

Akreos[®] Acrylic IOLs

A Record of Exceptional Performance

M. Assouline, M.D., Rothchild Foundation

K. Weber, M.D., Municipal Clinic, Ludwigshafen

R. Welt, M.D., Prof., Municipal Clinic, Ludwigshafen

G. D. Barrett, M.D., Assoc. Prof., Lions Eye, Perth

Overview

Akreos® Adapt, Fit, and Disc are hydrophilic acrylic intraocular lenses that ophthalmic surgeons throughout Europe have implanted in patients more than 500,000 times over the last six years, and now that Akreos is available in other markets, it is anticipated that the total implants will exceed 700,000 by the end of 2004. This publication summarizes the available information on the key characteristics of Akreos IOLs that have made them so popular, including: biocompatibility, optical clarity, stability, and low incidence of posterior capsular opacification and anterior cell growth. It is intended to help ophthalmic surgeons better evaluate the role that the Akreos Adapt, Fit, and Disc hydrophilic IOLs can play in today's cataract surgery practice.

Background

The rapid evolution of intraocular lenses in recent years has increased the chances for confusion about the designs and materials with which IOLs are made. The earliest intraocular lenses were made of polymethylmethacrylate (PMMA), the plastic that IOL inventor Harold Ridley, MD, had noticed was inert in the eyes of World War II aviators struck by flying plastic during battle. For the next 30 years, removal of the crystalline lens required large incisions, and the hard, rigid PMMA became the material of choice for IOL optics.¹

It wasn't until phacoemulsification made it possible to remove the cataract through a smaller incision that ophthalmic companies began looking for foldable and compressible materials to allow an IOL to be inserted through an unenlarged phacoemulsification incision.² This search for a pliable material led to the exploration for intraocular use of poly-HEMA – the hydrogel material Bausch & Lomb had used to create the first soft contact lenses during the 1960s. A watershed in the history of hydrophilic IOLs came in 1986 and 1987, when Barrett et al. reported on the first large clinical studies of poly-HEMA lenses.^{3,4} Later, publication of a prospective study with five, then 12 years of follow-up demonstrated the long-term compatibility of IOLs made from poly-HEMA.^{5,6}

However, the quest for smaller, clear-corneal incisions without sutures spawned further experimentation on ways to make foldable and injectable IOL optics thinner yet robust.

It was in this context that materials for the first hydrophilic acrylic IOLs were created by modifying poly-HEMA.² There have been a variety of formulations developed, but most of them share a common structure: a copolymer of the hydrophilic hydroxyethyl methacrylate (HEMA) and the hydrophobic methylmethacrylate (MMA). These copolymers have water contents around 25%, are mechanically robust and foldable, and have a higher refractive index than the pure poly-HEMA materials. This allows for thinner lens designs that fold and compress easily without the damage and fold marks that have been reported in silicone and hydrophobic acrylic IOLs.⁷⁻¹⁰

The Akreos® IOLs

Over the past five years, continuous research and development at the Chauvin division of Bausch & Lomb has led to three different models of Akreos IOLs. Their physical designs vary, but all are one-piece equiconvex IOLs made from a single poly-HEMA/MMA copolymer. Akreos IOLs have a moderate refractive index of 1.46. All also have double square edges to inhibit posterior capsular opacification. The three Akreos models are:

Adapt – This one-piece IOL features four haptics for stable fixation within the capsular bag. The optic body measures 6.0 mm in diameter. Because the diameter of the capsular bag increases with the axial length of the eye,^{8,9} the Adapt's total diameter ranges from 10.5-11.0 mm depending on its refractive power. This optimizes posterior and edge contact with even the largest capsular bags. The Adapt is inserted one-handed with the closed, single-use Hydroport injector system.



Fit – This IOL has C-shaped haptics (0-degree angulation) and an optic diameter of 5.7 mm. The diameter with haptics is 11.5 mm. The Akreos Fold device is used to prepare this IOL for insertion, which is accomplished with forceps.



Disc – This circular IOL has two fenestrated plate haptics. The optic body measures 6.0 mm, and the total diameter is 10.7 mm. After folding, it is inserted with forceps.



Scanning Electron Micrographs of Akreos square edge

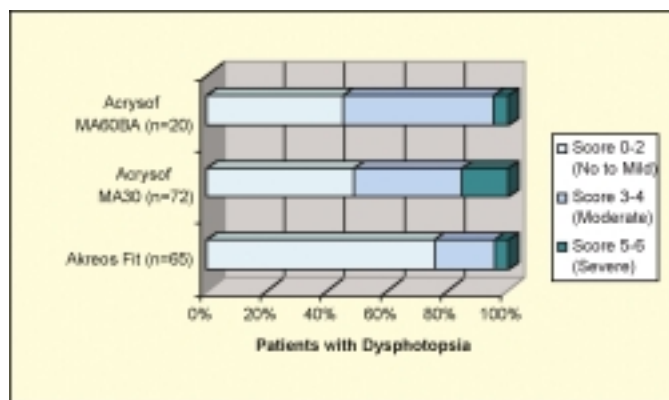


Advantages of Hydrophilic Acrylic Materials

Hydrophilic acrylics offer physical, biological, and optical qualities that make them attractive for use in foldable intraocular lenses. An IOL made from a hydrophilic acrylic:

Induces less dysphotopsia: Because of their water content, hydrophilic acrylics have a lower refractive index than hydrophobic acrylics, which minimizes problems with glare, external and internal reflections, and other unwanted visual phenomena seen in IOLs with a higher refractive index.¹³⁻²² Glare accounted for about 3% of the hydrogel explantations reported in a large 2001 survey of ophthalmic surgeons, compared to 29% for three-piece hydrophobic acrylic IOLs.⁷ A comparison between the Akreos Fit and hydrophobic Acrysof MA30 and MA60 IOLs (157 patients) found severe glare symptoms in 4.6% of the Akreos Fit eyes, compared to 13% for the Acrysof lenses.²² Lack of glare was reported by 28% of the Akreos Fit patients, and 18% of the Acrysof recipients.

Acrysof vs Akreos IOLs: A Comparison of Dysphotopsia²²



- 157 patients recruited prospectively within 12 months of uncomplicated cataract surgery
- Patients assessed using a combined questionnaire and examination scoring system
- The examination used a slit lamp beam that was angled 30° at the pupil under standardized conditions and was designed to illicit symptoms of dysphotopsia.
- No statistically significant difference between the 2 types of Acrysof IOLs.

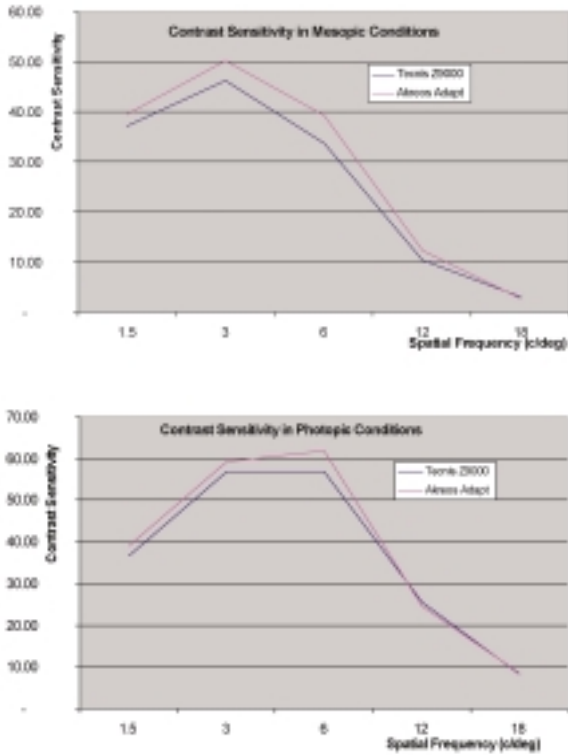
Exhibits good biocompatibility: After prospectively following patients with hydrophilic IOLs for 12 years, Khan and Percival concluded that poly-HEMA “can be unreservedly recommended for incorporation into acrylic lenses to improve flexibility and hydrophilicity.”⁵⁻⁶ In addition to this indication of long-term biocompatibility, researchers have shown that hydrophilic acrylics are very “quiet” in the eye.²³⁻²⁵ This has led many ophthalmic surgeons to use them in cataract patients with inflammatory conditions or comorbidities such as diabetes.

Has good optical clarity: The Khan and Percival study found that, among the 35 surviving recipients of poly-HEMA IOLs (Iogel PC12, 38% water content), the four cases of visual acuity worse than 20/40 could be attributed to age-related maculopathy or late endophthalmitis.⁶ Because of their hydrophilic nature, poly-HEMA IOLs have a typical aspect under slit lamp examination that is different from hydrophobic IOLs and similar to that of the cornea or the young natural lens. These researchers noticed this difference but found there was no discoloration, nor were there the microvacuoles or “glistenings” that have been observed in hydrophobic acrylic lenses.²⁶⁻²⁸ The final visual acuities were slightly superior to those achieved with PMMA.

In a more recent study in uveitis patients, the hydrophobic Acrysof MA60BM was 38.5 times more likely than other foldable IOLs to accumulate unexplained brown deposits within the optic (95% CI 6.9-200, $P < 0.001$). Eighteen of 22 Acrysof IOLs examined showed the deposits. Two of the three IOLs showing no deposits were hydrophilic: the Akreos Fit and the Bausch & Lomb Hydroview. The third was a silicone lens, the Allergan AR-40.²⁹

IOLs made from newer hydrophilic materials, such as the poly-HEMA/MMA copolymer in Akreos, may have a further advantage because of improvements in IOL designs and manufacturing methods, according to a report at the 2003 meeting of the European Society for Cataract and Refractive Surgery. Vryghem and Cools implanted 29 patients with the Akreos Adapt and Pfizer Tecnis Z9000 contra-laterally, and found no significant difference in their optical performance.³⁰ Seventeen of the patients rated their vision as similar in both eyes, seven preferred the Akreos Adapt eye, and five the Tecnis eye. Wavefront analysis in seven subjects found lower levels of higher-order aberrations in four Tecnis eyes and in one Adapt eye.

Contrast sensitivity comparing the Pharmacia Tecnis Z9000 and the Bausch Lomb Akreos Adapt³⁰



In the past, there have been reports of opacification due to calcification in some hydrophilic IOLs,^{7, 31-38} but these lenses have a different copolymer composition from that of the Akreos models. The problems with these other IOLs generally occurred within two years of implantation.^{35, 39} Nick Mamalis, MD, a University of Utah professor well-respected for his IOL biocompatibility studies, has said that follow-up of two years is sufficient for him to conclude that a hydrophilic IOL has no calcification problems similar to those previously reported in other hydrophilics.⁴⁰ More than 110,000 Akreos IOLs have passed this two-year milestone without any reports of such complications.⁴¹

Resists damage during insertion: Hydrophilic acrylic resists the fold marks and forceps damage that have been reported in silicone and other foldable acrylic IOLs.⁷⁻¹⁰ In the 2001 survey of IOL complications by the American Society for Cataract and Refractive Surgery, there wasn't a single report of explantation of a hydrophilic IOL because of damage during insertion.⁷ (However, damage to a hydrophilic acrylic IOL is possible through incorrect loading or use of an injector, or through inappropriate use of forceps.)⁴²

Stands up to Nd:YAG laser energy: As long ago as 1987, researchers reported that HEMA and HEMA/MMA copolymer were less susceptible to damage during Nd:YAG laser irradiation than PMMA.^{43, 44} More recently, a comparison among foldable IOL materials found that the three hydrophilic IOLs tested had higher thresholds for damage than did IOLs made of hydrophobic acrylic or silicone.⁴⁵

Appears to be less susceptible to biocontamination: In February 2003, a paper by Schauersberger et al. proposed that the wider use of hydrophilic acrylic IOLs might reduce the incidence of endophthalmitis after cataract surgery.⁴⁶ The researchers exposed nine different types of IOLs to standardized suspensions of *Staphylococcus epidermidis* for five minutes, then rinsed them and tested for continued presence of bacteria. The IOLs made from PMMA or hydrophobic acrylic had bacterial densities two or more times as high as those seen on hydrophilic IOLs. "Our data suggest that the higher the hydrophilicity of the IOL material, the lower the early adhesion and bacterial density on the IOL surface," the authors wrote.

Advantages Specific to Akreos

Stability in the capsular bag

For an implant's power calculation to be accurate, the IOL must be firmly fixated to prevent anterior or posterior shifting.⁴⁷ Surveys of ophthalmic surgeons indicate that incorrect lens power and decentration/dislocation are two of the most common reasons for IOLs to be explanted.^{7, 48} In clinical studies, the Akreos line of IOLs has demonstrated a reliable A-constant for power calculation, and excellent positional stability in the eye.⁴⁹⁻⁵¹

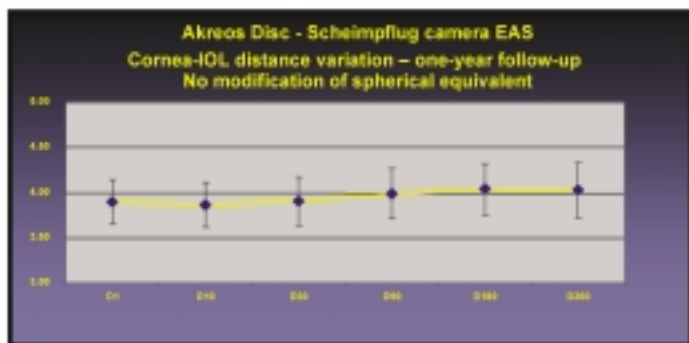
At France's Ophthalmic Institute of Somain, Thierry Amzallag, MD, compared IOLs with different types of haptics *in vitro* and found that the plate haptics of the Akreos Disc had two to six times the contact length with a simulated capsular bag than did other IOLs.⁴⁹

In a clinical study of decentration, Laube and colleagues compared the Akreos Fit to the three-piece Alcon Acrysof in 62 patients. They found that, after six months, decentration had occurred in 39% of the Acrysof eyes, compared to 10% with Akreos Fit.⁵⁰

In a German study of 27 patients with Akreos Fit and Disc IOLs, Spath et al. concluded that the lenses' biogeometry gave them good contact between optic and the capsular bag's equator, producing stable centration.⁵¹

In another study, at one year after surgery, 24 Akreos Disc patients showed a difference between expected and observed refraction averaging -0.10 D. The mean refraction shifted to the hyperopic by a mean of 0.18 D between 10 days and one year after surgery, without refractive effect. The subjects' mean refraction at one year was +0.03 D (SD: 0.56).⁵²

Anatomical and functional results with the Akreos Disc IOL⁵²



A British study of 30 Akreos Adapt patients confirmed the accuracy of the A-constant for this newest IOL in the Akreos line, finding that the difference between the mean expected and mean observed refractions at three weeks was +0.17 D. The patients' refraction through one year remained stable (mean difference: -0.66 D; SD 1.25). In addition, decentration of the Adapt was minimal, with a mean lateral movement of 0.048 mm (SD: 0.02).⁵³

Akreos Adapt Decentration ⁵³	3 weeks	3 months	6 months	1 year
Mean (mm)	0.04	0.05	0.05	0.05
SD (mm)	0.02	0.02	0.02	0.02

In-vitro studies of cell migration

With its four-haptic design, the Akreos Adapt maximizes the contact between the IOL surfaces and the capsular bag. In one study, six IOL models were implanted in an artificial capsular bag and 3D ultrasound biomicroscopy was used to measure IOL-bag contact. The researchers found that all the IOLs were in contact with the central part of the bag, but the Akreos Adapt was one of two that had complete contact along the equatorial zone.⁵⁴ This correlated with reduced spreading of cultured human lens epithelial cells on the Adapt. The other IOL with complete equatorial contact and reduced LEC migration was the Acrysof MA60.

Low PCO

In addition to double square edges intended to minimize posterior capsular opacification via a sharp bend in the capsular bag,⁵⁵⁻⁶⁶ Akreos IOLs are designed to minimize the chances of lens epithelial cell migration by producing a maximum of contact with the capsular bag ("no space, no cells").

In a clinical study on 68 eyes, Arné reported that the Akreos Disc's circular design produced an even distribution of tension on the capsular bag; he also noted the enhanced angle of contact that Amzallag had measured in vitro.^{49, 67}

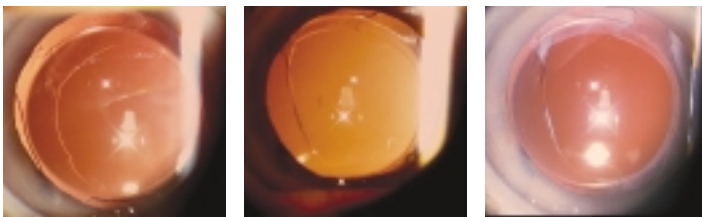
Clinical studies of the Akreos line's PCO performance are also positive. They include:

- The longest-running clinical study of an Akreos IOL, by Bendayan in France, using the Akreos Disc.⁶⁸ This research used EPCO software analysis in 48 patients to determine that they showed a medium index of PCO: 0.46 in the 6 mm optical zone, and 0.29 for the 3 mm central optical zone. (On the EPCO scale, 0 equals no PCO, and > 1 means Nd:YAG performed.) In the overall group of 127 patients, this study found the 2-year incidence of Nd:YAG laser capsulotomy was 8.8%.
- A Swiss study, which included 80 each of three IOL models. It found the Nd:YAG capsulotomy rate for the Akreos Disc was 15% after three years, compared to more than 33% for the Octobag (IOLTech) and the Allergan AR-40.⁶⁹

- After a mean follow-up of one year in 101 Akreos Adapt recipients, Robin et al. reported a 3.9% Nd:YAG rate. The mean time to laser capsulotomy was 12.6 months.⁷⁰
- A German study of Akreos Disc and Fit in 27 patients found PCO was low and progressed only slightly during the first postoperative year.⁵¹

These figures compare to a meta-analysis that estimated incidence of PCO across all IOL types at 11.8% at one year after surgery and 20.7% at three years.⁷¹

Post-operative pictures of the same patient implanted with an Akreos Adapt lens (courtesy Dr. Amzallag, Somains, France)



1 month post-op 6 months post-op 4 years post-op

Less anterior cell growth

The incidence of either anterior capsule opacification (ACO) or cellular attachment to the IOL differs among all types of IOL materials, and within the hydrophilic acrylic materials category itself.^{72, 73} Akreos IOLs have shown very little propensity for either inflammatory cell attachment or the lens epithelial cell outgrowth that has been reported in some other hydrophilic acrylics. A recently reported in vivo study in 180 patients found the Akreos Fit had fewer small cells, giant cells, or LECs at six months than either Alcon Acrysof or the hydrophilic Centerflex 570H (Rayner).⁷⁴

The long-running Bendayan study of Akreos Disc found “slight and peripheral” anterior fibrosis without capsular contraction among 13.4% of the 127 patients followed for at least two years.⁶⁸ The fibrosis had no effect on visual function and was stable between six months and two years.

Adapt: A solution to posterior capsular rupture

The four-point fixation design of the Akreos Adapt can secure the IOL firmly even when the complication of posterior capsular rupture has occurred, according to a paper delivered

at the 2003 ASCRS meeting.⁷⁵ In a Belgian study, Smeets reported success with placing two of the Adapt’s haptics behind the capsular bag and two in front. This creates crossed bag/sulcus fixation and good separation between the chambers without putting pressure on the ciliary body. Follow-up of three to 14 months showed good centration and stability of the IOLs, and stable UCVA in all patients. There was no inflammation, vitreous loss, or refractive shift.

Planar, one-handed insertion of the Adapt

The surgeon places the Akreos Adapt in the eye using the Hydroport® one-handed inserter system. This single-use injector eliminates the risk of contamination and reduces preoperative preparation time. It allows flat loading of the lens, and planar delivery through an incision of under 3 mm. Ophthalmic surgeons who have used the Hydroport report that it accomplishes the Adapt insertion safely and easily.^{49, 70}



Future development of hydrophilic acrylic lenses

Hydrophilic acrylic lenses such as Akreos are manufactured in a single piece using a lathing process. Not only does this process create better optical performance than molding at the high powers required for IOLs,⁷⁶ it also permits the creation of aspheric and non-rotationally symmetrical surfaces. Therefore, in the future Bausch & Lomb anticipates creating lens designs that limit or eliminate the higher-order aberrations inherent in conventional IOL designs.

In addition, the compressibility of hydrophilic materials in the future will permit the creation of designs that can be injected through smaller incisions, improving the speed and quality of visual recovery after surgery.

Conclusion

Both in research studies and in clinical use, the Akreos® Adapt, Fit, and Disc intraocular lenses have demonstrated advantages that include good biocompatibility, optical clarity, stability in the capsular bag, and inhibition of cell growth on the optic.

Akreos IOLs are made from a combination of two materials with the longest track record for ocular biocompatibility, poly-HEMA and MMA. The moderate refractive index gives Akreos lenses a significantly lower rate of dysphotopsias than is experienced with high-index hydrophobic IOLs (4.6% vs 13% in one study).²² Hydrophilic acrylic maintains its clarity over time, with none of the glistenings observed in hydrophobic acrylics.²⁶⁻²⁸ Akreos also is very stable within the capsular bag; for example, the Akreos Fit undergoes nearly four times less decentration than the three-piece Acrysof (10% vs 39%).⁵⁰ The Akreos Adapt exhibits the same amount of equatorial contact with the capsular bag as Acrysof,⁴⁹ and it also has double square edges that, in the Akreos Disc, have yielded a two-year Nd:YAG rate of only 8.8%.⁶⁸

With the wealth of experience that has been gained using them, hydrophilic acrylic lenses have been shown to be a significant addition to the surgeon's range of clinical options and have become the lens of first choice for many in Europe and Asia.

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