7 Image of ischemic occlusion of lower temporal branch of central retinal vein in LE

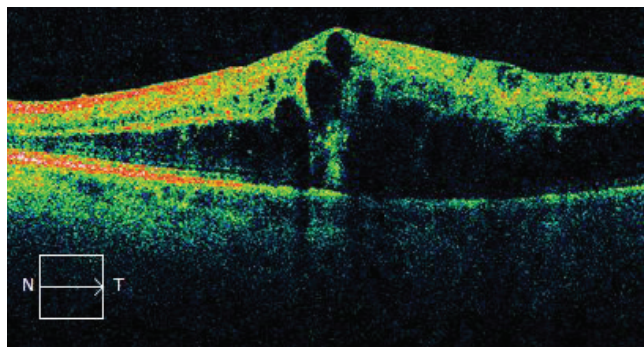


Fig. 8 Macrocystic swelling of macula demonstrable on OCT (Cirrus, Zeiss)

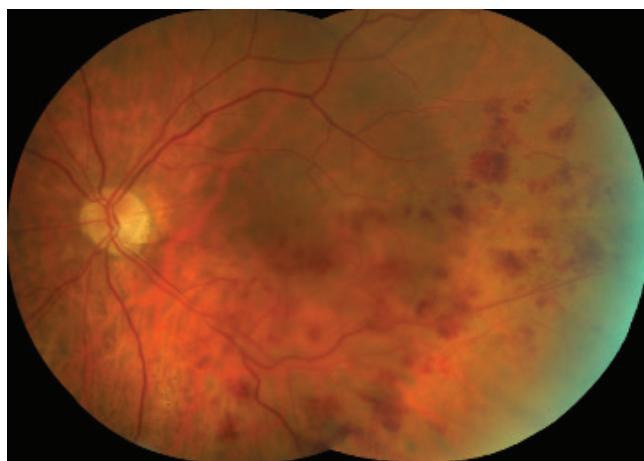


Fig. 9 Regression of swelling and haemorrhages of retina in lower temporal quadrant of retina of LE following repeated therapy with OZURDEX

of the closure of the venous branch in the area of arteriovenous crossing there are a number of cotton-wool spots, the venous branches in the place of closure are dilated and undulating (fig. 7). On OCT there is an image of macrocystic diffuse macular oedema with CRT 615 μm (fig. 8). The patient was treated generally for hyperlipoproteinemia, her BMI was 31.2. Since 2004 she had been treated for arterial hypertension, and takes a dual combination of antihypertensive drugs. After determination of the diagnosis, laser barrage of the lower part of the central region of the retina and lower temporal quadrant of the retina of the LE was performed.

At a follow-up examination in March 2014, despite a reduction of CRT to 515 μm , a further deterioration of VA in LE to 20/100 was determined, and the patient was indicated for application of OZURDEX. In April 2014, one month after application, BCVA had improved to 20/63, CRT was reduced to 344 μm . In July 2014, four months after the first application, BCVA remained at 20/63, but CRT had increased to 593 μm . On the retina persistent intraretinal haemorrhages are perceptible, as well as swelling in the macula. With regard to the deterioration of macular oedema, a second application of OZURDEX was performed into the left eye. In September 2014, two months after the second application, BCVA in the LE had again improved to 20/32, with a reduction of CRT to 417 μm , however, after the elapse of another two months macular oedema again

worsened, CRT increased to 480 μm and BCVA deteriorated to 20/50. On the retina intraretinal haemorrhages decreased, but macular oedema persisted, and hard exudates appeared in the upper half of the macula (fig. 9). With regard to the indication limitation of payment we were unable to continue with therapy, and the patient was indicated for therapy with ranibizumab (Lucentis, Novartis AG) (8). Throughout the entire duration of treatment with OZURDEX, intraocular pressure was within the norm, and the intraocular lens remained clear.

DISCUSSION

The closure of the upper branch of the central retinal vein in our first case report afflicted a man with typical risk comorbidities – diabetes, high blood pressure and atherosclerotic affliction of the retinal blood vessels. With regard to the poor compensation of these internal pathologies and poor co-operation of the patient within the framework of the therapeutic process, there was a worsening of the clinical finding before the commencement of intravitreal therapy with corticosteroids and laser treatment. Also in the case of the second case report, the patient had typical risk symptoms – hyperlipoproteinemia, obesity and arterial hypertension.

The performance of laser treatment in the case of branch occlusion of the central retinal vein complicated by macular oedema is purposeful for two fundamental reasons. Laser treatment of macular oedema is effective, as demonstrated by the Branch Vein Occlusion Study Group (BVOS), and laser treatment of the ischemic part of the retina causes a reduction of expression of growth and angiogenic factors (e.g. vascular endothelial growth factor (VEGF)), which reduces their effect on the occurrence and growth of neovascularisations of the retina or iris, thereby also reducing the risk of incidence of neovascular glaucoma (11, 12). However, the performance of laser treatment may be difficult and contentious for pronounced retinal haemorrhage. With regard to the indication limitation of payment for therapy with OZURDEX, it is nevertheless necessary to at least attempt laser treatment (8). Treatment of macular oedema in the case of branch occlusion of the central retinal vein with OZURDEX is effective, as demonstrated by the GENEVA study (6). In contrast with laser treatment, this therapy can be used also in the case of extensive retinal haemorrhage. Another intravitreal drug paid for by the health insurance company which can be used in the treatment of macular oedema upon closure of the branch of the central retinal vein is Lucentis (1, 2). However, treatment with OZURDEX does not require regular monthly follow-up examinations, which cannot be expected in all patients treated with Lucentis. As a result, OZURDEX is more suitable for patients with worse availability of treatment. In the GENEVA study, a higher frequency of occurrence and development of cataract was demonstrated (6). In our case also we determined the occurrence of a secondary cataract in the first patient, although this was simple to solve by means of capsulotomy using a YAG laser. We did not observe the development of a cataract in the second case. Absorption of oedema following the application of OZURDEX was demonstrable on OCT already within the

first three months of treatment, similarly as in the GENEVA study (6). In the case of the first case study, it was not necessary to add a further application of OZURDEX in the first year, although this was required in the second case. In the literature there is a number of studies describing the results in patients with repeated application (3, 4, 9, 10). In all cases this concerns retrospective analyses of patient databases. The characteristics of patients thus corresponds to regular clinical practice. Repeated application demonstrated that the efficacy of the preparation OZURDEX was maintained also upon more than two applications. In our case we were unable to continue with therapy with regard to the limitation on the number of re-applications due to the indication limitation of payment. A frequent documented adverse effect is an increase in intraocular pressure, however we did not record this in either of our case reports.

CONCLUSION

Treatment of macular oedema due to branch occlusion of the central retinal vein using the intravitreal application OZURDEX is effective, and in certain cases requires only one application of the therapeutic substance. Its application

is more suitable for patients with chronic macular oedema and arterphakia. Its use is also more advantageous for patients who are not able to visit an application centre regularly within shorter time intervals. However, it requires regular monitoring of intraocular pressure and the intraocular lens, and also the posterior capsule of the lens in the case of arterphakia. With regard to the temporary effect of corticosteroids on macular oedema, it can be favourably combined with laser treatment of the retina. Indication of OZURDEX is bound to application centres, and its payment from health insurance is limited by the fulfilment of the indication limitations of payment. At present payment of only two applications of OZURDEX is approved in the Czech Republic, which limits its repeated indication, despite the fact that its efficacy has been demonstrated also upon repeated use. With regard to the temporary effect of corticosteroids, it is necessary to ensure regular follow-up examinations upon their use. The most beneficial possibility of determining structural changes of the retina upon treatment with OZURDEX is OCT with the option of measuring CRT. In combination with examination of VA on ETDRS optotypes, it is possible to determine precisely the response to treatment, and if applicable the necessity of further re-application.

LITERATURE

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