OPEN

Disruptive Innovation and Refractive IOLs: How the Game Will Change With Adjustable IOLs

David F. Chang, MD

Abstract: The light-adjustable lens is the first Food and Drug Administration (FDA)-approved product from an entirely new category of intraocular lenses (IOLs). The 3-piece foldable silicone light-adjustable lens is implanted through a small incision after phacoemulsification. A slit-lamp-based digital light delivery device is used to adjust and then lock-in the IOL power during the first postoperative month. Up to 4.5 diopters (D) of cylindrical or spherical adjustment can be achieved. This should offer significant advantages in difficult IOL power calculation cases, such as postrefractive eyes. In addition to achieving better refractive accuracy, an adjustable IOL will now allow patients to test and elect a different refractive target postoperatively. This paradigm shift will change how cataract patients choose their refractive objectives, and how ophthalmologists will be able to achieve them. For example, adjustable IOLs may increase the popularity of pseudophakic monovision and bilateral same-day sequential surgery. For those electing adjustable IOL, preoperative patient counseling will change and certain pre- and intraoperative technologies, such as intraoperative aberrometry and digital astigmatic axis marking, would become superfluous.

Key Words: adjustable IOL, monovision, refractive enhancement, refractive IOL

(*Asia Pac J Ophthalmol (Phila)* 2019;8:432–435)

The relatively flat growth in refractive IOL implantation worldwide is indicative of the continuing challenges that cataract surgeons face in meeting the refractive goals and expectations of their patients. These challenges make preoperative counseling time-consuming and stressful for both patients and their ophthalmologists. However, rushed or ineffective communication risks increase postoperative dissatisfaction and chair time. Although cost is obviously a potential barrier, there are other important obstacles that fall into 1 of 3 categories.

BARRIERS TO PATIENT SATISFACTION WITH REFRACTIVE IOLs

The first problem is the limitations of current IOL technology. An FDA-approved accommodating IOL is still many years away and until then, reducing spectacle dependence will always invoke optical tradeoffs. The most popular presbyopia-correcting IOLs have utilized diffractive optics. High and low-add multifocal, trifocal, and extended depth of focus (EDOF) diffractive optics all reduce spectacle wear compared with monofocal IOLs, but produce halos and unwanted images at night.[1,2] Individual patient tolerance is unpredictable, and IOL exchange may be the only recourse for those that cannot adapt.[3] Diffractive multifocal IOLs reduce contrast sensitivity, which can noticeably diminish optical quality and performance in the presence of ocular comorbidities, such as maculopathy, optic neuropathy, keratopathy, or ocular surface disease. Multifocal IOLs are also much less forgiving of residual refractive error, IOL tilt, and decentration. For the surgeon, nothing is more demoralizing than when patients are dissatisfied with visual quality or dysphotopsias despite careful preoperative counseling, and perfectly performed IOL calculations and surgery.

The second problem is our inability to consistently achieve LASIK (laser-assisted in situ keratomileusis)-like refractive accuracy. The 2018 European Society of Cataract and Refractive Surgery Eurequo study showed that 27% of eyes failed to land within ±0.5 D of the target refraction.[4] Despite improvements in biometry and IOL formulae, and the availability of intraoperative aberrometry, we must still correctly estimate the effective lens position (ELP), and surgically induced and posterior corneal astigmatism. Previous LASIK and photorefractive keratectomy introduce 3 different errors into our IOL calculations: inaccurate estimates of central corneal curvature, a reduction of the corneal Gullstrand ratio, and erroneous assumptions of ELP based on corneal curvature.[5] Although residual refractive error can be treated with keratorefractive surgery,[6] many cataract surgeons do not perform these procedures and they pose the psychological barrier of undergoing another surgery. Patients may be disappointed with the additional procedure and expense that they did not expect, and the several-month delay until the refraction is stable.

A third major factor is the difficulty that so many patients have in understanding the refractive IOL value proposition. We require them to make an expensive purchase decision preoperatively, often without a way to fully comprehend or try out the outcome. We describe the benefits of different IOLs using confusing terminology such as astigmatism, presbyopia, depth-of-focus, and multifocality. In addition to these, patients struggle to understand other key optical concepts such as lenticular myopia, focal distance, anisometropia, halos, and contrast sensitivity. After describing the benefits, we then add disclaimers about still needing reading or distance glasses and not being able to guarantee a specific outcome. Finally, feedback from friends confuses patients even more in that some do not wear eyeglasses after cataract surgery, whereas others are unhappy with the IOL that they paid extra for.

From the University of California, San Francisco, and private practice Los Altos, CA.
Submitted July 7, 2019; accepted September 30, 2019.
Financial interest: consultant for RxSight, Zeiss, J&J Vision, Perfect Lens.
The authors have no conflicts of interest to disclose.
Address correspondence and reprint requests to: David F. Chang, 762 Altos Oaks Drive, Los Altos, CA 94024. E-mail: dceye@earthlink.net.

ISSN: 2162-0989
DOI: 10.1097/APO.0000000000000266

ADJUSTABLE IOLs

I believe that adjustable IOL technology will enable us to overcome most of these noneconomic barriers. Although there are several different technologies under development,[7] the RxSight light-adjustable lens (LAL) has recently become commercially available in the United States.[7–16] This 3-piece, foldable monofocal IOL is implanted through a 2.8-mm clear corneal incision with a proprietary injector. Approximately 3 weeks postoperatively, the patient is refracted and a slit lamp-based digital light delivery device is used to adjust the IOL power by delivering ultraviolet (UV) light in a precisely programmed pattern. This causes spatially modulated polymerization of diffusible, photosensitive macromers within the 6-mm diameter silicone optic. The resulting diffusion gradient causes unpolymerized macromer to diffuse into irradiated zones with a resulting change in the shape and refractive power of the optic. Treatment times range between 50 and 90 seconds. One treatment can adjust up to 2 D of cylinder or sphere (in either direction). Additional staged treatments can bring the total adjustment up to 4.5 D of cylinder or sphere. After the newly adjusted refraction is confirmed several days later, a second 1-minute lock-in dose is given with the light delivery device to polymerize all remaining macromer, at which point no further refractive change can occur. Patients wear special UV blocking spectacles until the adjustment and lock in steps are completed.

REFRACTIVE ACCURACY—SPHERE AND CYLINDER

Advances in biometry and IOL formulae have improved refractive outcomes, but because the calculations still estimate ELP, surgically induced astigmatism, and posterior corneal astigmatism, they improve the average but do not eliminate the standard deviation. The effectiveness of astigmatic keratotomy varies with corneal rigidity and can regress over time. Accurate surgical toric IOL alignment is critical, but even after intraoperative aberrometry and digital alignment technology, the IOL can still rotate postoperatively.[17,18] In contrast, the LAL allows us to treat the stabilized postoperative refraction after the IOL can no longer shift or rotate. Because this timing eliminates so many variables and the need to predict them, we won't need to employ multiple formulae and measurements preoperatively. Although I currently employ topography, multiple advanced formulae, intraoperative aberrometry, and digital intraoperative axis localization, I expect newly graduated residents using none of these will achieve better astigmatism outcomes with the LAL than I currently do using all of these technologies. Adjustable IOLs will be particularly helpful for challenging cases, such as post LASIK or radial keratotomy eyes, those following rigid contact lens wear, those with advanced cataracts precluding optical biometry, and outliers with unusual axial lengths, keratometry, or anterior chamber depth.[16,19]

ADJUSTABLE MINI-MONOVISION

As a pseudophakic strategy to reduce spectacle dependence, mini-monovision using monofocal IOLs is consistently the most popular choice among American Society of Cataract and Refractive Surgery Clinical Survey respondents.[20–22] Monofocal IOLs provide excellent optical quality while avoiding night-time halos and starbursts. Spectacles solve any visual problems with mini-monovision, which cannot be said about unwanted night-time images or reduced contrast sensitivity. Adjustability should significantly improve outcomes with this strategy, starting with achieving emmetropia in the distant eye. Next, we can allow the bilaterally pseudophakic patient to preview different amounts of myopia in the near eye postoperatively, and then adjust in that optimal amount. As we know from contact lens monovision, some patients tolerate and prefer more anisometropia than others. Knowing that we can experiment with, and then modify or reverse different amounts of myopia in the distance and near eye should allow us to replicate the high levels of patient satisfaction seen with contact lens monovision. In addition, we can determine ocular dominance and select the distant eye after removal of the cataracts, which is not possible with conventional monofocal monovision.

This low-risk, reversible strategy will appeal to both patients and their ophthalmologists, who with diffractive IOLs, face uncertainty about who might be intolerant of night-time halos, and who might have or later develop maculopathy. Finally, RxSight has recently released an EDOF presbyopia treatment in Europe, enabling patients to achieve their desired function with less anisometropia. The EDOF effect is produced by manipulating spherical aberration, rather than with a diffractive or small aperture optic.

Offering monofocal IOL quality with EDOF range, adjustable IOLs may prove to be a popular strategy for refractive lens exchange in presbyopes. Unlike cataract patients, this population has good preoperative quality of vision, and is therefore less tolerant of unwanted night-time images or reduced contrast sensitivity. Many of these refractive lens exchange candidates are already satisfied with contact lens monovision, and the EDOF LAL might offer significant advantages over current diffractive IOL technology.

IMPROVING THE PATIENT EXPERIENCE—"CHOOSING YOUR VISION"

Perhaps the most overlooked benefit will be how much adjustable IOL technology will improve the patient's experience. The anxiety and stress of selecting their IOL and refractive goal preoperatively will be alleviated by allowing patients to choose and prioritize their refractive objectives postoperatively. Using a phoropter, loose trial lenses, or trial soft contact lenses, the patient can experience what correcting astigmatism does, without actually understanding its optics. They can test the effect of being slightly more or less myopic. Some patients desiring good distance vision may actually prefer −0.75 to plano. Others that prioritize reading without glasses may prefer being −1.75 to −2.75. These differences are difficult to describe and comprehend preoperatively, but quite easy to demonstrate once the patient is pseudophakic. Thus, much of the preoperative refractive counseling can now be shifted postoperatively, where it will be much more understandable. Using trial lenses, the refractive counseling can be done by an optometrist instead of the surgeon. A soft contact lens trial could be offered to the most analytical or demanding patients.

This system will not only help patients decide what refractive outcomes they prefer, but may also largely reduce their preoperative anxiety over whether they have chosen the correct IOL and target. Patients will also understand the advantage of essentially customizing their IOL and eyesight. Even if little postoperative adjustment is required, they will appreciate the increased refractive precision of this approach, and that it gave them the ability to change their mind about their refractive preference.

BILATERAL SAME-DAY SEQUENTIAL CATARACT SURGERY

There is a growing interest in and experience with bilateral same-day sequential cataract surgery.[23–25] One advantage of staged sequential surgery is the ability to modify the IOL power selected for the second eye following a power surprise in the first eye.[26–28] The second advantage is giving patients the opportunity to change the refractive target for their second eye based on their first eye outcome. For example, lifelong myopes requesting emmetropia are often surprised by how blurry their near vision is, and may want some myopia for their second eye. These cease to be important considerations if we can adjust the spherical refraction postoperatively. Performing both cataract surgeries either simultaneously or within a few days of each other will make it easier for patients to test their pseudophakic refractive preferences, especially if some degree of anisometropia is intentionally chosen. This will also make the LAL experience more convenient by shortening the period requiring UV glasses and allowing both eyes to be refracted and adjusted simultaneously.

ADJUSTABLE IOLs WILL BE A DISRUPTIVE INNOVATION

Harvard Business School professor Clayton Christensen popularized the concept of disruptive innovation to explain why the most successful companies eventually fail.[29] Although such companies continue to develop better and more expensive technology, they fail to anticipate a paradigm shift in the way new technology will be used and incorporated into their business or field—the disruptive innovation. I believe that adjustable IOLs are the new pseudophakic paradigm that will ultimately disrupt the field of refractive IOL surgery for both cataract and refractive patients alike.

In many global markets, socialized medicine has constrained patient access to premium refractive IOLs because the government payment must cover all the bundled costs of cataract surgery. Adjustable IOLs have the advantage of separating the timing and location of the refractive service from the medically necessary cataract operation. Like pseudophakic LASIK, it should be a separate and elective, self-pay refractive service. Clear differentiation between the cataract operation and the refractive service will hopefully allow scores of international cataract patients to access refractive IOL technology that their health care system currently restricts access to.

Overall, patients will be the greatest beneficiaries. In addition to providing better refractive accuracy, this technology will disrupt the patient experience—the process by which they choose their refractive objective, and how ophthalmologists will deliver it. Much of the refractive counseling will shift from preoperative to postoperative, with the cataract surgeon delegating this important but time-consuming role to an optometrist. The smaller incremental gains afforded by new IOL formulae, and pre- and intraoperative diagnostic technology will be rendered superfluous by postoperative adjustability.

CONCLUSIONS

By previewing and comparing different refractive outcomes, pseudophakic patients will better understand the options and be happier with their decisions. After experiencing the refractive adjustment and understanding the separate value of customizing their "prescription" postoperatively, patients will champion the technology and the process to their friends. Surgeons will no longer have to guess which patients will prefer a diffractive optic and which will not. Finally, adjustable IOLs can help our profession meet the challenge of rising cataract surgical volume by facilitating bilateral simultaneous surgery, and delegation of most pre- and postoperative refractive counseling to optometrists.

REFERENCES

1. Breyer DRH, Kaymak H, Ax T, Kretz FTA, Auffarth GU, Hagen PR. Multifocal intraocular lenses and extended depth of focus intraocular lenses. *Asia Pac J Ophthalmol*. 2017;6:339–349.
2. Cao K, Friedman DS, Jin S, et al. Multifocal versus monofocal intraocular lenses for age-related cataract patients: a system review and meta-analysis based on randomized controlled trials. *Surv Ophthalmol*. 2019;64:647–658.
3. Fernandez-Buenaga R, Alio JL. Intraocular lens explanataion after cataract surgery: indications, results, and explantation techniques. *Asia Pac J Ophthalmol*. 2017;6:372–380.
4. Lundstrom M, Dickman M, Henry Y, et al. Risk factors for refractive error after cataract surgery: analysis of 282,811 cataract extractions reported to the European Registry of Quality Outcomes for cataract and refractive surgery. *J Cataract Refract Surg*. 2018;44:447–452.
5. Abulafia A, Hill WE, Wang L, Reitblat O, Koch DD. Intraocular lens power calculation in eyes after laser in situ keratomileusis or photorefractive keratectomy for myopia. *Asia Pac J Ophthalmol*. 2017;6:332–338.
6. Sáles CS, Manche EE. Managing residual refractive error after cataract surgery. *J Cataract Refract Surg*. 2015;41:1289–1299.
7. Ford J, Werner L, Mamalis N. Adjustable intraocular lens power technology. *J Cataract Refract Surg*. 2014;40:1205–1223.
8. Chayet A, Sandstedt C, Chang S, et al. Correction of myopia after cataract surgery with a light-adjustable lens. *Ophthalmology*. 2009;116:1432–1435.
9. von Mohrenfels CW, Salgado J, Khoramnia R, Maier M, Lohmann CP. Clinical results with the light adjustable intraocular lens after cataract surgery. *J Refract Surg*. 2010;26:314–320.
10. Hengerer FH, Conrad-Hengerer I, Buchner SE, Dick HB. Evaluation of the Calhoun Vision UV Light Adjustable Lens implanted following cataract removal. *J Refract Surg*. 2010;26:716–721.
11. Lichtinger A, Sandstedt CA, Schwartz DM, Chayet AS. Correction of astigmatism after cataract surgery using the light adjustable lens: a 1-year follow-up pilot study. *J Refract Surg*. 2011;27:639–642.
12. Hengerer FH, Hütz WW, Dick HB, Conrad-Hengerer I. Combined correction of axial hyperopia and astigmatism using the light adjustable intraocular lens. *Ophthalmology*. 2011;118:1236–1241.
13. Hengerer FH, Dick HB, Conrad-Hengerer I. Clinical evaluation of an unltraviolet light adjustable intraocular lens implanted after cataract removal: eighteen months follow-up. *Ophthalmology*. 2011;118:2382–2388.
14. Hengerer FH, Hütz WW, Dick HB, Conrad-Hengerer I. Combined correction of sphere and astigmatism using the light-adjustable intraocular lens in eyes with axial myopia. *J Cataract Refract Surg*. 2011;37:317–323.

15. Villegas EA, Alcon E, Rubio E, Marín JM, Artal P. Refractive accuracy with light-adjustable intraocular lenses. *J Cataract Refract Surg*. 2014;40:1075–1084.
16. Brierley L. Refractive results after implantation of a light-adjustable intraocular lens in postrefractive surgery cataract patients. *Ophthalmology*. 2013;120:1968–1972.
17. Inoue Y, Takehara H, Oshika T. Axis misalignment of toric intraocular lens: placement error and postoperative rotation. *Ophthalmology*. 2017;124:1424–1425.
18. Lee BS, Chang DF. Comparison of the rotational stability of two toric intraocular lenses in 1273 consecutive eyes. *Ophthalmology*. 2018;125:1325–1331.
19. Hoffer K, Savini G. IOL power calculation in short and long eyes. *Asia Pac J Ophthalmol*. 2017;6:330–331.
20. Zhang F, Sugar A, Jacobsen G, Collins M. Visual function and patient satisfaction: comparison between bilateral diffractive multifocal intraocular lenses and monovision pseudophakia. *J Cataract Refract Surg*. 2011;37:446–453.
21. Zhang F, Sugar A, Jacobsen G, Collins M. Visual function and spectacle independence after cataract surgery: bilateral diffractive multifocal intraocular lenses versus monovision pseudophakia. *J Cataract Refract Surg*. 2011;37:853–858.
22. Wilkins MR, Allan BD, Rubin GS, et al., Moorfields IOL Study Group. Randomized trial of multifocal intraocular lenses versus monovision after bilateral cataract surgery. *Ophthalmology*. 2013;120:2449–2455.
23. Rush SW, Gerald AE, Smith JC, Rush JA, Rush RB. Prospective analysis of outcomes and economic factors of same-day bilateral cataract surgery in the United States. *J Cataract Refract Surg*. 2015;41:732–739.
24. Donaldson KE. Current status of bilateral same-day cataract surgery. *Int Ophthalmol Clin*. 2016;56:29–37.
25. Shorstein NH, Lucido C, Carolan J, Liu L, Slean G, Herrinton LJ. Failure modes and effects analysis of bilateral same-day cataract surgery. *J Cataract Refract Surg*. 2017;43:318–323.
26. Aristodemou P, Knox Cartwright NE, Sparrow JM, Johnston RL. First eye prediction error improves second eye refractive outcome: results in 2129 patients after bilateral sequential cataract surgery. *Ophthalmology*. 2011;118:1701–1709.
27. Olsen T. Use of fellow eye data in the calculation of intraocular lens power for the second eye. *Ophthalmology*. 2011;118:1710–1715.
28. Jivrajka RV, Shammas MC, Shammas HJ. Improving the second-eye refractive error in patients undergoing bilateral sequential cataract surgery. *Ophthalmology*. 2012;119:1097–1101.
29. Christensen CM, Raynor ME, McDonald R. What Is disruptive innovation? *Harvard Business Review*. 2015;93:44–53.