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*Case Report*

# The usage of CustomFlex iris prosthesis for uveitis-induced iris defects

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## ABSTRACT

Iris defects can cause glare and poor cosmesis that affects a patient's quality of life. These defects may be caused by congenital aetiologies such as aniridia or acquired ones such as trauma and intraocular surgeries. Iris prostheses, like the CustomFlex Artificial iris by HumanOptics, were created to address these symptoms. The CustomFlex device is a stand-alone thin and foldable silicone coloured implant that could be placed in either the capsular bag or the sulcus. Because the majority of iris defects requiring prosthetic use was secondary to trauma, congenital aniridia and intraocular surgeries, our case report aims to describe usage of the CustomFlex in a patient with iris defects secondary to uveitis. Our patient presented with photophobia caused by bilateral diffuse iris atrophy with a history of herpes zoster ophthalmicus and underwent simultaneous iris prosthesis and intraocular lens implantation. The procedure improved his vision while reducing photophobia and glare. This case report shows how endocapsular implantation of the CustomFlex artificial iris, along with cataract surgery, is feasible for patients with uveitis related iris defects.

**Keywords:** Iris defects, Iris prosthesis, CustomFlex

## INTRODUCTION

The iris and its functions are vital to vision. It controls the amount of light reaching the retina, decreases corneal and lenticular optical aberrations and increases the accommodative depth of focus. Iris defects may therefore cause blurriness, photophobia, glare and poor cosmesis. They can be congenital from aniridia, albinism, coloboma and anterior segment dysgenesis like Axenfeld-Rieger syndrome. They can also be acquired from blunt or penetrating trauma, uveitis, uveitis-glaucoma-hyphema (UGH) syndrome, iridocorneal endothelial syndrome, endothelial down growth and intraocular surgeries.[1] Oftentimes, the patient's symptoms may be compounded by associated pathologies such as corneal scars, aphakia, retinal damage, or secondary glaucoma.[2] These patients may suffer debilitating visual symptoms and visible deformities that undermine their quality of life.

Prosthetic devices were then created to address these iris defects. They were first placed in the anterior chamber by Choyce in 1956 and then in the posterior chamber by Pearce in the 1970s.[3] The iris prosthesis was then combined with an intraocular lens (IOL) to create the single-piece black iris-diaphragm IOL, first described by Reinhard *et al.*[4] and Sundmacher *et al.*[5] in 1994 and then used in the United States in 1999.[6] Since then, other reports have described further uses for this black IOL.[7,8] In 2018, the Food and Drug Administration (FDA) approved the CustomFlex Artificial Iris (HumanOptics AG, Erlangen, Germany), a stand-alone thin and foldable silicone-coloured implant that could be placed in either the capsular bag or the sulcus, with or without suture fixation. It revolutionised the field of iris prosthetics by simultaneously addressing iris defect symptoms, cosmesis and ease of implantation.[1]

The use of the CustomFlex for uveitis-induced iris defects has not been greatly reported in the literature as most cases are caused by trauma, congenital aniridia and intraocular surgery.[1] In 2018, Mayer *et al.*[9] described the implantation of bilateral CustomFlex and IOLs for a patient with cataracts and iris defects secondary to remote iritis. These artificial irises were placed in the sulcus with pre-made peripheral iridotomies to prevent post-operative intraocular pressure (IOP) spikes. Similarly, we present a case of simultaneous IOL and CustomFlex implantation – although endocapsular – for uveitis-induced iris defects.

## CASE REPORT

A 62-year-old Caucasian male had left herpes zoster ophthalmicus (HZO) iritis and forehead rash treated

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by an outside institution in 2016. He was presumed to have an HZO flare-up in February 2021 with a left eyelid stye and bilateral photophobia. Despite a lack of ocular inflammation, he was treated with prednisolone and referred to a uveitis specialist to be evaluated for bilateral anterior uveitis.

His initial examination revealed visual acuities of 20/25 for the right eye (OD) and 20/30 for the left eye (OS), anisocoria of 2 mm OD > OS without a relative pupillary afferent defect, IOP of 16 OD and 10 OS, diffuse severe iris stromal atrophy in both eyes (OU) [Figure 1], quiet anterior chambers OU and 1.5+ nuclear sclerosis OU. His recent rapid plasma antigen, fluorescent treponemal antibody, human immunodeficiency virus and human leukocyte antigen B-27 tests were negative.

The patient was treated with several prednisolone tapers over the next 2 months for recurring photophobia, each time without ocular inflammation. In August 2021, he was referred to a glaucoma specialist who ruled out pigment dispersion syndrome through gonioscopy and UGH syndrome with ultrasound biomicroscopy. The patient initially deferred the recommendation for bilateral cataract surgery with artificial iris implantation but was eventually amenable when he re-presented in June 2022 with progressing iris atrophy and cataracts.

He underwent cataract extraction with IOL and endocapsular black CustomFlex implantation OD and then OS 2 weeks later in November 2022. For both eyes, the iris prostheses were inserted inside the capsular bag on top of the IOLs with the help of capsular tension rings. Subconjunctival Kenalog injections were given bilaterally. By 1-month post-operative, the patient's vision was 20/20 bilaterally and the transillumination defects were successfully covered by the endocapsular black iris prostheses, as seen on slit-lamp examination [Figure 2]. The prostheses significantly improved photophobia in the right eye but only mildly in the left eye, for which he sees uveitis and cornea for further investigation and treatment.

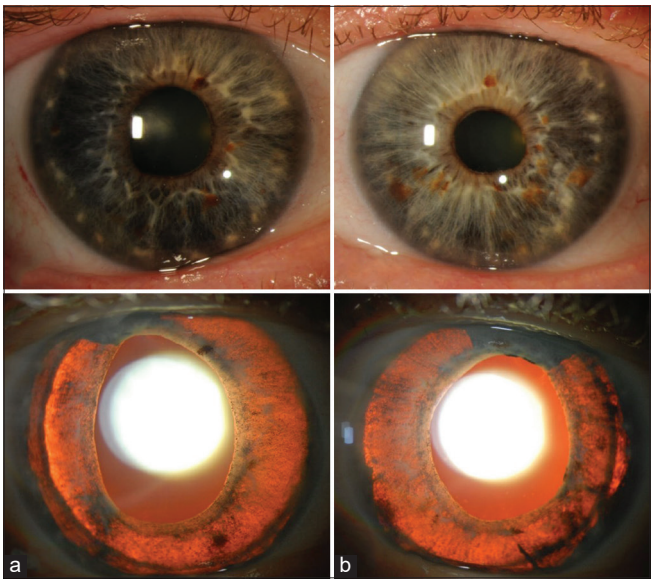


**Figure 1:** Slit-lamp photos of the right (a) and left (b) eyes with corresponding retro-illumination revealing significant and diffuse transillumination defects of the right (a) and left (b) eyes.

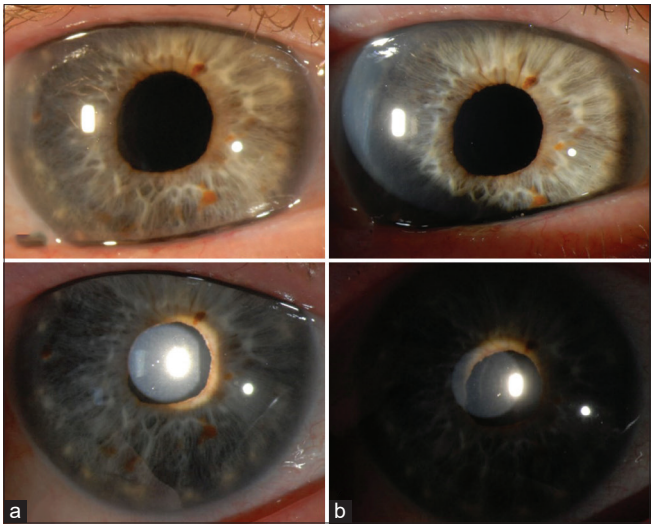


**Figure 2:** Post-operative slit-lamp photos of the right (a) and left (b) eyes with corresponding retro-illumination revealing resolved transillumination defects of the right (a) and left (b) eyes. The CustomFlex Artificial Iris implant is hidden from view behind both the irises.

## DISCUSSION

The CustomFlex has enjoyed success in a multitude of studies like the FDA Clinical Trial in 2022. This was an unmasked, non-randomised and multicentre interventional trial that showed significant reductions in light sensitivity and glare and improvements in visual function and cosmesis.[1] These findings were previously supported by the prospective studies done by Mayer *et al.*[2] in 2016, Bonnet and Miller[10] in 2020 and Figueiredo and Snyder[11] in 2020. If necessary, simultaneous CustomFlex implantation and IOL procedure is a viable option as 84% of the FDA Clinical Trials had this performed. A previous study by Snyder *et al.*[12] in 2017 also showed that cataract surgery with CustomFlex implantation improved visual acuity and cosmesis while reducing photophobia and glare. Adverse events during these procedures were more related to the complex anterior segment surgery rather than the iris prosthetic itself. These included the following in decreasing order: elevated IOP (7.8%), vitreous haemorrhage (4.3%), hyphema (4.0%), iritis after 1 month (3.4%), cystoid macular oedema (2.9%) and new-onset corneal oedema after 1 month (2.5%).[1]

Complications related directly to the iris implant were low, including a few cases of dislocation, decentration, and inflammation.[2] Given its positive outcomes and good safety profile, the CustomFlex continues to be a go-to the option for iris defects.

The CustomFlex iris prosthesis can be placed primarily in three different manners: Passively in the capsular bag, passively within the sulcus, or actively in the sulcus with scleral fixation. The choice depended on the surgeon's assessment of the anterior segment anatomy. Of note, placement was never done in a phakic eye. Endocapsular placement was the most common (43%) followed by active suture fixation within the sulcus (42%).[1] Assuming adequate zonular support and capsular bag integrity, endocapsular placement of the CustomFlex is preferred because it maximises device centration and minimises uveal tissue contact associated with sulcus positioning. This method, however, requires the use of capsular tension rings to not only stabilise the bag for device placement, but to measure the capsular bag diameter for accurate prosthesis sizing. Amaral and Snyder describe a novel method of loading the CustomFlex into an IOL injector using a trifold conoid approach to avoid device catching or damage during the injection.[13] Because the capsular bag and zonules were intact for the patient in this case report, the CustomFlex was successfully placed in the capsule after IOL insertion.

Usage of the CustomFlex for uveitis-induced iris defects has not been greatly described. Although low, iritis is a known complication for iris prostheses as described above. It is therefore reasonable to be concerned for an increased inflammation risk in patients with a history of uveitis. To avoid this, it may be prudent to perform the operation in the absence of active inflammation, as was done in both this case report and in Mayer's *et al*. study.[2] Although prior studies have not directly examined the association between sulcus placement and post-operative iritis, there may even be more reason in these cases for endocapsular placement to minimise further irritation of the ciliary body and iris, thus possibly decreasing the risk for a uveitis flare up.

## CONCLUSION

This case report demonstrates how the CustomFlex iris prostheses were successfully used to manage uveitis-induced iris defects. For the patient's right eye, it achieved the primary goal of covering the iris transillumination defects and reducing symptomatic photophobia without significant complications, like triggering an HZO recurrence. The left eye also had successful implantation but did not enjoy the same degree of photophobia reduction, suggesting that iris transillumination defects may not be the only contributor to photophobia in patients with a history of uveitis. Other causes may include corneal hypersensitivity and chronic surface irritation or inflammation. The iris prosthesis implantations were also done alongside cataract surgery, restoring the patient's distance best-corrected visual acuity to 20/20 bilaterally. This case overall supports the use of the CustomFlex for similar patients with uveitis-induced iris defects and cataracts.

### Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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