Clinical and Pathologic Characteristics of Biopsy-Proven Iris Melanoma

A Multicenter International Study

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Objective: To collaborate with multiple centers to identify representative epidemiological, clinical, and pathologic characteristics of melanoma of the iris. This international, multicenter, Internet-assisted study in ophthalmic oncology demonstrates the collaboration among eye cancer specialists to stage and describe the clinical and pathologic characteristics of biopsy-proven melanoma of the iris.

Methods: A computer program was created to allow for Internet-assisted multicenter, privacy-protected, online data entry. Eight eye cancer centers in 6 countries performed retrospective chart reviews. Statistical analysis included patient and tumor characteristics, ocular and angle abnormalities, management, histopathology, and outcomes.

Results: A total of 131 patients with iris melanoma (mean age, 64 years [range, 20-100 years]) were found to have blue-gray (62.2%), green-hazel (29.1%), or brown (8.7%) irides. Iris melanoma color was brown (65.6%), amelanotic (9.9%), and multicolored (6.9%). A mean of 2.5 clock hours of iris was visibly involved with melanoma, typically centered at the 6-o’clock meridian. Presentations included iritis, glaucoma, hyphema, and sector cataract. High-frequency ultrasonography revealed a largest mean tumor diameter of 4.9 mm, a mean maximum tumor thickness of 1.9 mm, angle blunting (52%), iris root disinsertion (9%), and posterior iris pigment epithelium displacement (9%). Using the American Joint Commission on Cancer–International Union Against Cancer classification, we identified 56% of tumors as T1, 34% of tumors as T2, 2% of tumors as T3, and 1% of tumors as T4. Histopathologic grades were G1-spindle (54%), G2-mixed (28%), G3-epithelioid (5%), and undetermined (13%) cell types. Primary treatment involved radiation (26%) and surgery (64%). Kaplan-Meier analysis found a 10.7% risk of metastatic melanoma at 5 years.

Conclusions: Iris melanomas were most likely to be brown and found in the inferior quadrants of patients with light irides. Typically small and unifocal, melanomas are commonly associated with angle blunting and spindle cell histopathology. This multicenter, Internet-based, international study successfully pooled data and extracted information on biopsy-proven melanoma of the iris.


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agnosis was not histologically confirmed. Second, many were completed years ago, before current investigation techniques (eg, high-frequency ultrasonography) were developed. Third, they were single-center studies prone to both location- and referral-based selection bias. Although these published studies have provided valuable information aiding in the diagnosis, treatment, and prognosis, not enough detailed data are available to form an evidence-based AJCC-UICC staging system for iris melanomas.

Herein, we developed a novel approach that involved the construction and use of an Internet-based, international, collaborative, multicentered ophthalmic oncology database of clinical, ultrasonographic, and pathologic characteristics of biopsy-proven melanoma of the iris.

Our study conforms to the Declaration of Helsinki and the US Health Insurance Privacy and Portability Act of 1996. An online database was created with mutually acceptable epidemiological, clinical, pathologic, management, and outcome parameters based on previously described features of iris melanomas and guidelines determined by the AJCC-UICC Ophthalmic Oncology Task Force. Each center was provided with an online user name, password-protected computer program was created to allow for a collaborative multicenter, international, online data entry portal (ScienceTrax; Macon, Georgia) that provided a secure online framework with technical support. In terms of the Web-based setup, StudyTRAX is a research software application that complies with Title 21 CFR Part 11 of the Code of Federal Regulations that deals with the US Food and Drug Administration guidelines on electronic records and electronic signatures. It is in part of an international eye cancer database project.

Method

Clinical and pathologic staging data were collected. Clinical data on tumor size and extension, presence of secondary glaucoma, regional lymph nodes, and distant metastasis (tumor, node, metastasis [TNM] data) were documented to allow for tumor staging based on the 7th edition AJCC-UICC eye cancer staging system. Histopathologic grade and presence of a residual tumor were recorded. Like the clinical data, data on the histopathologic characteristics (ie, grade) were determined by specialists at the local institution. Subsequent management of iris melanomas included initial observation, resection, and radiation (data on radiation type and radiation dose were collected). This part of the management process included data on final visual acuity, months of patient follow-up, and survival status.

Statistical Analysis

Categorical data were summarized as proportions, and continuous data as mean values with ranges. We described the distribution of patient characteristics, tumor color, tumor location, tumor size, clinical features, tumor stage, and treatment management among patients with iris melanoma. In addition, we used an unconditional logistic regression model to examine the relationship between selected clinical factors and tumor size (largest diameter as measured by ultrasonography, <5 mm vs ≥5 mm). In the model analysis, we estimated both univariate and multivariate mutually adjusted odds ratios (ORs).
with 95% confidence intervals (CIs) for correlations between some clinical factors and tumor size. An OR of greater or less than 1.0, together with a P value of less than .05, was necessary to demonstrate an association between a clinical factor and tumor size.

We used the Kaplan-Meier method to draw survival curves and estimate the 5-year survival rate according to AJCC iris melanoma staging. Survival times were computed for 10 years to better show early survival, and they were censored at the time of death associated with metastasis, at the date last known alive, or at the date last followed up, whichever came first. The statistical significance of the difference in survival curves was tested by use of a log-rank test. The Cox proportional hazards model was used to analyze the risk of mortality associated with tumor stage or grade. When the stage- or grade-related mortality risk was analyzed, both univariate- and multivariate-adjusted hazard ratios and 95% CIs were estimated. The model-adjusted factors included sex, age (<50, 50-69, and ≥70 years), histopathologic grade (grades GX and G1 and grades G2 and G3), and tumor stage (pT0 to pT3). A mortality hazard ratio of greater than 1 with a P value of less than .05 indicated a significant risk of mortality.

### RESULTS

**PATIENT CHARACTERISTICS**

All patients were selected from populations in North America and Europe. Patient demographic data from each individual center as well as the mean values from combined data are presented in Table 3. The total number of patients with iris melanoma was 131, with a mean age of 64 years (range, 20-100 years). Of these 131 patients, 125 (95.4%) were white; of 128 patients, 74 (57.8%) were women. Iris color was predominantly light for 116 of 127 patients (91.3%): 79 patients (62.2%) with blue-gray irides and 37 patients (29.1%) with green-hazel irides. Only 11 of the 127 patients (8.6%) had brown irides (Table 4).
PRESENTING CHARACTERISTICS

Initial visual acuity ranged from 20/16 to 20/1600. Anterior chamber inflammation was present in 5 eyes (in 5 of 131 patients [3.8%]), and 4 eyes had a hyphema (in 4 of 129 patients [3.1%]). There was a 1:1 ratio between affected eyes and patients. A sector cataract was detected in 17.6% of patients (in 23 of 131 patients). Glaucoma was present in 26.8% of patients (in 34 of 127 patients), and the mean intraocular pressure in these patients was 24.0 mm Hg (range, 14-64 mm Hg). The mechanism for the glaucoma was identified in 27 patients and included pigment dispersion in 53 of 120 patients (44.2%), synechiae in 10 of 131 patients (7.7%), correctopia in 34 of 131 patients (26.0%), and ectropion uveae in 55 of 129 patients (42.6%).

Additional statistical associations between clinical factors and tumor size are shown in Table 5. A cutoff point of 5 mm was arbitrarily made based on the mean tumor size for analysis. By the use of multivariate, mutually adjusted ORs, it was found that a large tumor size (diameter, >5 mm) was associated with the presence of intrinsic tumor vessels (OR, 4.4 [95% CI, 1.4-13.8]; P = .01), an angle involvement exceeding 0.5 clock hours (OR, 4.84 [95% CI, 1.4-17.2]) and OR, 5.69 [95% CI, 1.3-24.0]; P = .01 for trend), and the presence of epithelioid cells (OR, 2.91 [95% CI, 1.0-8.6]; P = .06).

TUMOR CHARACTERISTICS

Most iris melanomas were found in the inferior iris between the 5- and 7-o’clock meridians (in 103 of 130 patients [79.2%]). Tumors were typically unifocal (in 111 of 126 patients [88.1%]) and involved a mean of 2.5 total clock hours. Of 131 patients, 58 (44.3%) had tumors that extended to the pupillary margin, and 98 (74.8%) had tumors that involved the midzone of the iris (11 [11.2%] of whom had a tumor that extended from the pupil to the peripheral iris). Angle involvement was present in 66.7% of patients (in 76 of 114 patients). Mean clock hours of angle involvement by the tumor was 2.0 clock hours. The clinically measured mean (SD) tumor diameter was 5.2 (2.8) mm.

Tumor color was predominantly brown (in 86 of 131 patients [65.6%]), followed by amelanotic (in 13 of 131 patients [9.9%]) and multicolored (in 9 of 131 patients [6.9%]). Tumor color heterogeneity was present in 37 of 125 patients (29.6%). Of 126 patients, 14 (11.1%) had iris heterochromia (ie, heterochromia iridis) (Table 4).

The tumors’ surface contours were noted to be either smooth in 51 of 130 eyes (39.2%) or irregular in 79 of 130 eyes (60.8%). Intrinsic tumor vessels were visualized in 70 of 124 eyes (56.5%). Nine of 124 patients (7.3%) had a tumor that had a posterior iris feeder vessel, and 21 of 125 patients (16.8%) had a tumor that had a sentinel episcleral vessel. Other findings included anterior segment pigment dispersion in 53 of 120 patients (44.2%), synechiae in 10 of 131 patients (7.6%), correctopia in 34 of 131 patients (25.9%), and ectropion uveae in 55 of 129 patients (42.6%) (Table 4).

Additional statistical associations between clinical factors and tumor size are shown in Table 5. A cutoff point of 5 mm was arbitrarily made based on the mean tumor size for analysis. By the use of multivariate, mutually adjusted ORs, it was found that a large tumor size (diameter, >5 mm) was associated with the presence of intrinsic tumor vessels (OR, 4.4 [95% CI, 1.4-13.8]; P = .01), an angle involvement exceeding 0.5 clock hours (OR, 4.84 [95% CI, 1.4-17.2]) and OR, 5.69 [95% CI, 1.3-24.0]; P = .01 for trend), and the presence of epithelioid cells (OR, 2.91 [95% CI, 1.0-8.6]; P = .06).

HIGH-FREQUENCY ULTRASONOGRAPHIC IMAGING

High-frequency ultrasonography (ultrasonographic biomicroscopy) showed a largest mean tumor diameter of 4.9 mm (range, 1.7-16.7 mm) and a mean thickness of 1.9 mm (range, 0.5-8.3 mm). Other noted features were angle blunting (in 65 of 126 patients [51.6%]), iris root disinsertion (in 11 of 118 patients [9.3%]), and iris pigment epithelio-
lium displacement (in 11 of 118 patients [9.3%]). A slightly smaller mean tumor diameter was noted using ultrasonography. This was likely due to the fact that the pigmented tumor edge is typically thin and may not thicken the underlying tissues. In our study, extrascleral tumor extension was determined by clinical examination.

TUMOR STAGING

The clinical and pathologic staging guidelines of the 7th edition AJCC-UICC system were applied in this series (Tables 1 and 2).4 Fifty-six percent of patients had tumors that were T1, 34% had tumors that were T2, 2% had tumors that were T3, and 1% had a tumor that was T4. Owing to the retrospective nature of our study, in 7% of cases, the contributing physicians from one center did not have enough information to accurately assess tumor T stage. An additional 14 patients with histopathologically proven iris melanoma who had radioactive plaque therapy did not have pathologic staging performed. No patients were noted to have melanoma spread to regional lymph nodes or metastases on initial examination.

HISTOPATHOLOGY

Histopathologic data on melanoma cell type were as follows: G1-spindle cell type in 71 of 131 eyes (54.2%), G2-

mixed cell type in 36 of 131 eyes (27.5%), and G3-

epithelioid cell type in 6 of 131 eyes (4.6%); in 17 of 131 eyes (13.0%), the cell type was not classified. For the 102 tumors primarily excised, positive tumor margins were found in 4 eyes microscopically and in 1 eye grossly (in 5 of 102 eyes [4.9%]).

TREATMENT

Four of 129 patients (3.1%) were observed. In this subgroup, 1 patient was reported to be lost to follow-up, 1 patients refused treatment, and 1 patient was not treated owing to poor health (and the tumor slowly enlarged). Thirty-three of 118 patients (28.0%) underwent primary radiotherapy, and 79 of 123 patients (64.2%) had primary surgery. Data were not entered in 13 patients regarding primary radiotherapy and in 8 patients regarding primary surgery. Combination therapy comprising radiation therapy and surgery were employed for 10 of 129 patients (7.8%). Radiation therapy involved the use of iodine 125 plaques in 3 of the 8 centers. The New York Eye Cancer Center used palladium 103 plaques.22-26

Table 6 shows that the smaller tumors (diameter, <5 mm) were more likely to be managed by surgery alone and that the larger tumors (diameter, ≥5 mm) were more likely to be managed by radiotherapy (P < .001). Of the 80 patients with combined pathological AJCC tumor cat-

<table>
<thead>
<tr>
<th>Table 5. Association of Clinical Factors With Tumor Size in Patients With Iris Melanoma</th>
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<tr>
<td>Clinical Factor</td>
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<tr>
<td>Age, y</td>
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<tr>
<td>&lt;50</td>
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<tr>
<td>50-69</td>
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<tr>
<td>≥70</td>
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<tr>
<td>Sex</td>
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<tr>
<td></td>
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<tr>
<td>Eye color</td>
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<tr>
<td></td>
</tr>
<tr>
<td>Starting clock hours</td>
</tr>
<tr>
<td>3:00 to &lt;9:30</td>
</tr>
<tr>
<td>&lt;3:00</td>
</tr>
<tr>
<td>Tumor color</td>
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<tr>
<td></td>
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<tr>
<td>Tumor vessels</td>
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<tr>
<td></td>
</tr>
<tr>
<td>Angle involvement,^b clock hours</td>
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<tr>
<td>0.5-2.0</td>
</tr>
<tr>
<td>&gt;2.0</td>
</tr>
<tr>
<td>Histopathologic grade</td>
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<tr>
<td></td>
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</tbody>
</table>

Abbreviations: CI, confidence interval; OR, odds ratio.
^a Mutually adjusted by age, sex, eye color, starting clock hours, tumor color, presence of intrinsic tumor vessels, angle involvement, and histopathologic grade.
^b P = .012 for trend.

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categories of T1 to T4, 61 (76.3%) were more likely to have surgery only, whereas, of the 22 patients with tumor categories of TX and T0, 9 (40.9%) were managed by surgery only, and 9 (40.9%) were managed by radiotherapy only. Only tumors in the combined stages of TX and T0 were treated by observation (4 of 22 patients [18.2%]). The proportion of treatment methods was significantly different between the 2 groups, the group of patients whose tumors were classified as TX or T0 and the group of patients whose tumors were classified as T1, T2, T3, or T4 (P < .001). In both groups, there was 1 patient for which the mode of treatment was not available for analysis.

METASTASIS-SPECIFIC SURVIVAL ANALYSIS

This survival analysis excluded 8 patients whose tumor could not be staged and 27 patients without adequate follow-up. Thus, 96 patients were used for this analysis. Metastatic death was verified by the scientists who enrolled the patients. For analysis, the incidence of metastatic disease was correlated with AJCC categories. Analysis of this cohort (n = 96) revealed a 10.7% chance of melanoma metastases at 5 years. Of the 56 patients whose tumors were classified as T0, T1a, T1b, or T1c, there were no metastases. Overall, 5 of 36 patients (13.9%) with T2- or T2a-stage iris melanomas died with metastasis, and 1 patient with metastasis had not died by the time of data acquisition. Grouped together owing to small numbers, 3 of the 4 remaining patients (all with T3-, T3a-, or T4-stage tumors) died of metastatic disease. Thus, our study demonstrated a trend toward increasing T categories and metastatic disease.

Estimated by use of the Kaplan-Meier method (Figure 2), the metastasis-specific survival curves were significantly different among the 4 AJCC stages (χ² = 13.59, P = .004, determined by use of a log-rank test). The 5-year survival rate was estimated to be 100% for the patients whose tumors were classified as T0, T1a, T1b, or T1c, 90.4% for the patients whose tumors were classified as T2, 63.6% for the patients whose tumors were classified as T2a, and 50% for the patients whose tumors were classified as T3, T3a, or T4.

Lastly, pathologic staging and histopathologic grade were correlated with mortality (Table 1). Our study analysis (data not shown) suggested that the risk of mortality was not significantly different between pT0 + pT1 and pT2 + pT3 + pT4 (age-, sex-, and grade-adjusted hazard ratio, 1.37 [95% CI, 0.4-4.4]). Of note, the risk of mortality was found to be 8 times higher from grade G2 and G3 tumors than from grade GX and G1 tumors after adjusting for the effects of sex, age, and grade (adjusted hazard ratio, 9.27 [95% CI, 1.1-80.3]; P = .04).

Our study of 131 patients with biopsy-proven iris melanoma who were treated in 8 ophthalmic oncology centers showed that patients tended to be elderly whites with a light iris color. Glaucoma was the most common presenting finding. The tumors were typically brown, without color heterogeneity, unifocal, and inferior (between the 3- and 9-o’clock meridians). The mean diameter was 5.0 mm. Larger tumor size (>5 mm) was associated with the presence of intrinsic tumor vessels, more than 0.5 clock hours of angle involvement, and epithelioid melanoma cytomorphology. Most tumors were managed surgically, although larger tumors (>5 mm) were more likely to be managed by radiotherapy. Lastly, Kaplan-Meier analysis found a 10.7% risk of metastatic melanoma at 5 years.

Our study also demonstrated how a multicenter retrospective study could be performed to acquire significant amounts of data on a rare disease (iris melanoma) within a relatively short time. Specifically, 18 scientists from 8 centers in 6 countries entered privacy protected data into an Internet-based portal.

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**Table 6. Analysis of Treatment Strategy, Tumor Size, and Pathologic Tumor Stage for Patients With Iris Melanoma**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Tumor Size, No. of Patients</th>
<th>P</th>
<th>Valuea</th>
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<tbody>
<tr>
<td></td>
<td>&lt;5.0 mm (n=57)</td>
<td></td>
<td></td>
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<tr>
<td>No surgery and no radiation</td>
<td>0 (0.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery only</td>
<td>42 (73.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation only</td>
<td>13 (22.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery and radiation</td>
<td>2 (3.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>≥5.0 mm (n=38)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No surgery and no radiation</td>
<td>0 (0.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery only</td>
<td>12 (31.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation only</td>
<td>20 (52.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery and radiation</td>
<td>6 (15.8)</td>
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</table>

**Figure 2. Iris melanoma–related survival rates, by American Joint Commission on Cancer (AJCC) stage.** Estimated by use of the Kaplan-Meier method, the metastasis-specific survival curves were significantly different among the 4 AJCC stages. The 5-year survival rate was estimated to be 100% for the patients whose tumors were classified as T0, T1a, T1b, or T1c, 90.4% for the patients whose tumors were classified as T2, 63.6% for the patients whose tumors were classified as T2a, and 50% for the patients whose tumors were classified as T3, T3a, or T4.
STRENGTHS AND WEAKNESSES

The strengths of our study include the relatively large number of patients derived from multiple centers (from 6 countries) using common data fields. Thus, the findings of our study are more likely representative of patients currently being seen in North America and Europe. Another major strength is that, in this series, the diagnosis of melanoma was histologically confirmed. This is particularly important in that there is a clinical difficulty in distinguishing some iris melanomas from nevi, melanocytomas, adenomas, and other iris tumors.

Another strength of our study involves our use of AJCC-UICC staging. Increasingly, cancer staging is becoming evidence-based and relies on data collected through collaborative efforts. This makes staging data less likely to be subject to referral bias. For example, the most recent 7th edition of the AJCC-UICC TNM classification of uveal melanoma was derived from a multicenter retrospective evaluation of more than 8000 patients. Ideally, in the forthcoming TNM editions, such data would be collected prospectively and used to further validate the staging systems for each ophthalmic site. Our study shows the limitations of collecting such data retrospectively in that 8% of iris melanomas staged clinically and 22% staged histopathologically could not be classified according to the present 7th edition of the TNM system.

Therefore, the major limitation of our study is rooted in its retrospective design. Clinical methods and histopathologic analysis varied from center to center. Although this characteristic makes our data more likely to be representative of nonparticipating centers, we must also consider that all our centers were located in North America and Europe. Thus, the findings of our study may not be as relevant to nonwhites. A limited amount of data was entered for patients with regard to lymph node spread (78% of patients were not checked) and pathologic staging (22% of patients had tumors that could not be staged). In addition, because most benign-appearing iris tumors are managed by observation, the metastasis-related mortality in this series may be skewed to represent the subset of more aggressive iris melanomas that warranted biopsy.

Future studies should include patients from all parts of the world. Although TNM staging was used, determinations of the presence of clinical and histopathologic features remain subjective. For example, tumor-color grading was merely that recorded. With greater funding, these clinical and pathologic diagnoses would have benefited from multicenter data validation (eg, pathologic specimens, photography, and ultrasonographic images). However, we realize that these limitations are also found in published single-center retrospective studies.

IMPLICATIONS OF OUR STUDY

In ocular oncology, large ophthalmic oncology centers have both improved clinical care and generated a tremendous amount of data. To date, these centers have guided clinical practice and management. However, collaborative studies have many advantages over single centers. They are able to examine the similarities and differences in clinical practice among groups of specialists.

Multicenter collaborative studies allow recruitment of larger numbers of patients and/or clinical samples in relatively short periods of time.

Of great importance, consider that collaborative data collection and evaluation offer the potential to minimize duplication of ineffective treatments, more quickly validate effective treatments, and more efficiently allocate resources. In addition, collaborative studies foster communication and cooperation among eye cancer specialists and thereby raise the standards of clinical care.

To the best of our knowledge, our study presents results from the first multicenter, international, Internet-assisted study of iris melanoma. This collaborative study was successful because (1) the same terminology was used; (2) there was a willingness to share patient data; (3) specialists entered the data; (4) data were statistically analyzed; and (5) all involved researchers were credited for their contributions. Herein, 18 scientists were able to use a standard tumor grading system to pool their data and to analyze results in an effort to provide high-quality information about melanoma of the iris.

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