# Stereotactic Radiosurgery Outcomes in Uveal Melanoma Patients: A 3-year Retrospective Study

**Sklenka Jozef[1,2], Horňáčková Pavla[1,2], Vysloužilová Daniela[1,2], Matušková Veronika[1,2], Němčanský Jan[3], Uhmannová Radoslava[1], Goutaib Moussa[1], Chrapek Oldřich[1,2]**

[1]Eye Clinic, University Hospital, Brno, Czech Republic
[2]Department of Ophthalmology, Faculty of Medicine, Masaryk University Brno, Czech Republic
[3]Department of Ophthalmology, University Hospital Ostrava, Czech Republic

MUDr. Jozef Sklenka

*Correspondence address:*
Oční klinika LF MU a FN Brno
Jihlavská 20
62500 Brno
Czech Republic
E-mail: sklenka.jozef@fnbrno.cz

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## SUMMARY

**Aim:** To evaluate the three-year survival rate, local tumor control rate and complications of stereotactic radiosurgery in patients with uveal melanoma and compare the outcomes with the available literature.

**Material and Methods:** In this study, data were evaluated from 122 patients treated for uveal melanoma, of whom 33 met the inclusion criteria for retrospective analysis of stereotactic radiosurgery outcomes using the CyberKnife system. These patients received radiotherapy for uveal melanoma during the period of 2016–2021. The data were collected during regular follow-up visits consisting of best-corrected visual acuity assessment, slit-lamp examination, indirect ophthalmoscopy, intraocular pressure measurement and ultrasound measurement of tumor prominence. As part of the metastases screening, abdominal ultrasound, chest X-ray, and magnetic resonance imaging (MRI) of the brain and orbits were performed regularly, with additional positron emission tomography (PET) combined with MRI performed as required.

**Results:** In our cohort, the three-year eye preservation rate was 72.7%, while the three-year local tumor control reached the level of 75.8%. The three-year survival was 81.8%. Overall, metastases were detected in 30.3% of patients with the liver being affected in 44% of cases, the bones in 28%, and the lungs in 17%. The most common ocular complications of radiotherapy included cataracts (58.3% of phakic patients), neovascular glaucoma (39.4%), radiation maculopathy (27.3%) and radiation retinopathy (18.2%).

**Conclusion:** Stereotactic radiosurgery is a safe treatment method for uveal melanoma with the potential for eye preservation. However, it carries the risk of tumor recurrence and ocular complications. Three-year survival and the incidence of ocular complications in our study were consistent with the data reported in the literature. By contrast, three-year local tumor control reached lower values compared to the relevant studies. Some results may be limited due to the small number of subjects in our cohort.

**Key words:** radiosurgery, CyberKnife, uveal melanoma, radiation retinopathy, neovascular glaucoma

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## INTRODUCTION

Uveal melanoma is the most common intraocular tumorous pathology in the adult population. With reference to its pronounced tendency towards the formation of metastases by a hematogenous route and an unfavorable prognosis of the disseminated pathology, the choice of an adequate therapeutic procedure has important consequences not only for the function of the affected eye, but especially for the patient's overall condition. In the last 30 years, large multicentric studies on patients with uveal melanoma treated by radiotherapy have produced results of equal value in terms of overall survival and survival without metastases in comparison with enucleation. These results have therefore provided solid arguments for the implementation of radiotherapy in therapeutic procedures for this pathology [1,2]. The use of radiotherapy is possible by the method of brachytherapy, in which a radioactive source is applied locally, directly to the wall of the eyeball, or by the method of teleradiotherapy, in which the source of radiation is placed at a distance from the patient. Brachytherapy can be used on melanomas with a prominence of up to 7–10 mm, depending on the used ruthenium or iodine applicator. When indicating brachytherapy it is necessary also to take into account the width of the base and the position of the tumor. Tumors with a higher prominence are indicated for irradiation using the method of teleradiotherapy. In the Czech Republic the most widely used teleradiotherapy techniques are Leksell gamma knife (LGN) and CyberKnife [3]. These techniques enable precise and relatively noninvasive irradiation of the tumor with the possibility of anatomical and to a certain extent also functional preservation of the affected eyeball. However, their use entails several serious complications.

The CyberKnife method works on the principle of a linear accelerator producing 6 MV photons, placed on a robotic arm with a scope of movement of 358 degrees around the patient bed with the possibility of movement in six directions. This arrangement, in combination with the system of monitoring the patient's movements in real time by means of two X-ray detectors and a Synchrony system, enables irradiation of both intracranial and extracranial pathological lesions with an accuracy of 0.5 mm [4]. For precise radiotherapy of uveal melanoma, retrobulbar anesthesia is used for preventing movement of the eye, or a flashing fixation point is placed in front of the healthy eye and a camera recording eye movement placed in front of the irradiated eye. Figure 1 illustrates the radiotherapy plan of a patient with uveal melanoma. Radiotherapy using the CyberKnife system may take place as radiosurgery in a single session or as fractionated radiotherapy arranged in multiple sessions [3]. The first prototype of the system was designed by the team of Professor John Adler of Stanford University in 1994. In the Czech Republic therapy, using the CyberKnife instrument has been available since 2010 at the University Hospital in Ostrava, and since 2021 at the Military University Hospital in Prague. Studies incorporating large numbers of observed patients have recorded successful local tumor control in 71–95% of cases. The eye preservation rate in these studies is stated at 73–97% [5,6].

Radiotherapy of uveal melanoma using the CyberKnife system provides the option of a minimally invasive therapeutic solution for patients with advanced findings, for whom brachytherapy is not indicated. After receiving a sufficient dose of radiotherapy the melanoma tissues succumb to a degradation of cellular organelles, infiltration and liquidation by immune cells, occlusion of tumor blood vessels and subsequently fibrotic changes [7]. Despite substantial advances in the precision of targeting radiotherapy, this process always also affects the surrounding healthy tissue, which results in the occurrence of complications of radiotherapy.

The objective of this study was to analyze the results of stereotactic radiosurgery (SR) in our patients by evaluating the three-year survival rate, local tumor control rate, incidence of ocular complications and the development of best corrected visual acuity (BCVA).

## MATERIAL AND METHOD

In the study we retrospectively analyzed data of patients observed with a diagnosis of choroidal melanoma at the University Hospital Brno, who underwent treatment using the CyberKnife system in the period from 2016 to 2021. The cohort was reduced by the patients who did not adhere to the stipulated observation intervals or who were observed at another center. In total the study included 33 patients, with a minimum period of 36 months from radiotherapy treatment.

The diagnosis of uveal melanoma was determined by means of an examination on a slit lamp, indirect ophthalmosco-

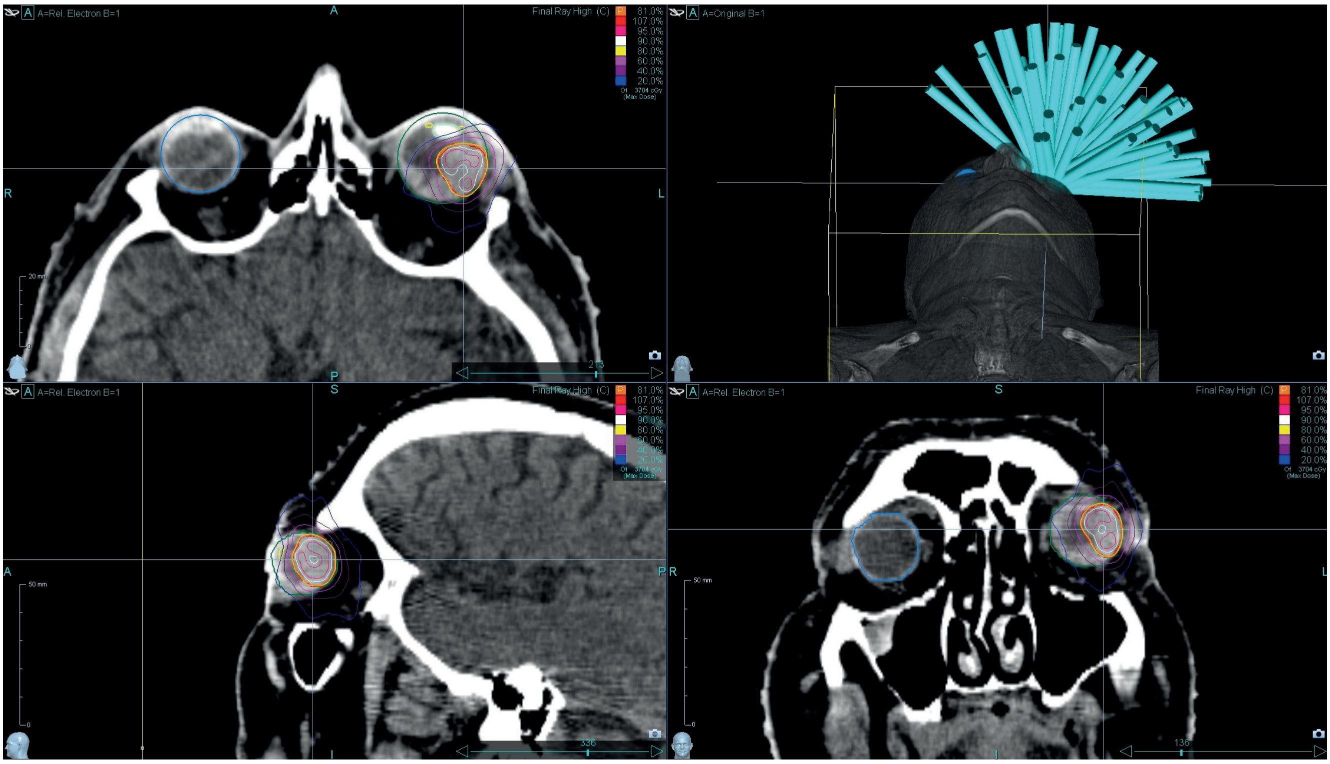



**Figure 1.** Stereotactic magnetic resonance image showing the treatment plan for CyberKnife (Used with permission of Oncology clinic, University Hospital Ostrava)

py, fluorescein angiography (FAG) and ultrasound (US) B-scan and A-scan (Figure 2). At the initial examination, all patients underwent screening in hospitalization with abdominal US, chest X-ray, and magnetic resonance imaging (MRI) of the brain and orbits. The patients were indicated for SR treatment upon a tumor height of more than 4–6 mm or width of the base of more than 16 mm. Other criteria considered when deciding between an indication of brachytherapy and SR included the distance of the tumor from the optic nerve, distance from the limbus and the patient's ability to manage the possibility of an isolation regimen in connection with brachytherapy. SR was contraindicated in the case of extrabulbar spread, neovascular glaucoma, or metastatic spread.

SR was performed at the Oncology Clinic of the Ostrava University Hospital using the CyberKnife® system (from the manufacturer Accuray Incorporated, Sunnyvale, CA, USA). All the patients were treated in a single session with a dose of 30–40 Gy. A combination of thermoplastic mask with retrobulbar anesthesia of the eyeball was used for fixation.

Follow-up examinations took place at the Clinic of Eye Treatments at the University Hospital Brno, as a rule three, six and twelve months after radiotherapy treatment, and subsequently every six months or according to the need for screening examinations. Within the follow-up examinations patients underwent regular examination of BCVA on a Snellen chart, examination of the anterior segment on a slit lamp, indirect ophthalmoscopy, measurement of intraocular pressure and ultrasound measurement of the dimensions of the tumor. Increase of the prominence of the tumor according to US at two consecutive follow-up measurements was evaluated as progression of the tumor. When evaluating progression, attention was paid also to change of shape of the tumor after a period of stability or change of reflectivity of the tumor. Within regular screening the patients also underwent abdominal US, chest X-ray, and magnetic resonance imaging (MRI) of the brain and orbits. In case of necessity, additional positron emission tomography and magnetic resonance (PET MR) was performed in order to exclude metastatic scattering. In the event of complications, adequate therapeutic methods were implemented. A finding of an amaurotic painful eyeball with secondary glaucoma, without the possibility of compensation of intraocular pressure was an indication for enucleation of an irradiated eyeball, despite the fact that local tumor control had been achieved. Data on patient survival were supplemented with records from the National Oncology Register.

The results are presented in the form of percentages, arithmetical averages, medians, first and third quartiles, bar charts, Q-Q plots, histograms and Kaplan-Meier curves. The statistical analysis was conducted within the R studio environment. A Chi-square test, Mann-Whitney test and normality test were used for evaluation.

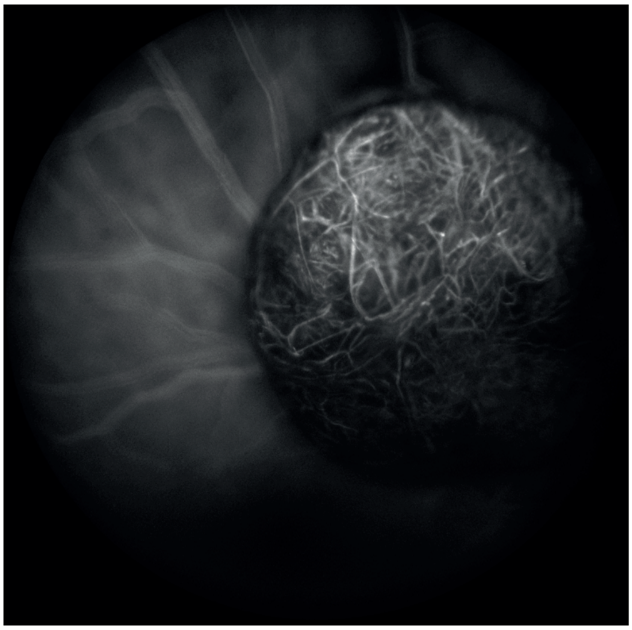


**Figure 2.** Characteristic double circulation of uveal melanoma during fluorescein angiography

## RESULTS

In the study, data were evaluated from 145 patients examined at the Clinic of Eye Treatments at the University Hospital Brno with a diagnosis of malignant tumor of the choroidea in the period from 2016 to 2021. A further examination confirmed a diagnosis of choroidal melanoma in 122 patients. Of these, 36 patients underwent primary enucleation of the eyeball, 14 patients were treated by means of photodynamic therapy and two patients were treated with transpupillary thermotherapy. A total of 21 patients were indicated for brachytherapy treatment. The method of stereotactic radiosurgery was indicated for 49 patients, 14 of whom did not meet the inclusion criteria because they were treated outside of the stipulated period or primarily monitored at another center.

A total of 33 (17 men and 16 women) patients treated using the CyberKnife system, with an average age of 63 years at the time of diagnosis, met the inclusion criteria. In 23 patients the melanoma was localized in the right eye, and 31 patients suffered choroidal melanoma, while in two patients the choroidea was affected in combination with the ciliary body. The average observation period was 45 months. Table 1 describes selected attributes of the tumor. Table 2 summarizes the observed ocular parameters and their development over time.

Three-year local tumor control rate was recorded in 25 patients (75.8%). Within the entire observation period, progression of the tumor was identified in nine patients. The median tumor recurrence time was 20 months after radiotherapy treatment. Enucleation due to recurrence was performed on eight patients. One patient refused enucleation and one patient underwent enucleation due to post-radiation complications. The three-year eyeball preservation rate in our cohort was 72.7%. Graph 1 illustrates the Kaplan-Meier curve of local tumor control over time after radiotherapy treatment. The analysis of our cohort did not demonstrate a statistically significant dependency of the incidence of tumor progression on its localization or size.

Metastatic spread was detected in 10 patients during the entire follow-up period. The median time to metastasis detection was 28 months after radiotherapy treatment, which was preceded by negative oncological screening without a finding of metastatic lesions. The most commonly affected organs were the liver (44%), bones (28%) and lungs (17%). The parotid gland was affected in one patient, and in one patient metastasis was evaluated as generalized. The three-year survival rate in our cohort reached 81.8%. Graph 2 illustrates the Kaplan-Meier curve of survival over time. The analysis of our cohort demonstrated a statistically significant dependency of the incidence of metastases on the localization of the tumor. Graph 3 illustrates that the metastatic potential in anteriorly or peripherally localized tumors was markedly higher than in tumors localized on the posterior pole of the eyeball. The dependency of the incidence of metastases on tumor size was not demonstrated to be statistically significant in our data.

Ocular complications of radiotherapy affected 75.8% of patients. The most common complication in our cohort was the development of cataract in 58.3% of phakic patients in whom cataract was not identified at the baseline examination. Other complications included the onset of neovascular glaucoma in 39.4% of patients, followed by radiation maculopathy (27.3%), radiation retinopathy (18.2%) and radiation-induced optic neuropathy (12.1%) (Figure 3). Less common complications were central retinal vein occlusion and toxic tumor syndrome, manifested in 3% of patients. One patient proceeded to enucleation of the eyeball due to uncorrectable neovascular glaucoma in an amaurotic eye. To address radiation retinopathy and maculopathy, four patients underwent laser photocoagulation and three patients underwent therapy with anti-VEGF preparations. Two patients suffering from decompensated glaucoma had to undergo cyclophotoco-

**Table 1.** General tumour characteristics in our study group

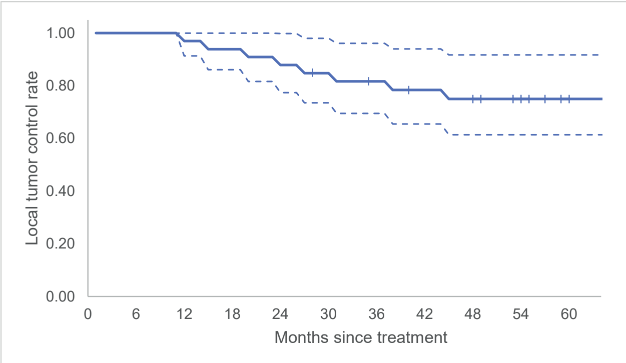
| | N (%) |
|---|---|
| **Laterality** | |
| Right eye | 23 (69.7) |
| Left eye | 10 (30.3) |
| **Affected structure** | |
| Choroid | 31 (93.9) |
| Choroid + ciliary body | 2 (6.1) |
| **Tumour location** | |
| Anterior | 11 (33.3) |
| Peripheral | 12 (36.4) |
| Posterior pole | 10 (30.3) |
| **Tumour pigmentation** | |
| Melanotic | 30 (90.9) |
| Amelanotic | 3 (9.1) |

*N – number of patients*

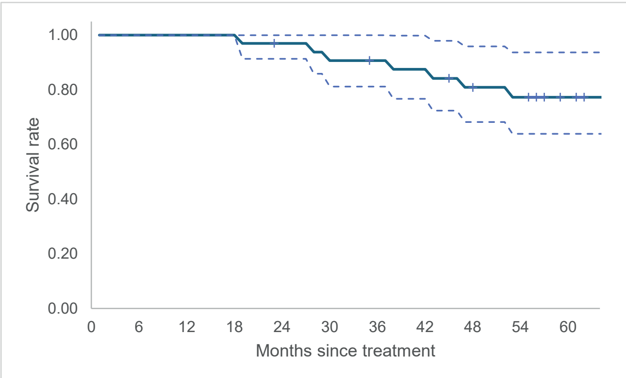
**Table 2.** Selected clinical parameters at baseline, 12 months after treatment and at last visit

| | Median | (Q1–Q3) |
|---|---|---|
| Age at treatment (years) | 64 | (53–72) |
| Follow-up period (months) | 40 | (35–58) |
| **Tumour height (mm)** | | |
| At diagnosis | 6.7 | (4.9–8.9) |
| 12 months after treatment | 5 | (3.2–7) |
| At last visit | 3.9 | (1.8–6.2) |
| **Tumour base (mm)** | | |
| At diagnosis | 12.1 | (9.4–13.6) |
| 12 months after treatment | 10 | (7.9–12.6) |
| At last visit | 8 | (6.1–11.5) |
| **BCVA (Snellen. decimal)** | | |
| At diagnosis | 0.4 | (0.1–0.8) |
| 12 months after treatment | 0.2 | (0–0.5) |
| At last visit | 0.014 | (0–0.2) |
| **Intraocular pressure (mmHg)** | | |
| At diagnosis | 14 | (13–16) |
| 12 months after treatment | 16.5 | (13.3–22.5) |
| At last visit | 19.5 | (15.8–28.5) |

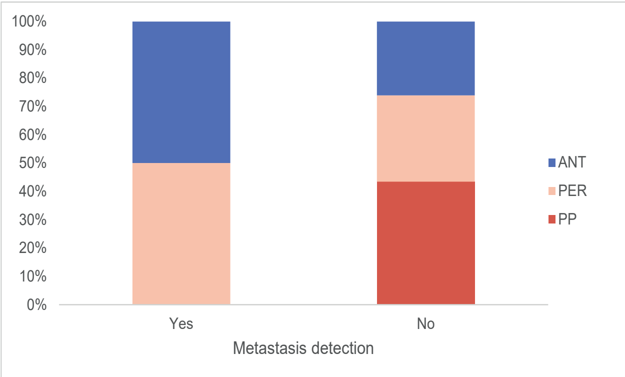
*BCVA – best corrected visual acuity, Q1 – first quartile, Q3 – third quartile*




**Graph 1.** Kaplan-Meier curve of local control rate




**Graph 2.** Kaplan-Meier curve of overall survival rate




**Graph 3.** Metastasis occurrence by tumor location
*ANT – anterior, PER – periphery, PP –posterior pole*

agulation. The median baseline BCVA in decimal values was at the level of 0.4, with a decrease to 0.014 at the first visit. Graph 4 illustrates the incidence of ocular complications over time after radiotherapy treatment.

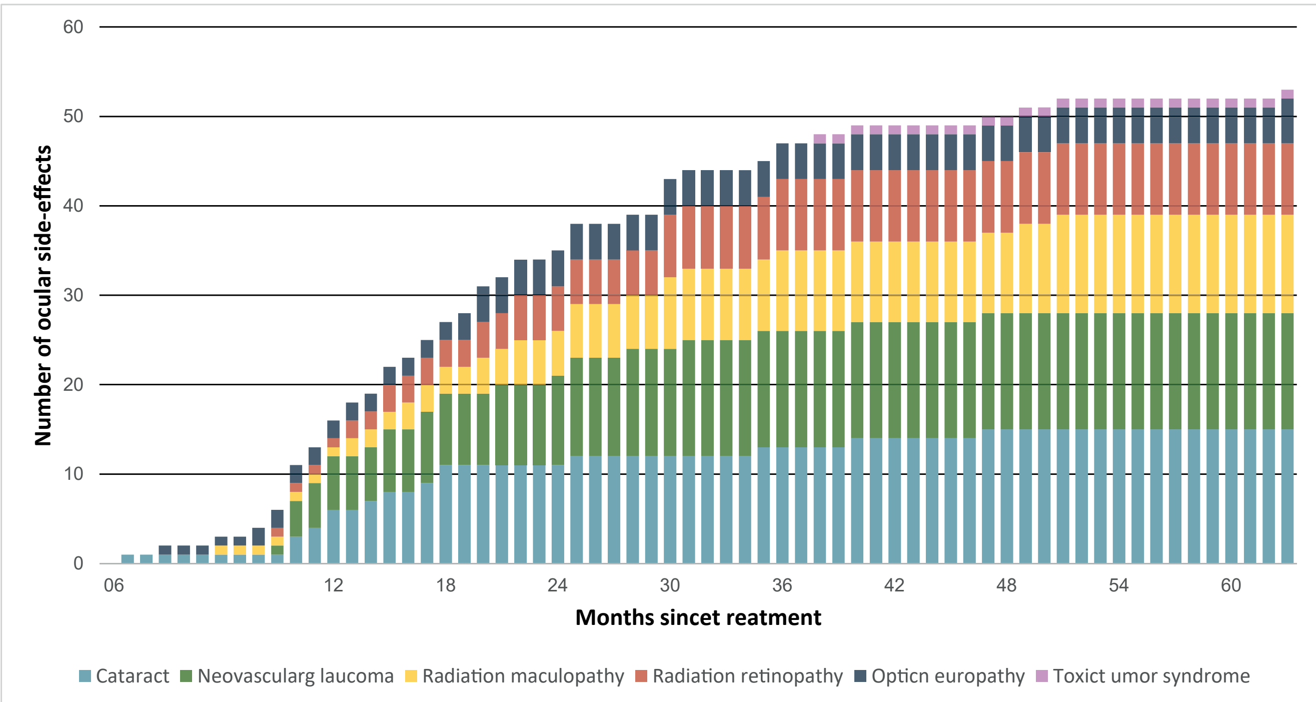
## DISCUSSION

An important factor for evaluating the combination of the success rate of radiotherapy and the severity of the complications is the preservation rate of the treated eye. In our cohort this reached a value of 72.7% in the period of three years from radiotherapy treatment. Yazici et al. in their study state a lower value of 62% [8], while by contrast Mueller et al. achieved a higher rate of eye preservation, as high as 94% [9]. These values may be important

**Figure 3.** Radiation retinopathy combined with optic neuropathy after stereotactic radiosurgery of peripapillary uveal melanoma

data for patients who are faced with a choice of therapeutic method and fear loss of their organ. However, these are only referential values of the effectiveness of therapy, and are influenced by the amount of recurrences of the tumor, as well as the amount of ensuing ocular complications and the procedure chosen for addressing them.

A more specific criterion for evaluating the success rate




**Graph 4.** Incidence of ocular side effects over time

of radiotherapy is local tumor control rate. Studies on large cohorts of patients state successful local control in 84% in the study conducted by Šimonová et al. [10], and as high as 95.9% in the study conducted by Dunavoelgyi et al. [11]. The reasons for the lower value of local tumor control in our study (75.8% within a period of three years from radiotherapy treatment) may be the different observation time or the different evaluation criteria for progression of the tumor. For example, in the study conducted by Šimonová et al. the minimum observation time was stated at 10 months, which may cause an artificial increase in local tumor control rate, with reference to the fact that the median time to tumor recurrence in our study was 20 months. Dunavoelgyi et al. recorded the median time to tumor recurrence as late as 53 months after radiotherapy treatment. This markedly longer time until the identification of recurrence may be due to the fact that they classified recurrence of a tumor as a growth by 25% at two follow-up examinations at least six months after radiotherapy treatment. In our study we considered ultrasound progression or change of shape of the tumor lesion after a period of stability at two consecutive follow-up examinations to constitute recurrence, which may have reduced our rate of local tumor control. Eibl-Lindner et al. in their cohort of 217 patients treated using the CyberKnife system declared local tumor control at a rate of 87.4% within a period of three years after radiotherapy treatment and 70.8% five years after treatment [5]. The results of our study are limited by the smaller cohort of observed patients.

The three-year survival rate reached 81.8% in our patients. In the professional literature, similar values were observed by Eibl-Lindner et al., with a three-year survival rate of 84.8% [5]. Other studies with similar values include the cohorts in the study conducted by Schmelter et al. with a survival rate of 82 % at 4.5 years [12] and Yazici et al. with a five-year survival rate of 87% [8]. However, both studies presented a longer observation period, and for this reason the possibility of comparison is limited. In our cohort, metastatic potential reached a significantly higher value in anteriorly and peripherally localized tumors than in tumors localized on the posterior pole of the eyeball. A similar trend was observed by Krohn et al., who also confirmed a higher risk of metastases in the case of larger tumors in their cohort [13]. However, in our data this dependency was not demonstrated to be statistically significant.

In the area of ocular complications of SR, the results of our study correlate with the data of other authors. One of the most common complications in both the literature and in our cohort is the development of cataract. In the COMS study doses of radiation of more than 12 Gy were associated with a higher incidence of cataract, and developed in 83% of patients within a period of five years from radiotherapy treatment [14]. With regard to the average age of patients with uveal melanoma, the development of cataract may partially be attributed to the physiological aging of the lens, and in most cases can be easily treated. The high incidence of cataract in our patients (58.3%) may also be a consequence of the absence of fractionated doses of radiation, as stated by Groenewald et al. [7]. No corneal complications were observed in any of our patients in the sense of trophic defects or disorders, even in anteriorly localized tumors. The majority of studies present only a sporadic incidence of corneal affliction, although Zehetmayer et al. in their study for example recorded these complications in 12% of patients. In addition to the direct impact of radiation on the corneal tissues, these complications may also be associated with the type of eyeball fixation used. In our patients the eyeball was immobilized by means of retrobulbar anesthesia, while Zehetmayer et al. describe the use of a vacuum immobilization system [15]. The incidence of neovascular glaucoma, which is a significant complication and a possible cause of subsequent enucleation, was 39.4% in our cohort. Similar values are described by the team of authors Modorati et al., using LGN, who recorded a rate of 27.3%, and the team of authors from Munich Klingenstein et al. on a cohort of patients treated with the CyberKnife system, in whom secondary glaucoma developed in 33% [6,16].

On the posterior segment the most common complication is radiation retinopathy, the incidence of which is stated at rates ranging from 12.7% [12] to 81% of irradiated eyes [17]. In radiation retinopathy the retinal blood vessels succumb to similar changes as the blood vessels of the tumor, specifically the development of microaneurysms and capillary occlusion leading to hemorrhage, ischemia, the formation of neovascularizations and edema. The photoreceptors themselves and retinal cells with low mitotic activity are resistant to radiation to a certain degree, but their atrophy may occur upon a background of long-term retinal detachment, disorder of blood supply or atrophy of the retinal pigment epithelium [7]. The incidence of radiation retinopathy and maculopathy in our patients reached values of 18.2% and 27.3% respectively. The data from the authors Sarici and Pazarli are similar, with retinopathy in 24% and maculopathy in 30% [18]. However, in studies conducted by some other authors substantially lower values of radiation maculopathy have been recorded [19,20]. Dinca et al. in their study illustrated a correlation of the applied dose with the incidence of retinopathy when they divided their cohort of patients according to dose of 35 Gy, 45 Gy and 50–70 Gy, and subsequently recorded radiation retinopathy in 25.8%, 35.2% and 41.7% of the patients respectively. Lower doses of radiation in their study did not lead to a higher mortality rate, while at the same time they fundamentally reduced the toxicity of therapy [21]. Post-radiation optic neuropathy is associated in particular with doses of radiation of more than 50 Gy. Due to the impact of apoptosis of the auxiliary cells and disorder of vascular supply, the optic nerve succumbs to necrosis and infiltration by immune cells. The incidence of post-radiation optic neuropathy varies in the literature from 4% [19] to as high as 64% [17], while the

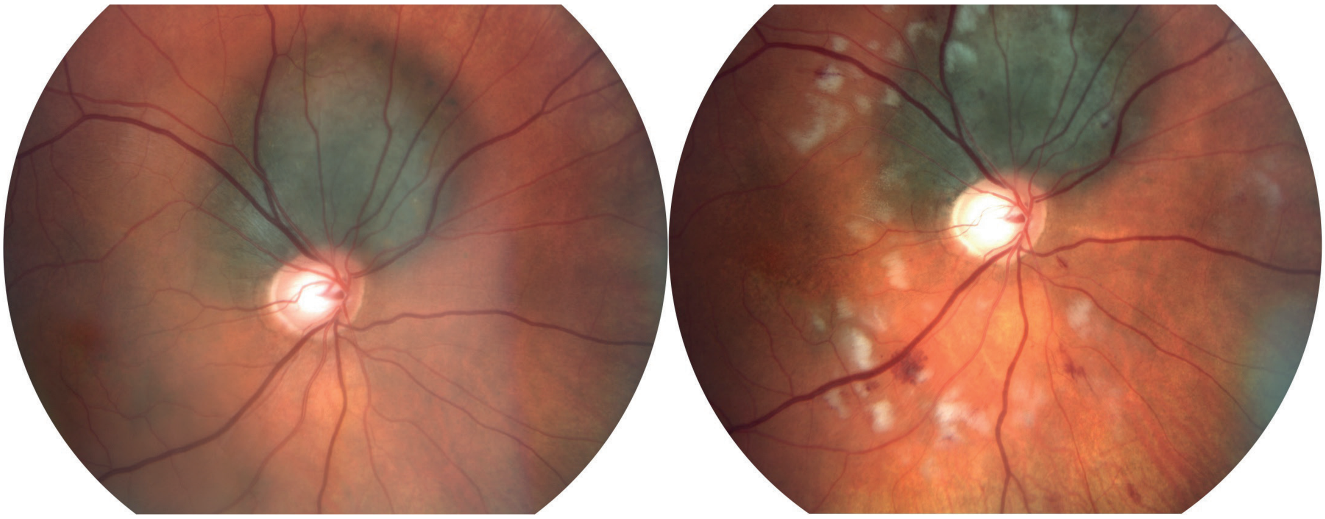


**Figure 4.** LEFT – Peripapillary uveal melanoma before treatment. RIGHT – Same patient 9 months after stereotactic radiosurgery developing radiation retinopathy and radiation optic neuropathy

incidence in our cohort is around the lower limit, with a value of 12.1% (Figure 4).

The greatest limitation of our study is the small cohort of patients. A large proportion of patients report for treatment with a tumor of low prominence, which is suitable for treatment by brachytherapy. In addition many patients still prefer enucleation as a more radical therapeutic option. Future studies may include a comparison of stereotactic radiosurgery in a single session as against fractionated radiotherapy divided into multiple applications. When planning the observation intervals for patients following enucleation of the eyeball it is possible to take into account the data obtained from cytogenic testing of the lesion and correlate this with the potential incidence of metastasis and data on the overall survival rate of patients [22].

The method of proton therapy is also now available to patients abroad as part of teleradiotherapy. It is used on large uveal melanomas and minimizes the doses absorbed by the surrounding healthy tissues thanks to the "Bragg peak" effect [23]. Studies conducted up to now show a similar degree of local tumor control across all methods of teleradiotherapy [24]. However, despite achieving local tumor control, high incidence of metastases still represents a limitation of the available therapeutic methods. Within a 10-year observation period it is stated in the literature at the level of 30–40% [23,25,26]. Finally, it is necessary to note the limited possibility of comparing the specific results of individual studies in this area due to their retrospective character, and the absence of uniform recommendations for radiotherapy.

## CONCLUSION

Stereotactic radiosurgery is a safe treatment method for uveal melanoma with the potential for eye preservation, which is nevertheless associated with the risk of tumor recurrence and multiple ocular complications, which may require subsequent enucleation. Three-year local tumor control rate was lower in our patients in comparison with studies conducted by other authors, though this may be influenced by the small number of patients in our cohort. The three-year survival rate and the incidence of ocular complications in our study were consistent with the data reported in the literature.

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