Phakic IOLs: Where Are We Now?

BY ERIK L. MERTENS, MD, FEBOPHTH
WITH AN EXCERPT FROM “REFRACTIVE PHAKIC IOLS OF THEN AND NOW,” BY GEORGES BAIKOFF, MD, PUBLISHED IN APRIL 2004

A long history continues.
A look back at the 2007 article by Georges Baikoff, MD, excerpted here (page 66), shows that the history of phakic IOLs is long and complex, reaching back to the 1950s. Many styles have come and gone since that time. His article is full of company and phakic IOL brand names that few young surgeons may remember today: The Phakic Refractive Lens (PRL, Ciba Vision), the Adatomed Implant (Chiron Adatomed), the Vivarte (IOLTech), and even Professor Baikoff’s own ZB5M (Domilens) are long departed from the market.

The departures of these phakic lens technologies were due to a number of reasons, among them iatrogenic damage to the corneal endothelium or the crystalline lens, difficulty of implantation or fixation, and induced astigmatism due to the large incisions needed for implantation of rigid PMMA IOLs. These issues have been largely addressed through incremental improvements over the decades, and in 2018, two major designs endure (see Today’s Phakic IOLs).

According to Market Scope data, in 2016, the Visian ICL (STAAR Surgical) accounted for approximately 62% of the global market for phakic IOLs, and the Artisan/Verisyse and Artiflex/Veriflex (Ophtec/Johnson & Johnson Vision) lenses together accounted for approximately 36%. There are other phakic IOLs still on the market, but they made up only about 2% of the total global market, according to that 2016 data.

Indications for phakic IOL implantation (Figure) have also changed over the decades. Dr. Baikoff noted that they were originally indicated only for patients with very high ametropias, but phakic IOLs are now used in patients with lower degrees of error as well. On top of this, they may be appropriate for patients who are contraindicated for LASIK or PRK because of corneal abnormalities or dry eyes. Indications for the iris-fixated models depend on the dimensions of the anterior chamber, as sufficient depth is required to avoid endothelial touch.

**Comparisons**

Kobashi and coauthors\(^1\) compared quality of life following Visian ICL implantation in patients with mean preoperative manifest refraction with correction compared with myopic wavefront-guided LASIK.

A multicenter Japanese study recently assessed the results of currently used refractive surgical procedures, including phakic IOLs, in more than 15,000 eyes.\(^2\) The study by the Survey Working Group of the Japanese Society of Cataract and Refractive Surgery included patients who underwent LASIK, excimer laser surface ablation, refractive lenticule extraction, or posterior chamber or iris-supported phakic IOL implantation at one of 42 major institutions.

In brief, at 3 months postoperative, these authors found that 99% of patients with posterior chamber phakic IOLs and 84% with iris-supported phakic IOLs achieved within ±1.00 D of attempted correction. This compared with 96% for LASIK, 93% for surface ablation, and 97% for refractive lenticule extraction. The authors concluded

“It is safe to say that phakic IOLs are now a familiar and versatile tool in the refractive surgeon’s toolkit, and they are likely to be with us for many years to come.”

—Erik L. Mertens, MD, FEOphth

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—Georges Baikoff, MD
Refractive Phakic IOLs of
Then and Now

Herein, I share the development of and experience with these implants.

BY GEORGES BAIKOFF, MD

In the 1950s, José Ignacio Barraquer, MD, of Spain; Benedetto Strampelli, MD, of Italy; M. Dannheim, MD, of Germany; and D. Peter Choyce, MD, FRCS (Ophth), of London—the pioneers of intraocular implants—conducted the first trials using anterior chamber refractive lenses to correct high myopia in phakic eyes. Unfortunately, the initial experiments revealed unacceptable complication rates due to imperfections in IOL design. Glaucoma, corneal dystrophy, and hyphema were commonly observed, and anterior chamber implants—particularly refractive phakic implants—acquired a bad reputation.

EARLY PROTOTYPES

It was not until the mid-1980s that Svyatoslav N. Fyodorov, MD, of Moscow; Paul U. Fechner, MD, of Germany; and I resumed developing phakic implants. Dr. Fyodorov began experimenting with a collar-button, pupil-fixated posterior chamber implant that ultimately led to the development of the Implantable Contact Lens (ICL; STAAR Surgical), the Adatomed implant (Chiron Adatomed), and the Phakic Refractive Lens (PRL; Ciba Vision). Dr. Fechner designed the Worst iris claw implant (Ophtec) and adapted it to correct high myopia. Later, Ophtec modified the implant to also correct hyperopia and astigmatism. I imagined an angle-supported implant to correct myopia similar to that designed by Charles D. Kelman, MD, of New York.

Over the last decade, the development of phakic implants has been erratic: first one type met with success, then another. In fact, the progress of these lenses was largely hindered by the importance of concurrent investment and research into corneal surgery, microkeratomes, and the excimer laser. Because LASIK developed so rapidly, today, its advantages and limitations are much better known. Due to the procedure’s drawbacks, interest and research in refractive implants are once again gaining momentum.

ADVANTAGES OF REFRACTIVE IMPLANTS

Apart from progressive myopia and cataract development, the stability of refractive results has been confirmed regardless of the implant type. Safety and efficacy ratios are superior to those obtained with LASIK, and optical aberrations are fewer. In most instances of high ametropia, the effective optical zone is larger, and the rate of nighttime halos is lower with refractive implantation versus corneal surgery. Additionally, fewer optical defects occur with industrial lens implantation compared with corneal surgery, because the ultimate shape of the corneal tissue depends on the individual’s healing ability. In most cases, refractive implant procedures are reversible. In the event of a sizing or power error, the lenses can be exchanged.

DISADVANTAGES OF REFRACTIVE IMPLANTS

The disadvantages of refractive implants depend on the lens model and its anatomical situation. Each new modification can induce an unexpected iatrogenous complication.
TODAY’S PHAKIC IOLS

IRIS-FIXATED
- Originally called the Worst iris-claw phakic IOL (Ophtec)
- Now known as the Artisan (Ophtec) in Europe and the Verisyse (Johnson & Johnson Vision) in the United States, and their foldable cousins, the Artiflex (Ophtec) in Europe and the Veriflex (Johnson & Johnson Vision) in the United States

POSTERIOR CHAMBER
- Originally known as the Implantable Contact Lens (STAAR Surgical)
- Most recently called the EVO Visian ICL (STAAR Surgical)

that all of these approaches to refractive surgical correction “have good safety and efficacy outcomes, yielding predictable and stable results [and] appear to be feasible options for the treatment of refractive errors.”

The possibility of providing substantial gains in quality of life for our patients creates a strong incentive for surgeons to consider phakic IOL implantation.

FUTURE PROSPECTS

Today, the long-term safety and effectiveness of current phakic IOL models is well established. Regarding the ICL in particular, there have been more than 900,000 implants to date, and some ICLs have now been in patients’ eyes for more than 20 years.

The history continues to unfold, as STAAR Surgical received US FDA approval earlier this year for the Visian Toric IOL—the first toric phakic IOL to be approved in the US market. The Visian Toric has been approved for use in Europe since December 2002, and toric versions of the Artisan and Artiflex are also available in Europe.

In this era of aging baby boomers, it is worth noting that phakic IOLs work with the patient’s residual accommodation, preserving the cornea and lens for future procedures. The lenses are removable, and, therefore, reversible if other options to address a patient’s change in refractive status become available.

It is safe to say that phakic IOLs are now a familiar and versatile tool in the refractive surgeon’s toolkit, and they are likely to be with us for many years to come.


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