

An Accommodative IOL With a New Approach

The Kellan TetraFlex IOL is based on the Helmholtz theory of accommodation.

BY ROBERT KELLAN, MD

When I designed the TetraFlex IOL (model KH-3500; Lenstec, St. Petersburg, FL) (Figures 1 and 2), with the help of Deepak Chitkara, MBCHB, I wanted to meet the recognized criteria for the “ideal” accommodating IOL: (1) to fit through a 3-mm or smaller clear corneal incision, (2) to be made of a material that is 100% biocompatible, (3) to have no more than 1 mm of touch at any of its fixating points, and (4) to be as readily explantable as implantable in order for the lens to be exchangeable. If for some reason we want to change the power of the TetraFlex lens, we can remove it through the same incision and replace it with a differently powered lens. We can also remove the lens without replacing it, and in this case the lens will not disrupt the wound and induce astigmatism.

A DIFFERENT DESIGN

I wanted to address the current holy grail of ophthalmology, accommodation, so I designed the lens’ haptics to take advantage of how the crystalline lens moves during accommodation according to the Helmholtz theory. This theory states that contraction of the ciliary muscles relaxes the lens zonules, thereby allowing the lens to move forward during accommodation.

The TetraFlex IOL is based on an entirely different concept from other accommodative lenses. It is not designed on a hinge principle, but rather on a haptic configuration to allow the lens to move with the entire capsular bag. Furthermore, the lens does not require postoperative cycloplegia. The TetraFlex is intended to deliver a degree

“The TetraFlex IOL is based on an entirely different concept from other accommodative lenses.”

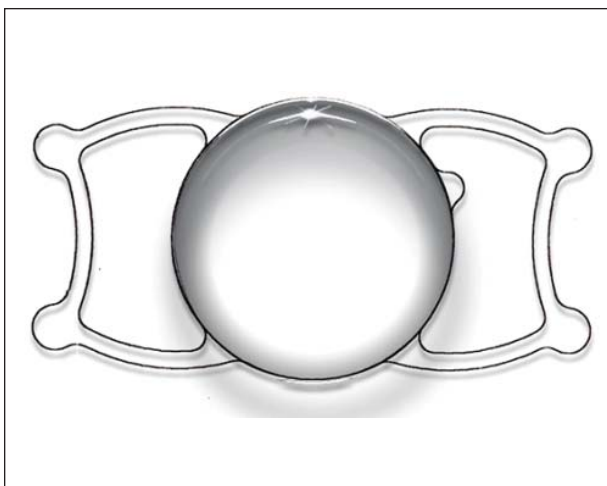


Figure 1. The Kellan TetraFlex KH-3500 IOL’s haptics are designed to capitalize on the movement of the ciliary muscles.

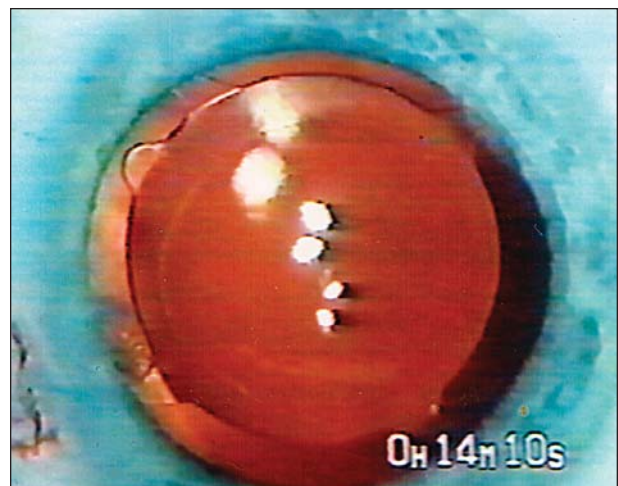


Figure 2. The TetraFlex lens in situ shows good centration and orientation.

of accommodation (between J3 and J5) that allows the patient to read and perform daily activities without the need for glasses.

The TetraFlex IOL is made from hydroxyethylmethacrylate (HEMA), a material composed of 26% water, which makes the lens highly flexible. It can easily pass through a 2.5-mm incision into the capsular bag. The lens has a 5.75-mm optic with square edges to prevent glare effects and reduce the risk of posterior capsular opacification.

The TetraFlex uses a commercially available injector with a 1.8-mm cartridge, which many surgeons already utilize. The insertion technique for the lens is also familiar to surgeons. Furthermore, the IOL can be used for refractive lens exchange in younger patients with larger pupil sizes.

UNVEILING THE INITIAL RESULTS

Dr. Chitkara presented the interim results with the TetraFlex at the ESCRS Winter Refractive Surgery Meeting on January 24, 2004.¹ Of the 48 eyes initially implanted with the lens, Dr. Chitkara saw 28 at 3 months and 11 at 6 months. The mean accommodation achieved binocularly was 3.42 D and 3.75 D, respectively. Moreover, 89% of the patients achieved J3 or better unaided binocular near vision at 6 months, and 100% achieved J5 or better.

CURRENT STATUS

By John Clough

The Kellan TetraFlex IOL is currently CE Marked in Europe as a posterior chamber aphakic lens. It is not yet approved as an accommodating lens because it is still undergoing protocols to prove accommodation. We currently have approximately 40 patients in the UK, Belgium, and Italy who have the implant and who are reading with it quite successfully. We plan to claim accommodation once we have accumulated sufficient data. The TetraFlex IOL is available in powers ranging from +5.00 to +36.00 D.

We are also applying for permission to conduct a clinical study on Dr. Kellan's phakic IOL in the UK in order to gain CE Marking. We intend to run a 6-month clinical study beginning in early 2004 so that the lens will be available within 9 months. This lens fits in the anterior chamber, as opposed to the accommodating IOL's posterior chamber placement.

John Clough is President and CEO of Lenstec in St. Petersburg, Florida. He may be reached at (727) 571-2272; jclough@lenstec.com.

Dr. Chitkara will present the lens' full 6-month results at the ASCRS annual meeting in May in San Diego, California. We are also conducting comparative trials regarding the accommodative capabilities of the TetraFlex lens versus the Crystalens accommodative IOL (Eyeonics, Inc., Aliso Viejo, CA). In 40 cases at 6 months, the patients' accommodation has been adequate for social reading.

"My primary concern with creating this lens was to eliminate any potential harm to recipients."

We are encouraged by these results, and our patients have experienced no ill effects to date (my primary concern with creating this lens was to eliminate any potential harm to recipients). This lens will address patients' distance vision problems as well as any other aphakic lens will, but with the added bonus of a strong accommodative potential.

THE PHAKIC LENS

Dr. Chitkara and I have also developed a phakic lens, which is made from the same material as the accommodative lens and resembles its design. The lens is meant to be an injectable anterior chamber phakic IOL that can enter through a microincision. Although this lens is angle supported, it has less than 1 mm of touch at each of the four haptics in the angle, thereby minimizing trauma to the angle. The IOL centers beautifully, and the haptics splay out instead of pushing the lens forward. The phakic lens also has a large optic to prevent glare and halos. The vaulting of the lens is such that no part of the optic is less than 1 mm from the corneal endothelium in order to avoid any endothelial damage. ■

Robert E. Kellan, MD, is Director of the Kellan Eye Center in Boston and Assistant Professor of Ophthalmology at Boston University. He is the inventor of the TetraFlex lenses. Dr. Kellan may be reached at (978) 682-8661; bobkellan@webtv.net.



Deepak K. Chitkara, MBChB, serves as Consultant Ophthalmic Surgeon and Director for the Rosen Eye Clinic in Manchester, United Kingdom. He is also Medical Director for Lenstec. Dr. Chitkara may be reached at +44 77 03 19 67 61; chitkaradeepak@aol.com.



1. Chitkara DK. Accommodation in pseudophakia with Lenstec KH-3500 lens by Kellan. Paper presented at: The ESCRS Winter Refractive Surgery Meeting; January 23-25, 2004; Barcelona, Spain.