Implantable Collamer Lens Use in a Spaceflight Participant During Short Duration Spaceflight

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BACKGROUND: The purpose of this report is to document the first use of a single piece, posterior chamber phakic implantable collamer lens (ICL) with a central port in the right eye (OD) of a spaceflight participant (SFP) during a 12-d Soyuz mission to the International Space Station (ISS). We also briefly document the stability of a pre-existing pachychoroid pigment epitheliopathy (PPE) in the macula of his left eye (OS) during this mission.

- **CASE REPORT:** Ocular examination, including refraction, slit lamp examination, macular examination by optical coherence tomography (OCT), and tonometry were performed before and after his mission and he was questioned regarding visual changes during each portion of his flight.
- **DISCUSSION:** We documented no change in ICL position during his spaceflight. He reported stable vision during liftoff, entry into microgravity, 12 d on the ISS, descent, and landing. Our results suggest that the modern ICL with a central port is stable, effective, and well tolerated during short duration spaceflight. His PPE also remained stable during this mission as documented by OCT.
- **KEYWORDS:** implantable collamer lens, pachychoroid pigment epitheliopathy, vision, spaceflight.

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uring spaceflight the eyes of astronauts are exposed to an extremely unique microgravity environment that may result in a spectrum of ocular anatomic changes including optic disc edema, flattening of the posterior globe, choroidal expansion, shallowing of the anterior chamber (AC) with anterior movement of the iris, and alterations in aqueous flow.^{4,5,7} These microgravity-induced changes, as well as increased G forces during takeoff and re-entry, have the potential to impact the position and associated optical stability of an implantable collamer lens (ICL). Also, the expanding choroid during microgravity exposure could potentially exacerbate pre-existing pachychoroid pigment epitheliopathy (PPE). In this report we document the first successful use of an ICL (OD) during 12 d of spaceflight onboard the International Space Station (ISS). We also briefly describe the stability of a mild, pre-existing PPE OS in this same spaceflight participant (SFP) during this mission.

CASE REPORT

The spaceflight participant, a 46-yr-old Japanese man, had a Visian implantable collamer lens with CentraFLOW

KS-AquaPORT technology implanted OD on December 18, 2017, in Japan. His preoperative refractive errors were $-0.75-1.00 \times 085$ OD and $-1.00-0.50 \times 070$ OS, correctable to 20/13 OD and 20/10 OS. His postoperative course OD was uneventful with 20/16 uncorrected distance visual acuity, a 1-mo postoperative refraction of plano-0.50 × 075 correctable to 20/10, a central corneal thickness (CCT) of 595 µ, an ICL vault of 0.20 CCT, and a tonometry reading of 16 mmHg. In December 2020, a 3-yr postoperative eye exam documented uncorrected distance visual acuity 20/40 OD and 20/50 OS with refractive errors of $-1.00-0.75 \times 075$ OD and $-1.50-1.00 \times 075$ OS, correctable to 20/10 OD and 20/12 OS, with an ICL vault of 0.16 CCT. He had a history of subfoveal retinal pigment epithelium (RPE) irregularities from mild previous

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central serous chorioretinopathy (CSC) OS with no history of decreased vision or metamorphopsia.

A pre-mission eye examination, performed in Houston, TX, USA, 3 mo prior to his December 2021 flight documented an uncorrected visual acuity of 20/40 OD and 20/100 OS, with manifest refractions of $-1.25-0.25 \times 075$ OD and $-1.75-0.75 \times$ 075 OS correcting to 20/20 OU. His Goldmann tonometry readings were 14 mmHg OD and 15 mmHg OS. His corneas and irises were clear OU. A properly positioned ICL with a central hole was present OD. His dilated fundus exam noted lens nuclear sclerosis and cortical changes OD and clear OS. This new onset of nuclear sclerosis since his 2017 ICL insertion was thought to be responsible for his myopic shift and he was prescribed single vision distance glasses for correction. The vitreous and AC were clear OU. His optic discs and retinal vasculature were normal OU. Macular optical coherence tomography (OCT) (Heidelberg Spectralis, Franklin, MA, USA) documented a thickened choroid OU with mild RPE changes OS consistent with PPE with no evidence of subretinal fluid.

His last preflight eye examination was performed in Star City, Russia, 20 d before launch. At this time, his autorefraction (Huvitz Charops MRK-3100P autorefractor keratometer; Huvitz, Gyeonggi-do, Republic of Korea) was –1.00 sph OD, and –1.75 sph OS with each eye correctable to 20/20. His noncontact tonometry (Reichert AT 550) was 14 mmHg OU. He launched on a Soyuz spacecraft from the Baikonur Cosmodrome in Kazakhstan on December 8, 2021, on a 12-d Russian mission to the ISS. During private medical conferences held on Flight Days 2, 3, 7, and 11, he was routinely asked about visual changes. He denied any change in vision or ocular discomfort throughout the mission. Given the largely near vision environment on the ISS, he only used his single vision distance glasses to look out the window from his crew quarters. No in-flight testing was planned or performed.

He also experienced no visual changes during his atmospheric entry in the Soyuz Descent Module that reached a deceleration of more than $+4.0 \text{ G}_{v}$ (eyeballs in) or during the parachute-assisted landing in Kazakhstan. Following return to Star City on the same day, a basic eye exam was performed and demonstrated uncorrected visual acuity 20/16 OU at 1 m. One day after return autorefraction was -1.25 sph OD and -1.75 sph OS, correcting to 20/20 in each eye at distance. There was no change in his cornea, iris, or lens from his pre-mission examination and slit lamp examination confirmed no postflight change in ICL position. His fundus exam was normal OU and there was no change in macular appearance on OCT OU. His noncontact tonometry was 15 mmHg OD and 16 mmHg OS. Optic discs were normal OU with no evidence of edema. A follow-up exam was performed in Japan 18 d after return. On this visit his uncorrected distance visual acuity was 20/30 OD and 20/80 OS with manifest refractions of $-0.75-0.50 \times 050$ 20/10 OD and -1.50-1.00 × 060 20/10 OS, an ICL vault of 0.10 CCT and tonometry readings of 16 mmHg OD and 18 mmHg OS. The remainder of his eye exam was unchanged and he had no visual complaints.

DISCUSSION

Intraocular lenses (IOL) can trace their origin to World War II aviation. During the Battle of Britain, in 1940, fragments of Plexiglass from the shattered canopies of British Hurricane and Spitfire aircraft sometimes became lodged within the eyes of pilots. The British ophthalmologist Harold Ridley (later to become Sir Harold Ridley) carefully monitored these plastic intraocular splinters and determined that they produced little or no inflammation.¹ This led to the concept that an intraocular plastic lens of the proper size and power could potentially restore vision following the removal of an opacified natural lens. Ridley became the first to surgically implant an IOL in a human in 1949.¹ This landmark surgical procedure set the stage for the gradual evolution and improvement of IOL design and surgical techniques. The first use of IOLs in terrestrial aviation was reported by the U.S. military in 1987.⁶ IOL use was subsequently documented in an astronaut during a 2-wk space shuttle mission in 1999⁹ and during a 6-mo ISS mission in 2018.⁸ These reports documented stable vision and position of IOLs inserted within the capsular bag following the surgical removal of a cataractous lens by phacoemulsification. It is important to note that IOL capsular bag stability was demonstrated even following the emergency ejection of an aviator from a high-performance U.S. Air Force aircraft.¹¹ Currently, this type of capsular bag fixated IOL can be approved for use in flight personnel in all four military services and the NASA astronaut corps.

The surgical approach, insertion, and positioning of the ICL contrasts with the standard phacoemulsification/IOL surgery used in the above reports. In the ICL procedure, a 3.0–3.4 mm clear cornea tunnel incision is made at the corneal limbus on the steep meridian using topical or peribulbar anesthesia. The foldable Visian ICL is then injected into the posterior chamber between the iris and crystalline lens with support from the ciliary sulcus. Although this procedure has demonstrated postoperative safety and stability for the correction of myopia in the terrestrial environment,^{2,10} this is the first report of ICL use during spaceflight.

The insertion of an ICL in an astronaut raises several potential concerns related to the interaction of the lens implant with the changing anatomy and physiology of the posterior chamber during spaceflight. Within seconds of exposure to microgravity, there is a sudden expansion of the choroid. Several studies have quantified this choroidal expansion using OCT during longduration spaceflight.^{4,5,7} This choroidal expansion may cause an anteriorly directed force on the vitreous, a concomitant anterior movement of the crystalline lens, and some narrowing of the AC. A study by Macias et al.⁵ demonstrated peripapillary choroidal expansion during and after 6 mo of spaceflight. Although equipment for AC measurement was not available during spaceflight, AC narrowing was also documented following 6 mo of spaceflight in these normal phakic astronauts.⁵ These spaceflight-induced anatomical changes could potentially adversely impact the position of an ICL during spaceflight as well as the status of a preexisting maculopathy.

In phakic terrestrial patients, safety concerns related to ICL vault and positioning include the potential for pupillary block with elevated IOP, corneal endothelial cell loss, iris pigment dispersion, and anterior subcapsular cataract formation.¹⁰ Given the ocular physiological changes that occur during spaceflight, these concerns are magnified in astronauts. In an astronaut with an ICL, even a slight anterior displacement of the crystalline lens during microgravity exposure could set the stage for pupillary block and pathologically elevated IOP. Early ICL versions with no central opening were of particular concern, even in the terrestrial environment, and necessitated the need for prophylactic laser peripheral iridotomy. However, the addition of a 0.36-mm central hole in the Visian ICL allows for free aqueous flow through the ICL and has largely addressed the potential for pupillary block in terrestrial patients.^{2,10} This central hole also improves aqueous circulation and decreases the incidence of cataracts with no effect on vision.^{2,10} Proper vaulting (central separation between the ICL and the anterior surface of the natural lens) is essential to allow adequate separation between the ICL and the anterior lens capsule to avoid the formation of an anterior subcapsular cataract. The degree of vault is related to the interaction of the ICL with the anatomy and physiology of the posterior chamber.¹⁰ Current vault recommendations based on the nonfenestrated version of the ICL are for 50-100% central corneal thickness or 250 μ to 750 μ with a maximum recommendation of 1000 µ. There are no published changes to the guidelines for the fenestrated ICL. Given this SFP's normal postflight intraocular pressure (IOP), lack of symptoms suggestive of elevated IOPs, clear anterior lens capsule, and stable vision, it appeared that the central hole, ciliary sulcus fixation, and vaulting in his ICL permitted sufficient free flow of aqueous to avoid pupillary block and lens contact during spaceflight.

An increase in episcleral venous pressure also occurs during head-down tilt, parabolic flight, and microgravity exposure and may impact AC aqueous volume. However, since the aqueous outflow is only approximately 3 $\mu L \cdot min^{-1}$, this process would not account for the quick spike in IOP noted in analog and microgravity studies. More likely, as the choroid is drained by the vortex vein system and largely not autoregulated, craniocervical venous congestion may inhibit choroidal drainage and lead to a sudden expansion of relatively stagnant blood in the choroid and a concomitant quick rise in IOP.⁷

Greenwald reported choroidal thickness increased during long-duration spaceflight using a single OCT B scan aligned through the fovea and optic disc.³ Choroidal expansion during spaceflight is also hypothesized to set the stage for choroidal folding, which is well documented.⁷ This SPF's preexisting PPE and macular RPE irregularity could theoretically predispose him to CSC from the anterior force created from increased choroidal expansion during spaceflight. Since CSC is caused by leakage from the choroid through a defect in the RPE,¹² spaceflightinduced choroidal expansion might exacerbate this condition. However, we noted no change in his macular RPE status or evidence of subretinal fluid after 12 d of microgravity exposure.

This report describes the first use of an ICL during spaceflight. Following spaceflight, we documented no change to the iris or lens and no change in ICL position. Stable vision during launch, entry into microgravity, 12 d of spaceflight, re-entry, and parachute-assisted landing in this SFP suggests that the low mass, sulcus fixation, central port, and vaulting of the ICL protected it from displacement. Our report suggests that the ICL with a central port is stable, safe, and effective during short-duration spaceflight. Also, this SFP's preexisting PPE was not exacerbated by choroidal expansion during this short-duration spaceflight.

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REFERENCES

- 1. Apple DJ. Sir Harold Ridley and his fight for sight. Thorofare (NJ): Slack; 2006.
- Fernández-Vega-Cueto L, Lisa C, Esteve-Taboada JJ, Montés-Micó R, Alfonso JF. Implantable collamer lens with central hole: 3-year follow-up. Clin Ophthalmol. 2018; 12:2015–2029.
- Greenwald SH, Macias BR, Lee SMC, Marshall-Goebel K, Ebert DJ, Liu JHK, et al. Intraocular pressure and choroidal thickness respond differently to lower body negative pressure during spaceflight. J Appl Physiol (1985). 2021; 131(2):613–620.
- Macias BR, Ferguson CR, Patel NB, Gibson CR, Samuels BC, et al. Changes in the optic nerve head and choroid over 1 year of spaceflight. JAMA Ophthalmol. 2021; 139(6):663–667.
- Macias BR, Patel NB, Gibson CR, Samuels BC, Laurie SS, et al. Association of long-duration spaceflight with anterior and posterior ocular structure changes in astronauts and their recovery. JAMA Ophthalmol. 2020; 138(5):553–559.
- Mader TH, Carey WG, Friedl KE, Wilson WR. Intraocular lenses in aviators: a review of the U.S. Army experience. Aviat Space Environ Med. 1987; 58(7):690–694.
- Mader TH, Gibson CR, Pass AF, Kramer LA, Lee AG, et al. Optic disc edema, globe flattening, choroidal folds and hyperopic shifts observed in astronauts after long-duration space flight. Ophthalmology. 2011; 118(10):2058–2069.
- Mader TH, Gibson CR, Schmid JF, Lipsky W, Sargsyan AE, et al. Intraocular lens use in an astronaut during long duration space flight. Aerosp Med Hum Perform. 2018; 89(1):63–65.
- Mader TH, Koch DD, Manual K, Gibson CR, Effenhauser RK, Musgrave S. Stability of vision during space flight in an astronaut with bilateral intraocular lenses. Am J Ophthalmol. 1999; 127(3):342–343.
- Packer M. The implantable collamer lens with a central port: review of the literature. Clin Ophthalmol. 2018; 12:2427–2438.
- Smith P, Ivan D, LoRusso F, MacKersie D, Tredici T. Intraocular lens and corneal status following aircraft ejection by a USAF aviator. Aviat Space Environ Med. 2002; 73(12):1230–1234.
- van Rijssen TJ, van Dijk EHC, Yzer S, Ohno-Matsui K, Keunen JEE, et al. Central serous chorioretinopathy: towards an evidence-based treatment guideline. Prog Retin Eye Res. 2019; 73:100770.