CASE REPORT

Manufacturing defect of a Zeiss multifocal intraocular lens

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Introduction: A case of cataract surgery with multifocal intraocular lens (IOL) insertion where the lens was found to have a manufacturing defect with decentred diffractive rings on the optic is reported.

Patient and clinical findings: A toric AT LISA tri (Carl Zeiss Meditec AG) IOL was implanted into the capsular bag in the right eye of a 58-year-old woman. After implantation it was noted that the diffractive rings were off center and not aligned with the toric lens markings.

Diagnosis, intervention, and outcomes: The IOL was explanted and another IOL of the same type and power was inserted.

Conclusions: This case shows that centration defects of multifocal IOLs exist. Surgeons need to be aware of this and make sure they have instruments on hand for explantation and backup IOLs for each case.

CASE REPORT

A 58-year-old woman was referred for cataract surgery. She had a low hyperopia, and the rest of history and examination was unremarkable. Seeking spectacle independence after cataract surgery, it was decided to use a toric multifocal IOL. Right eye surgery was initially without complications, and the IOL was implanted into the capsular bag. However, prior to aspiration of the ophthalmic viscosurgical device, it was noted that the diffractive rings were off-center and out of alignment with the toric markings (Figure 1). The IOL was not tilted, so it was assumed that there was a manufacturing defect. Ophthalmic viscosurgical device was injected to prolapse the IOL out of the capsular bag. A replacement IOL was injected into the bag beneath the defective IOL. The defective IOL was then cut into 4 pieces using IOL-holding forceps and IOL-cutting scissors (MicroSurgical Technology), and the fragments were explanted.

The postoperative period was unremarkable, and the left eye underwent insertion of a toric trifocal IOL 1 week later. At the 1-month postoperative visit, the uncorrected distance visual acuity in the right eye was 6/7.5 + 2 correcting to 6/6 with a low myopic correction.

DISCUSSION

To the authors’ knowledge, this is the first report of a manufacturing defect in the multifocal component of an IOL. There are few reports of IOL manufacturing defects in the literature. Most describe either glistenings or calcification, which develop postoperatively.
Ideally, the surgeon would check for IOL defects under the operating microscope prior to insertion into the eye. However, this may have an undesirable effect on workflow. Moreover, many IOLs, including multifocal ones, now come in a pre-loaded format, making a preimplantation check impossible.

Therefore, it is important that surgeons are familiar with explantation techniques and have dedicated instruments to facilitate removal on hand at all practice locations. Ideally, explantation of the lens needs to occur without wound enlargement as one would expect that any induced cylinder from wound enlargement would be poorly tolerated by a patient seeking a good refractive outcome. This case also underlies the need for keeping a backup IOL on hand.

The 2 main types of manufacturing of IOLs are injection molding or lathe cutting of a blank.4 We assume the Zeiss hydrophilic range is lathe cut. This would presumably mean that in this case, both the optic and the diffractive rings were decentered. This raises the serious concern that the same defective process could occur with manufacture of a nonmultifocal IOL. For example, the Zeiss Torbi or Asphina range, which could result in an off-center optic that would go completely undetected by the clinician but result in a significant drop in visual quality for the patient.

Surgeons need to remain vigilant that IOL manufacturing defects can occur. If defects do occur, surgeons need to pressure industry both to address these instances and to disseminate this information to other surgeons and the regulatory authorities. Returning defective fragments to the manufacturer may not achieve this, so we would encourage surgeons to retain explanted fragments for further examination and proper documentation of the defects.

**WHAT WAS KNOWN**
- Manufacturing defects of IOLs can occur.

**WHAT THIS PAPER ADDS**
- This is the first report, to the authors’ knowledge, of a decenteration defect of the diffractive rings of a multifocal IOL.
- Surgeons need to be aware that this possible complication exists and be prepared to explant.
- This finding raises the possibility of manufacturing defects occurring in centration of monofocal IOLs that would not be obvious to the surgeon but could cause visual degradation.

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