Long-Term Efficacy of Dexamethasone Intravitreal Implant in the Treatment of Vogt-Koyanagi-Harada (VKH) Disease Relapsing Posterior Uveitis

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Research Article

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Abstract

Purpose: To investigate the efficacy and safety of dexamethasone intravitreal implant in the treatment of relapsing posterior uveitis in patients with chronic recurrent VKH disease.

Methods: This is a prospective study of 29 eyes of 16 patients with posterior uveitis in chronic recurrent VKH disease. All patients received previous systemic steroid and immunosuppressive regimens. All patients underwent a comprehensive ophthalmic examination, including BCVA (log MAR), IOP, FFA, and SD-OCT. All patients underwent intravitreal injection with sustained-release dexamethasone 0.7 mg implant (Ozurdex®).

Primary outcome measures included mean change in best corrected visual acuity (BCVA) and central foveal thickness (CFT) at 24 months follow-up compared to baseline.

Results: At 24 months follow-up, the mean BCVA improved from 0.82 ± 0.13 to 0.38 ± 0.06logMAR (P <0.0001). The mean CFT reduced from 505 ± 29 to 244 ± 23 um (P <0.0001). The mean IOP changed from 15.1±2.2 to16.9±3.1 mmHg with no significant value. Twenty-one eyes (72.4%) received one injection, while eight eyes (27.6%) required two injections. The mean number of injections was 1.2± 0.60. The mean follow-up time was 24.75± 0.9months.

No serious ocular or systemic adverse events were noted during the follow-up period. Ocular hypertension was recorded in there (10.3%) eyes and controlled by IOP lowering medications. Cataract progression occurred in 11 (37.9%) eyes.

Conclusions: Our cohort highlights the beneficial effects of the Dexamethasone implant 0.7 mg in the treatment of VKH disease relapsing posterior uveitis improving visual acuity, reducing macular edema, and minimizing the burden of systemic steroid in this sample study.

Introduction

Vogt-Koyanagi-Harada (VKH) disease is an autoimmune disease against the melanocytes that affects the eyes, skin, and central nervous system. It is a systemic chronic inflammatory disorder characterized a bilateral progressive asymmetrical granulomatous panuveitis often associated with exudative retinal detachment, with or without extraocular manifestations as poliosis, vitiligo, alopecia, and hearing loss that mainly affects adults. The clinical stages of VKH disease include prodromal, uveitic, chronic and chronic recurrent stages. Exudative retinal detachment is the hallmark of acute disease while the sunset glow fundus is a unique feature of chronic disease. [1–4]

The treatment of choice for VKH disease is systemic high-dose corticosteroids in combination with immunosuppressive agents followed by a slow tapering of the drugs over at least 3–6 months to suppress intraocular inflammation and prevent further recurrence or chronicity. While appropriate corticosteroid therapy may adequately control the condition in some cases, recurrent and chronic disease

is common. Long-term high-dose systemic corticosteroid and immune-modulating therapy might result in systemic side effects such as hypertension, diabetes mellitus, osteoporosis, and long-term risks for cancer and mortality. [5–9]

Chronic recurrent VKH disease and the relapse of the ocular inflammation may reflect improper, insufficient, delay initiation, rapid tapering of immune-modulator therapy, or subclinical choroiditis. Recurrences become increasingly steroid-resistant and usually take the feature of chronic anterior uveitis and/or posterior segment involvement, which is mainly predominant as exudative retinal detachment. Relapses occur in 60% of cases in the first four years. The chronic recurrent form of VKH disease may last for months to years and is associated with an unfavorable long-term prognosis and vision-threatening complications including cataract, glaucoma, optic atrophy, subretinal fibrosis, and choroidal atrophy. [10–13]

Dexamethasone 0.7 mg intravitreal implant (Ozurdex; Allergan Inc., CA, USA) is a biodegradable implant, has been approved by the Food and Drug Administration (FDA) for treatment of noninfectious uveitis improving intraocular inflammation and visual acuity. Intravitreal dexamethasone implant provides high drug concentration in the retina, which is slowly released over an interval of six months with its peak levels at two months. [14–17]

The aim of this cohort to investigate the efficacy and safety of dexamethasone 0.7 mg intravitreal implant in the treatment of relapsing posterior uveitis VKH disease in patients with systemic steroid and/or immune-suppressive agents comorbidity, dependence, or non-compliance.

Patients And Methods

Patient selection

this is a prospective study of 29 eyes of 16 patients with relapsing posterior uveitis in recurrent chronic VKH disease.

Inclusion criteria: the study included at least18 years of age patients with relapsing posterior uveitis in recurrent chronic VKH disease. All patients had been previously treated with systemic steroid regimen (at 1.5-2 mg/kg/day) and Azathioprine (at 1-2.5 mg/kg/day) for at least 6 months. [7, 8] All patients had systemic steroid and/or immunosuppressive comorbidity, dependency, and non-compliance. The diagnosis and classification of VKH disease were established according to the criteria of the International Workshop of Vogt-Koyanagi-Harada Disease. [10, 18]

Recurrent chronic VKH was defined as a relapse of intraocular inflammation after inactivity for 3 months or more without systemic steroid therapy. [19– 21]

Exclusion criteria: a history of previous intravitreal injections (anti-VEGF, triamcinolone acetonide), history of other causes of posterior uveitis, Chronic or recurrent anterior uveitis cases of VKH disease without

posterior manifestations and patients receiving other drugs affect their vision and/or retina.

Patient evaluation: was done at baseline, 1 week, 1 month, and then every 3 months for 2 years after receiving IVI Ozurdex implant.

All patients underwent a comprehensive ophthalmic examination including best corrected visual acuity (BCVA) measured using a logarithm of the minimum angle of resolution (logMAR) Landolt C chart at 4 meters, slit lamp biomicroscopy, intraocular pressure (IOP) measurement, and funduscopy.

Imaging:

- Spectral-domain optical coherence tomography (SD-OCT) (3D OCT-2000, Topcon, Japan): to determine central foveal thickness (CFT) and evaluate the presence of subretinal fluid (SRF) or serous retinal detachment (SRD). The resolution was defined as a decrease of CFT to < 260 μm and the disappearance of fluid. [22]
- FFA was done for all patients.

Treatment

All patients underwent intravitreal injection with dexamethasone 0.7 mg implant (Ozurdex; Allergan, Inc, CA, USA) with an interval of one week for the bilateral patient. [9, 23] Re-treatment was indicated in the case of the presence of SRF with CFT ≥ 260 μm.

Ocular hypertension was defined as IOP measurement over 24 mmHg during the follow-up period after receiving IVI implant. [24]

Study Approval

the study was approved by the local ethics committee of Ibn Nafees medical center; Abu Dhabi; UAE. This cohort has followed the tenets of the Declaration of Helsinki.

Statistical Analysis

Variables were represented as mean ± standard deviation or percentage. For statistical analysis, BCVA was expressed in logMAR (logarithm of the minimum angle of resolution). Windows SPSS software version16.0 (SPSS, Chicago, USA) was used for statistical evaluation. Student's paired t-test was used to analyze changes in variables and evaluate the level of significance. A P value < 0.05 was considered statistically significant. The statistical significance was defined at 95% confidence intervals.

Primary Outcome Measures

included mean change in BCVA and CFT at 24 months follow-up compared to baseline.

Results

Study population:

This is a prospective study that included 29 eyes of 16 patients with relapsing posterior uveitis in recurrent chronic VKH disease from March 2017 to March 2021. Mean follow up was 24.75 ± 0.9 months (range: 24–26; median: 24.5). The mean age of patients was 41.5 ± 5.1 years (range: 35–49; median: 40.5) with 11 males (68.75%) and 5 females (31.25%). Bilateral IVI of dexamethasone implant was recorded in 13 patients (81.25%).

Clinical results

At 24-months follow-up, the mean BCVA improved from 0.82 ± 0.13 to 0.38 ± 0.06 LogMAR ($P < 0.0001$). The mean CFT reduced from 505 ± 29 to 244 ± 23 μm ($P < 0.0001$). Mean IOP changed from 15.1 ± 2.2 to16.9 ± 3.1 mmHg without any significant value. Twenty-one eyes (72.4%) received one injection while eight eyes (27.6%) required two injections. The mean number of injections was1.2 ± 0.60 injection. The mean interval between the first and the second injection was 13.6 ± 1.70 months.

Safety

No serious ocular or systemic adverse events were recorded during the follow-up period. Ocular hypertension was recorded in there (10.3%) eyes and controlled by IOP lowering medications. Cataract progression occurred in 11 (37.9%) eyes. Intralenticular ozurdex implant was recorded in one eye on the first follow-up visit after one week of receiving IVI implant. The Ozurdex implant was removed by phacoemulsification during cataract extraction after 10 months of receiving IVI implant. Neither capsular defect nor intra-operative complications were recorded. None of the patients received systemic steroid or immunosuppressive agents during the whole study. (Table 1), (Figs. 1–4)

Table 1
Study demography and clinical results

Variable	Result (mean ± SD), Range, Median or total (%)
CFT (um)*	
• Pre IVI	505 ± 29 (range: 493–565; median: 507)
• 24 months follow-up	244 ± 23 (range: 201–254; median: 241)
BCVA (Log MAR) *	
• Pre IVI	0.82 ± 0.13 (range: 0.8–1.3; median: 0.90)
• 24 months follow-up	0.38 ± 0.06(range: 0.2–0.4; median: 0.30)
IOP (mmhg)	
• Pre IVI	15.1 ± 2.2 (range: 12–19; median: 14.5)
• 24 months follow-up	16.9 ± 3.1 (range: 13–23; median: 16.5)
Number of injections(mean):	1.2 ± 0.6
• Eyes received one injection	21 (72.4%)
• Eyes required two injections	8 (27.6%)
Follow-up time(months)	24.75 ± 0.9
Pattern of VKH disease(patients):	
• Complete	3
• Incomplete	5
• Probable	8
*CFT (Central foveal thickness), um (micrometer), BCVA (best corrected visual acuity), IOP (intraocular pressure), IVI (intravitreal), VKH (Vogt-Koyanagi-Harada), SD (standard deviation), *A significant different at P value < 0.05.*	
BCVA (best corrected visual acuity), LogMAR (logarithm of the minimum angle of resolution), VKH(Vogt-Koyanagi-Harada), IVI (intravitreal), (M) Month	
CFT (Central foveal thickness), um(micrometer), VKH(Vogt-Koyanagi-Harada), SRD (serous retinal detachment), IVI (intravitreal), M (month)	

Discussion

The treatment of chronic relapses of VKH is an enigma. Chronic recurrent VKH requires a long term use of systemic corticosteroids and immunosuppressive drugs which increases the risk of systemic side-effects. Intravitreal steroids, anti-VEGF and recently immunosuppressive treatment have been also reported as adjuvant options in the treatment of VKH disease. Macular edema; one of the most visions threatening

complications of VKH disease is sometimes refractory to systemic steroid therapy. Intravitreal injections of corticosteroids treatment play an important role in the management of uveitic macular complications.[25–29]

Dexamethasone 0.7 mg implant has been approved to treat non-infectious posterior uveitis for controlling intraocular inflammation, especially in resistant uveitis macular edema. The dexamethasone implant provides a localized targeted therapy avoiding systemic complications but is associated with local ocular side effects such as cataract, glaucoma, risk of endopthalmitis and retinal detachment.[30–33]

All patients in this cohort showed relapsing posterior uveitis of VKH disease after receiving previous long term treatment course including oral steroid regimen (at 1.5-2 mg/kg/day) and azathioprine (at 1-2.5 mg/kg/day) for at least 6 months. Concurrent relapsing posterior uveitis with systemic steroid and/or immunosuppressive comorbidity, dependency, or non-compliance was the indication of the initiation of IVI dexamethasone 0.7 mg implant therapy. Besides, relapsing posterior uveitis was unilateral in 3 patients which might give more superiority for local treatment.

The results of our cohort ensure efficacy of dexamethasone 0.7 mg implant therapy in the treatment of relapsing posterior uveitis associated with VKH disease improving the vision with optimal control of inflammation and a remarkable systemic and immune modulator agents sparing effect.

Ocular hypertension was developed in there (10.3%) eyes and was controlled by IOP lowering medications. Episodes of ocular hypertension are recorded with dexamethasone implant therapy but usually transient and controlled with topical treatment or no therapy. [15, 24]

Cataract progression in our cohort was noted in 11 (37.9%) eyes; while the incidence of cataract progression was about 10% within 6 months in other studies. The study's relatively long follow-up time might explain the higher incidence of cataract progression. [11, 34, 35]

Intralenticular dexamethasone 0.7 mg implant was recorded in one eye. Resolving of macular edema despite intralenticular location might be explained by the partial intravitreal location of the implant. Previous studies followed up intralenticular Ozurdex implant for duration of 7 to 12 months and they reported cataract progression and ocular hypertension. [36, 37]

Our result agreed with previous studies stated that dexamethasone 0.7 mg implant is an effective therapy in patients with refractory posterior uveitis in VKH disease avoiding the side effects of systemic corticosteroids and immune suppressive agents. *Pacella et al*, in a short follow-up cohort, concluded the improvement of macular edema in 3 eyes of 3 patients of VKH disease for 4–6 months with dexamethasone implant. *Latronico et al* reported efficacy of dexamethasone 0.7 mg implant in the treatment of refractory bilateral panuveitis in a young VKH syndrome patient.[38, 39]

The efficacy of other intravitreal corticosteroids, such as triamcinolone acetonide and fluocinolone 0.59 mg implant (Retisert; Bausch and Rochester, USA) in the improvement of visual acuity, macular edema

and serous retinal detachments associated with VKH disease has been proven. The advantages of dexamethasone implant over these intravitreal corticosteroids are its biodegradability, not need to be removed and less frequent injections. Compared to Dexamethasone implant, triamcinolone acetonide has a short duration and required repeated injections to expose patients to a greater risk of endophthalmitis, glaucoma, and cataracts. Retisert is associated with a higher incidence rate of ocular hypertension and cataract. Besides, Retisert implant dissociation, protrusion, re-implantation in chronic uveitic patients, and explanation in case of adverse effects are other drawbacks. [40–44]

Fluocinolone0.19 mg (Iluvien; Alimera Sciences, USA) intravitreal implant showed an improvement in vision, macular edema, and control of ocular inflammation secondary to noninfectious uveitis in off-label use case report.[45]

The main limitation of this study is the small cohort of patients and the absence of a control group. While, the long term follows up in our study is one of the strong points in this cohort.

Further prospective, large comparative clinical trials are required to evaluate the efficacy and safety of different intravitreal agents as Ozurdex implant, Iluvien implant, and intravitreal immunosuppressive agents like Sirolimus and Infliximab.

Conclusion

Our cohort highlights the beneficial effects of the Dexamethasone implant 0.7 mg in the treatment of VKH disease relapsing posterior uveitis improving visual acuity, reducing macular edema, providing systemic and immunosuppressive agents sparing effect, and minimizing their burden in this sample study.

Abbreviations

VKH (Vogt-Koyanagi-Harada), CFT (Central foveal thickness), um (micrometer), BCVA (best corrected visual acuity), (logMAR) logarithm of the minimum angle of resolution, IOP (intraocular pressure), SRD (serous retinal detachment), SD (standard deviation).

Declarations

Acknowledgment:

Part of this study was presented by Dr. Tarek Roshdy Elhamaky as a free paper abstract in AOP (Advanced Ophthalmologic Practice) 2020 annual meeting, Paris, France (10–11 January 2020).

Disclosure: The author declares no conflict of interest. No financial support was received for this submission. No substantial contribution was provided for this submission.

Data Sharing Statement: All data used to support the findings of this study are available from the corresponding author upon request without an end date.

Study Approval

the study was approved by the local ethics committee of Ibn Nafees medical center; Abu Dhabi; UAE. This study has followed the tenets of the Declaration of Helsinki.

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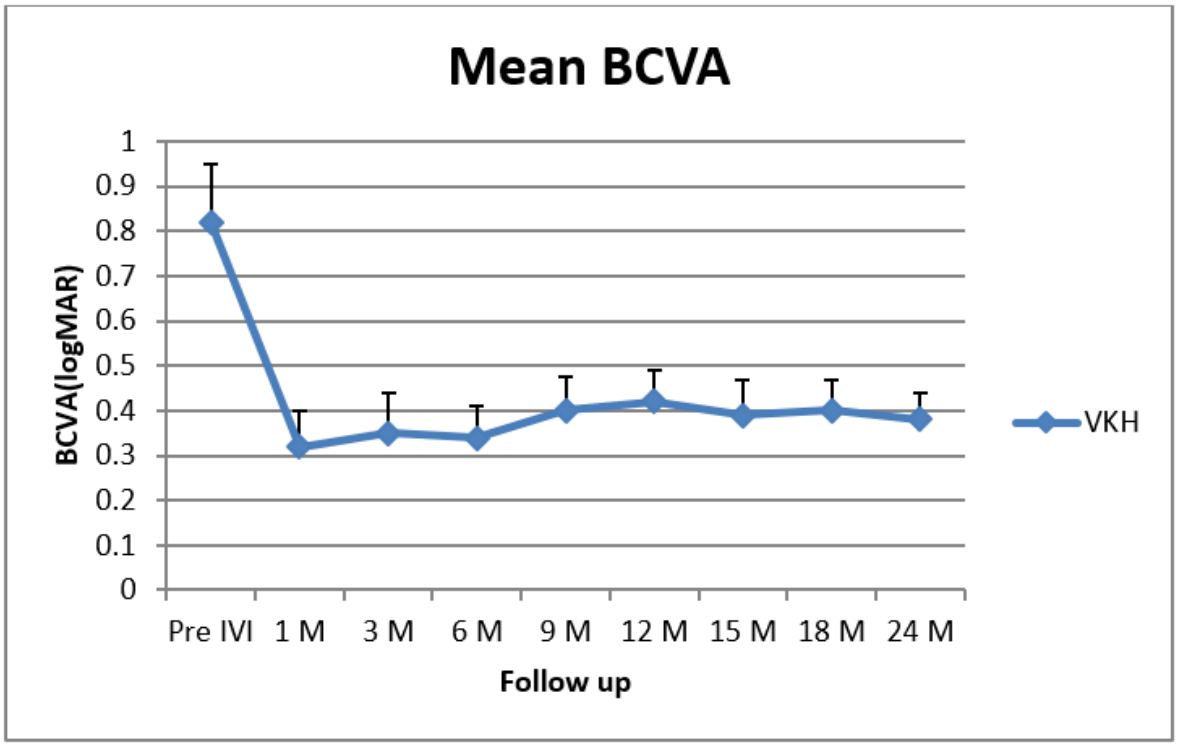
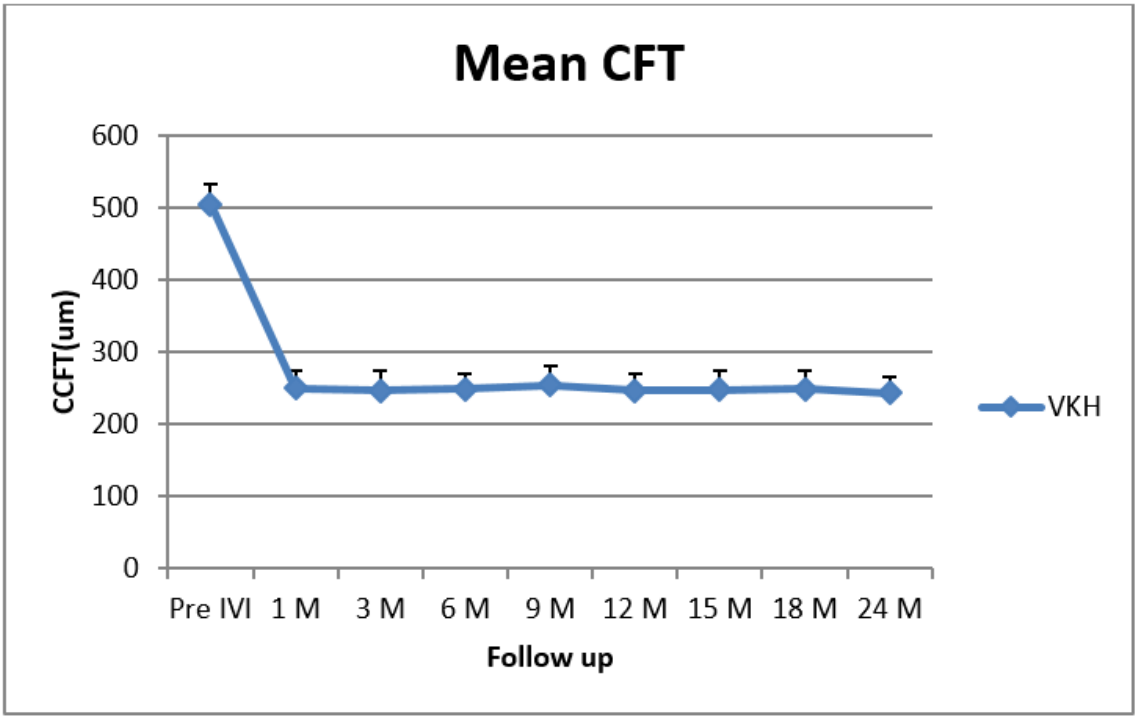
Figures



BCVA (best corrected visual acuity), LogMAR (logarithm of the minimum angle of resolution), VKH(Vogt-Koyanagi-Harada), IVI (intravitreal), (M) Month

Figure 1

Changes in mean BCVA at follow-up.



CFT (Central foveal thickness), um(micrometer), VKH(Vogt-Koyanagi-Harada), SRD (serous retinal detachment), IVI (intravitreal), M (month)

Figure 2

Changes in mean CFT at follow-up

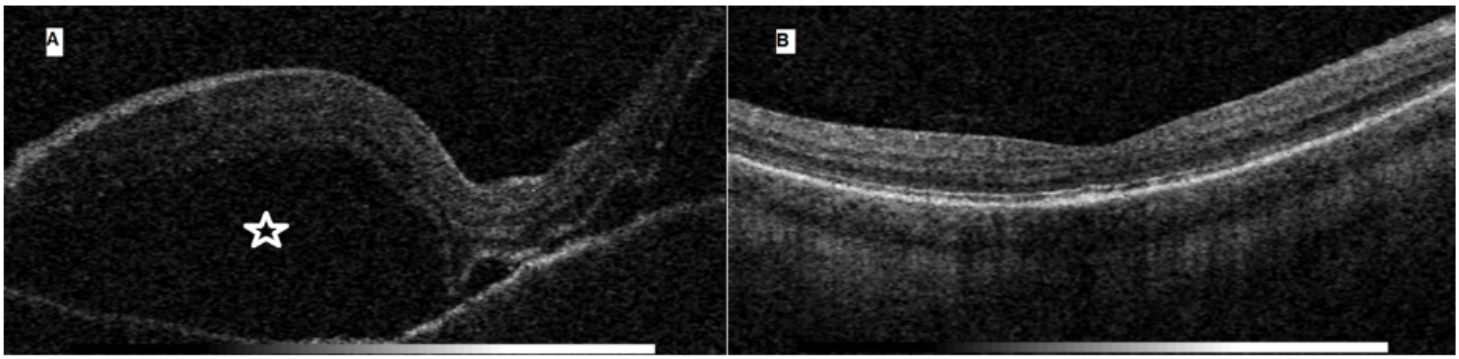


Figure 3

SD-OCT image of the right eye shows a serous retinal detachment (SRD) in VKH disease patient; [A] Baseline: extensive SRD (asterisk) [B] 24 months follows up after intravitreal injection with dexamethasone 0.7 mg implant: none.

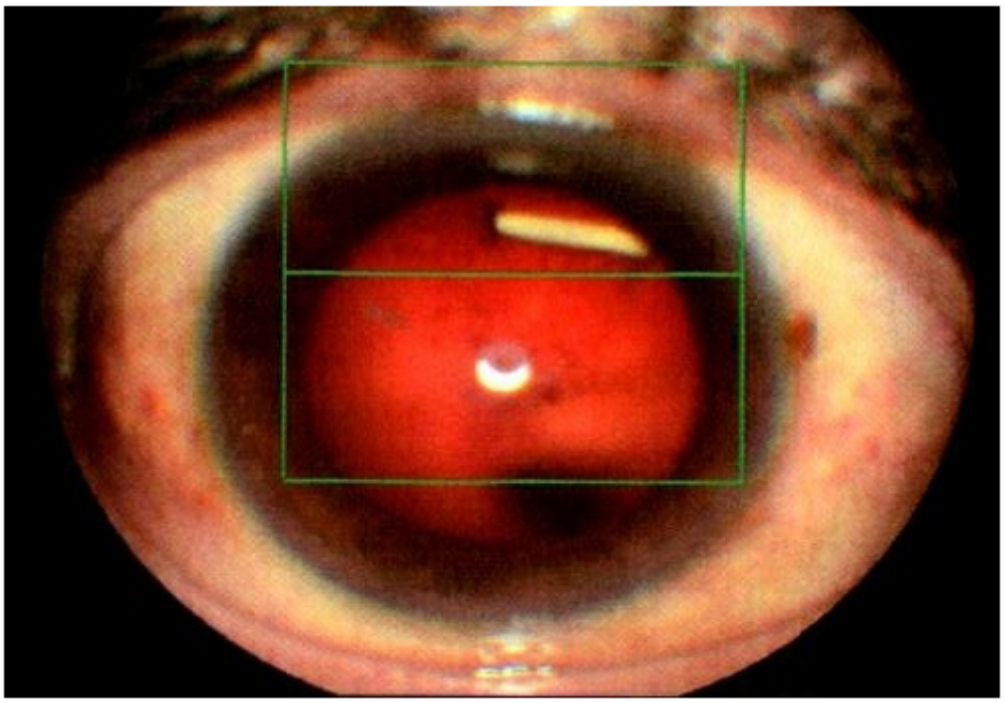


Figure 4

Slit-lamp photo shows intralenticular Ozurdex implant.