Increased Risk of Corneal Haze Associated with the Raindrop Near Vision Inlay: FDA Safety Communication

Date Issued: October 23, 2018

Audience:

- People who have had surgery to implant the Raindrop Near Vision Inlay
- Eye care providers

Medical Specialties:

Ophthalmology, Optometry

Device:

The Raindrop Near Vision Inlay is a transparent, curved hydrogel disc smaller than the eye of a needle. The device was designed to be surgically placed (implanted) into the cornea of one eye. The U.S. Food and Drug Administration (FDA) granted approval of this device in 2016 to ReVision Optics to improve near vision and offer an alternative to eyeglasses or contact lenses in healthy patients. The device is now owned by RVO 2.0, doing business as Optics Medical.

Purpose:

This notice is to alert eye care providers and patients already implanted with the device of the increased risk of corneal haze (a type of cloudiness in the cornea due to inflammation) associated with the device. The FDA is advising that eye care providers not implant Raindrop inlays and is working with Optics Medical to have all remaining product on the market recalled. Raindrop Inlays are no longer being distributed in the U.S.

Summary of Problem and Scope:

People who undergo implantation of the Raindrop Near Vision Inlay device are at risk for the development of corneal haze that can affect clear vision. Haze can cause blurry vision or glare by clouding the cornea, or by changing the focusing power of the eye. The impact of haze on the patient's vision is dependent on the severity of haze and its location in the cornea.

The FDA's approval of the Raindrop Near Vision Inlay device in 2016 was supported by a prospective, non-randomized clinical study in patients who had the device implanted. At the time of device approval, the two-year clinical study results showed that 16.1 % (60 of 373) of patients had central corneal haze of any severity at some point during follow-up. The percentage of patients with two or more lines of loss in vision on the eye chart caused by corneal haze was 1.1 % (4 of 373 patients). The number of patients who had the device removed was 24 of 373 patients (6.4%) at the two-year follow-up visit, and 29% of device removals (7 of 24 patients) at this time point were due to corneal haze.

As a condition of approval, FDA mandated that the sponsor perform a post-approval study (PAS) designed to follow patients enrolled in the original study at least through five years after surgery. Of the 373 patients from the original study, 150 were enrolled in the PAS. The most recent interim data from this ongoing study, including 5

years of follow-up in some patients, showed that the rate of central corneal haze, at any time during the study, was 42% (63 of 150 patients). The presence of haze at any location within the cornea was 75% (113 of 150 patients). Twenty-two (22) patients developed their first episode of haze 60 months after the device was implanted. The percentage of patients with two or more lines loss on the eye chart caused by corneal haze (2.0%, 3 of 150 patients) was greater than what was observed during the original clinical study.

Steroid eye drops are commonly used to treat corneal haze. Of the 150 patients enrolled in the PAS, 31 subjects (20.7%) were treated at any time during this study and 29 of 122 (23.7%) patients who still had the device implanted were prescribed steroid eye drops for corneal haze. Of these 29 patients, 8 were treated with steroids for 3 months or more, and an additional 10 patients were being actively treated at the time of the study report or left the study while on active treatment. In some cases, the steroid eye drops did not make the haze go away, and the device had to be removed.

While steroid eye drops are commonly used to treat corneal haze, this medication is associated with the risks of increased eye pressure (a possible sign of glaucoma) and cataract. There were instances in the post-approval study where patients who were treated successfully for corneal haze with a course of steroid eye drops had a recurrence of haze at a later time.

Corneal haze has been a significant reason for device removal over time. Of the 150 patients enrolled in the PAS, 35 patients (23.3%) to date have had their device removed either during the post-approval study or after they left the original clinical study. Of these 35 patients, 31% (11 of 35) had the device removed due to corneal haze, and 28% (10 of 35) had the device removed due to unresolved inflammation (which may include additional cases of haze). It is important to note that there was one patient who first developed haze 6 months after removal of the device. In addition, some patients continued to have corneal haze even after the device was removed. This study is ongoing and patient follow-up is continuing.

Recommendations for Patients:

- At the current time, FDA is recommending that patients should not receive the Raindrop Near Vision Inlay device.
- If already implanted with the device, be sure to keep your regularly scheduled appointments with your eye care provider. You should seek sooner evaluation if you have or develop any new or bothersome visual symptoms such as blurry vision or glare. Your physician will determine appropriate treatment options based on the results of an evaluation.

Recommendations for Eye Care Providers:

- Do not implant Raindrop inlays.
- Contact Optics Medical (Phone: 949-330-6511) for instructions on returning any unused product to the firm.
- Be aware of the new data from the ongoing post-approval study, which is showing high rates of corneal haze in both implanted and explanted patients, and an increasing rate of device removal.
- Monitor patients with the implant for the development of corneal haze.
- Monitor patients whose device has been explanted for the development of corneal haze.

FDA Actions:

FDA is currently working with Optics Medical on a plan to collect remaining devices that have already been distributed. The FDA will continue to gather and evaluate data related to this issue, and will communicate new information as warranted.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks related to the use of medical devices. If you suspect or experience a problem with this device, we encourage you to file a voluntary report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)**. Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Contact Information:

If you have questions about this communication, please contact CDRH's Division of Industry Communication and Education (DICE) at **DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV)**, 800-638-2041, or 301-796-7100.

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