

# **ARTISAN<sup>®</sup> Aphakia IOL**

## **Training Manual**

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11.4 <b>Long-term follow-up of the corneal endothelium after artisan lens implantation for unilateral traumatic and unilateral congenital cataract in children: two case series.</b> Odenthal MT, Sminia ML, Prick LJ, Gortzak-Moorstein N, Volker-Dieben HJ. Cornea 2006; 25(10):1173-7.	11-31
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**[1**  
**ARTISAN<sup>®</sup> Aphakia IOLs**  
**General Information**





## 1.1 ARTISAN® Aphakia Training Program



### ARTISAN® TRAINING PROGRAM REQUIREMENTS

Welcome to the ARTISAN® Aphakia Training Program. You are joining a growing number of ophthalmic surgeons trained to implant ARTISAN® Aphakia Intraocular Lenses (IOLs) after cataract surgery.

The ARTISAN® Aphakia Training Program and Wetlab is a comprehensive course designed to provide you with the information and skills necessary to prescribe and surgically implant the ARTISAN® Aphakia IOLs.

In addition to the ARTISAN® Aphakia Training Program, an educational program on ARTISAN® and ARTIFLEX® Phakic IOLs is available. You are advised to participate in these advanced educational programs as well.

### MAINTENANCE OF SKILLS

Staying up-to-date on your education and skills can be accomplished by:

- thoroughly reading all literature on ARTISAN® and ARTIFLEX® IOLs;
- maintaining regular contact with your local OPHTEC representative;
- participating in continuing education programs sponsored by OPHTEC BV.

We value you as a customer and greatly welcome any and all suggestions for ways to improve our training materials and courses.

## 1.2 About ARTISAN®

### ARTISAN® LENS

The delicate and elegant microsurgical skill of a surgeon is an ART form. The Ophthalmic Surgeon is a Medical ARTISAN.

Prof. Jan G.F. Worst M.D. has long recognized the need to simplify ophthalmic surgery and make treatments available to a greater number of individuals worldwide. He has developed many IOLs, surgical techniques and instruments.

One of Jan Worst's significant contributions to Cataract and Refractive surgery is the development of the ARTISAN® Intraocular Lens. The ARTISAN® lens is the result of clinical experience with a unique fixation concept, first developed for the correction of aphakia (originally called the "Lobster Claw" or "Iris Claw" lens). In 1986 the concept was modified to be used in the phakic eye.

The name ARTISAN® was chosen to recognize the abilities of the ophthalmic surgeon and to honor one of ophthalmology's first ARTISANS, Jan Worst, for his significant contributions to eye care worldwide.

*"Remarkable things occur in accordance with nature. The opening and closing mechanism of the Lobster Claw inspired me in designing an IOL with Claw fixation"*  
Jan G.F. Worst, MD

### OPHTEC

OPHTEC is proud to manufacture and represent ARTISAN® and ARTIFLEX® Intraocular Lenses throughout the world and offers a full line of unique ARTISAN® products for aphakia, and various refractive solutions as myopia, hyperopia and astigmatism.

The company holds exclusive license and distribution rights for the ARTISAN® and ARTIFLEX® Lenses.

**The ARTISAN® and ARTIFLEX® phakic and aphakic IOLs form the flagship of the company today.**

## 1.3 History of the Iris Claw® Lens

### 1.3.1 Introduction

Since Harold Ridley implanted the first Intraocular Lens (IOL) in the capsular bag in 1949, a large variety of IOL designs have appeared on the market. The evolution of these designs form a reflection of the history of fixation principles. Some of these fixation methods have become obsolete due to severe early or late complications, while others have never completely disappeared.

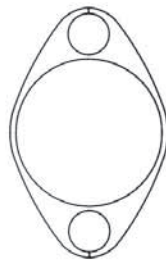
An analysis of the various advantages and disadvantages of these methods of fixation have resulted in a number of clinical and biochemical conclusions, which have been important to judge the clinical value of modern IOLs.

### 1.3.2. Serendipitous discovery of the Iris Claw® principle

Using an early model, the Slotted Medallion lens, Jan Worst sometimes observed that some iris tissue was caught in the slot of his lens. This clasping of iris tissue proved to be a serendipitously discovered new possibility for stable fixation of the IOL.

Once the efficacy of this additional fixation method had been proven in a number of cases additional iris stitching seemed no longer necessary.

### 1.3.3. Peripheral Iris Supported IOLs (“Iris Claw®” lenses)



The “Iris Claw®” lens (later on called the ARTISAN® Aphakia lens) has been introduced by Jan Worst. The design was relatively simple: one piece, one material, without additional loops.

The fixation mechanism is based on the enclavation of a fold of iris tissue. The formation of two diametrically opposed iridoplastic bridges in the virtually immobile midperiphery of the iris stroma does not interfere with the normal vascular- and nerve supply.

Jan Worst implanted the first Iris Claw® lens in 1978. Initially he implanted this lens only as secondary implant in traumatic cataract cases. Soon after he used it as a primary implant in ECCE as well as in ICCE cases.



Fig. 1.1: Iris Claw® IOL attached to the iris

## 1.4 Evolution from Iris Claw® Lens to ARTISAN® Aphakia IOL

1978

The Iris Claw® lens has been designed and used since 1978 as a universal lens to be used for primary or secondary implantation after ICCE, ECCE and later on after Phako-emulsification. The lens has been implanted in approximately 450.000 aphakic eyes worldwide.

Nowadays ARTISAN® Aphakia lenses are used increasingly as the back-up lens of choice by many modern cataract surgeons

The ARTISAN® Aphakia IOL is available as a standard IOL (5/8.5mm) or in two smaller sizes (4.4/6.5mm and 4.4/7.5mm) for pediatric application or for eyes where a smaller size IOL is preferred.

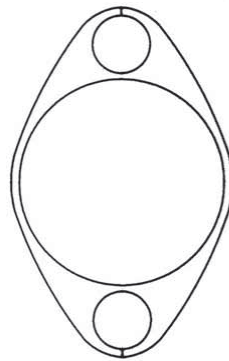


Fig. 1.2a: Worst Iris Claw® IOL (left)

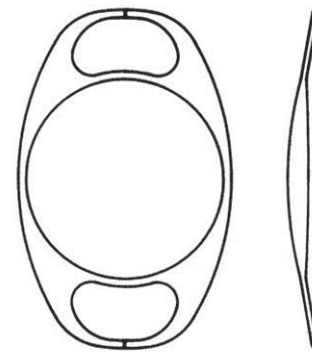


Fig.1.2b: ARTISAN® Aphakia IOL

1997

In 1997 an improved vaulted design of the ARTISAN® Aphakia Lens (Fig.1.2b/ 1.3b) was introduced with a number of new characteristics.

- The lens configuration was made vaulted to create distance to the iris;
- Enclavation was made easier by using a lens with a larger and oval aperture between optic and haptics than the original circular shape.



Fig.1.3a : Worst Iris Claw® design



Fig.1.3b Vaulted ARTISAN® design

### ARTISAN® APHAKIA IOL

#### 1.5.1. Lens Design

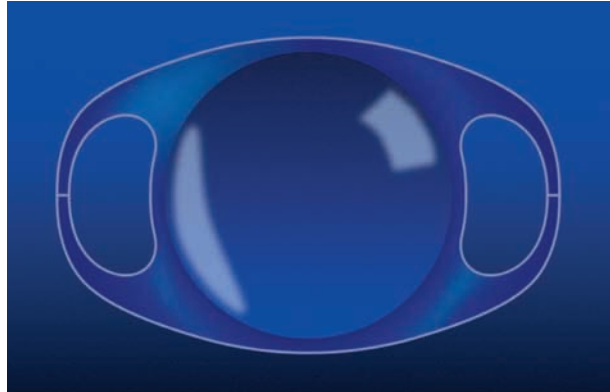


Fig.1.4: The ARTISAN® Aphakia IOL

##### **"Iris Bridge" support**

- ARTISAN® Aphakia IOLs are peripheral "iris bridge" supported lenses. The fixation points of these lenses are located in the virtually immobile part of the peripheral iris;
- The "iris bridges" form a shield and protect the cornea from touching the PMMA haptics of the IOL. (see Fig. 2.10 & 2.11, page 2-5).

##### **Stable "Claw" fixation**

- The fixation concept permits to position ARTISAN® Aphakia IOLs in the optical axis of the eye and permits excellent centration;
- The two diametrically opposed haptics secure stable fixation on the iris and prevent the risk of postoperative decentration;
- The system is extremely versatile as ARTISAN® Aphakia IOLs may be fixated horizontally, vertically or obliquely and is independent of the overall size of the eye.

##### **Unrestricted dilatation**

- The haptics (fixation arms) attach to the midperipheral virtually immobile iris stroma, thus allowing the pupil unrestricted ability to dilate and constrict (Fig.1.5);

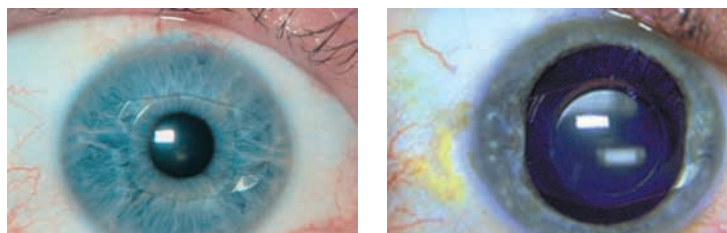


Fig 1.5 : Constricted and widely dilated pupil.

**ARTISAN® LENS  
 MANUFACTURING**

- Fluorescein angiographic studies by Strobel<sup>1</sup> and Izak<sup>2</sup> have shown no leakage of the iris vessels at the enclavation sites. Only a few cases of iris atrophy in the area of the fixation have been reported in the literature (see below);

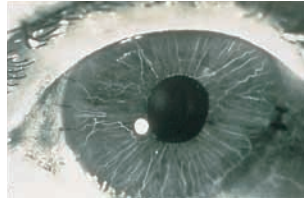


Fig.1.6: Fluorescein Angiography.

- Since the start of the original design of the Iris Claw® lens (1978), the fixation concept of this lens has remained unchanged;
- Only the lens design has slightly changed in 1997 (vaulted design and oval aperture).

**1.5.2. ARTISAN® Lens Manufacturing**

OPHTEC BV has developed a unique manufacturing process for the ARTISAN® Aphakia IOLs using Perspex C.Q. UV (polymethylmetacrylate).

**Compression Molding Technology**

During the compression molding process the molecular structure of PMMA is enhanced by redistributing the molecules into longer chains, resulting in a much stronger material.

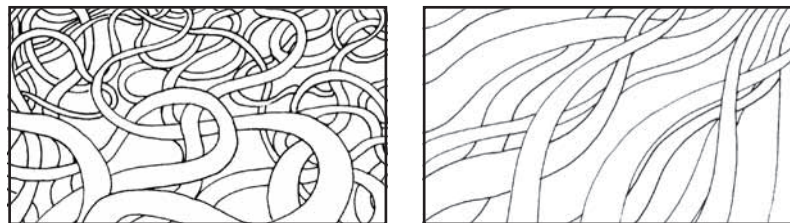


Fig.1.7: PMMA before and after compression molding.

**Extreme flexibility of the haptics**

This unmatched technology gives a high tensile strength, combined with superb flexibility of the lens haptics. The risk of fracture is minimal.

**Proprietary Tumbling Process**

The proprietary tumbling process gives a special surface treatment to the ARTISAN® IOLs. An ultra smoothness of the IOL is the result.

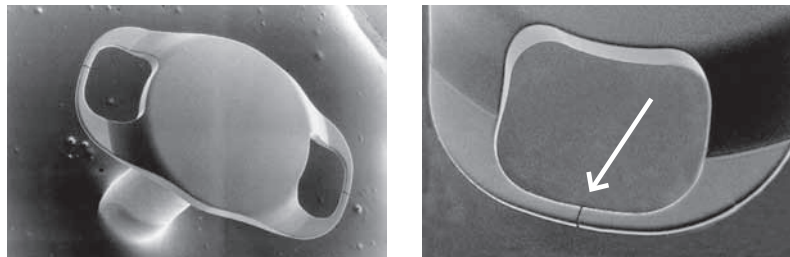


Fig.1.8: SEM Photographs of ARTISAN® IOLs with details of the "Claw"

<sup>1</sup> P.U. Fechner, J. Strobel & W. Wichmann: Correction of Myopia by Implantation of a Concave Worst-Iris Claw lens into Phakic Eyes. Refractive & Corneal surgery. July 1991; vol 7: 286-298;

<sup>2</sup> M. Izak: Surgical trauma, not lens Design, Responsible for Myopia Claw IOL Irritation. Ocular Surgery news. Sept. 1998; 38.

## 1.6 ARTISAN® | Benefits and Drawbacks



Fig 1.9: "vaulted" lens configuration

### BENEFITS

#### Review of the benefits

- The "iris bridge" protects the endothelium from touching the PMMA;
- Safe clearance from vital structures (corneal endothelium);
- Unrestricted pupil dilatation and constriction (sphincter independent);
- Unique possibility to position the lens in the optical centre of the eye;
- Excellent centration; once fixated the lens will not decenter;
- Maximal surgical visibility, accessibility and controllability;
- Optimal postoperative visibility of lens and lens fixation;
- Cosmetically invisible;
- Easy to reposition, reversible and exchangeable;
- No interference with vascular iris physiology (no leakage of iris vessels);
- Universal lens for ECCE and Phaco/Primary and secondary implantation;
- One size fits all.

### DRAWBACKS

#### Review of the drawbacks

- Requires surgical skill but has a short learning curve;
- Requires an incision of 5.4 mm.



# 1.7 ARTISAN® | Technical Specifications

REF. 205

ARTISAN® Aphakia IOL

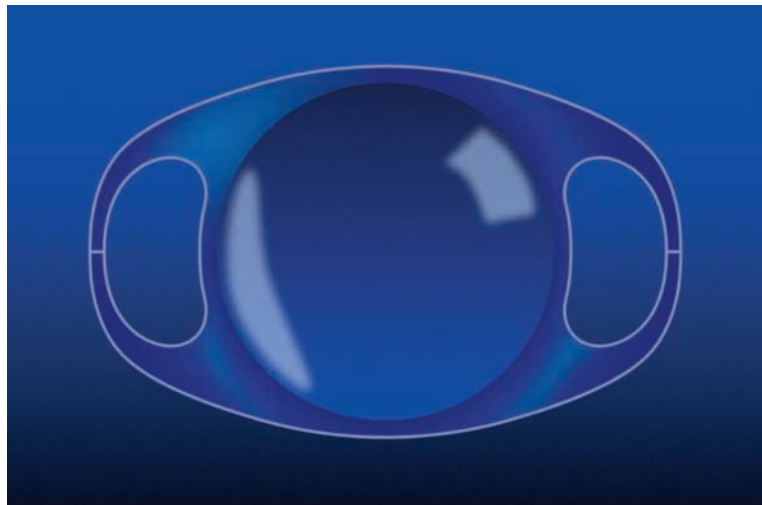


Fig.1.10a: Ref. 205 - Standard ARTISAN®Aphakia IOL

Lens type:	AC Iris Fixation ("Iris Bridge");
Lens material:	Perspex-CQ UV;
Fixation:	Mid-Peripheral, Iris Stromal Support;
Overall diameter:	8.5 mm;
Body diameter:	5.4 mm;
Optic diameter:	5.0 mm;
Total height:	0.76 mm;
Weight:	8mg in air (20D lens);
Sterilisation:	Ethylene oxide;
AC Depth:	3.3 mm;
A-constant:	115.0 (Ultrasound); 115.7 (Optical);

**Powers available:** +2.0 D to +30.0 D (1.0 D increments);  
 +14.5 D to +24.5 D (0.5 D increments).

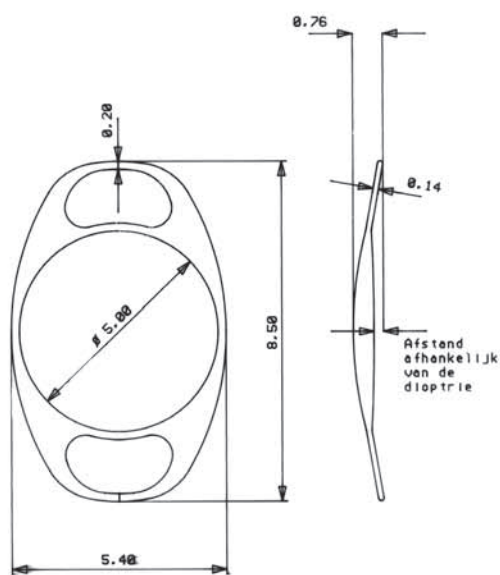


Fig.1.10b: Ref. 205 - Standard ARTISAN®Aphakia IOL

**REF. 205651**

**Pediatric ARTISAN® Aphakia IOL**

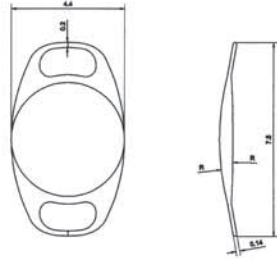


Fig. 1.11: Ref. 205651 - 6.5mm overall size

Lens type: AC Iris Fixation ("Iris bridge");  
 Lens material: Perspex-CQ UV;  
 Overall diameter: 6.5 mm;  
 Body diameter: 4.4 mm;  
 Optic diameter: 4.4 mm;  
 Total height: 0.56 mm;  
 Weight: 8mg in air (20D lens);  
 Sterilisation: Ethylene oxide;  
 AC Depth: 3.5 mm;  
 A-constant: 115.2 (Ultrasound);  
 115.9 (Optical);

**Powers available: +10.0 D to + 30.0 D (0.5 D increments)**

The Pediatric ARTISAN® Aphakia IOL is recommended for patients with small eyes.

**REF. 205671**

**Pediatric ARTISAN® Aphakia IOL**

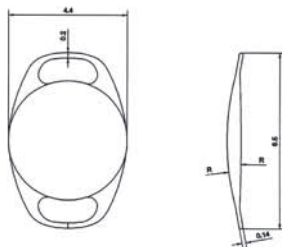


Fig.1.12: Ref. 205671 - 7.5 mm overall size

Lens type: AC Iris Fixation, ("Iris Bridge");  
 Lens material: Perspex-CQ UV;  
 Overall diameter: 7.5 mm;  
 Lens width: 4.4 mm;  
 Optic diameter: 4.4 mm;  
 Total height: 0.56 mm;  
 Weight: 8mg in air (20D lens);  
 Sterilisation: Ethylene oxide;  
 AC Depth: 3.5 mm;  
 A-constant: 115.1 (Ultrasound);  
 115.8 (Optical);

**Powers available: Only on special request: +10.0 D to + 30.0 D (0.5 D increments).**

The Pediatric ARTISAN® Aphakia IOL is recommended for patients with small eyes.

## 1.8 ARTISAN® | Other Indications

Apart from the correction of the aphakic eye with an ARTISAN® Aphakia IOL, the concept of the ARTISAN® fixation can be used for a number of other indications.

ARTISAN® Custom-made IOLs include lenses for the treatment of unique ocular conditions like Aniridia, Coloboma, Diplopia (Double Vision) etc.

These IOLs are manufactured on special request of the surgeon and are designed on the basis of clinical data, slides or drawings of the ocular condition of the patient.

### There are two categories of ARTISAN® Custom-made lenses:

- A. ARTISAN® Iris Reconstruction IOLs (made of coloured & clear PMMA)
- B. ARTISAN® Pupil Occluder for Diplopia Correction (made of black PMMA).

### A. ARTISAN® Iris Reconstruction IOLs

ARTISAN® Iris Reconstruction IOLs with coloured haptics (blue, brown, green or black) are ideal for anterior segment reconstruction when iris damage has occurred or is already congenitally present. Even large iris colobomata can be covered by the coloured haptic of the IOL.

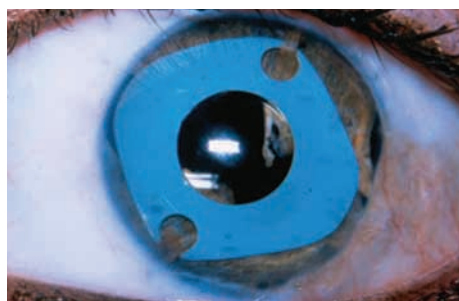


Fig.1.13a



Fig.1.13b

The Iris Reconstruction IOLs are available in various dioptric powers and colours (Blue, green, brown and black) and are custom-made. The optic is made of clear PMMA and the haptic of the coloured material.

Efforts have to be made to design a lens using a colour similar (or adjusted) to the colour of iris of the fellow eye. To correct dark brown eyes cosmetically acceptable it is wise to select the black material.

Usually two and sometimes three "claws" are positioned around the optic and are used as fixation points in areas where there is still some iris present for fixation.

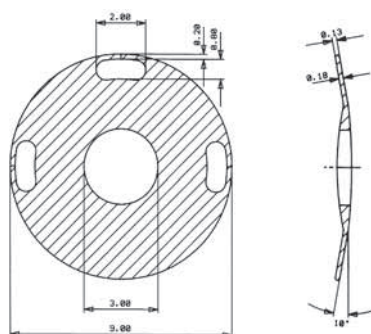


Fig.1.14

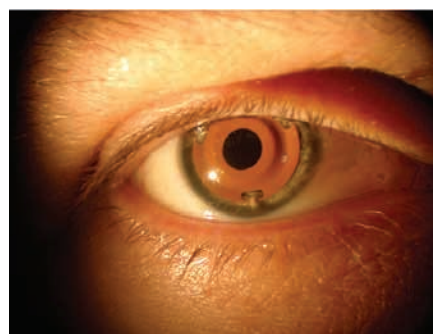


Fig.1.15

### B. ARTISAN® Pupil Occluder for Correction of Diplopia

Another application of the ARTISAN® Fixation Concept is Pupil Occlusion in case of intolerable Diplopia due to ocular muscle imbalance. The ARTISAN® Pupil Occluder functions as a cover over the pupil to prevent double images. The lens is cosmetically almost invisible. The black ARTISAN® Pupil Occluder is made of black polycarbonate and covers the pupil completely, on condition that it is positioned perfectly central over the pupil.

Due to the vaulted configuration it can be applied in both phakic and aphakic eyes. If necessary the ARTISAN® Pupil Occluder can be removed when vision is again demanded in case of blindness occurring in the fellow eye.

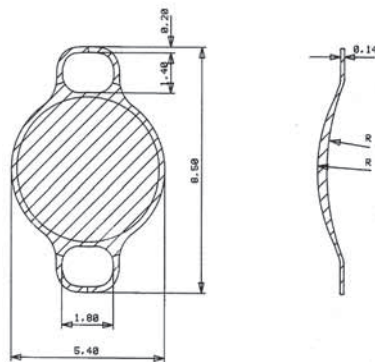


Fig. 1.16: 8.5mm overall size

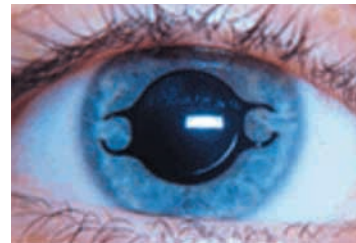


Fig.1.17: Pupil Occluder in situ

### Implantation Technique

It seems useful to describe some important details of the implantation technique as the final post-operative result depends on this. Essentially the implantation technique described for the ARTISAN® Aphakia IOL can be followed (see chapter 5). The measurements are about the same: A central zone of 5.4mm and an overall diameter of 8.5mm. The lens has a vaulted configuration to prevent contact between the optic and the iris.

### PERFECT CENTRATION

Condition for an optimal occluding effect of the lens is an absolute perfect centration. This is less easy than one thinks. When an IOL is positioned somewhat decentered and the pupil is very dilated, the pupil border gets free from the rim of the lens. This may lead to double images again. Even when this free zone of the pupil is very small, a stenopeic effect will occur and the covered eye will get some vision again. In that case an IOL with a larger central zone has to be used.

If a patient has a large pupil under dark circumstances it is wise to order an IOL with a larger central zone. The overall diameter should not exceed 9.0 mm!

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# [2

## Anatomy of the Aphakic Eye



## 2.1 Anatomy of the Iris

### THE IRIS AND THE IMPLANTS

It is important to understand why Iris Fixation of the ARTISAN® lenses is fully reliable. An explanation of the various physiological and anatomical aspects will be given here:

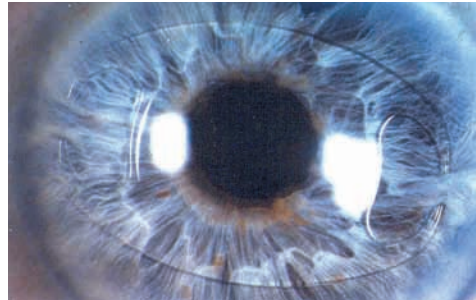


Fig. 2.1: The ARTISAN® IOL in situ

### The Iris consists of a:

#### Pupil Border

- The sphincter mechanism of the pupil border is functioning due to a smooth muscle with a great constricting and dilating capacity.

#### Pupil Dilatation Mechanism (4 concentric areas);

- The central part is highly mobile, (dilatable and constrictable);
- The paracentral mobile thickened area lies at two-third from the iris base;
- The practically immobile area is fit for iris enclavation of an ARTISAN® IOL;
- The iris base is immobile.

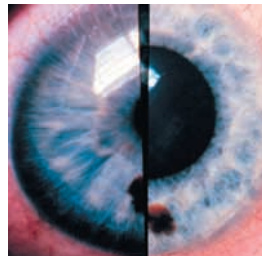


Fig. 2.2: Pupil constriction/dilatation

#### Practically Immobile Iris Area for Fixation of ARTISAN® IOLs

- Fixation of an ARTISAN® IOL is performed by gently creating an iris fold under the “claw” and consequently enclavating the iris in the “claw”;
- Proper enclavation guarantees prevention of lens luxation.

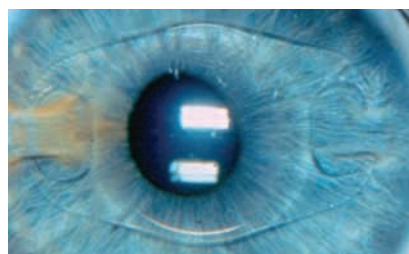


Fig. 2.3: ARTISAN® Aphakia IOL

### Iris Stroma - Vascular network

- The vascular network of the iris consists of an arterial inflow and venous backflow;
- The vessels are radially oriented and sectorially distributed;
- In very rare cases a nerve may be incarcerated in the “claw”. Reorientation of a few degrees will be sufficient to correct the situation.

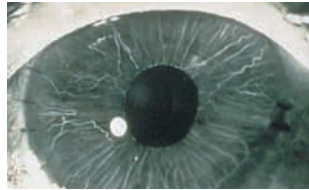


Fig. 2.4: Vascular network of the iris visualized by Fluorescence Angiography

### Iris Root - Area where cornea and iris meet, the so-called chamber angle

- Compression of the terminal end arteries interferes with iris metabolism;
- When the sectorial end arteries fail to function properly as a result of compression in the chamber angle, this will lead to ischaemic iridopathy, (“iris infarction”);
- Iris root support tends to fail in the long run;
- Chamber angle supported lenses can cause several complications f.i. pupil ovalisation.

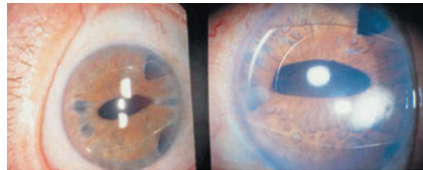


Fig. 2.5: Pupil ovalisation

### Surface Configuration

- Blue eyes and brown eyes have a totally different surface configuration;
  - Blue eyes have a pronounced trabecular structure with crypts
  - Brown eyes usually have a cryptless, non-trabecular structure.

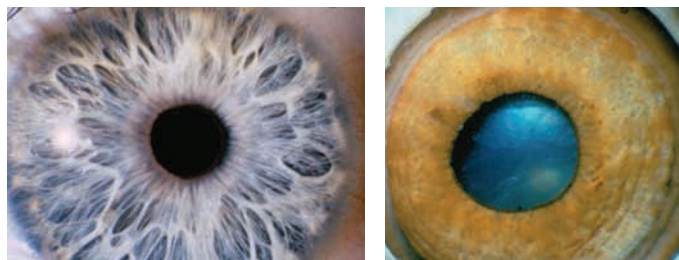


Fig. 2.6: The different surface configuration of blue (left) and brown (right) eyes

### Pigment Layer

- Blue eyes have no pigment within the iris stroma. They only carry a deep brown layer of pigment cells on the rear iris surface;
- Brown eyes have pigment within the iris stroma plus a deep brown layer of pigment cells on the rear iris surface.



THE IRIS AND THE  
ARTISAN® IMPLANT

Pigment on Front and Rear Side in Brown Eye



Fig. 2.7: Six years after implantation the eye was removed postmortally. No sign of pigment loss at the rear side of the iris and at the enclavation sites. On the front side the effect of a too tight use of the forceps is visible.

Minimal risk surgery

The anatomy of the iris and its specific features allow surgery with minimal risks. Fixation is performed to the iris periphery.

The main features are:

- Pressure free iris fixation;
- No iris atrophy when the recommended surgical technique is used (see chapter 5);
- Optimal dilatation if needed. The fixation arms are attached to the immobile iris and don't inhibit pupil dilatation (fig 2.9), allowing inspection of the posterior segment;
- Reversible fixation. Even after many years the lens can be exchanged without any damage to the iris structure;
- "Iris Bridge" fixation prevents endothelial touch.



Fig. 2.8: Gonioscopic image showing the distance to the corneal endothelium after ARTISAN® implantation

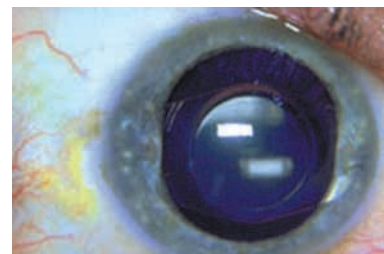


Fig. 2.9: The fully dilatable pupil

"IRIS BRIDGE"  
FIXATION



Fig.2.10: Artisan® lens attached to the iris



Fig. 2.11: Safe distance to the endothelium

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# [3

## Preoperative Care and Management



### 3.1 Patient Selection, Indications and Contraindications

#### INDICATIONS

Implantation of the ARTISAN® Aphakia IOL may be indicated under the following conditions:

- Senile cataract;
- Traumatic cataract;
- Congenital or juvenile cataract;
- Secondary implantation after aphakia.

#### CONTRAINDICATIONS

The following contraindications are circumstances where the physician should consider whether implanting an intraocular lens might create an undue risk. Physicians considering implantation in such patients should explore the use of alternative methods of aphakia correction and consider lens implantation only if alternatives are deemed unsatisfactory to meet the needs of the patient.

1. Only one eye with visual acuity;
2. Congenital bilateral cataract;
3. Recurrent or chronic iritis;
4. Rubella cataract;
5. Retina and optic nerve defects;
6. Corneal dystrophy (except in preparation for penetrating keratoplasty);
7. Diabetic retinopathy;
8. Acute inflammation;
9. Severe iris atrophy;
10. Uncontrolled chronic glaucoma;
11. Vitreous loss or choroidal haemorrhage during surgery.

## 3.2 Patient Examination

### INTRODUCTION

The eye surgeon can organize, maintain and evaluate the data of his/her cataract operations in a simple database in which preoperative and postoperative data are compiled.

### EXAMINATIONS

✓ **Best spectacle corrected near and distant visual acuity in both eyes**

Snellen-charts are most frequently used to test the visual acuity (BSCVA);

✓ **Subjective Refraction and/or Cycloplegic Refraction**

The subjective refraction (12 mm vertex distance) determined with the phoropter is the most important variable. The cycloplegic refraction is determined after paralyzing the lens accommodation with cycloplegic eye drops. Variability in optical power will thus be eliminated;

✓ **Intraocular pressure**

A tonometer is used to check the pressure of the eye;

✓ **Slitlamp Examination;**

- Corneal and chamber angle status;
- Iris Status;
- Status of the posterior segment;

✓ **Corneal curvature;**

- A keratometer is used to measure the curvature of the cornea (K1 and K2);
- The keratometry values are used for Lens Power Calculation (see chapter 4);

✓ **Biometry of both eyes;**

- Ultrasound or optical methods are used to measure the axial length of the eye, the lens thickness and the distance between cornea, lens and retina;
- The axial length value is used for Lens Power Calculation (see chapter 4).

✓ **Status of the fellow eye**

The status of the fellow eye is important, because most of the time both eyes develop cataract. It is therefore advised to keep the time between the operations as short as possible. (i.e. 2 to 3 weeks);

✓ **External examination**

An external examination reveals abnormalities in the function of the pupil, the eye muscles and the eyelids;

### 3.3 Preoperative Patient Preparation

#### PREOPERATIVE PATIENT PREPARATION

The following regime is recommended although the surgeon should tailor this regime to meet the patients need.

##### **Prior to surgery**

- The patient should use an topical antibiotic prior to surgery: for 3 days: 1 drop, 3 times daily.

##### **Medications on the day of surgery**

- 2 to 4 drops of a topical NSAID;
- 2 to 4 drops of topical antibiotic;
- 2 to 4 drops of miotic in case of secondary implantation of an ARTISAN Aphakia IOL.

#### PRESURGICAL PATIENT PREPARATION

##### **Anesthesia/Akinesia**

- The surgeon makes the choice between local and topical anesthesia;
- If local anesthesia is given, the parabolbar or subtenon injection is recommended. They both result in total immobility of the globe and eyelids;
- Nowadays most surgeons only apply some drops of topical anesthesia to give a favorable situation.

##### **Prevention of infection**

- Desinfect the skin and fornix with povidon-iodine;
- Cover all eyelashes since they are a potential source of infection;
- Furthermore use surgical sponges to prevent stagnant fluid during surgery.

##### **Bulbus Compression**

- Ocular compression and/or massage are given until low preoperative vitreous pressure is obtained. This will improve the accessibility and operative space in the anterior chamber;
- Any pressure from the retrobulbar spaces may lead to pressure on the lens diaphragm, which may result in iris prolapse.

##### **Pupil Constriction**

- Preoperative application of topical miotic results in pupillary miosis;
- A narrow pupil is essential for the centration of the ARTISAN® Aphakia IOL and proper fixation to the iris;
- When the cataract has been removed with the phako procedure and unfortunately a capsule rupture has occurred the large pupil has to be constricted before implantation of an ARTISAN® Aphakia IOL can be performed.

### 3.4 ARTISAN® IOLs, Instruments and Supplies

#### ARTISAN® APHAKIA IOL

The ARTISAN® Aphakia IOLs are supplied sterile and dry in a lenscontainer, which is sealed in a blister pack and placed in a box together with the identifying labels. Before opening, the label should be checked for lens model, dioptric power and expiration date.

#### Instructions for Use

- Open the blister packaging;
- Tap slightly on the lid before opening the lens container to detach the lens, which may stick to the lid;
- Keep the container in a horizontal position;
- Unscrew the cap and lift it;
- Grasp the lens gently with a forceps.

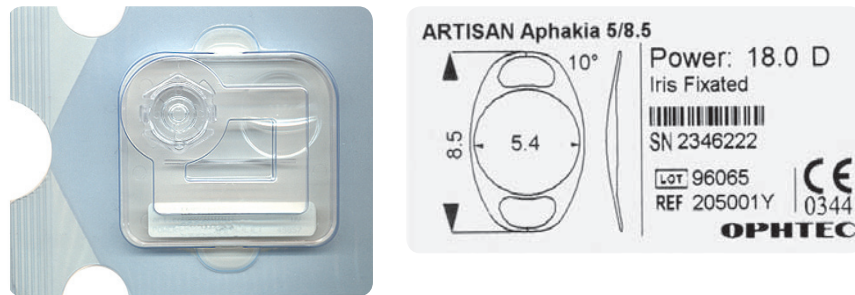


Figure 3.1: Blister packaging with label

#### ARTISAN® SURGICAL INSTRUMENTS

Specially designed ARTISAN® Instruments for implantation and enclavation of the ARTISAN® IOLs, are required. Depending on the enclavation technique, use the ARTISAN® Enclavation Forceps or the ARTISAN® Enclavation Needle.

#### ARTISAN® Implantation Forceps Standard (D02-74)



Figure 3.2: D02-74

#### ARTISAN® Implantation Forceps, long (Refractive) (D02-70)



Figure 3.3: D02-70

#### ARTISAN® Enclavation Forceps (D02-40)



Figure 3.4: D02-40

**ARTISAN® Enclavation Needle (box of 5; OD-125)**



Figure 3.5: OD-125

**ARTISAN® Lens Manipulator Standard, Straight (DO-06-41)**



Figure 3.6: DO-06-41

**ARTIFIX for Retropupillary Fixation**



Fig. 3.7a: Artifix forceps



Fig. 3.7b: Artifix forceps with IOL

Before using the ARTISAN® Instruments carefully read the Directions for Use concerning handling and care of the ARTISAN® Instruments.

**OTHER MATERIALS**

In addition to the ARTISAN® Instruments listed above, other instruments and supplies are available for the ARTISAN® IOL implantation, i.e:

**Supplies**

- ArtiVisc® and ArtiVisc®Plus (chapter 3.5), (sodium hyaluronate).

**Instruments**

- Cannulas;
- Knives;
- Surgical sponges / drains;
- Lidholders;
- Eye Shields.



### 3.5 ArtiVisc® and Sodium Hyaluronate

#### CHARACTERISTICS

ArtiVisc® and ArtiVisc® Plus are viscoelastic solutions that combine high viscosity, high elasticity and high molecular weight. They provide protective coating of endothelial cells during intraocular manoeuvres in cataract and refractive surgery.

Sodium Hyaluronates are produced by extraction of high molecular weight molecules from rooster combs. The resulting polymer is a large molecular coil with improved rheological properties. Because it is a native hyaluronic acid, it has a high degree of biocompatibility. The most important properties of hyaluronic acids are: protecting, lubricating and supporting delicate cells and tissues. ArtiVisc® and ArtiVisc® Plus form a thin layer without causing compression of delicate cells or tissues.

#### INDICATIONS

ArtiVisc® and ArtiVisc® Plus are used especially during the following ophthalmic procedures:

- Cataract surgery and IOL implantation;
- Glaucoma surgery;
- Corneal transplantation;
- Anterior segment surgery;
- Refractive surgery with PIOL implantation.



Fig 3.8: ArtiVisc®

#### TECHNICAL DATA

- Single use;
- Sodium Hyaluronate;
- 0.85 ml;
- Iso-osmolar, buffered solution pH 7.0 - 7.5;
- Sterile, non-pyrogenic, non-immunogenic;
- 27 Gauge cannula;
- Luer-lock fixation;
- Double packaging.

REF H53.16.010 ArtiVisc®	1.0% 0.85 ml
REF H53.16.020 ArtiVisc® Plus	1.4% 0.85 ml

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# [4

## Lens Power Calculation



## 4.1 Lens Power Calculation

### INTRODUCTION

The preoperative calculation of the lens power of a PMMA IOL for the correction of aphakia has been worked out by various authors. (Binkhorst, v.d. Heijde, Colenbrander, Sanders, Retzlaff, Kraff, Hoffer, Holladay etc.). A variety of formulas has been developed a/o the SRK/II formula. This formula uses the so-called A-constant.

The A-constant of a given lens is found experimentally. The method has been published in 1981 by Sanders et al.

$$A = P + (2.5 \times L) + (0.9 \times K)$$

Where:

A = The approximate A-constant derived for each lens type and individual manufacturer;

P = Predicted implant power for emmetropia in diopters;

L = Axial length in millimetres;

K = Average keratometry reading in diopters (Corneal curvatures have to be translated to diopters, see the table)

Experiments done with at least 100 patients establish an approximate A-constant for an individual surgeon and a special lens type.

### CORNEAL CURVATURE IN MM VERSUS DIOPTER

Table 1. Corneal curvatures in mm versus equivalent dioptic power

Corneal Curvatures (mm)	Equivalent Dioptic power (dpt)	Corneal Curvatures (mm)	Equivalent Dioptic power (dpt)	Corneal Curvatures (mm)	Equivalent Dioptic power (dpt)	Corneal Curvatures (mm)	Equivalent Dioptic power (dpt)
6.80	49.56	7.24	46.55	7.68	43.88	8.12	41.50
6.82	49.41	7.26	46.42	7.70	43.77	8.14	41.40
6.84	49.27	7.28	46.29	7.72	43.65	8.16	41.30
6.86	49.13	7.30	46.16	7.74	43.54	8.18	41.20
6.88	48.98	7.32	46.04	7.76	43.43	8.20	41.10
6.90	48.84	7.34	45.91	7.78	43.32	8.22	41.00
6.92	48.70	7.36	45.79	7.80	43.21	8.24	40.90
6.94	48.56	7.38	45.66	7.82	43.09	8.26	40.80
6.96	48.42	7.40	45.54	7.84	42.98	8.28	40.70
6.98	48.28	7.42	45.42	7.86	42.88	8.30	40.60
7.00	48.14	7.44	45.30	7.88	42.77	8.32	40.50
7.02	48.01	7.46	45.17	7.90	42.66	8.34	40.41
7.04	47.87	7.48	45.05	7.92	42.55	8.36	40.31
7.06	47.73	7.50	44.93	7.94	42.44	8.38	40.21
7.08	47.60	7.52	44.81	7.96	42.34	8.40	40.12
7.10	47.46	7.54	44.69	7.98	42.23	8.42	40.02
7.12	47.33	7.56	44.58	8.00	42.13	8.44	39.93
7.14	47.20	7.58	44.46	8.02	42.02	8.46	39.83
7.16	47.07	7.60	44.34	8.04	41.92	8.48	39.74
7.18	46.94	7.62	44.23	8.06	41.81	8.50	39.65
7.20	46.81	7.64	44.11	8.08	41.71		
7.22	46.68	7.66	43.99	8.10	41.60		

**ULTRASOUND BIOMETRY**

**Biometry performed with ultrasound technique**

The approximate A-constant for the ARTISAN® Aphakia IOL has been established at 115.0. Another parameter, which is used in several calculation formulas, is the AC-depth (distance from the epithelium to the natural lens). Manufacturers provide data for the A-constant as well as the AC-depth on the lens labels.

**OPTICAL BIOMETRY**

**When biometry is performed with an optical technique, the approximate A-constant is 115.7**

**EXAMPLE CALCULATION FOR APHAKIC EYE**

**Lens to be implanted: 205 - ARTISAN® Aphakia IOL**

**Patients data**

- Axial length: 22.0 mm;
- Keratometry readings: 44.0 / 45.0 - average 44.5 diopters (Equal to curvature 7.66 / 7.49 mm - table 1).

**Approximate A-constant (provided by OPHTEC BV): 115.0**

**Method:  $A = P + (2.5 \times L) + (0.9 \times K)$**

$$115.0 = P + (2.5 \times 22) + (0.9 \times 44.5)$$

$$115.0 = P + (55) + (40.05)$$

$$115.0 = P + 95.05$$

$$P = 115.0 - 95.05$$

**Result: P = 19.95 diopters**

**Lenspower to be implanted: 20.00 diopters**

The method described above is a basic lens power calculation method, using the approximate A-constant.

Many authors published new formulas, where other parameters are used for additional corrections like:

- Extremely Short or Long Eyes;
- Central IOL thickness of Planoconvex, Biconvex and Meniscus IOLs;
- Influence of Retinal Thickness, etc.

<sup>1</sup> Retzlaff, J.A., et al, Development of the SRK/T intraocular lens implant power calculation formula, J Cataract Refract Surg, Vol 16; May 1990

**[5**  
**ARTISAN<sup>®</sup>**

**Implantation Technique**



## 5.1 Introduction

### CAPSULE RUPTURE

When capsule rupture after a cataract extraction occurs and a regular PC lens can not be implanted due to absence of capsular support, a sutured posterior chamber lens could be used. The suturing technique however is difficult, the surgical time is long and the intraocular manipulation is excessive.

Therefore the implantation of an ARTISAN® Aphakia IOL is preferable as it can be fixated to the iris without sutures. The iris can be incarcerated between the “claws” of the IOL. The surgical time is shorter, the intraocular manipulation is simple and less traumatic.

### STANDARD IMPLANTATION TECHNIQUE

The Standard Implantation Technique (5.2), which positions the ARTISAN® Aphakia IOL in the anterior chamber is used by most surgeons. The advantage of this technique is the visibility of the IOL postoperatively. The IOL can be well controlled.

#### Note

*The incision after Phako must be enlarged to 5.5 mm and the pupil has to be constricted with a miotic solution to facilitate the centration of the ARTISAN® Aphakia IOL by centering it over the pupil.*

### RETROPUPILLARY FIXATION TECHNIQUE

An alternative low-risk technique is the Retropupillary Fixation Technique (5.5) of the ARTISAN® Aphakia IOL. The implantation of the ARTISAN® Aphakia IOL behind the iris preserves the anatomy of the anterior chamber, but on the other hand the lens will not be visible postoperatively. Recently several authors have reported studies with this new approach which was first developed by dr. A. Mohr from Germany.

#### Note

*Contrary to the Standard Implantation Technique the pupil should be approx. 3 mm and should not be constricted at the start of the operation!!*



## 5.2 Standard Implantation Technique of ARTISAN® Aphakia IOL

Contribution by Jan G.F. Worst, M.D. and Camille Budo, M.D.

Artist drawings by Mrs. Jessica Leenen

The description and drawings following here represent the Standard Technique for implantation of ARTISAN® Aphakia IOLs.

The ARTISAN® Aphakia IOLs are peripheral “iris bridge” supported lenses. The fixation points of these lenses are located in the virtually immobile part of the peripheral iris and form “iris bridges”.

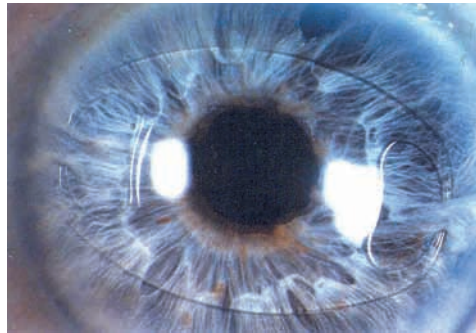
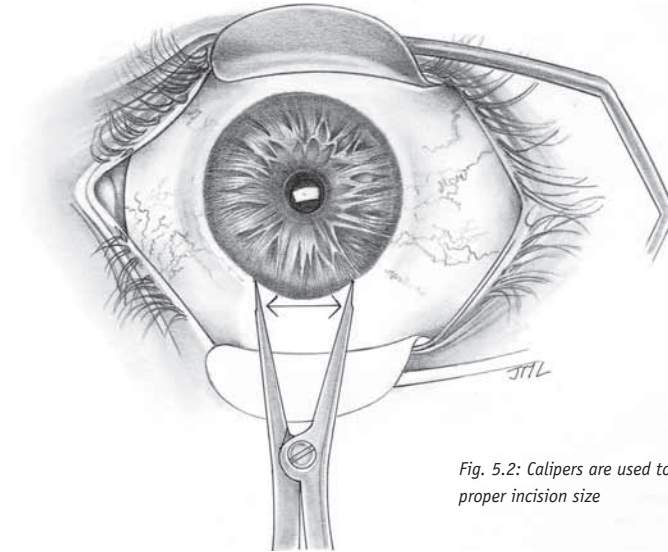


Figure 5.1: ARTISAN Aphakia IOL in situ

- The “iris bridges” form a shield and protect the cornea from touching the PMMA haptics of the IOL;
- The two diametrically opposed haptics ensure stable fixation on the iris, preventing; pseudophakodonesis and the risk of post-operative decentration;
- The fixation concept permits ARTISAN® Aphakia IOLs to be centered on the pupil and positioned in any meridian;
- Dilatation and constriction of the pupil is relatively unrestricted.

**MAIN INCISION**

A technique is recommended with a 12 o'clock incision and two paracenteses using the Enclavation Needles or Enclavation Forceps for fixation of the IOL. Use calipers to mark the 5.5 mm incision width. Make a non-perforating half-depth central corneal or corneo-scleral incision.



*Fig. 5.2: Calipers are used to indicate the proper incision size*

**PARACENTESES**

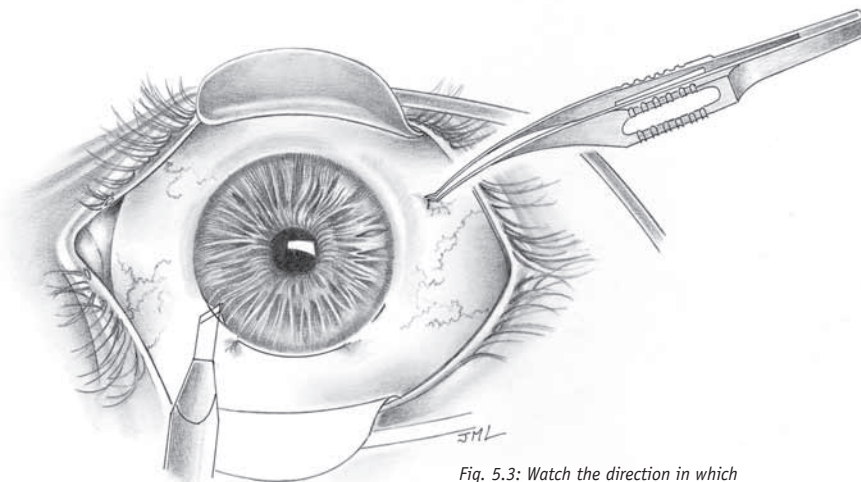
Paracenteses are used for the introduction of the instruments needed for enclavation of the ARTISAN® lenses. Paracenteses for two different types of enclavation instruments are described.

**Paracenteses for Introduction of the Enclavation Needles** (see Fig. 5.7)

- Make two paracenteses of 1.2 mm, one beginning at 2 o'clock and one beginning at 10 o'clock. The tip of the knife should be pointed downwards (Fig 5.3), oriented toward the enclavation sites for introduction of the Enclavation Needles.

**Paracenteses for Introduction of the Enclavation Forceps** (see Fig. 5.9)

- Make two paracenteses of 1.6 mm at 3 and 9 o'clock directed to the pupil. Use this technique when using the Enclavation Forceps.



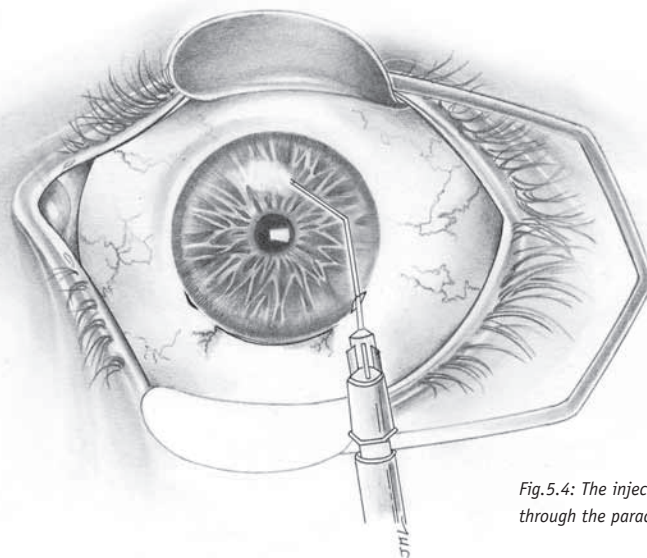
*Fig. 5.3: Watch the direction in which the knife is oriented*

**CONSTRICT THE PUPIL**

Inject a miotic solution into the anterior chamber to constrict the pupil. The pupil has to be very small to facilitate the centration of the IOL on the pupil.

**USE A HIGH VISCOSITY VISCOELASTIC**

Filling the AC with a high viscosity viscoelastic substance greatly facilitates the visibility of the various manoeuvres, creates space and protects the endothelium. Inject a small amount of viscoelastic like ArtiVisc® 1.0% or ArtiVisc Plus® 1.4% through each paracentesis to maintain the anterior chamber.



*Fig.5.4: The injection needle is passed through the paracentesis*

The material must be injected slowly from the periphery of the eye toward the pupil, but never directly into the pupillary area. Inject just enough viscoelastic to fill the anterior chamber to a volume slightly larger than its preoperative state. Do not overfill the AC!

The iris should be flat or slightly convex. If the iris is concave, there is too much pressure caused by the viscoelastic. This may result in unwanted pupil dilation and will increase the difficulty of the enclavation and lens centering manoeuvres.

Also cover the conjunctiva with viscoelastic to prevent contamination of the lens (Galand). Put a layer of viscoelastic over the exterior of the cornea to enhance visualization throughout the case.

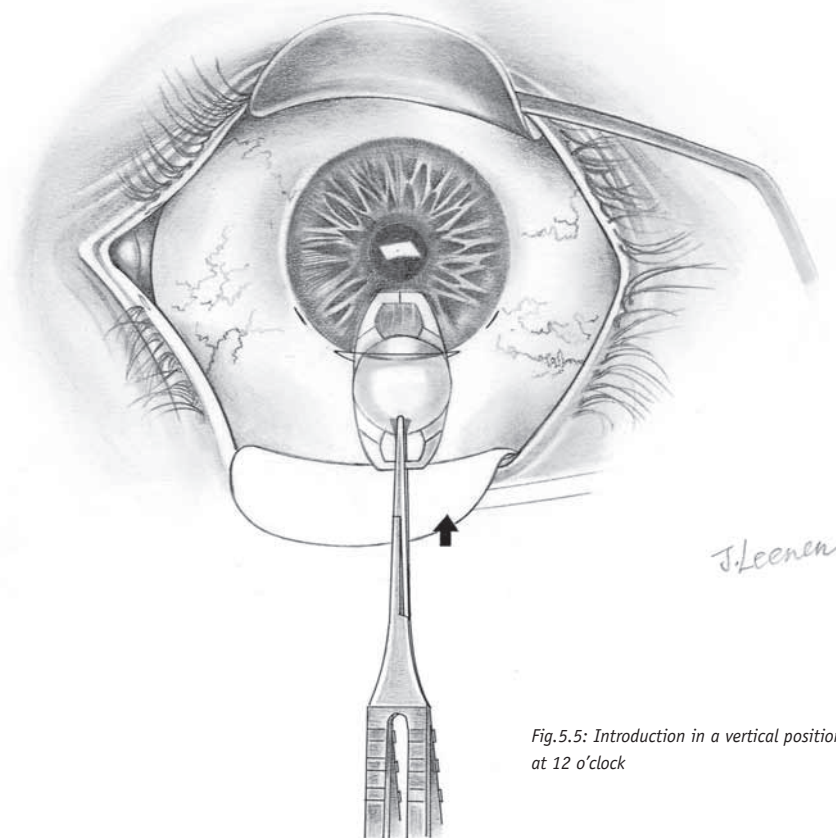
Open the anterior chamber by completing the half-depth incision to full-depth.

**IMPLANTATION OF AN  
ARTISAN® IOL**

Make sure the pupil is adequately constricted with a miotic solution. This facilitates the proper centration of the IOL. Insert the lens through the incision and gently apply some viscoelastic on top of lens to prevent movement of the lens during the enclavation procedure.

Test whether the Enclavation Needle enters the paracenteses easily before introducing the IOL in the anterior chamber.

The ARTISAN® Aphakia IOL is introduced in a vertical position with the ARTISAN® Implantation Forceps.



*Fig.5.5: Introduction in a vertical position  
at 12 o'clock*

Rotate the lens into the desired position (haptics at 3 and 9 o'clock) using the ARTISAN® Lens Manipulator. Make sure that the lens is well centred on the pupil. Care must be taken to avoid contact with the corneal endothelium.

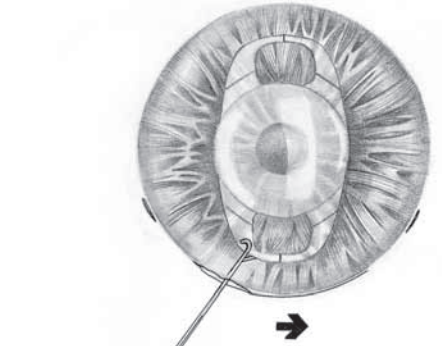


Fig. 5.6a



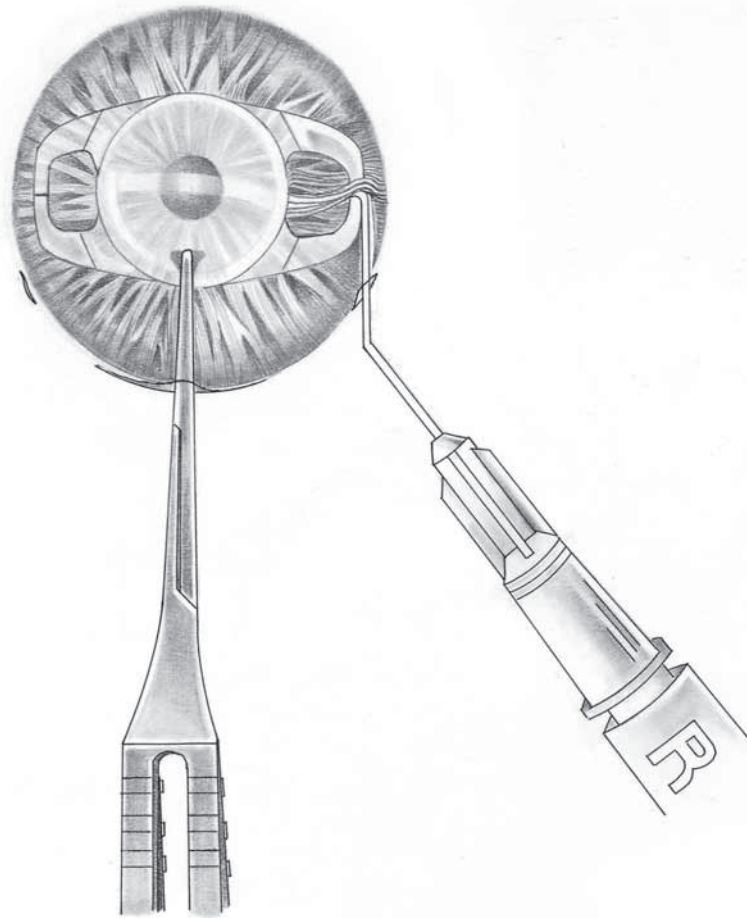
Fig. 5.6b



Fig. 5.6c

Fig.5.6a-c: Rotation of the PIOL to the horizontal position

Close the incision with two sutures leaving a space of 3 mm at 12 o'clock to allow 'closed chamber' surgery.



*Fig. 5.7: Firmly grasping the PIOL with the Implantation Forceps, the Enclavation Needle creates a "fold" of iris tissue*

**IRIS ENCLAVATION  
WITH ARTISAN®  
ENCLAVATION NEEDLE**

- Perform the first enclavation with the non-dominant hand (Fig. 5.7)
- Insert the Iris Enclavation Needle (left or right) through one of the paracenteses to fixate the lens to the iris;
- Insert the Implantation Forceps through the main incision, firmly grasping the lens at the optic edge;
- While securely holding the lens body with the Implantation Forceps, use the Enclavation Needle to create a small "knuckle" of iris tissue;
- Make a 'snow-ploughing' movement at the desired fixation site (Fig. 5.8a);
- Hold the knuckle of iris with the needle while gently pressing the slotted centre of the lens haptic over the knuckle, thus grasping the iris tissue (Fig. 5.8b);

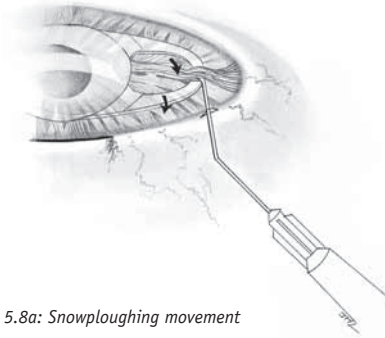


Fig. 5.8a: Snowploughing movement

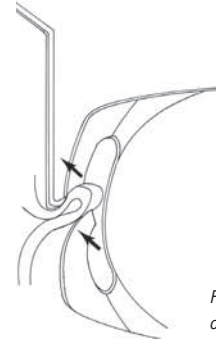


Fig. 5.8b: Gently pressing over the knuckle

- A significant fold of iris tissue (Fig. 5.11) must be delivered through the haptic slot to ensure adequate lens stability. If the fold is too small, the IOL can luxate into the anterior chamber and cause damage to the cornea;
- Avoid clamping the main horizontal artery within the “claws”. Try to keep the artery within the “bulge” of the “iris bridge”;
- Carefully retract the Enclavation Needle to avoid damage to the iris surface;
- Transfer the instruments to the opposite hands and repeat the enclavation for the second haptic while ensuring that the lens is well centred;
- Enclavate the other side with the dominant hand.

**Note**

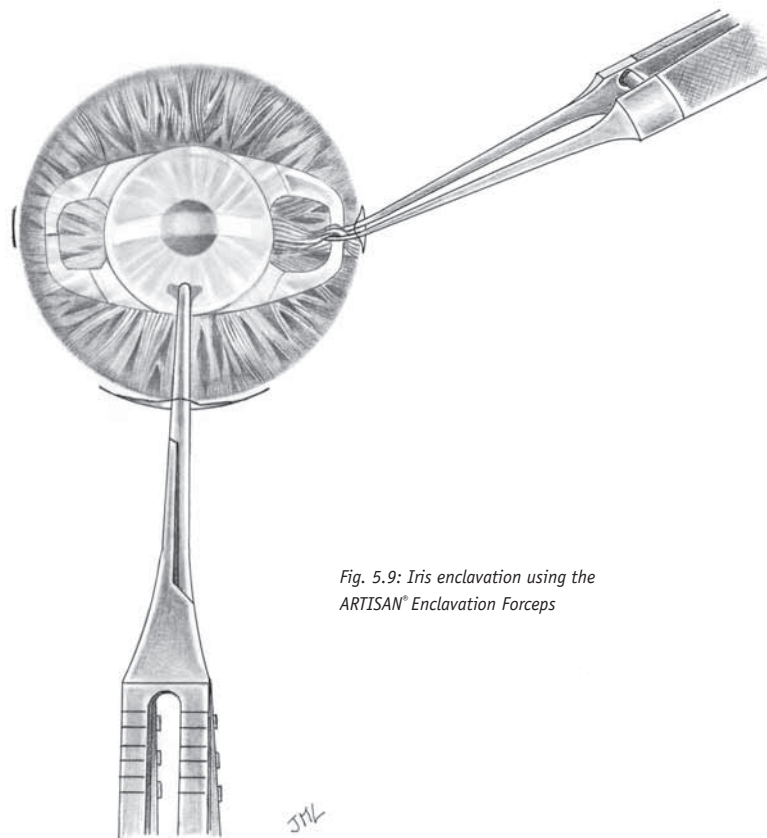
*Advantage of the use of Enclavation Needles is the relaxed position of the surgeon's arms against his body during the enclavation procedure (Budo).*



**IRIS ENCLAVATION  
WITH ARTISAN®  
ENCLAVATION FORCEPS**

**Iris Enclavation with the ARTISAN® Enclavation Forceps**

- Perform the first enclavation with the non-dominant hand (Fig. 5.9);
- Insert the Implantation Forceps through the main incision, firmly grasping the lens at the optic edge;
- Insert the Iris Enclavation Forceps through the paracentesis (see Fig. 5.9);
- While securely holding the lens body, take up a fold of iris below the slit in the “claws”;
- Depress the lens over the iris fold with the Implantation Forceps, while holding the Enclavation Forceps at the original level;
- The lens haptics will grasp the iris and the lens will be fixated;
- First retract the Implantation Forceps before releasing the iris bridge;
- Finally retract the Enclavation Forceps.



*Fig. 5.9: Iris enclavation using the ARTISAN® Enclavation Forceps*

**“FOUR EYES  
OBSERVATION”**

While the surgeon is concentrating on the enclavation act, the well-trained assistant watches the overall situation and guides the surgeon to ensure that the lens optic is located well centred “on the pupil”. Don’t pull on the iris. Bring the iris gently in-between the claws. Proper centration of the lens needs a lot of attention.

The surgeon is usually able to determine the desired temporal / nasal axis position but requires assistance for placement in the inferior / superior axis. Full attention of both surgeon and assistant is needed during this phase of the procedure (“Four Eyes” Observation).



**PERIPHERAL  
IRIDECTOMY OR  
IRIDOTOMY**

Although all Aphakia IOLs are vaulted and allow some free flow of aqueous, it is highly recommended to perform an iridectomy or iridotomy. It can either be made at the start of the operation or at the end, depending on the surgical situation. The pigment layer needs to be perforated completely.

**Note**

- An iridectomy or iridotomy has to be made to avoid a postop pupil block;
- It can also be used to manage an unwanted iris prolapse.

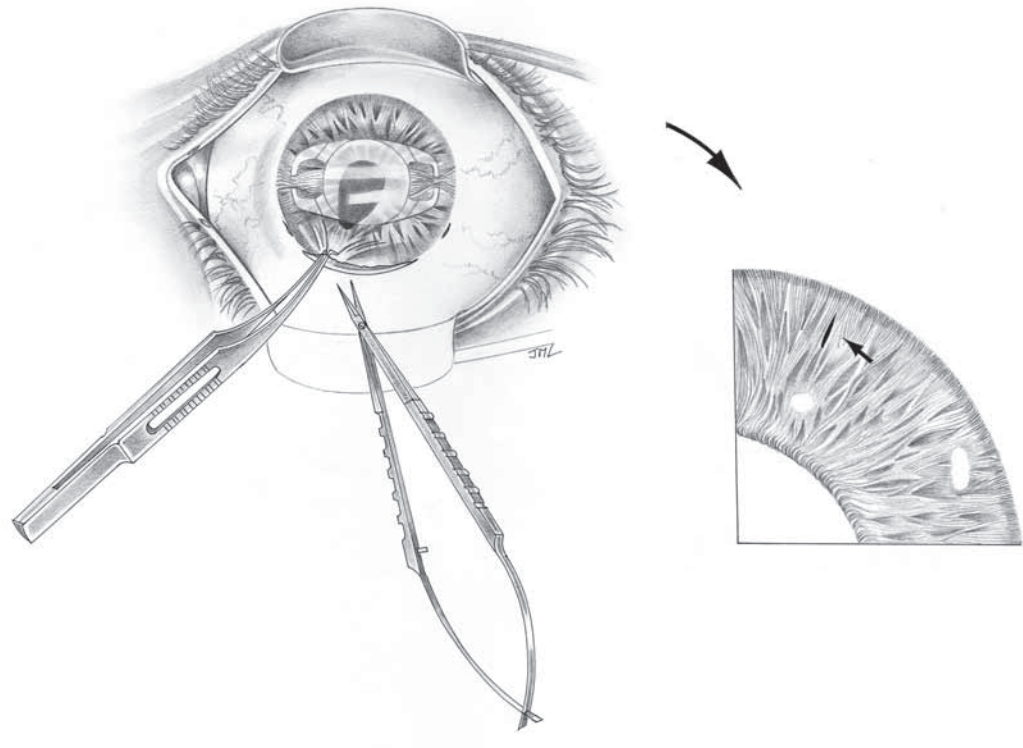


Fig. 5.10: Peripheral iridectomy or iridotomy

**REMOVAL OF  
VISCOELASTIC**

Carefully remove all of the viscoelastic by making a semi-circular movement from 6 o'clock towards the main incision with manual I/A using an irrigating solution. Careful removal is crucial.

Incomplete removal of the viscoelastic may cause high pressure. When a high pressure is not treated in time it may result in an Urrets-Zavalía syndrome (fixated dilated pupil). Removal of Artivisc® Plus 1.4% starting at 6 o'clock will usually result in complete removal "in one glob".

Removal of the standard Artivisc® 1.0% can not be performed "in one glob".

**SUTURING**

Close the wound with 2 - 4 sutures. Suturing details depend on the kind of incision. Watertight wound closure is of paramount importance to prevent a shallow anterior chamber in the immediate postoperative period. Do not suture too tight to avoid surgically induced astigmatism.

Administer 1 drop each of antibiotic, NSAID and mydriatic. Patch the eye.

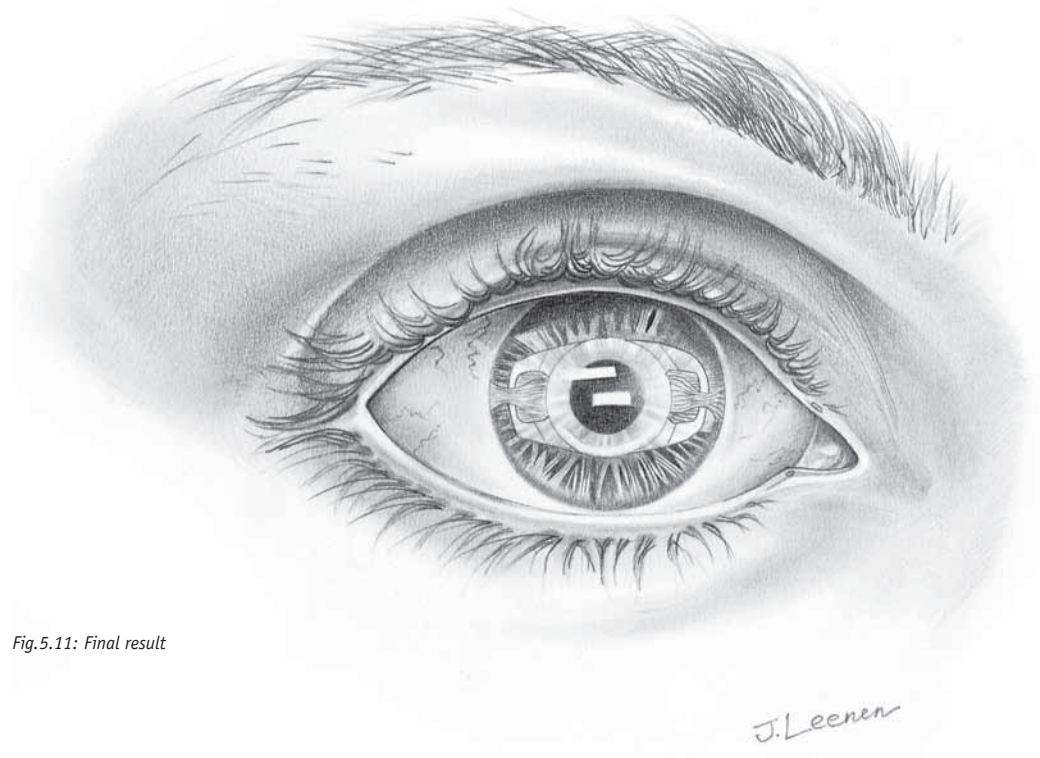


Fig.5.11: Final result

## 5.3 Checklist

### Standard Implantation Technique

#### In case of capsule rupture after phaco emulsification

- ✓ Enlarge the main incision to 5.5 mm;
- ✓ Make two paracenteses of 1.2 mm at 10 and 2 o'clock, pointing downwards, oriented towards the enclavation site;
- ✓ Introduce a miotic solution to constrict the pupil;
- ✓ Introduce a viscoelastic through the paracenteses both left and right. Don't overfill the AC and avoid the pupillary area! (Note: Only use a high viscosity sodium hyaluronate\*);
- ✓ Test the access of the two paracenteses with the Enclavation Needle;
- ✓ Introduce the lens in the vertical position;
- ✓ Apply more viscoelastic on top of the lens to protect the endothelium and to get optimal contact between lens and iris;
- ✓ Rotate the lens in the horizontal position and center on the pupil;
- ✓ For lens fixation, first introduce the Enclavation Needle through the paracentesis, than grasp the lens at the rim of the optic. Perform the first enclavation with the non-dominant hand;
- ✓ Change hands and enclavate the other side with the dominant hand;
- ✓ Perform a peripheral iridectomy or iridotomy;
- ✓ Close the main incision and use kerato-illumination to check and possibly correct surgically induced astigmatism;
- ✓ Remove the viscoelastic by making a semi-circular movement while aspirating from 6 o'clock towards the main incision (Note: Incomplete removal of the viscoelastic may cause high pressure).

## 5.4 Recommendations and Warnings

### WELL TRAINED ASSISTANT

#### **A well-trained assistant is essential.**

He/she should know these Recommendations & Warnings as well as the surgeon.

A surgical technique is recommended with a **12 o'clock central incision of 5.5 mm and two paracenteses made with a 1.2 mm knife.**

### CONSTRICTED PUPIL!

**It is most important to start with constriction of the pupil.** A narrow pupil facilitates centration. When the pupil is not sufficiently constricted the following events may occur:

- Viscoelastic material gets trapped in the pupillary area under the implant and is hard to remove;
- Centration of the lens around the pupil is more difficult.

### HIGH VISCOSITY VISCOELASTIC

The use of a high viscosity sodium-hyaluronate like ArtiVisc® or ArtiVisc Plus® is mandatory!

- Other materials than ArtiVisc®, Healon® or Amvisc® fail to create space;
- Other materials can not be washed out completely (100%!) and can cause high IOP;
- High pressures which are not treated immediately can cause fixated dilated pupils (Urrets-Zavalía syndrome);
- Inject the viscoelastic material through the paracenteses to create a deep AC. Not too much! Avoid the pupillary area;
- After implantation there should be no viscoelastic under the lensimplant!

### CONTRAINDICATED VISCOELASTICS

- Healon 5®;
- HPMC;
- Chondroitin sulphate (Viscoat®).

### “FOUR EYES OBSERVATION”

Various incision techniques can be used, even tunnel incisions, although not the easiest in the beginning. The lens is implanted vertically, then rotated and centred on the pupil. With too much viscoelastic in the AC the IOL may slide away from its centred position.

Before the actual enclavation inject again some viscoelastic, this time on top of the lens to protect the endothelium during the enclavation procedure. Use the ARTISAN® Enclavation Forceps or ARTISAN® Enclavation Needles.

Full attention of both surgeon and assistant is needed during this phase of the procedure (“Four Eyes” Observation). While the surgeon is concentrating on the enclavation act, the well-trained assistant watches the overall situation and guides the surgeon to ensure that the lens optic is located well-centred “on the pupil”. Don’t pull on the iris. Bring the iris gently in-between the claws.

### PERIPHERAL IRIDECTOMY OR IRIDOTOMY

#### **An iridectomy or iridotomy is essential!**

The iridectomy or iridotomy serves as a “safety belt”. Although not always necessary experience has shown that an elevated IOP can be avoided by making an iridectomy or iridotomy as a standard procedure. Placement of at least one or more sutures is recommended. Use a bimanual I/A system to maintain the AC and avoid emptying the AC while aspirating the viscoelastic. Further suturing depends on the kind of incision.

**REMOVE VISCOELASTIC**

Removal of all viscoelastic material is crucial!!!  
Otherwise a high IOP may be expected.

Use the ARTISAN® instruments especially designed for this type of surgery.

**With inadequate instrumentation the following events can occur**

- Struggle to get the iris enclavated leading to tissue damage of iris and/or endothelium;
- Use of “home-made” enclavation needles, with sharp tips. Special ARTISAN® Enclavation Needles have soft polished tips.

**Prevention of external pressure on the eye should be avoided by**

- Total immobility of the eyelids;
- Preoperative bulbus compression;
- Choice of eyelidholder.

**PATIENT INSTRUCTION**

**Note**

To avoid Endothelial Cell Loss, all patients should be instructed not to rub their eyes.

**Watch videos of experienced users of ARTISAN® IOLs !**

## 5.5 Retropupillary Fixation Technique of the ARTISAN® Aphakia IOL (as recommended by A. Mohr, M.D.)

### A-CONSTANT DIFFERS FROM STANDARD TECHNIQUE

The A-constant differs from the A-constant using the Standard Technique because of the position of the IOL in the eye. The recommended A-constant is 116.8 (ultrasound) or 116.9 (optical) for the retropupillary position, while the prepupillary position asked for an A-constant of 115.0 (ultrasound) or 115.7 (optical).

### MAIN INCISION

A technique is recommended with a 12 o'clock frown incision (corneo-scleral 5.5mm) while some authors from Bursa-Turkey use a scleral tunnel incision to avoid the formation of postoperative astigmatism. The width of the incision should be 5.5 mm.

### PARACENTESIS

Two paracenteses are used for the introduction of viscoelastic materials and the instruments needed for the retropupillary fixation of the ARTISAN® Aphakia IOL. They are positioned at 3 o'clock and 9 o'clock.

### DO NOT CONSTRICT THE PUPIL

Leave the pupil at a minimum size of approximately 3mm to allow the lens to reach the retropupillary position through the pupil.

### USE A HIGH VISCOSITY VISCOELASTIC

Inject a small amount of viscoelastic like Artivisc® 1% from the periphery of the eye, but never directly into the pupillary area.

### IMPLANTATION OF THE IOL

The ARTISAN® Aphakia IOL will be inserted into the anterior chamber with the convex side downwards (upside down) holding it in the Artifix forceps. With a manipulator, the IOL will be brought into the horizontal position from 3 o'clock to 9 o'clock.



Fig. 5.12: Artifix forceps



Fig. 5.13: Artifix forceps with IOL

### BRINGING THE IOL BEHIND THE IRIS AND CONSTRICT THE PUPIL

The IOL will be grasped again in the centre of the optic with the Artifix forceps and inserted behind the iris through the 3 mm wide pupil, while simultaneously injecting a miotic solution to constrict the pupil. Make sure to hold the IOL firmly until it is fixated on both sides.

### IOL FIXATION ON THE IRIS

After the IOL has been brought behind the iris and the pupil is constricted, the IOL will be lifted and tilted slightly in order to show the contour of the "claws" through the iris stroma. A fine spatula is inserted through the corresponding paracentesis and exerts gentle pressure on the slotted centre of the lens haptic, the "claw". The same manoeuvre is now repeated on the other side. The IOL is now retropupillary fixated.

### PERIPHERAL IRIDECTOMY

It is not absolutely essential and strictly recommended to perform an iridectomy.

### REMOVAL OF ALL VISCOELASTIC

Carefully remove all of the viscoelastic to avoid a high pressure.

### SUTURING

Close the incision with sutures.  
Administer 1 drop each of antibiotic and NSAID. Patch the eye.

---

# [6

**Peroperative  
Problems**





## 6.1 Anesthesia Risks, Advantages & Disadvantages

### INTRODUCTION

In every hospital or outpatient setting surgeons want to work as safely as possible with little discomfort for their patients. Local anesthesia or topical anesthesia are used today for implantation of the ARTISAN® Aphakia IOLs. The surgeon selects which of these is used. Basically it is desirable to obtain akinesia (the eye should be immobile) and full analgesia (the patient should have no pain).

### LOCAL ANESTHESIA

#### Risks

Caution is advised for cataract patients with high myopia. When a retrobulbar injection is given, pressure from the retrobulbar spaces may lead to forward pressure on the lens diaphragm with the risk of globe perforation. Parabulbar or subtenon injection is preferred.

#### Advantages

- Fast recovery;
- No risk of allergic reaction;
- Local anesthesia can be given by the surgeon.

#### Disadvantages

- Anesthesia given by the surgeon is time consuming;
- Difficult to anesthetize high myopic eyes;
- Risks of globe perforation, when retrobulbar injection is used;
- Risk of iris prolapse, which is difficult to reposition.

### TOPICAL ANESTHESIA

#### Risks

Exclusion criteria have to be well observed:

- Anxious and nervous patient;
- Patient who is hard of hearing (communication problem);
- Long operation time;
- Patient with a relevant medical problem.

#### Advantages

- Fast recovery;
- Topical anesthesia results in analgesia.

#### Disadvantages

- The eye can still move somewhat (no full akinesia);
- Risk of damage to the eye, when it moves during surgery;
- Some discomfort for the patient, although no pain.

**All known risks of the various procedures should be discussed with the patient prior to the surgical procedure!**

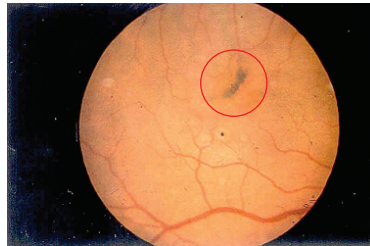
## 6.2 Problems, Prevention and Solutions

### PEROPERATIVE PROBLEMS

Surgical procedures like Phako emulsification with Intraocular Lensimplantation have their specific surgical risks. Some of the Peroperative Problems will be discussed in this chapter.

#### **Problem: Macular burns**

The light of the surgical microscope may cause damage to the macula during surgery.



#### **Prevention**

Use a protecting filter on the microscope or cover the pupil with a surgical sponge.

#### **Problem: Iris Prolapse**

An iris prolapse occurs more often when making a corneoscleral incision, than when making a tunnel incision.



#### **Prevention**

Place one or two sutures after the insertion of the lens and before the enclavation.

#### **Solution**

Make an iridectomy as soon as possible.

#### **Problem: Lens not centered properly**

A decentered IOL may cause glare or halos.



#### **Prevention**

Check the centration of the IOL on the pupil after removal of the viscoelastic.

#### **Solution**

It can be corrected by re-enclavation.

**Problem: Insufficient Iris Enclavation**

Insufficient Iris Enclavation can lead to postoperative dislocation.



*Courtesy dr. Mertens*

**Prevention**

Use the specific instruments developed for the ARTISAN® Aphakia IOL implantation!

**Solution**

Re-enclavate a dislocated IOL.



*Courtesy dr. Mertens*

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# **[7**

## **Postoperative Care and Management**



## 7.1 Postoperative Medication

### POSTOPERATIVE MEDICATION

A recommended postoperative regime has been developed to provide consistency in the treatment of all patients. There may be circumstances where, at the surgeon's discretion, it becomes necessary to modify this regime for a specific patient.

#### Immediate post operative care

It is recommended that the patient leaves the operating room with a shield to protect the eye. The patient should be advised that there might be a sensation of "sand in the eye" during the first few days. This is normal. If pain is noticed the surgeon should be contacted immediately.

#### Postoperative medication regime

The following postoperative medication regime is recommended although the surgeon should tailor this regime to meet the patients needs:

<b>Antibiotic:</b>	Topical antibiotic	1 drop	3x daily, during the first post-op week, then taper the usage for the next 2 weeks.
<b>Corticosteroid:</b>	Topical Steroid	1 drop	3x daily, during the first post-op week, then taper the usage for the next 2 weeks.

**Avoid Pressure Rise:** Prescribe f.i. Diamox® if indicated.

## 7.2 Postoperative Care and Patient Instructions

### RECOMMENDED PATIENT INSTRUCTIONS

The surgeon should be available during the first 24 hours after surgery.

- ✓ Instruction to use an eye shield for 1 day and then at night for 1 week;
- ✓ Instruction not to rub the operated eye; eye rubbing may lead to corneal oedema and endothelial cell loss;
- ✓ Instruction not to lift heavy objects, sneeze or press to avoid pressure on the eye;
- ✓ Instruction to use sunglasses in bright sunlight;

Any residual refractive error can be corrected after 6 to 8 weeks when the refraction is stable.

### TRACEABILITY

It is important that each implanted IOL will be registered accurately in the hospital files to be able to trace back the manufacturing details at the factory in case of complaints.

IOL labels are enclosed in the packaging for the hospital file and Patient Identification Card.



Figure 7.1: IOL Label

Fill out Identification Card and give it to the patient.

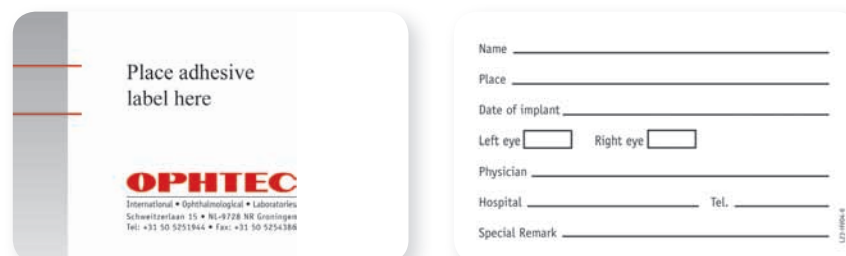


Figure 7.2: Patient Identification Card, front (left) and backside

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# [8

## Postoperative Complications





## 8.1 Introduction

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The ARTISAN® Aphakia IOL (Iris Claw lens) was introduced by Worst in 1978.

The ARTISAN® Aphakia IOL was first used for secondary lens implantation, soon followed by primary implantation after ECCE and ICCE and later on after phakoemulsification.

In 1989 a Retrospective Clinical Study with 10 Year Follow-up was presented by Gerard van der Veen M.D. The study concerned 2488 subjects operated in the period of 1979 – 1989 by four Dutch surgeons. The results of this study are demonstrated in Chapter 9.

Because of the favorite clinical results the ARTISAN® Aphakia IOL was gradually introduced as a primary lens implant after phakoemulsification in case of a ruptured posterior capsule.

## 8.2 Potential Post-op Complications

### LENS RELATED COMPLICATIONS

Potential complications associated with the implantation of an ARTISAN® Aphakia IOL has been reported in the Retrospective Study (Chapter 9).

Some of the Potential Lens Related Complications will be described here:

#### **Lens tilting**

Lens tilting can occur without luxation of the claws. Severe lens tilting could lead to endothelial touch. Surgical lens repositioning is needed.

#### **Lens decentration**

Sometimes, when the implantation is performed when the pupil is not constricted properly, the lens can be somewhat decentered. This may lead to glare or halos. Surgical lens repositioning is needed.

#### **Subluxation**

After ocular trauma or spontaneously, luxation of one of the claws can occur, leading to subluxation of the IOL, when a too small amount of iris tissue is enclavated. The IOL has to be reenclavated immediately to minimize endothelial damage.

### SECONDARY SURGICAL INTERVENTIONS

#### **Lens repositioning**

Is necessary after lens decentration and in cases in which a preventive repositioning was performed in subjects with too small amounts of enclavated iris tissue.

#### **Lens removal**

The IOL has to be removed in complicated cases, when the IOL - endothelial touch has been leading to corneal edema.

#### **Lens replacement**

An IOL can be removed and replaced by a new ARTISAN® Aphakia IOL.

**For an overview of all possible complications see our “Instructions for Use” which is included in the lens packaging.**

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# [9] Long-term Clinical Experience



## 9.1 Retrospective Study of the ARTISAN® Aphakia IOL (Iris Claw) with 10 Year Follow-up | G. van der Veen, MD

A retrospective study was started by Gerard van der Veen, MD to meet the growing demand for data concerning short- and long-term results of ARTISAN® Aphakia IOL (Iris Claw lens) implantation. In the four regional hospitals where this study had been performed, the lens was used mainly for primary implantation after ECCE .

This retrospective study concerns lens implantations performed in the period 1979 - 1989. The total number of evaluated subjects is 2488. The number of subjects per surgeon is given in table 1. The follow-up varies from 3 months to 9 years and 7 months, with an average of 3 years.

Surgeon	Number of implantations	Period
1	1362	'79-'89
2	506	'84-'89
3	480	'83-'89
4	140	'87-'89

Table 1: Number of implantations per surgeon.

### Materials and methods

The evaluated group consisted of 41% males and 59% females.

Sex of subjects	'79-'84	'85-'89	Total
Male	234	793	1027
Female	327	1134	1461
Total	561	1927	2488

Table 2: Number of Subjects in early and late period.

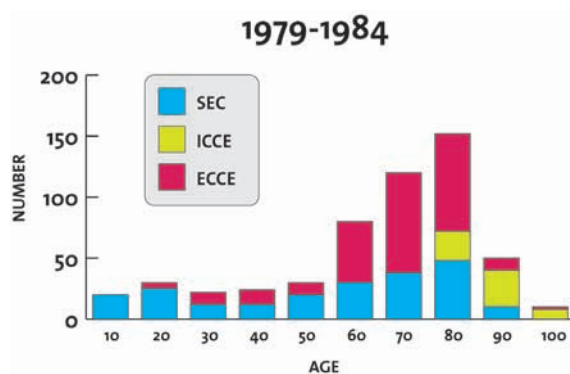


Fig. 9.1: Number of implantations per age group in early period 1979-1984.

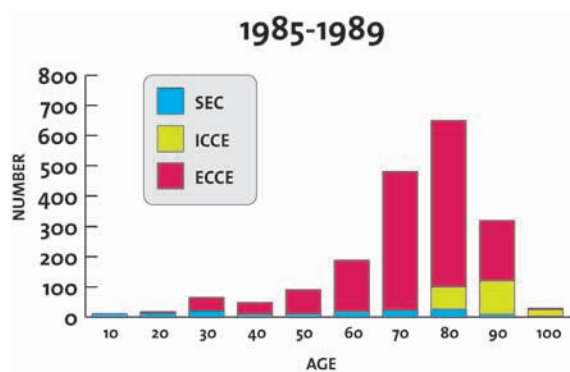


Fig. 9.2: Number of implantations per age group in late period 1985-1989.

Fig. 9.1 & 9.2 illustrate the type of IOL implantation for the various age groups in the two periods, 1979-1984 and 1985-1989. Both graphs show that ICCE is almost exclusively done on subjects in the older age groups. The percentage of extracapsular surgery clearly increased in the second period. The number of secondary implantations in the early period is relatively high in the younger age group. These cases represent secondary implantations in traumatic and congenital cataract. The overall numbers are presented in Table 3.

Type of implantation	'79-84	'85-'89	Total
ECCE primary IOL implantation	286	1563	1849
ICCE primary IOL implantation	79	225	304
Secondary implantation	196	139	335
<b>Total</b>	<b>561</b>	<b>1927</b>	<b>2488</b>

Table 3: Type of implantation during the two time periods.

#### Multi-center Study

The four Dutch eye surgeons participating in this study, used the lenses mostly as primary implants after senile cataract extractions. One of the surgeons implanted the Worst-Singh variation exclusively.

Type of lens	'79-'84	'85-'89	Total
Worst Iris Claw Lens	539	1480	2019
Worst-Singh Iris Claw Lens	22	447	469

Table 4: Type of IOL used during the two period.

#### Results

Data concerning type of implantation, type of IOL, age distribution, sex of subjects are listed in Fig. 9.1 and 9.2 and Tables 1, 2, 3 and 4 for the early (1979 - 1984) and later series (1985 - 1989).

Though standard ARTISAN® Aphakia IOLs (Iris Claw lenses) have a 5 mm optic, one of the surgeons used lenses with an optical diameter of 6 mm with an overall diameter of 9.5mm until 1986. The IOL diameter was not consistently specified in his surgical reports. The polishing techniques have improved since 1985. The IOL design has not changed during the period of this Retrospective Study.

In 1997, the new ARTISAN® Aphakia IOL (Iris Claw lens) with a biconvex optic replaced the original plano-convex design.

**Visual Acuity**

In order to compare the visual acuity results of the various surgical procedures and to allow comparison with data in the literature the exclusion criteria mentioned in Table 5. have been applied. A total of 27% of the subjects has been excluded (Table 10).

Exclusion Criteria
Congenital cataract
Traumatic cataract
Amblyopia
Diabetes Mellitus
Corneal Pathology
Glaucoma
Iritis / iridocyclitis
Fundus pathology
Follow-up less than 3 months
Last preoperative VA over 6 months ago

Table 5.

	Total	After Exclusion
ECCE	1849	1408
ICCE	304	214
SEC	335	201

Table 6.

The visual acuity results of the early and later time periods hardly differ. Therefore both groups were combined in this part of the study.

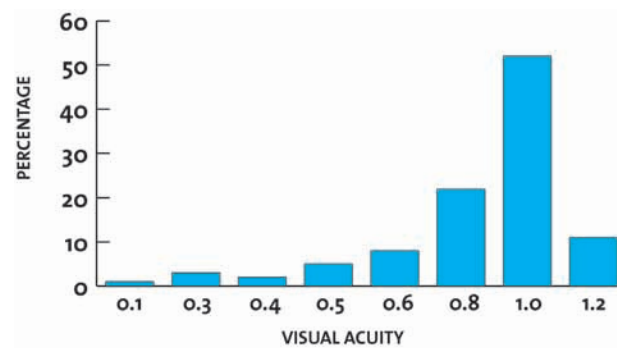


Fig.9.3: ECCE maximum postoperative visual acuity 1979-1989.

The average postoperative visual acuity after ECCE was 0.85, with a mean preoperative visual acuity of 0.19.

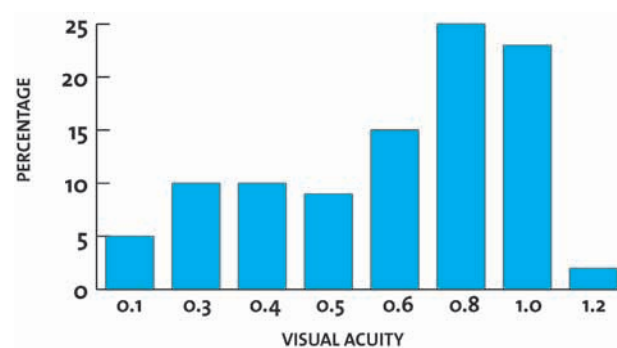


Fig.9.3: ICCE maximum postoperative visual acuity 1979-1989.

The average maximum postoperative visual acuity after ICCE was 0.65, with a preoperative visual acuity of 0.15. The lower postoperative visual acuity in this group can be partially explained by the higher age of the subjects.



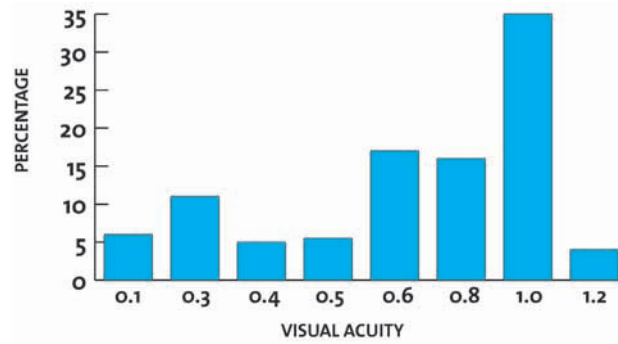


Fig 9.5: Secondary implantation maximum postoperative visual acuity 1979-1989.

The average maximum postoperative visual acuity after secondary implantation of ICCE and ECCE subjects was 0.7, with a preoperative visual acuity of 0.6.

## 9.2 Complications

To evaluate the complications of ARTISAN® Aphakia IOL (Iris Claw lens) implantation, a distinction has been made again between subjects of the earlier (1979 -1984) and later period (1984 -1989). The reason for making this distinction is that until 1985 the claw mechanism has been of lower quality resulting in a higher percentage of lens related complications.

Specific complications related to the fixation mechanism and the location of the lens in the eye can occur and are listed under "Lensrelated Complications".

Enclavation of too small amounts of iris tissue can lead to subluxation, spontaneously or after ocular trauma; postoperatively remaining of a large airbubble can lead to tilting of the IOL in the immediate postoperative period.

The lens related complications will be discussed in two parts. The first part concerns complications where the IOL itself is involved. The second part concerns general complications related to the surgical technique.

Complications (%)	'79-'84 (n=561)	'85-'89 (n=1927)
Iris capture	0.3	0.05
IOL tilting	1.1	0.2
IOL subluxation	3.0	0.5
IOL repositioning	1.6	0.1
IOL removal	0	0.3
IOL replacement	2.1	0

Table 7: Complications, lens related.

### Iris capture

In two cases the iris moved in front of the lower part of the lens optic. The situation could be corrected and did not have any clinical consequences.

### Lens tilting

Lens tilting occurred in a few cases without luxation of the claws.

In most cases it was caused by surgical discission of an opacified posterior lens capsule resulting in vitreous prolapse into the anterior chamber. In one subject tilting of the IOL was caused by an airbubble. Endothelial touch, which needed surgical lens repositioning, was seen in two subjects.

### Subluxation

Luxation of one of the claws leading to subluxation of the IOL, spontaneously or after ocular trauma, occurred in several subjects.

In the early series it was caused by too flexible claws, in the later series mostly by enclavation of too small amounts of iris tissue. All IOLs were repositioned.

### Lens repositioning

Listed in the table are those cases in which a preventive repositioning was performed in subjects with too small amounts of enclavated iris tissue.

### Lens removal

Lens removal was done in complicated cases with either vitreous loss or incorrect centration of the lens. In some cases the lens had to be removed due to corneal edema caused by touch of the IOL to the endothelium.

Four of the six subjects had IOLs with an optical diameter of 6 mm and an overall diameter of 9.5 mm instead of the standard diameter of 8.5 mm.

The use of the 9.5mm lenses has been discontinued since 1986.

**Lens replacement**

Some of the early implants were removed and replaced by other ARTISAN® Aphakia IOLs (Iris Claw ) lenses. Reasons were mainly too flexible claws with a too small amount of enclavated iris tissue, sometimes leading to lens subluxation or repeated lens subluxations.

**Surgical Complications Related to the Surgical Technique**

Complication rates are practically similar to data in the literature.  
Pre-existing pathology is indicated between brackets.

Complications (%)	'79-'84 (n=561)	'85-'89 (n=1927)
Iridodialysis	0.2	0.4
Acute Glaucoma	0.4	0.8
Iritis / Uveitis	1.4 (0.2)	0.9 (0.3)
Corneal Edema / Dystrophy	3.9 (0.5)	0.8 (0.3)
Keratoplasty	0.7	0.2
Panophthalmitis	0.4	0.05
Ablatio Retinae	2.1	0.9
Cystoid Macular Edema	3.4	3.5

Table 8: Complications, surgery related.

**Iridodialysis**

This complication occurs by mistakenly lifting the iris stroma into the claw. It was mainly seen in the early series of one of the surgeons.

**Acute glaucoma**

Acute glaucoma can occur postoperatively, due to pupil block. In almost all of these cases the iridectomies were either too small or incomplete, closing off by the intact iris pigment layer. Surgical intervention normalized the intraocular pressure.

**Iritis / Uveitis**

Postoperative iritis was seen in 26 subjects.

Four cases were clearly IOL related: one complicated case with a badly centered Worst-Singh lens implantation (early series), two Worst Iris Claw lens implantations (later series), and one poorly polished early implant (1980), which caused a hemorrhaged iritis.

**Penetrating keratoplasty**

In some cases penetrating keratoplasty had to be performed because of corneal decompensation. Most of these subjects had preoperatively existing chronic simple glaucoma.

**Panophthalmitis**

In three of the early cases panophthalmitis occurred postoperatively. One eye had to be enucleated one month postoperatively.

The two complications in table 9 and 10 (Retinal Detachment and CME) are reported below in relation to the surgical techniques used.

**Cystoid Macular Edema**

	'79-'84	'85-'89	Average Visual Acuity
ECCE	10 (3.5%)	48 (3.1%)	0.6
ICCE	3 (3.8%)	12 (5.5%)	0.6
Secondary Implantation	7 (3.6%)	3 (2.9%)	0.8

Table 9: Cystoid Macular Edema; n=83 (3.2%).

The percentages of CME in the early and later series are comparable. A relation between surgical procedure (ICCE/ECCE) and occurrence of CME is manifest, especially in the later series in which a higher incidence of CME is seen after ICCE.

**Retinal Detachment**

	Number (%)	Age (average)	Interval (month)	Visual Acuity (end)
ECCE	25 (1.4%)	63	28.3	0.2 (n=12)
ICCE	4 (1.3%)	83	18.9	0.3 (n=3)
Secondary Implantation	5 (1.5%)	41	17.9	?

Table 10: Retinal Detachment; n=34 (1.3%).

The interval in months between surgery and the occurrence of retinal detachment is longer in subjects with ECCE than in subjects with ICCE. Retinal detachment often occurs after a Yag-laser treatment for secondary cataract.

**Secondary Cataract Treatment**

As a last complication the formation of secondary cataract is presented. The percentages of subjects who needed treatment are listed in Table 11. The results are within the limits given in the literature (3-50%).

	YAG (%)	Discission (%)	Cleaning (%)	Total (%)
ECCE	23.5	3.9	1.9	29.3
Secondary Implantation	14.3	5.7	1.8	21.8

Table 11: Secondary Cataract Treatment; n=613 (30.9%).

## 9.3 Conclusion

In the early days of ARTISAN® Aphakia IOL (Iris Claw lens) implantation ('79-'84), some complications occurred which were clearly related to the imperfect lens polishing technique. The "claws" were of lower quality, leading to a relatively large risk of lens luxation. Furthermore, the early Iris Claw lenses were often poorly polished. The IOL design and polishing technique have improved since 1985, reducing the risk of lens related complications to a minimum.

Analysis of the results of ARTISAN® Aphakia IOL (Iris Claw lens) implantation shows some remarkable facts:

***ARTISAN® Aphakia IOL (Iris Claw lens) related complications are few and mostly preventable by following the correct implantation technique.***

The results show that the visual rehabilitation of the subjects after lens implantation is good and the occurrence of complications is comparable to data from the literature concerning posterior chamber lenses. Further analysis of the complications shows that the occurrence of specific lens related complications differs significantly between the four surgeons participating in the study. Erosion or atrophy of iris tissue, as caused by pupil fixated Iris Clip lenses (Binkhorst), is not seen.

Iris angiography has shown that the "claws" of the IOL do not interfere with the blood and nerve supply of the iris. There is no leakage of iris vessels at the enclavation sites (nine cases were presented by Kappelhof at the annual meeting of the Dutch Ophthalmological Society, February 1990) and 23 cases were investigated by Strobel in 1989 ( see bibliography).

The only visible 'damage' to the iris tissue, which is sometimes noticed, is a slight depigmentation at the sites of "claw" enclavation. This was also noticed by Fechner and Singh. Rarely some hyper pigmented spots can be formed in the iris.

The ARTISAN® Aphakia IOL (Iris Claw) has to be enclavated by depressing the lens over the iris fold without moving the Iris Enclavation Forceps. Lifting the iris tissue into the "claw" will easily lead to iridodialysis as is seen in 0.5% of the cases.

The amount of enclavated iris tissue should be about 1 mm, a smaller "irisbridge" carries the risk of subluxation, both "spontaneously" and after minor ocular trauma.

A patent iridectomy has proven to be essential. Without a proper iridectomy a pupil block is likely to develop. Clinical results reflect the influence of surgical experience: in the early series acute glaucoma due to pupillary block occurred four times more frequently than in the later series.

Eccentric placement of the IOL can lead to iris capture: movement of iris tissue in front of the lens optic.

Synechia between an irisbridge and the cornea can occur when the IOL is placed eccentrically.

The elevated "irisbridges" protect the corneal endothelium against contact with the IOL during and after surgery. Any flattening of the anterior chamber can lead to contact between the "irisbridges" and the cornea.

The ARTISAN® Aphakia IOL (Iris Claw) can be used in many situations, e.g. as a primary or secondary implant lens (after ICCE or ECCE), posterior capsule rupture after Phako and in the triple procedure and in cases of ocular trauma.

The ARTISAN® Aphakia IOL (Iris Claw) is also very suitable for secondary lens implantation in children. Any IOL-exchange, necessary because of ocular growth can be done easily. Specially adapted -small- models are available on request. In over 500 cases of Iris Claw lenses used in children, Singh saw only minor complications.

The fixation principle of the ARTISAN® Aphakia IOL (Iris Claw) has now also been applied to minus and plus power IOLs in phakic subjects.

**Summary**

This review of visual results and complications of ARTISAN® Aphakia IOL (Iris Claw) implantation shows that there are only few complications, which can hardly be prevented.

These are:

- subluxation of the lens caused by ocular trauma;
- tilting of the lens caused by either the formation of fibrous strands, synechiae between iris and remaining lens capsule or by vitreous prolapse into the anterior chamber.

**Iris Claw lens implantation is a safe procedure in the hands of a surgeon who has mastered the implantation technique.**

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**[11**  
**Articles of Interest**



## 11 Articles of Interest

- 11.1 **Iris-Claw intraocular lenses in children.**  
van der Pol BA, Worst JG.  
Doc Ophthalmol. 1996-1997;92(1):29-35. .... 11-5
- 11.2 **Lens implant selection with absence of capsular support.**  
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- 11.3 **Secondary Artisan-Verisyse aphakic lens implantation.**  
Güell J, Velasco F, Malecaze F, Vázquez M, Gris O, Manero F.  
J Cataract Refract Surgery 2005; 31:2266-71. .... 11-25
- 11.4 **Long-term follow-up of the corneal endothelium after artisan lens implantation for unilateral traumatic and unilateral congenital cataract in children: two case series.**  
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- 11.5 **Penetrating keratoplasty combined with posterior Artisan iris-fixated intraocular lens implantation.**  
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### Iris-Claw intraocular lenses in children

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**Key words:** Cataract, Children, Congenital, Iris-Claw, IOL, Juvenile

**Abstract.** 27 children (38 eyes) with cataracts of different origins were treated using iris fixated one-piece Iris-Claw intraocular lenses. Visual acuities outcome in this group was comparable with the results in other series. The Iris-Claw lens is a very versatile IOL, which can be used in most cataract procedures, it can be removed and exchanged with minimal surgical trauma; therefore it is an effective modality in correction of the developmental changes in the refraction of the very young and growing, aphakic eye.

#### Introduction

The use of intraocular lenses in the eyes of young children is still a controversial subject among ophthalmic surgeons. Adequate refractive correction of the young aphakic eye is the primary condition to prevent deprivation amblyopia. Implantation of an intraocular lens appears to be quite successful in this respect as it spares the child and its parents the troublesome use of contactlenses or the wearing of heavy, cosmetically unacceptable spectacles.

With increasing experience several complications and problems in implant surgery in children have now become apparent. The eye of a young child shows more surgical reaction than an adult eye and tends to behave differently to surgical intervention. Special biochemical and anatomical aspects of the juvenile eye require technical adaptations during surgery. At present there is a tendency to change from discision/aspiration techniques to lensectomy and vitrectomy, mainly to prevent the formation of aftercataracts [1]. A major advantage of a carefully performed discision with aspiration of the lens, followed by secondary implantation is the fact that no invasion of the immature vitreous body, which is still in a developmental stage, is required.

One of the and as yet unsolved problems is the growth of the neonate eye, which has to be operated for a congenital cataract and requires a 'growing' IOL. This can only be solved with several IOL's with different power in the period in which developmental refractive change take place.

This retrospective case-analysis comprises 27 children, which were operated for bilateral or unilateral cataracts and were corrected with implantation of an Iris-Claw lens.



### Subjects and method

The medical records of 27 subjects were available for retrospective analysis. 38 eyes of these children were implanted with an Iris-Claw lens in the period from 1980 to 1992. The youngest child was 8 months and the eldest nearly 13 years of age at the time of the first operation. 15 of the children were girls and 12 boys. 17 children had bilateral, congenital or developmental cataracts. 28 eyes of this group were implanted. 10 children had an unilateral cataract of which 3 were of traumatic origin.

All implantations were done after discision and aspiration of the cataract. In six cases discision preceded aspiration by one day.

The Iris-Claw lens was developed by Worst in the late seventies. It is a one-piece PMMA-lens with an optical zone, which can vary in diameter from 4 to 5 mm. The overall length of the lens can vary from 6.5 to 8.5 mm. The optical zone is supported by two haptic 'arms', which grasp the iris stroma in the relatively immobile peripheral part of the iris, like the claws of a lobster (Figure 1).

There is a vast experience in adult eyes with this lens, not only in the Western world, but also in countries like India and Pakistan where several thousands were implanted. The Iris-Claw lens can be used in extracapsular as well as in intracapsular procedures. In the Netherlands it gains an increasing popularity as an 'emergency-IOL' after complicated extracapsular cataract extractions and phakoemulsifications. To obtain a safe fixation the haptics should not be too rigid nor too flexible. In the early years after the introduction of the Iris-Claw lens it became clear, that sometimes the lens dislocated due to slightly too rigid haptics, especially when a small tissue-bridge was enclavated. This problem was solved by the manufacturer in the mid-eighties and followed by a substantial decrease of reports on lens dislocations.

All lenses were implanted secondarily to be sure implantation was performed under optimal conditions in eyes with minimal reactive signs. As the anterior chambers of young children have diameters around 10 mm. the smallest lens type (4.0/6.5 mm.) (Figure 1) was used in most cases.

### Results

Congenital and developmental cataracts were not evaluated as special groups. The etiology was uncertain in many cases. 6 of the 17 children with bilateral cataracts showed preoperative nystagmus. The highest visual acuity of the best eye in this subgroup was 0.25. 7 children with bilateral cataracts had only a strabismus and scored a highest visual acuity of the best eye of 0.8 and of the squinting eye of 0.5. (Table 1 and 2). In the group of 10 unilateral cataracts

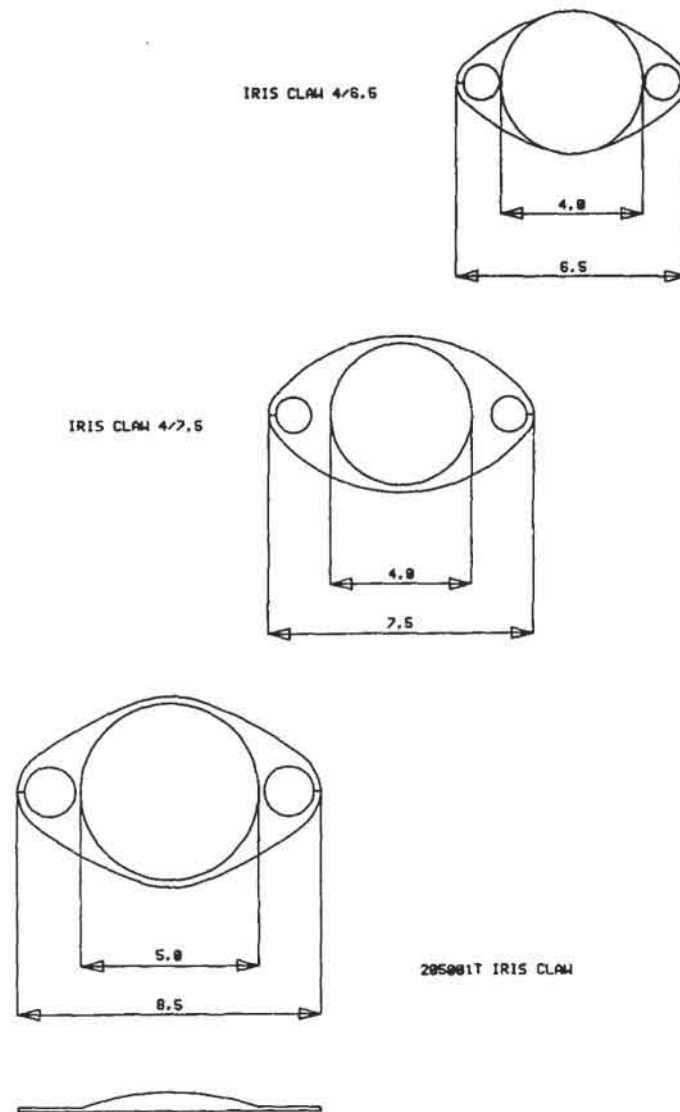


Figure 1. The three current versions of the Iris-Claw intraocular lens.

were three children with a traumatic cataract. In the children with unilateral cataracts the highest visual acuity of the operated eye was 0.75 and two eyes reached a visual acuity of less than 0.1. In this group the squinting eyes appeared to be the worst performing eyes. (Table 3). In the total population 3 children were lost to follow-up, caused by the fact that these children were

Table 1. Summary of 11 subjects with bilateral cataracts and bilateral implantations

	O	I	N	S	oth	VA	Comment
1:	0/3	0/9	-	+	-	0.5	dislocation
	0/3	0/9	-	+	-	0.5	sec.membr.:2x
2:	0/5	1.3	+	-	-	0.15	
	0/7	1/6	+	-	-	0.1	sec.membr.:1x
3:	0/9	1/11	+	+	+	0.1	mental retardation
	0/9	2/0	+	+	+	0.1	sec.membr.:1x
4:	10/10	1/5	+	-	-	0.03	hereditary
	1/0	1/10	+	-	-	0.03	
5:	1/0	1/4	+	-	-	0.07	hereditary/sec.membr.:1x
	1/1	1/5	+	-	-	0.07	
6:	1/1	8/0	+	-	+	0.1	irisanomaly/sec.membr.:1x
							lensexchange (miscalc.).
	1/1	8/1	+	+	+	0.25	irisanomaly/sec.membr.:1x
7:	1/3	1/7	-	-	-	0.8	
	8/2	8/2	-	+	-	0.05	dislocation
8:	2/4	8/11	-	+	-	0.2	dislocation.
	2/6	10/5	-	-	-	0.8	sec. membr.:1x
9:	3/0	4/9	-	-	-	0.8	
	3/0	8/4	-	+	-	0.15	ac. glaucoma
10:	5/3	5/5	-	-	-	0.5	
	5/4	5/6	-	-	-	0.75	
11:	7/9	9/5	-	-	-	1.0	dislocation/sec. membr.: 2x
	8/4	12/7	-	-	-	0.8	sec.membr.:2x

O: age (yr/mth) of first operation  
 I: age (yr/mth) of implantation  
 N: nystagmus; S: strabismus; oth: other abnormalities  
 VA: visual acuity

postoperatively looked after by other ophthalmologists. All three cases were operated more than 10 years ago and could not be traced.

In 7 eyes the lens had dislocated 4 months to 6.5 year after implantation. In all these cases the lens had detached on one side only and remained in the plane of the iris without corneal endothelial touch,

Two of these dislocations seemed to be related to a blunt trauma. One of these two eyes showed signs of contusion. All but one of the 7 dislocations took place in eyes with lenses manufactured in the early eighties, the period when the 'claws' were still rather rigid. Reattachment or exchange of the dislocated lens was done in all cases without any complication during

**Table 2.** Summary of 6 subjects with bilateral cataracts but unilateral implantations

	0	1	N	S	oth	VA	Comment
1:	0/4	12/9	+	+	+	0	microphthalmos./phtisis sec.membr.:4x
	0/6	-	+	+	+	0.03	sec.membr.:1x
2:	6/0	6/0	-	-	-	0.2	
	-	-	-	-	-	0.6	
3:	?	6/11	-	+	-	?	lost to follow-up
	?	-	-	-	-	-	?
4:	8/9	8/11	-	+	+	0.03	myop.grav./sec.membr.:5x
	-	-	-	-	+	0.4	myop.grav.
5:	8/11	8/11	-	-	-	0.8	
	-	-	-	+	-	0.4	
6:	12/4	12/4	-	-	+	0.07	neon.hypoglycemia.
	-	-	-	-	+	0.5	

0: age (yr/mth) of first operation  
 1: age (yr/mth) of implantation  
 N: nystagmus; S: strabismus; oth: other abnormalities  
 VA: visual acuity

**Table 3.** Summary of 10 subjects with unilateral cataracts and unilateral implantations

	0	1	N	S	oth	VAo	VA <sub>no</sub>	Comment
1:	0/4	0/8	-	+	-	?	?	lost to follow-up
2:	0/7	4/3	-	-	-	?	?	disloc./lost to follow-up
3:	1/8	1/11	-	+	-	0.02	1.0	sec.membr.: 4x
4:	3/0	3/10	-	+	-	0.08	1.5	
5:	3/0	4/8	-	+	-	0.1	1.0	traumatic/disloc.
6:	4/7	4/10	-	-	-	0.4	0.8	high myopia ou sec. membr: 1x
7:	5/0	5/0	+	+	-	0.02	1.0	traumatic
8:	5/2	5/3	+	+	-	0.1	0.5	sec. membr.: 2x
9:	6/6	7/4	-	-	-	0.6	1.2	traumatic
10:	10/2	10/9	-	-	-	0.75	1.2	dislocation

0: age (yr/mth) of first operation  
 1: age (yr/mth) of implantation  
 N: nystagmus; S: strabismus; oth: other abnormalities  
 VAo: visual acuity of operated eye  
 VA<sub>no</sub>: visual acuity of non-operated eye



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the operation or afterwards. Compared with the other eyes, the ones with dislocated lenses did not behave differently.

Other complications were: a miscalculation of the power of one lens, which was exchanged; a blocked pupil with glaucoma and a phthisis bulbi after retinal detachment in a microphthalmic eye. On these 27 children 121 operations were performed: 42 discisions and aspirations (in 6 eyes in two sessions); 35 secondary implantations; 29 aftercataract treatments; 7 other operations (strabismus, glaucoma) and 8 reattachments or exchanges.

### Discussion

In accordance with other publications [2, 3] the visual performance of these young eyes after cataract extraction and lens implantation appeared to be related to the preexisting level of deprivation indicated by nystagmus and strabismus. The group of children with bilateral implants showed the best visual outcome. The unilateral implanted subjects, with unilateral and bilateral cataracts, obtained less favourable visual results.

The rate of secondary membrane development (15 out of 38) in this series seemed to be lower than the numbers reported by other authors using a discision/aspiration technique [1].

The difference with other series is the use of the Iris-Claw lens in this group of children. The Iris-Claw lens can be placed, replaced and exchanged with minimal surgical trauma under nearly all circumstances. The ever present synechiae formation in the juvenile eye after cataract surgery make posterior chamber lens implantation difficult. The anterior chamber position of the Iris-Claw lens gets round this problem.

Especially in the eyes of very young children several surgeons feel the need for an easy-to-exchange IOL [2]. Theoretically the refractive development of the neonate eye should be followed in order to minimize the risk of deprivation. In the case of an older child most surgeons choose an IOL power based on the expected adult power or the schematic adult eye. For the very young eye that would result in a considerably undercorrected refractive state in a critical period of neurophysiological development [4]. The growth of the eye appeared not to be influenced by aphakia [5] and probably not by pseudophakia [6].

The relatively easy to handle Iris-Claw lens seems to be a more attractive option than for example a system as the 'piggyback' principle based on a posterior chamber IOL [7]. However, this group of children demonstrates a relatively high rate of lens dislocations. There are two causes for this phenomenon. In the early series of the Iris-Claw lens the 'claws' were a little too rigid, which sometimes caused the iris stroma sliding out of the slot of the lens

haptic, especially when a too narrow tissue bridge was formed. As already stated above, this technical problem was also well known in adult eyes and the lens quality was improved in the mid eighties. Bringing an appropriate amount of tissue through the 'claws', remains imperative to get a stable and safe fixation of the lens. Atrophy and leakage at the fixation sites have never been demonstrated.

Further advantages of this lens are easy access to possible secondary membranes and the possibility to choose the lens dimension appropriate for the eye to be operated.

### Conclusion

Effective treatment of children with congenital, developmental and traumatic cataracts has still to be developed. Prevention of deprivation amblyopia is the first therapeutical goal. Nystagmus and strabismus are prognostically unfavourable signs. Implantation of intraocular lenses gains an increasing interest as a promising method for effective visual rehabilitation. The current small diameter version of the Iris Claw intraocular lens for children could be a versatile lens in the treatment of cataracts in the very young eye.

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## 11.2 Lens implant selection with absence of capsular support.

Dick HB, Augustin AJ. *Curr Opin Ophthalmol.* 2001; 12(1):47-57.

If contact lens or spectacle correction is not viable, little debate exists that the secondary placement of an intra-ocular lens (IOL) is the method of choice in the absence of capsular support. The choice of IOL mainly depends on the preoperative status of the eye (eg, aphakia in children) and the selected location for the implant. Theoretically, there are several IOL implantation approaches in cases without capsular support: an angle-supported anterior chamber (AC) IOL, an iris-fixated ACIOL, an iris-sutured or iris-fixated posterior chamber (PC) IOL and a transsclerally sutured PCIOL. No consensus exists, however, on the indications as well as on the relative safety and efficacy of these different options. Implantation of modern ACIOLs, like the refined open-loop or iris-fixated claw (toric) ACIOLs, have regained popularity and provide a valuable alternative to sutured PCIOLs. However, in the absence of capsular support, the transsclerally sutured PCIOLs offer numerous advantages for certain eyes. Because of its anatomic location, the sutured PCIOL is more appropriate for eyes with compromised cornea, peripheral anterior synechiae, shallow anterior chamber, or glaucoma. Moreover, sutured PCIOLs are appropriate if the patient with aphakia is young or has a life expectancy of 10 years or more. Recent technological advances, including PCIOL with iris diaphragm for aniridia, toric ACIOLs, and small-incision surgery with foldable, transsclerally sutured IOLs, seem to further improve clinical outcomes. *Curr Opin Ophthalmol* 2001, 12:47-57 © 2001 Lippincott Williams & Wilkins, Inc.

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### Abbreviations

<b>ACIOL</b>	anterior chamber intra-ocular lens
<b>CME</b>	cystoid macular edema
<b>IOL</b>	intra-ocular lens
<b>OD</b>	optic diameter
<b>PCIOL</b>	posterior chamber intra-ocular lens
<b>PMMA</b>	polymethylmethacrylate
<b>PKP</b>	penetrating keratoplasty
<b>TD</b>	total diameter

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For a long period of time, anterior chamber intra-ocular lenses (ACIOLs) have been the predominant type of lens used in secondary IOL implantation. In the mid-1980s, however, it became evident that the rigid closed-loop ACIOLs were associated with several complications, including irreversible endothelial cell loss leading to pseudophakic bullous keratopathy, intractable inflammatory sequelae with or without cystoid macular edema (CME), angle structure damage, formation of peripheral anterior synechiae, fibrosis of haptics into the angle, pupillary block with increased intra-ocular pressure, iris chafe, and hyphema (Table 1).

Since then, there has been a propagation of techniques using sutures to secure posterior chamber intra-ocular lenses (PCIOLs) [1]. Parry [2] first described the use of sutures to enhance IOL fixation almost 45 years ago, by threading the ends of a tantalum wire through an iridectomy and a hole drilled into the optic of a Ridley IOL. This was fastened to a corneoscleral suture beneath the conjunctiva. In 1976, McCannel [3] reported the use of uveal fixation sutures to stabilize PCIOLs. Scleral-sutured PCIOLs are a more recent development than iris-sutured PCIOLs. Malbran *et al.* [4] were the first to describe transsulcus scleral fixation of PCIOLs in eyes with aphakia.

The indications, techniques, lens style, and incidence of complications associated with the use of either type of IOL in secondary implantation remain controversial. Several studies [5-27] demonstrated that secondarily implanted ACIOLs are associated with more complications and lower postoperative visual acuities than are PCIOLs. However, most of the relevant studies focused on either ACIOLs or PCIOLs alone. Only a few studies directly compared the results of patients receiving secondary ACIOLs with those receiving PCIOLs. We compared the results of previous reports of using both types of IOLs (Tables 2,3).

Presently, there are five primary methods for dealing with IOL requirements in the absence of capsular support, mainly depending on the preoperative status of the eye (Table 4): flexible open-loop ACIOLs and iris claw ACIOLs; iris-fixated retropupillary ACIOLs; iris-sutured PCIOLs; and transscleral-sutured PCIOLs. If both the iris and the capsule are absent or disrupted, sutured transscleral PCIOLs are the only option.

Today, considerable controversy remains over the relative efficacy and safety of the different implantation ap-



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plantation may decrease, if the haptics are in the sulcus and away from the pars plana.

**Conclusions**

Current indications for ACIOL or PCIOL implantation include large ruptures of the posterior capsule during cataract surgery or secondary implantation after previous intracapsular procedure. It is rare to find an elderly patient with aphakia, because primary IOL implantation is the rule in modern cataract surgery. The choice of method and success of the IOL implantation depends on the state of the eye.

Implantation of ACIOL in patients older than 80 years without corneal disease is an alternative to PCIOL implantation, especially if general health problems contraindicate prolonged surgical procedures or increase the risk of bleeding. The use of modern ACIOLs is justified ethically and medically in many cases, especially for surgeons who do not have extensive experience with alternative techniques, such as transscleral or iris fixation of PCIOLs.

Cataracts are the leading cause of blindness in the rural developing countries where microsurgical technology is limited. A backlog of several million patients suffers from mature cataracts. Therefore, implantation of modern ACIOL after an uncomplicated ICCE is a viable alternative to aphakic spectacle correction. The modern ACIOL will play a very useful role in these cases.

A number of techniques have been proposed, but none has clearly emerged as the optimal method for IOL fixation. With recent advances in IOL designs, surgical techniques, instruments, and maneuvers, and also by the use of ophthalmic viscosurgical devices, IOL implantation in the absence of capsular support now is usually associated with good visual outcomes.

Sulcus-fixated PCIOLs remain the preferred procedure to correct aphakia in eyes without capsular support that have significant loss of iris tissue from surgery or trauma. Sutured PCIOLs continue to play an important clinical role, especially in younger patients and eyes with glaucoma, peripheral anterior synechia, or corneal problems. Recent technological advances such as foldable PCIOL insertion with new designs, iris-diaphragm PCIOLs, or toric iris-fixated ACIOLs, seem to improve care of the patient with aphakia.

Prospective, randomized studies are needed to determine which IOL (ACIOL, iris-fixated claw IOL, or PCIOL) is safest and most effective for the correction of uncomplicated aphakia. Because of the potential complications of surgery, we advise secondary IOL implantation only when satisfactory vision cannot be achieved with glasses or contact lenses.

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**Table 1. Most common (mainly closed-loop) anterior chamber intra-ocular lenses frequently associated with pseudophakic bullous keratopathy (most anterior chamber intra-ocular lenses are no longer available)**

Angle-supported ACIOL models	Iris-supported ACIOL models
ORC 11 Stableflex	Worst medaillion
Iolab 91Z (Azar IOL, Duluth, GA)	Binkhorst 2-loop and 4-loop
Surgidev style 10 (Leiske IOL)	Copeland
Hessburg	
Dubroff	
Choyce	
Novaflex	
Kelman flexible 4-point fixation	

ACIOL, anterior chamber intra-ocular lens; IOL, intra-ocular lens; PBK, pseudophakic bullous keratopathy.

proaches when capsular support is absent. Anterior chamber intra-ocular lens implantation is coming back into favor among some surgeons, thanks to improved, open-loop ACIOL designs and re-emergence of the iris-fixed claw IOL. Sizing is less critical with the flexible haptics of the open-loop ACIOLs, as opposed to the more rigid or closed-loop ACIOL designs. Several recent studies demonstrated improved results with these modern devices [28,30]. Nevertheless, concern remains that ACIOLs are more damaging to the corneal endothelium than PCIOLs. Although the complications associated with the closed-loop ACIOLs have decreased with the changeover to the modern ACIOL designs, they have not been eliminated.

There are many theoretical reasons for preferring one of these lens types over the other. Table 5 reviews the advantages and disadvantages of each of these IOL styles.

**Anterior chamber lenses**

Open-loop ACIOLs are capable of providing a vastly superior tolerance during a long-term period, as opposed to their closed-loop counterparts. An unacceptable complication rate was associated with closed-loop ACIOL designs, which correlates with a chronic, insidious process caused by excessive and irritative tissue touch [28].

Current ACIOLs have a footplate that prevents erosion and usually prevents fibrous overgrowth of the haptic. This type of design, whether with three- or four-point fixation, is preferable because it has minimal and stable areas of angle contact. The presence of fixation elements with small holes (Fig. 1) is undesirable. Such holes cause unwanted peripheral anterior synechia and tend to function in a cheese-cutter effect as micro-closed loops (Aufarth, Personal communication) [29,30]. Point fixation is possible with footplate designs because haptics may extend only small areas of the angle outflow structures (Fig. 2). Most styles are easy to implant or remove, if necessary, especially those with Choyce-like foot-plates, which usually are not completely surrounded by gonio-

synechias. The haptic area usually will slide out with undue difficulty or excessive tissue damage. The explanation rate of modern ACIOLs is between 0.06 and 0.16% [31]. Clinical and pathologic data strongly suggest a state-of-the-art model with solid, well-polished Choyce-style footplates (Fig. 2).

A rethinking of the often summary condemnation of all ACIOLs is warranted. The only resemblance of the modern, flexible, one-piece all-PMMA, open-loop designs to the older closed-loop and miscellaneous IOL designs is the anatomic site of implantation. Modern ACIOLs have a low rate of complication, and their association with pseudophakic bullous keratopathy is, at least in part, a result of their use in complicated cataract surgery, rather than inherent design flaws [32].

The vault engineered into modern ACIOLs is maintained even under high compression, which minimizes IOL touch against the cornea. Most common modern ACIOL models now implanted are the Clemente Optifit 13A, the 351C or 352C (Pharmacia & Upjohn, Kalamazoo, MI); Corneal AJPR, S122UV or L122UV (Bausch & Lomb, Claremont, CA); and AC 260 (Ophtec, Groningen, Netherlands), to name a few. The interest and number of refractive surgeries including phakic ACIOL implantation is consistently increasing.

**Angle-supported lenses**

The ACIOL Kelman Omnifit (Bausch & Lomb, Claremont, CA) has been modified to the open-loop flexible one-piece Clemente Optifit (Model 13A; Acritec, Glienicke). It has a 5.5 mm biconvex optic and 13.3 mm total diameter (TD; IOL power: 10 to 27 diopters). Additional improvements include the following:

- No positioning hole.
- Reduction of the compression force to 0.38 gm.
- Increase in haptic angulation from 11.8° to 14° (requiring a minimum anterior chamber depth of 3.4 mm).
- Enlargement and remodelling of the single footplate.
- Thinning of the horizontal haptic.

Since 1991, Clemente [30] analyzed 1000 examples of this new type of ACIOL (Fig. 3), implanted either consecutively after intracapsular cataract extraction (ICCE) or as a secondary procedure after uneventful surgery. He observed 0.5% retinal detachments, 0% pseudophakic bullous keratopathy, 0.5% chronic CME, and 0.4% worsening of pre-existing glaucoma. In contrast, in 5% of eyes after 2175 implantations of the Kelman Omnifit II ACIOL (between 1983 and 1990), Clemente found a slow ingress of fibro-uveal tissue into the small positioning hole (diameter, 0.5 mm). Therefore, complications occurred mostly later than 5 to 16 years in about 80% of eyes. Sixty-eight Kelman Omnifit II ACIOLs had to be



**Table 2. Endothelial cell loss after secondary implantation of different intra-ocular lenses**

Study	Location	Type of IOL	Eyes, <i>n</i>	Time, <i>mo</i>	PBK*/Endothelial cell loss, %
Bayamlar	Angle	Ophtec AC260T (Groningen, Netherlands)	22	Min. 12	1.0*
Hayward		Cilco Multiflex	52	Min. 26	1.9*
Lois			101		10.8
Sawada			86		14.0
Menezo	Iris	Worst iris claw (Ophtec, Groningen, Netherlands)	41	14	4.8*
Menezo	Posterior chamber	PMMA	13	14	7.6*
Oshima		MA60BM (Alcon, Ft. Worth, TX)	24	6	7.8
Price			75		26.3
Walter			89	–	3.3

IOL, intra-ocular lens; PMMA, polymethylmethacrylate [5,7,9,10,12–14,25].

explained. Important aspects in ACIOL placement include the following:

- (1) Correct sizing (overall diameter should be 1 mm greater than horizontal white-to-white distance).
- (2) Avoid iris tuck and dialysis (*eg*, use of a Sheets guide).
- (3) Check if the haptics rest securely at the level of ciliary body band.
- (4) Rotate IOL away from iridectomies after insertion (haptics might rotate through them [Fig. 4]), or orient incision to place haptics away from peripheral iridectomies.

### Iris-fixated lenses

#### Claw lenses

The Artisan aphakia IOL design (optic diameter [OD], 5 mm; TD, 8.5 mm), a modification of the Worst Iris Claw Lens, is substantially different from that of past iris-supported lenses (Fig. 5). The Artisan IOLs are fixated to the midperipheral portion of the iris, and, therefore, do not interfere with the normal physiology of the iris or the angle structures. Recent studies of eyes with phakia that had iris-fixated lens implantation to correct myopia showed excellent visual outcomes and stability with a low complication rate. Fourteen months after implanta-

**Table 3. Cystoid macular edema, vitreal hemorrhage, and retinal detachment after secondary implantation of different intra-ocular lenses**

Study	Location	Type of IOL	Eyes, <i>n</i>	Follow-up, <i>mo</i>	Cystoid macula edema, %	Vitreal/choroidal hemorrhage, %	Retinal detachment, %
Bayamlar	Angle	Ophtec AC260T (Groningen, Netherlands)	22	min. 12	13.6	0.0	0.0
Belluci	ACIOL	Kelman Omnifit II	35	12–44	3.0	0.0	3.0
Ellerton		Open-loop, one-piece Multiflex	81		1.2		1.2
Hahn		28 flexible, 15 rigid open-loop	43	10	9.3	–	23
Hayward		Open-loop, one-piece Multiflex	52	min. 26	7.7	–	1.9
Kraff			190	17	0.0		1.6
Lois			101		13.9		2.0
Lyle		Open-loop, one-piece PMMA	234	19	5.9	–	0.9
Sawada			86		4.6		0.0
Schein		Open-loop, one-piece Multiflex	60	min. 6	>PCIOL		3.3
Weene		33 Kelman, 10 Tennant	43	12	2.3	–	4.6
Wong		ORC Stableflex, Hessburg, Iolab 91Z (Duluth, GA)	35	18	5.7	–	5.4
Menezo	Iris ACIOL	Worst Iris claw	41	14	4.8	0.0	0.0
Schein		7 mm OD, PMMA	56	min. 6	<ACIOL	0.0	0.0
Belluci	Posterior chamber IOL	728 C, Pharmacia (Kalamazoo, MI)	30	12–44	9.0	3.0	6.0
Bleckmann		7 mm OD, 13.5 mm TD, 10°	48	21	–	25.0	–
Price			75			13.0	
Holland		7 OD, 13–14 TD, PMMA	105	27	9.5	1.1	3.8
Lanzetta			18		15.7	10.6	
Lee		PMMA	122	min. 12		10.7	4.9
Lyle		PMMA	114	21	6.1	–	3.5
Menezo			13	14	7.6	7.6	0.0
Oshima		MA60BM, Alcon (Ft. Worth, TX)	30	9	0.0	3.3	0.0
Schein			60	min. 6			1.6
Solomon			30	25	23.0	3.0	0.0
Uthoff			624	min. 12	5.8	1.8	1.4
Walter			89	–	10	1.1	1.1
Wong		Sinsky-style model J-loop PMMA	40	18	0.0	10.0	2.5

ACIOL, anterior chamber intra-ocular lens; IOL, intra-ocular lens; min., minimum; OD, optic diameter; PCIOL, posterior chamber intra-ocular lens; PMMA, polymethylmethacrylate; TD, total diameter [5–27].

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**Table 4. Indications for anterior chamber intra-ocular lens versus iris- or sulcus-sutured posterior chamber intra-ocular lens**

ACIOL	PCIOL
Bleeding disorders	Endothelial dystrophy; corneal disorders (cornea guttata); PBK after ACIOL implantation (trabecular meshwork already compromised from the original ACIOL); surgery in conjunction with PKP
Extensive scleroconjunctival scarring (eg, after trauma)	Anterior chamber: peripheral synechiae, shallow (< 3.0 mm); abnormal angle
Intact anterior vitreous face	Defects of the iris; aniridia Glaucoma; surgery in combination with glaucoma filtering operation Young patients or relatively long life expectancy ( $\geq 10$ y)

ACIOL, anterior chamber intra-ocular lens; PCIOL, posterior chamber intra-ocular lens; PBK, pseudophakic bullous keratopathy; PKP, penetrating keratoplasty.

tion in eyes with aphakia, the Artisan IOLs offered favorable visual outcomes, a low incidence of intra-operative and postoperative complications, and were easy to remove or replace if necessary [12]. The Artisan IOL can be fixated at the anterior and posterior iris surface [33], and is available in power from 2 to 30 diopters as well as for pediatric aphakia (OD, 4 or 5 mm; TD, 6.5, 7.5, or 8.5 mm).

**Toric claw lenses**

Effective intra-ocular correction of high preoperative astigmatism in aphakia can be achieved in some cases. Ophtec [Groningen, Netherlands] combined both spherical and cylindrical correction in a new ACIOL design, the Artisan toric PMMA IOL. The Artisan toric ACIOL is very similar to the Artisan myopia and hyperopia ACIOL. The available power depends upon request (+12 to -20 diopters; cylindrical correction, 1-7 diopters). Power calculation is performed by Ophtec [Groningen, Netherlands] using the Van der Heijde formula. To allow the surgeons to implant the toric ACIOL in the position to which they are accustomed, two toric models are available. For proper ACIOL placement (in the cylindrical axis or perpendicular to the axis), and to avoid placement errors, the surgeon receives an illustration of the situation *in situ* (Fig. 6). The authors' experience with this toric ACIOL in 14 eyes with phakia and with at least 6 months follow-up is most promising [oral presentation, 18th Congress of the European Society of Cataract and Refractive Surgeons, Brussels, Belgium, September

2000], with very satisfying functional and morphological results (Fig. 7).

**Posterior chamber lenses**

As an alternative to ACIOL implantation in inadequate capsular support, fixation of posterior chamber intra-ocular lenses (PCIOLs) at the iris with claws or sutures and in the ciliary sulcus with transscleral sutures has allowed safe and effective visual rehabilitation in the setting of both primary and secondary IOL implantation. There are two basic surgical techniques of suturing PCIOLs. Iris fixation is achieved by threading the suture either through the positioning holes of the IOL optic or around the proximal portion of the IOL loop. The second technique consists of tying a suture around the distal portion or tip of the IOL loop, passing the suture through the ciliary body, and tying it to the sclera. The ciliary ring has a mean diameter of  $11.15 \pm 0.5$  mm [34,35].

**Iris-fixated lenses**

Iris-sutured PCIOLs offer such advantages as reduced surgical time. Fixation is relatively simple when performing penetrating keratoplasty (PKP). However, implementing this technique through a limbal approach is cumbersome. A modified C-loop PCIOL with a TD of 11.5 to 12.5 mm would conform well to the size and shape of the ciliary ring. A 13.5-mm TD of the IOL greatly exceeds the diameter of the ciliary ring, and the loops will extend into the pars plana. Apple [34] reported that in four cases using the iris-suture technique, only one of eight loops actually was found to be situated in

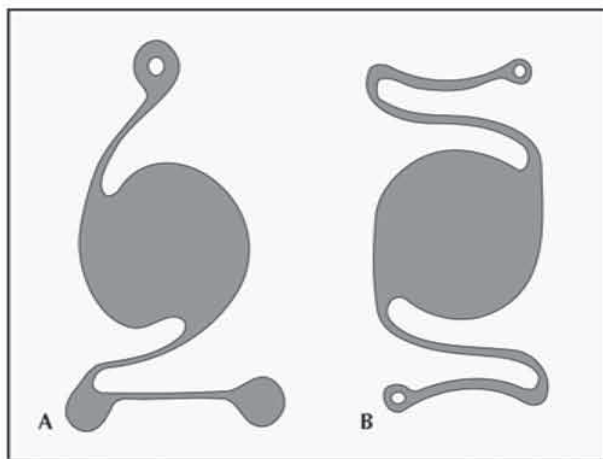
**Table 5. Theoretical properties of anterior chamber intra-ocular lens versus posterior chamber intra-ocular lens**

IOL type	Advantage	Disadvantage
ACIOL	Short operating time Easy insertion Easy to remove or replace No suture associated problems, eg, erosion, endophthalmitis Placement far away from ciliary body (reduced risk of hemorrhage)	Endothelial cell loss Need for iridectomy/iridotomy
Scleral-sutured PCIOL	IOL placement far away from the endothelium Preserves the eye's anatomy (minimize aniseikonia) Independent of presence of iris tissue Limited pseudophakodonesis Minimal uveal contact	Technically more complex Longer operating time (possible effect on complications) Extensive vitrectomy often required (risk of RD, CME) Long-term dependence on fixation of IOL by a suture Ciliary body erosion from haptics

ACIOL, anterior chamber intra-ocular lens; CME, cystoid macular edema; IOL, intra-ocular lens; PCIOL, posterior chamber intra-ocular lens; RD, retinal detachment.



**Figure 1. Schematic illustration of one-piece, all-polymethylmethacrylate, open-loop anterior chamber intra-ocular lenses**



Kelman designs: (A) flexible, three-point fixation; (B) flexible, four-point fixation. Note the small holes in the haptic.

the ciliary sulcus. With the optic sutured into the peripupillary iris, it is difficult to ensure true ciliary sulcus placement. Therefore, PCIOLs so implanted largely depend on the fixation sutures for stability. However, the attachments of sutures to the iris and ciliary body should not cause problems such as tearing, pseudophakodone-sis, or low-grade inflammation, particularly in younger patients with highly mobile irides. Finally, attention must be paid to ensure that the sutures attain a long-term retention of integrity.

### Scleral-fixated lenses

Transsclerally sutured PCIOLs reduce the risk of iris shafe, iritis, pigment dispersion, and cystoid macular edema, compared with iris-sutured PCIOLs. Any PCIOL used should have a well-polished, smooth-edged

optic to minimize chafing of the epithelia of the posterior iris and ciliary body.

Our recommendations for sutured PCIOL include the following:

(1) *Total diameter 12.5 to 13.0 mm:* It is not necessary to have a TD of 14.0 m when the size of the ciliary ring is only 11.1 mm in an eye without high axial myopia [36]. However, the anatomical variability is known to be very high.

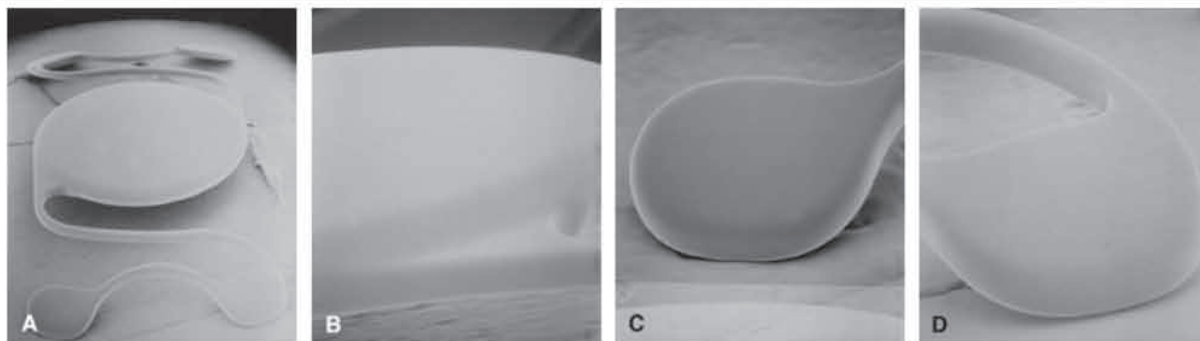
(2) *Large OD of 6 mm or more:* Lens tilt or decentration is found in 5 to 10% of patients after scleral-sutured PCIOL implantation. Intra-ocular lenses with large optics compensate for decentration. Proper suture placement and tension is important in avoiding this complication [37•].

(3) *Haptics: 10° angulation, eyelet:* Eyelets on the haptics prevent suture slippage and further decrease the potential for decentration and tilt [38•]. Before special PCIOLs were available, many surgeons used cautery to bread the tip of the haptics to avoid suture slippage. Hu *et al.* [39] suggested to use a PCIOL with a control tip or to create a club deformity at the end of the haptic with the use of thermal cautery to prevent suture slipping. Heat modification of IOL haptics may rarely lead to late vitreous hemorrhage [40]. Because this voids the warranty for the IOL and creates a rough surface, it is not recommended. Some commonly used models of scleral sutured IOLs include the P366UV (Bausch & Lomb, Claremont, CA), the 27SF (Acritec, Glienicke, Germany), and the PC279 (Ophtec, Groningen, Netherlands).

### Foldable lenses

All published reports have in common the use of a relatively large, rigid PMMA optic. To accommodate smooth

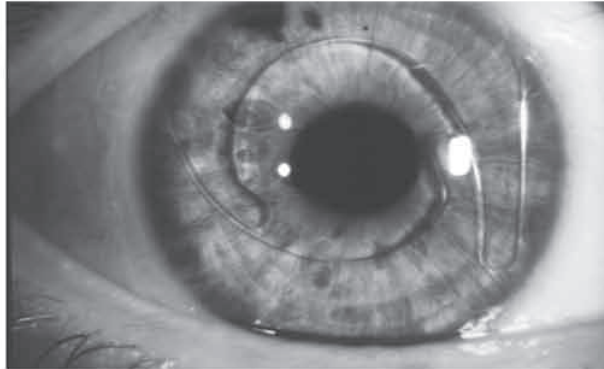
**Figure 2. Scanning electron micrograph of a fixible one-piece open-loop phakic anterior chamber intra-ocular lens (Nuvita, Bausch & Lomb, Rochester, NY) with four footplates**



(A) The overview demonstrates excellent finish with well-polished smooth surfaces and rounded edges (original magnification,  $\times 19.9$ ). (B) The gentle optic haptic junction area leads to a much gentler tissue contact with less possibility of chafing (original magnification,  $\times 70.0$ ) (C,D) Improved quality of the Choyce-style four-point fixation of footplates in combination with Kelman's concept of flexible open loops (original magnification,  $\times 61.0$  and  $\times 75.0$ , respectively).

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**Figure 3. Photograph of an anterior chamber intra-ocular lens**



Modern three-point fixation, one-piece, all-PMMA open-loop biconvex ACIOL (Clemente Optifit 13A, Acritec, Glienicke, Germany) with modified solid Choyce-style footplates. The hole-free haptics provide improved long-term performance.

insertion, an incision of an even larger size is required. Regillo and Tidwell [41] first reported on a small-incision technique for suturing a PCIOL. A relatively large incision often results in significant egress of intra-ocular fluids, with resultant intraoperative hypotony. The frequent need to pressurize the globe, to work with a relatively soft eye during lens insertion, and wound suturing to ensure a watertight closure often makes this procedure difficult and time consuming. An additional postoperative inflammation might result from the added manipulations. Implantation of foldable PCIOLs in aphakic eyes without capsular support requires a smaller incision of 3.5 mm. The smaller, self-sealing incision, in combination with the use of adequate ophthalmic viscosurgical devices, allows better maintenance of the anterior chamber during PCIOL insertion and suturing [42•]. The greater intra-operative control might be less likely to cause intraoperative complications, especially in eyes that are at high risk. It also allows for a shorter operative

time, minimized surgically induced astigmatism, and earlier visual rehabilitation [14]. One should be cautious about transscleral fixation of modern PCIOLs with sharp optic edge design, which are most commonly used in routine phacoemulsification (Fig. 8).

Schwenn *et al.* [43] first described their small-incision technique of transsclerally sutured, multifocal, foldable silicone Array IOLs (SA-40, Allergan, Irvine, CA) using the Unfolder (Fig. 9) and reported on satisfying results. These authors also achieved good outcome in some cases after transsclerally sutured, toric PCIOLs (PMMA and, more recently, foldable silicone toric PCIOLs [Dr. Schmidt-Intraokularlinsen, St. Augustin, Germany]) in high preoperative astigmatism and aphakia (Fig. 10).

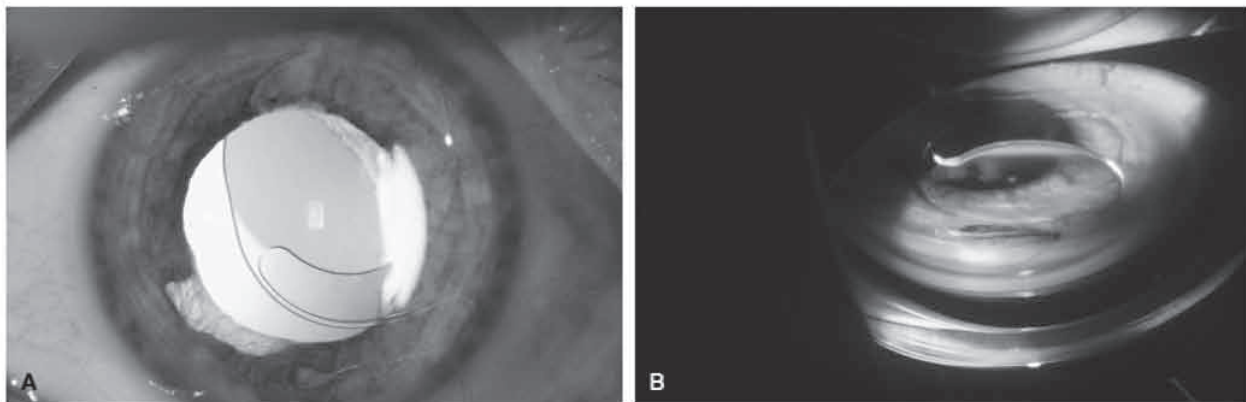
**Use in iris defects or aniridia**

Symptoms of aniridia range from decreased visual acuity and cosmetic concerns to incapacitating glare and photophobia. Various techniques have been used for treatment, including especially designed contact lenses or corneal tattooing.

Several iris–diaphragm PCIOLs are commercially available: The Morcher 67 A, F, G, L and S IOL (Stuttgart, Germany; TD, 12.5 mm; OD, 5 mm) with black diaphragm (diameter: 10.0 mm), and the Ophtec ANI 1 and ANI2 PMMA IOLs (Groningen, Netherlands; TD, 13.75 mm; OD, 4 mm; both IOLs differ in design) with green, brown, black or blue diaphragm (diameter: 9.0 mm). The ANI IOLs allow better cosmetic match with the fellow eye (Fig. 11). Most of these PCIOLs have two eyelets for suture fixation.

Iris–diaphragm aniridia PCIOLs are not without side effects. Colored PMMA is more breakable than standard PMMA. Persistent intra-ocular inflammation has been

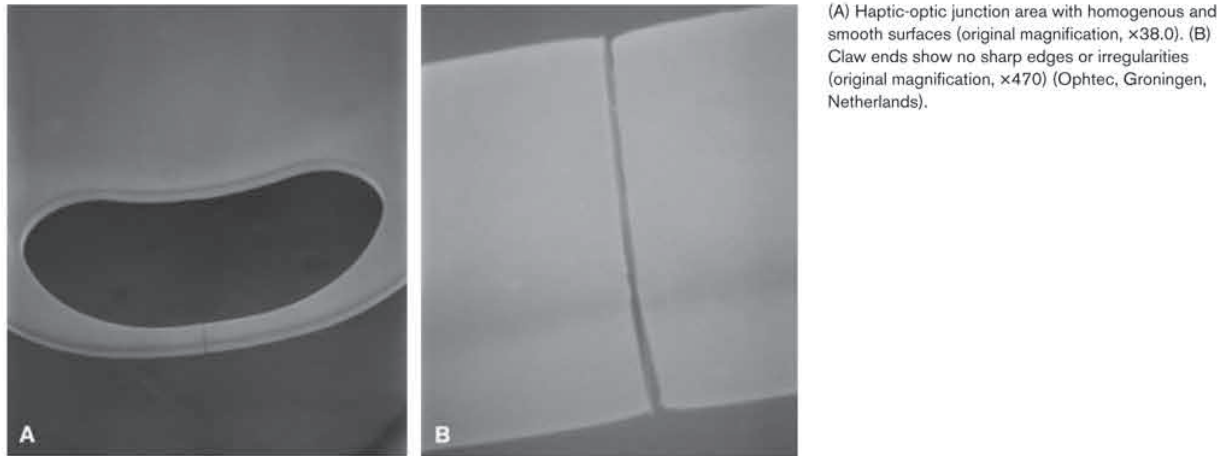
**Figure 4. Dislocation of a modern flexible, four-point fixation anterior chamber intra-ocular lens**



(A) Dislocation of a modern flexible, four-point fixation ACIOL. (B) Gonioscopy reveals rotation of the haptics through iridectomy at 12 o'clock.



**Figure 5. Scanning electron micrograph of the Artisan intra-ocular lens for iris fixation**



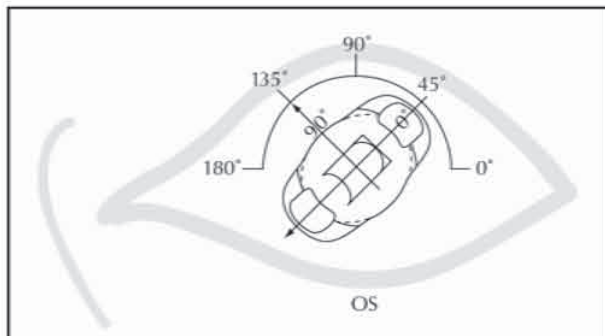
reported in some cases [44]. Functional results of iris-diaphragm PCIOL in both congenital and traumatic aniridia combined with aphakia were satisfactory [45].

The treatment of aniridia in a patient with aphakia who has contact lens intolerance presents a problem in the United States [46]. There are currently no US FDA-approved devices to treat these patients. It is unlikely that unrestricted use of this device will be allowed in the United States except on a compassionate-use basis.

**Use for pediatric aphakia**

Contact lenses frequently are used after lensectomy to correct pediatric aphakia. However, they are associated with problems like infection and corneal vascularization, particularly in eyes with continuous-wear soft lenses. Correction of unilateral traumatic aphakia by IOL in children resulted in better final visual acuities and binocularity, with smaller incidence of strabismus, than when correction was carried out by contact lens [47].

**Figure 6. Illustration for proper placement of the toric Artisan anterior chamber intra-ocular lens in the cylindrical axis**



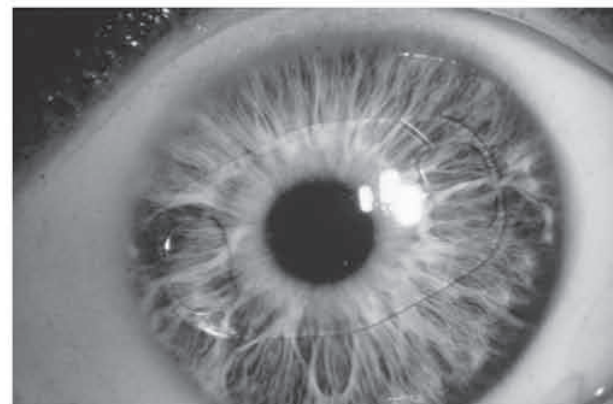
Refractive error: S +5.75  $\times$  C -4.5  $\times$  45 $^\circ$ ; ACIOL to be implanted: S +7  $\times$  C -6 in axis 45 $^\circ$ .

Intra-ocular lens implantation should be considered in children who have poor compliance or tolerance for contact lenses.

The question of implantation of an iris-fixated ACIOL in a child's eye has been raised by van der Pol and Worst [48]. The Artisan IOL, which is available with an OD of 4.0 to 6.0 mm and a TD from 6.5 to 8.5 mm, can be placed, replaced, and exchanged with little surgical trauma. Therefore, it is an interesting treatment modality in the correction of the developmental refractive changes of the growing aphakic eye.

Because of possible long-term complications like endothelial cell loss, a transsclerally sutured PCIOL seems to be preferable to an angle-supported or iris-fixated ACIOL [49•]. To anticipate suture-related complica-

**Figure 7. Slitlamp photograph of the toric Artisan polymethylmethacrylate intra-ocular lens**



Artisan PMMA-IOL (Model 203, Ophtec, Groningen, Netherlands), which has a 5.0 mm OD and a 8.5 mm TD.



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**Figure 8. Foldable silicone posterior chamber intra-ocular lens**



Scanning electron micrograph of the foldable silicone PCIOL (911, Pharmacia, Kalamazoo, MI) for implantation into the capsular bag. The sharp-edged optic shows small irregularities and molding flash (magnification  $\times 78.0$ ).

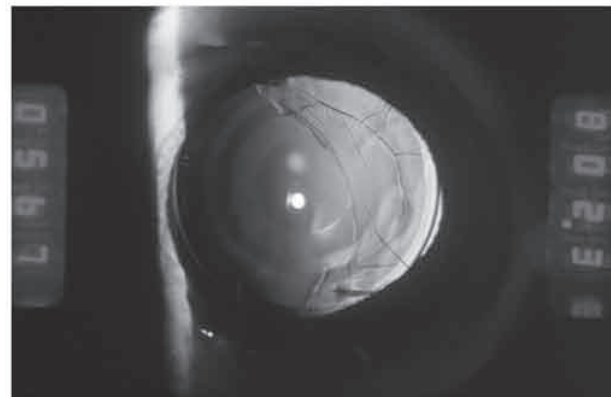
tions [50,51], Zetterström *et al.* [52•] recommended that all knots be rotated, buried in the scleral bed, and covered with conjunctiva. Because pediatric pupils have a diameter of 7.0 mm or more in darkness, a large OD with sufficient haptic angulation to avoid subluxation of the optic into the anterior chamber is needed.

Uncertainty about long-term safety of all treatment options for pediatric aphakia remains. There are many unresolved issues that require meticulous attention to detail, intensive long-term treatment, and lifelong follow-up.

**Use for pseudophakic bullous keratopathy**

If PKP is necessary because of pseudophakic bullous keratopathy, the surgeon faces a quandary: which IOL offers the best chance of avoiding further IOL-induced complications? A sutured PCIOL involves an obligatory anterior vitrectomy unless a large vitrectomy was done during earlier surgery. In specific cases with vitreous pathology, this is beneficial, but vitreous loss during PKP increases the incidence of CME. *Scleral fixation* requires suturing through the highly vascular ciliary body, possibly causing uveal irritation with low-grade chronic inflammation. An *iris-sutured* PCIOL causes even larger areas of uveal contact, which is the common denominator in the late-onset IOL syndrome of corneal endothelial

**Figure 9. Foldable multifocal silicone posterior chamber intra-ocular lens**

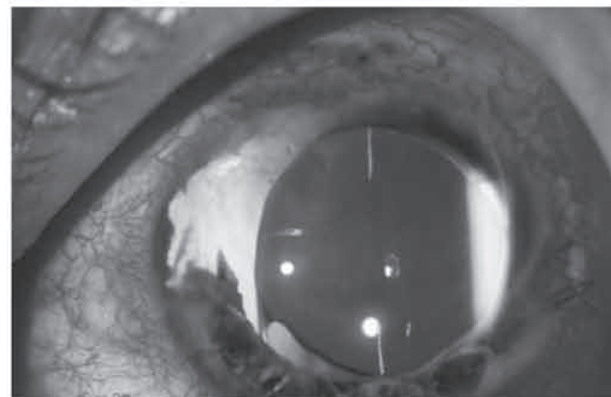


Well-centered transsclerally sutured foldable multifocal silicone PCIOL (SA-40N, Allergan, Irvine, CA) in aphakia, offering the advantages of small incision surgery and pseudoaccommodation.

decompensation and CME. Some surgeons try to reduce this contact by placing the knot between the optic and posterior iris [53]. Recent results [53–55] with sutured PCIOLs supported and extended earlier reports of favorable results with sutured PCIOLs. Unfortunately, the literature does not contain many series of PKP with secondary modern ACIOLs for comparison. Interestingly, there was no statistically significant difference in endothelial cell loss after PKP with scleral-sutured PCIOL versus modern ACIOL [56].

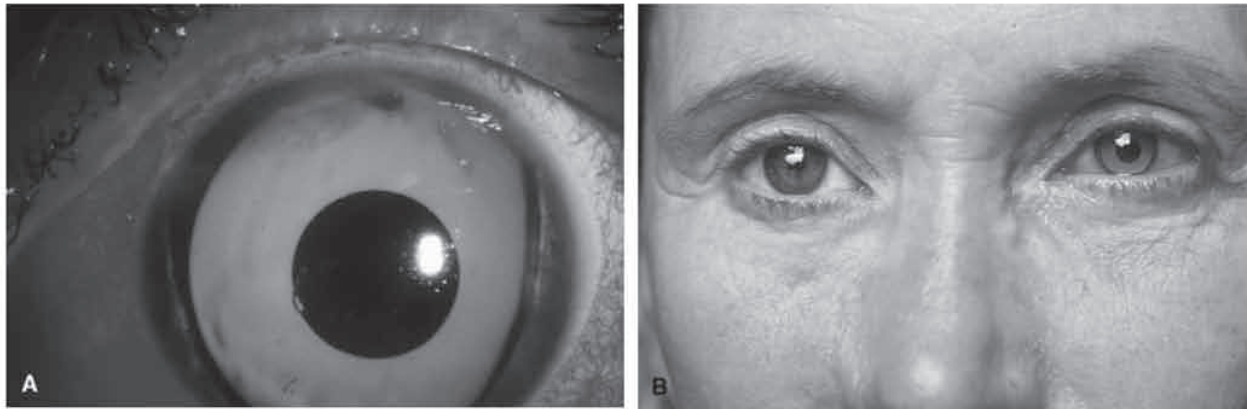
Some authors conclude that modern ACIOLs, scleral-sutured PCIOLs, and iris-sutured PCIOLs all achieve similar visual results if used with PKP [57,58]. Nevertheless, placement of PCIOLs at the time of PKP is likely to remain a frequent procedure [59,60].

**Figure 10. Transsclerally sutured toric polymethylacrylate posterior chamber intra-ocular lens**



Transsclerally sutured toric PMMA PCIOL (Dr. Schmidt-Intraokularlinsen, St. Augustin, Germany) to correct high corneal astigmatism (9.5 diopters) in traumatic aphakia.

Figure 11. Brown iris diaphragm intra-ocular lens



(A) Anterior segment 2 days after transscleral fixation of a biconvex PMMA-PCIOL (ANI 2, Ophtec, Groningen, Netherlands) with brown iris diaphragm (diameter, 9 mm), 4.0 mm OD, and 13.75 mm TD for traumatic aphakia with large iris defect. It has elliptical haptics (thickness, 0.13 mm) with two eyelets ( $\varnothing = 0.4$  mm). (B) The brown iris diaphragm allows an acceptable cosmetic match with the fellow healthy eye.

### Complications associated with posterior and anterior intra-ocular lenses

The relative rates of various complications among the different IOL options are summarized in Table 6, which extrapolates data derived from several studies. This table should be considered to be only a rough approximation of true complication rates. Most of the patients with good preoperative, corrected visual acuity and secondary PCIOL placement maintained their preoperative vision. However, eyes with previous complicated cataract surgery with vitreous loss have worse results regardless of IOL used at the second surgery, compared with an uncomplicated initial cataract surgery [61].

#### Endothelial cell loss

Kraff *et al.* [8] found that reduced preoperative endothelial cell count may increase the risk of losing additional cells during secondary lens implantation. Therefore, eyes with pre-existing corneal pathology have a higher risk of postoperative corneal complications and a poorer visual outcome than eyes without pre-existing pathology. Irreversible corneal irritation cannot be excluded in ACIOL implantation because of possible intermittent or permanent endothelial trauma provoked by the IOL [62].

#### Cystoid macular edema

Cystoid macular edema is one of the most common complications following secondary lens implantation. Cystoid macular edema occurred with almost equal overall frequency after PCIOL and modern ACIOL implantation, whereas it was more frequently associated with closed-loop ACIOLs than with open-loop ACIOLs [28]. Prolonged operating time, together with the lack of physiologic protective mechanisms of the eye (crystalline lens), probably plays a major role in excessive retina light levels, leading to light-induced injuries. Light from the operating microscope reaches the posterior pole through

the dilated pupil, especially during the surgical procedure of sclerally fixated PCIOL [23].

#### Retinal detachment

Vitreous prolapse and anterior vitrectomy is associated with a high risk of retinal detachment, which seems to be similar both in eyes in which ACIOLs have been implanted, and in eyes in which PCIOLs have been implanted. Vitreous loss during complicated cataract surgery is more likely to cause retinal complications than during secondary implantation [11]. Retinal detachments are more closely related to the surgical technique than to the IOL design. With more surgical experience and new techniques, such as intraoperative endoscopic sulcus verification [63], it is possible to localize more precisely the ciliary sulcus to assure the haptics are positioned there [64]. Retinal detachment rates after PCIOL im-

Table 6. Relative frequency of complications associated with secondary intra-ocular lenses

Complication	ACIOL	Iris-sutured PCIOL	Scleral-sutured PCIOL
Corneal edema	++	(+)	(+)
Long-term graft failure	+ (+)	(+)	-
Glaucoma	++	+	(+)
Synechia	++	+	-
Uveitis/iritis	++	++(+)	(+)
IOL tilt/decentration	+	++	++
Intraop bleeding	+	++(+)	+++
Choroidal detachment	+	+	++
Acute CME	+	++	+(+)
Chronic CME	+	+(+)	+
Retinal detachment	+	+	++
Polypropylene knot erosion	NA	NA	+(+)
Polypropylene suture failure	NA	+	+

-, not associated; +, mildly associated; ++, mediumly associated; +++, strongly associated; ACIOL, anterior chamber intra-ocular lens; CME, cystoid macular edema; IOL, intra-ocular lens; NA, not applicable; PCIOL, posterior chamber intra-ocular lens [5-27].





## 11.3 Secondary Artisan-Verysise aphakic lens implantation

Guëll JI, Velasco F, Malcaze F, Vázquez M, Gris O, Manero F; *J Cataract Refract Surg* 2005; 31: 2266-2271.

**PURPOSE:** To evaluate efficacy, predictability and safety of Artisan-Verysise intraocular lens (IOL) secondary implantation for aphakia correction.

**SETTING:** Instituto de Microcirugía Ocular, and Autònoma University of Barcelona, Barcelona, Spain.

**METHODS:** Uncorrected visual acuity, best spectacle-corrected visual acuity (BSCVA), manifest refraction, endothelial cell count, and clinical complications were evaluated. Sixteen consecutive eyes of 14 patients with aphakia were submitted to surgery. Postoperative examinations were done at 6 weeks, 6 months, 1 year, and every year for at least 3 years. An iris-supported Artisan-Verysise IOL was implanted for aphakia correction.

**RESULTS:** Thirty-six months after Artisan-Verysise lens implantation, BSCVA was 20/40 or better in 6 eyes (37.5%). Preoperatively, 5 eyes had the same BSCVA (31.25%). Mean postoperative spherical equivalent (SE) was 0.46 diopter (D). Mean endothelial cell loss was 10.9% 36 months postoperatively. The cell loss occurred predominantly during the first year (7.78%). Cystoid macular edema was observed in 2 cases, 1 of them associated with chronic unresponsive low intraocular pressure. No other serious complications were observed.

**CONCLUSION:** Artisan-Verysise IOL implantation seems a safe, predictable, and effective option for aphakic eyes without capsule support.

*J Cataract Refract Surg* 2005; 31:2266-2271 © 2005 ASCRS and ESCRS

The surgical correction of aphakic eyes without capsule support usually poses a difficult management problem. Most of these situations include posttraumatic or spontaneous dislocations of the crystalline lens as well as capsule loss during cataract extraction. The classic options for secondary intraocular lens (IOL) implantation include ciliary sulcus fixation and angle-supported implantation.<sup>1,2</sup> Posterior chamber IOL scleral fixation is the preferred procedure by most surgeons because the IOL position preserves the anatomy of the eye better than anterior chamber IOLs and they are theoretically safer long term because of the

more adequate preservation of the corneal endothelium.<sup>3,4</sup> Nevertheless, complications such as ciliary choroidal body hemorrhage; retinal detachment, sometimes with giant retinal break; cystoid macular edema (CME); vitreous prolapse into the anterior chamber; and conjunctival erosion by transscleral sutures with associated endophthalmitis risk have been described.<sup>5-7</sup> Meanwhile, different results have been reported using anterior chamber angle-supported IOLs, depending on the preoperative status of the eye, surgical technique, and lens style. Associations with corneal edema, CME, glaucoma, IOL instability, lens decentration, pupil distortion, and retinal detachment have been described with both the flexible open-loop anterior chamber IOL and Kelman tripod lens.<sup>8-10</sup>

In the early 1980s, an iris-fixated IOL was first introduced by Worst et al.<sup>11,12</sup> The Artisan-Verysise lens was fixed to the midperipheral iris and centered over the pupil. This IOL does not interfere with the physiologic vascularization and does not effect mydriasis or angle structures.<sup>13</sup> Some studies have already indicated favorable visual outcomes and a low incidence of intraoperative and postoperative complications with the current model.<sup>14</sup>

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No author has a financial or proprietary interest material or method mentioned.

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SECONDARY ARTISAN-VERYSISE APHAKIC LENS IMPLANTATION

In this retrospective study, we evaluated the efficacy, predictability, and safety of Artisan–Verysise lens implantation for aphakic correction during 3 years.

**PATIENTS AND METHODS**

This retrospective study comprised 16 eyes of 14 patients with ages ranging from 36 and 74 years, who had Artisan–Verysise aphakic IOL (Ophthec BV) implantation by the same surgeon (J.L.G.) between December 1997 and February 1999 at IMO, Instituto de Microcirugía Ocular, Barcelona, Spain. Eight eyes had complicated cataract surgery with extensive capsule rupture and vitreous loss at least 1 year before secondary IOL implantation; 3 eyes had congenital cataract extraction through a manual dissection–aspiration technique; 2 eyes had penetrating ocular trauma; 2 eyes had combined surgery, penetrating keratoplasty, and angle-supported anterior chamber IOL exchange; and 1 eye, had anterior vitrectomy and IOL exchange after a nontraumatic posterior chamber lens subluxation (Figure 1).

Indications for surgery were unsatisfactory correction with spectacles or contact lenses for medical, professional, or personal requirements; chronic corneal edema, CME; vitreous–endothelial touch; and posterior chamber IOL subluxation.

Exclusion criteria for IOL implantation were an endothelial cell count less than 1800 cells/mm<sup>2</sup>, anterior chamber depth less than 3.0 mm (i-Scan Ophthalmic Ultrasound Mode B scan, OTI Ophthalmic Technologies Inc.), glaucoma, recurrent uveitis history, proliferative diabetic retinopathy, and age-related macular degeneration. All patients were fully informed of the details and possible risks of the procedure in accordance to Helsinki declaration, and a written informed consent was obtained from each patient.

Preoperative and postoperative evaluations included subjective refraction, uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), Javal keratometry, slitlamp examination, Goldmann applanation tonometry, indirect fundus examination (fluorescein angiography when necessary), endothelial cell count, and morphologic evaluation by specular microscopy (Konan, Noncon ROBO). Postoperative examinations were done at 1 day, 6 weeks, 6 and 12 months, and every year for at least 3 years.

The Artisan–Verysise lens is a biconvex poly(methyl methacrylate) (PMMA) IOL with an 8.5 mm length, a 1.04 mm maximum height, and a 5.0 mm optical zone. The A-constant was 115, and the SRK/T formula<sup>15</sup> was used to calculate IOL power.

**Surgical Technique**

Under retrobulbar anesthesia (4 cc of a proportional combination of mepivacaine 2% and bupivacaine 0.75%), the first plane

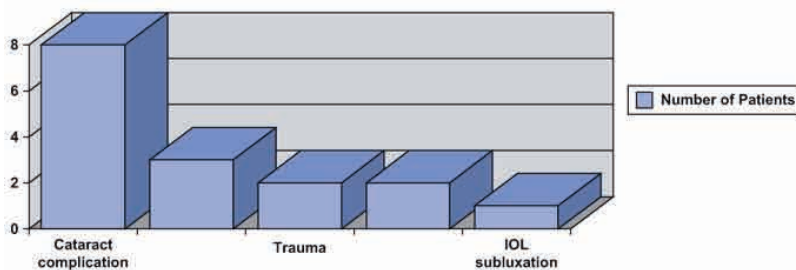
of a 5.2 mm long posterior vascular corneal incision and 2 vertical paracentral paracentesis (at 10 and 2 o'clock positions) were performed. After an intracameral injection of acetylcholine 1% (Acetylcolina 1%) and viscoelastic material through the paracentesis, the second plane of the incision was performed. The IOL was then inserted, rotated with a hook into a horizontal position, and centered over the pupil always under viscoelastic material protection. A lens fixation forceps was introduced through the large incision. At the same time, through the paracentral paracentesis, a modified blunt 36-gauge blended needle was introduced and a 1.0 mm iris fold was picked up and pulled through the “claw” into the haptic. The maneuver was then repeated on the other side, achieving perfect IOL centration over the pupil. This IOL fixation system was surgeon dependant, which is 1 of its main advantages. A peripheral slit iridotomy at 12 o'clock was then performed. Finally, all the viscoelastic material was carefully removed through an automated irrigation/aspiration system and the large incision was closed with 4 or 5 single 10-0 nylon sutures. Bimanual anterior vitrectomy was performed before IOL insertion, if needed, with a vitrector (Accurus, Alcon) and indirect intraocular illumination. Lighting was the only way to properly evaluate a clean anterior chamber before lens implantation. In 2 cases, penetrating keratoplasty with anterior vitrectomy were simultaneously performed and an angle-supported anterior chamber lens was exchanged through an open-sky technique. In another case, a posterior chamber subluxated lens was removed at the time of anterior vitrectomy and then the Artisan–Verysise lens was implanted (Figure 2).

**RESULTS**

**Efficacy, Predictability, and Stability**

Preoperative BSCVA was 20/40 or better in 5 eyes (31.25%) and postoperatively in 6 eyes (37.5%). Postoperative UCVA was equal to or better than preoperative BSCVA in 50% of eyes (8 of 16 eyes) at 36 months follow-up (Figure 3 and Table 1).

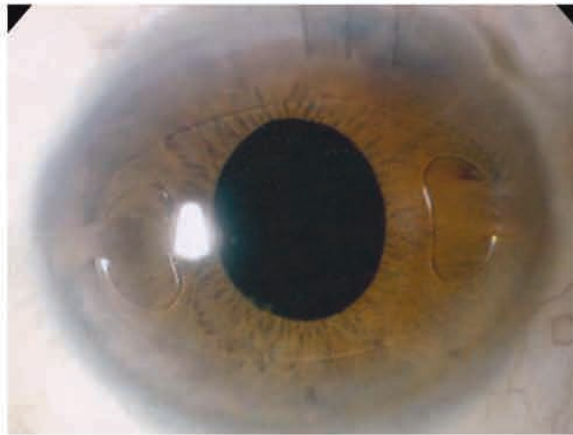
The goal refraction was emmetropia or slight residual myopia. Mean preoperative spherical equivalent (SE) refraction was +7.60 diopters (D) (range +4.75 to +14.50 D); this refraction decreased to a mean SE of –0.53 D (range –3.75 to +5.25 D), –0.51 D (range –3.00 to +5.00 D), and –0.46 (range –2.75 to +5.0 D) 3, 12, and 36 months after surgery, respectively. These results indicate stability in refractive outcome since the third month (Figure 4). In 56.25% of eyes (7 of 16 eyes) at 3 months, 62.50% of them (10 of 16 eyes) at 12 months, and



**Figure 1.** Indications for secondary Artisan–Verysise lens implantation.



SECONDARY ARTISAN-VERYSISE APHAKIC LENS IMPLANTATION

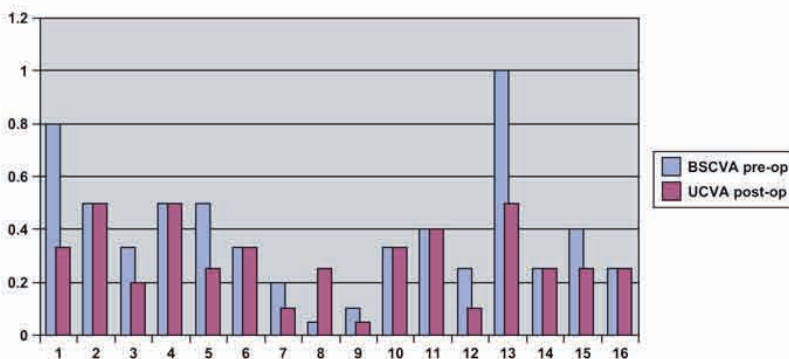


**Figure 2.** Artisan-Verysise lens in an aphakic eye with previous posterior chamber lens subluxation.

68.75% of eyes (11 of 16 eyes) at 36 months, the postoperative SE was within  $\pm 2.00$  D of emmetropia. In 31.25% (5 of 16 eyes) at 3 months, 43.75% (7 of 16 eyes) at 12 months, and 43.75% (7 of 16 eyes) at 36 months, the postoperative SE was within  $\pm 1.00$  D of emmetropia.

**Corneal Endothelium**

Preoperative mean cell density was 2345 cells/mm<sup>2</sup> (range 1934 to 2874 cells/mm<sup>2</sup>). This wide range is related to the varied corneal status of patients in this series. Twelve months after surgery, mean endothelial cell density was 2167 cells/mm<sup>2</sup> (range 1422 to 2681 cells/mm<sup>2</sup>), and at 36 months it was 2089 cells/mm<sup>2</sup> (range 1308 to 2480 cell/mm<sup>2</sup>). Mean endothelial cell loss during the first 12 months after the surgery was 7.78%. During the next 2 years, the loss was 3.12%, with a cumulative loss for the first 3 years of 10.9% (Table 1).



**Figure 3.** Preoperative BCVA and postoperative UCVA at 36 months.

**Complications**

During the surgery, the only complication observed was positive vitreous pressure and vitreous prolapse in 4 eyes (25%), all of which had previous complicated cataract extraction (3 eyes were very short and highly hyperopic). Significant postoperative flare was found in 6 eyes (60%); these eyes had an extensive anterior vitrectomy and iris manipulation, but they responded adequately to topical steroid treatment. An elevated intraoperative pressure (IOP; more than 20 mm Hg), probably steroid induced, was found in 3 eyes (18.75%) during the first 6 weeks after surgery. Once the steroids were discontinued, IOP decreased to normal values. Two patients complained of intermittent halos, and 1 patient had trauma history and an irregular pupil (Figure 5).

Postoperative CME was observed in 2 eyes (both were present preoperatively) (Figure 6), but both eyes responded angiographically well to subTenon's triamcinolone 40 mg (Trigon Depot) within 10 weeks after injection. In the second eye, visual acuity did not improve, probably because of chronic unresponsive low IOP.

**DISCUSSION**

During the past 2 decades, many surgeons have still been reluctant to perform secondary IOL implantation in aphakic eyes because of the associated risk for decreasing BCVA.<sup>16</sup> The main causes have been corneal edema and retinal complications.<sup>17</sup>

Several studies have focused on 2 secondary IOL designs: angle-supported anterior chamber IOLs<sup>1,5,10,16,17</sup> and scleral-sutured lenses.<sup>3,5,6,18-20</sup> There is no preference for either lens type at this time. Some individual factors such as age, ocular history, anatomic abnormalities, corneal status, and patient co-morbidities are taken into account to make the best choice for each patient. The general consensus is to use an anterior chamber IOL in patients older than 60 years with good endothelial cell counts and normal pupils, especially if health problems contraindicate prolonged

SECONDARY ARTISAN-VERYSISE APHAKIC LENS IMPLANTATION

**Table 1.** Preoperative and postoperative visual acuities and endothelial cell counts.

Patient	Preoperative Status	BSCVA Preop	BSCVA Postop 36 Months	UCVA Postop 36 Months	Endothelial Cell Count Preop (cells/mm <sup>2</sup> )	Endothelial Cell Count 12 Months (cells/mm <sup>2</sup> )	Endothelial Cell Count 36 Months (cells/mm <sup>2</sup> )	Variation Preop 36 Months (%)
1	Complicated cataract	20/25	20/30	20/60	2135	1954	1935	9.36
2	Complicated cataract	20/40	20/30	20/40	2514	2584	2350	6.52
3	Complicated cataract	20/60	20/60	20/100	2165	2014	1950	9.93
4	Complicated cataract	20/40	20/40	20/40	2605	2384	2360	9.40
5	Complicated cataract	20/40	20/40	20/80	2036	1422	1308	35.75
6	Congenital cataract	20/60	20/50	20/60	2674	2526	2480	7.25
7	Ocular trauma	20/100	20/80	20/200	2834	2522	2388	15.73
8	Angle-supported lens*	20/400	20/60	20/80	2112	2006	1908	9.65
9	Ocular trauma	20/200	20/200	20/400	2253	1982	1950	13.44
10	Congenital cataract	20/60	20/60	20/60	2353	2162	2068	12.11
11	Congenital cataract	20/50	20/35	20/50	2655	2410	1368	48.47
12	Angle-supported lens*	20/80	20/80	20/200	1934	1895	1886	2.48
13	Complicated cataract	20/20	20/25	20/40	2023	1833	1713	15.32
14	Subluxated lens†	20/80	20/80	20/80	2874	2681	2656	7.58
15	Complicated cataract	20/50	20/60	20/80	2028	1980	1908	5.91
16	Complicated cataract	20/80	20/80	20/80	2332	2252	2208	5.31

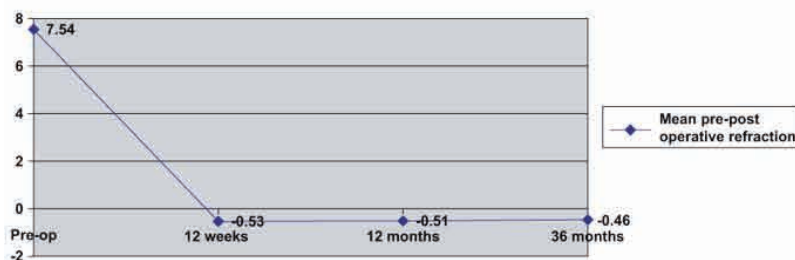
BSCVA = best spectacle-corrected visual acuity; UCVA = uncorrected visual acuity  
 \*Removal of the angle-supported lens and penetrating keratoplasty  
 †Removal of the lens and anterior vitrectomy

surgical procedures or when there is an increased bleeding risk. Sulcus-fixated posterior chamber IOLs are preferred in younger patients, especially those with a low endothelial cells count; scleral suture fixation depends on the amount of capsule support.

In this series, we studied the iris-fixated Artisan–Vervysise used as a secondary IOL in aphakic patients. The mean postoperative refraction at 36 months of -0.46 D was moderately predictable and highly stable compared that in with other published series of secondary IOL implantation in aphakic eyes.<sup>5,8</sup> Best spectacle-corrected visual acuity improved in most eyes except, temporarily, in 2 eyes with postoperative CME. Both patients subjectively observed similar clinical complaints, but at different postoperative time points: 4 weeks and 14 weeks, at which time visual acuity was clearly reduced over a period of 2 to 3 days. Both eyes regained 50% of the visual acuity loss

during the first 2 weeks. The first eye resolved completely after 4 months. The second eye did not resolve, probably because of secondary chronic unresponsive low IOP.

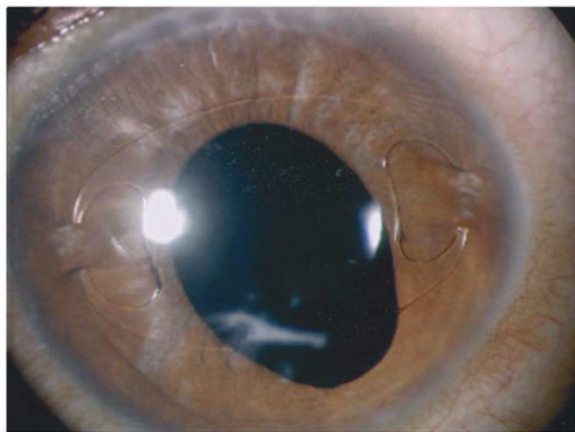
Endothelial cell loss during the first 3 years in this study was 10.9%, which is similar to other studies<sup>21,22</sup> examining the phakic Artisan–Vervysise lens. On the other hand, some authors<sup>23</sup> have not found any difference respect to endothelial cell loss and endothelial morphometric values between anterior chamber IOL implantation and sutured-fixated posterior chamber IOL implantation. Nevertheless, a greater endothelial attrition at 1 and 2 years after sutured posterior chamber lens implantation has been studied.<sup>24</sup> The greatest decrease in endothelial cell density is observed during the first 12 months (7.78%) and therefore most likely relates to the surgery.<sup>21</sup> During anterior chamber lens implantation in phakic eyes, the highest surgical risk for the endothelium is contact between



**Figure 4.** Refraction stability 12 weeks postoperatively.

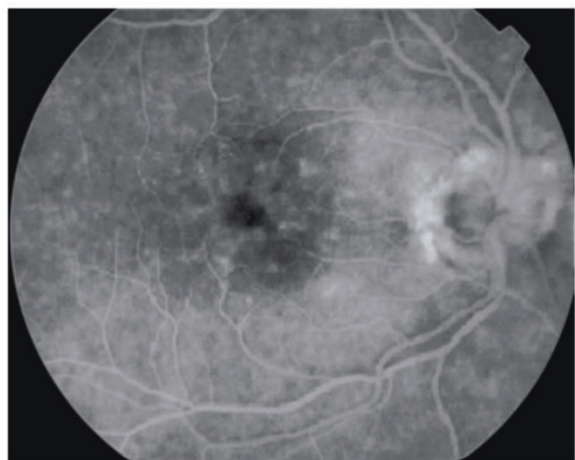


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**Figure 5.** Artisan-Verysise lens in an aphakic eye with trauma history and irregular pupil.

the endothelium and the IOL or surgical instruments. This is also true in aphakic eyes, although from our point of view factors such as anterior chamber collapse because of aphakic low scleral rigidity and the turbulence during the anterior vitrectomy maneuvers are more important. Two hypotheses describe how an iris-claw lens may induce postoperative endothelial cell loss. The mechanical hypothesis has different implications on aphakic eyes versus phakic eyes. While the distance between IOL and endothelium is more than adequate in aphakic cases (above 3.5 mm, including those associated with penetrating keratoplasty), there is likely more movement or IOL decentration than in phakic eyes. The inflammatory hypothesis involves biological mediators as an etiology in chronic cell loss and CME.



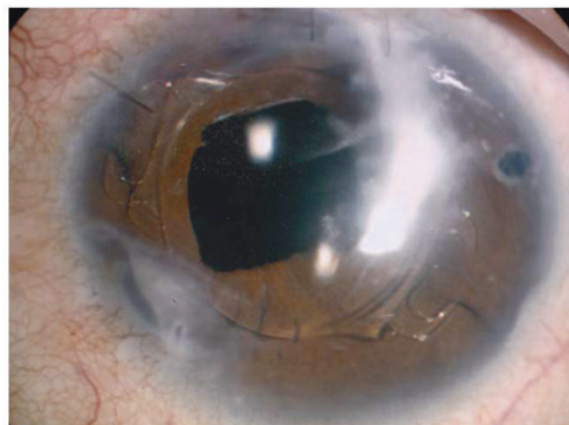
**Figure 6.** Cystoid macular edema following Artisan-Verysise lens implantation.

Endothelial cell counts criteria in aphakic IOL implantation are quite different than the criteria used in phakic IOL implantation studies. This is a consequence of the very different population who are typical candidates for secondary implantation. Most of them are older and have had at least 1 previous intraocular surgery, both factors contributing to the low preoperative endothelial cell counts.<sup>25-27</sup> In 1 eye in our study, we observed a postoperative increase in central cell density. This may be related to the discontinuation of an aphakic soft contact lens used before surgery, perhaps to a repopulation of the central corneal endothelium with cells from the periphery, or both.

The complication rate reported in previous studies with angle-supported or sulcus-sutured lenses is higher than in this study, although it is very difficult to properly compare these different groups because of the diversity of pathology and the varied number of eyes. Although it is difficult to learn proper surgical technique for Artisan-Verysise lens implantation, fixation, and centration,<sup>22</sup> we think that it will result in fewer complications for an experienced surgeon than other styles of secondary implantation, including pupillary distortion, CME, retinal detachment, and vitreous hemorrhage.

More data are required to evaluate the mid- and long-term safety of this lens style for secondary implantation. Nevertheless, the simplicity of the procedure compared with transscleral sutured techniques, the reversible-adjustable fixation, and centration characteristics and the relatively low rate of associated complications, compared with angle-supported anterior chamber lenses, make the Artisan-Verysise lens an attractive alternative.

The main disadvantage thus far has been wound size because the Artisan-Verysise lens is a single-piece PMMA lens.



**Figure 7.** Foldable Artiflex lens in an aphakic eye.



We have just started with the Artiflex project (Figure 7), a soft silicone iris fixated IOL that may be introduced through a 2.75 to 3.2 mm incision. Although it is too early for any clinical evaluation, this project might significantly improve our clinical and refractive results in both phakic and aphakic eyes.

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## 11.4 Long-Term Follow-Up of the Corneal Endothelium After Artisan Implantation for Unilateral Traumatic and Unilateral Congenital Cataract in Children

Odenthal MTP, Sminia ML, Pricck LJJM, Gortzak- Moorstein N, Völker-Dieben HJ  
Cornea 2006; 25: 1173-1177

**Purpose:** To retrospectively estimate the long-term corneal endothelial cell loss in children after perforating corneal trauma and implantation of an iris-fixated anterior-chamber intraocular lens (IOL), either the Artisan aphakia lens or the Artificial Iris Implant, and to compare this corneal endothelial cell loss to that in children who received an Artisan aphakia lens to correct aphakia after cataract extraction for unilateral congenital cataract.

**Methods:** A retrospective study was performed, evaluating the charts and endothelial photographs of 6 patients with unilateral traumatic cataract, with a mean age at IOL implantation of 9.5 years (range: 5.8–12.8 years) and a mean follow-up after IOL implantation of 10.5 years (range: 8.0–14.7 years), and of 3 children who were operated on for unilateral congenital cataract at a mean age of 2.7 years and who received an Artisan aphakia IOL, with a mean follow-up after IOL implantation of 9.5 years (range: 4.7–14.5 years). Parameters that were studied were central endothelial cell density (CECD) in both the operated and the normal eye at the last follow-up visit, percentage of cell loss in the operated eye compared with the normal eye, and length and location of the corneal scar in the injured eye.

**Results:** In the traumatic cataract group, CECD was, on average, 41% (range: 22%–58%) lower in the operated eye ( $1.647 \pm 322$  [SD] cells/mm<sup>2</sup>) than the normal eye ( $2.799 \pm 133$  cells/mm<sup>2</sup>). A significant negative linear correlation was found between the length of the corneal perforation scar and CECD. In the congenital cataract group, no statistical difference in CECD was found between the operated ( $3.323 \pm 410$  cells/mm<sup>2</sup>) and the unoperated ( $3.165 \pm 205$  cells/mm<sup>2</sup>) eye.

**Conclusion:** Endothelial cell loss 10.5 years after iris-fixated IOL implantation for traumatic cataract was substantial and related to the

length of the corneal scar of the original trauma. In children operated on for congenital cataract, no difference was found in CECD in the operated and unoperated eyes 9.5 years after Artisan aphakia IOL implantation.

**Key Words:** corneal endothelium, traumatic cataract, children, cataract surgery, intraocular lens

(Cornea 2006;25:1173–1177)

For the surgical correction of traumatic aphakia, several options are available. One of these is the Artisan aphakia intraocular lens (Ophtec, Groningen, The Netherlands). Despite more than 10 years of favorable clinical experience with this intraocular lens (IOL) in the Netherlands and elsewhere, very few studies on the use of the Artisan lens for this indication have been published.<sup>1–6</sup> In phakic eyes, uncertainty exists on the long-term safety of this iris-fixated anterior-chamber lens to the corneal endothelium.<sup>7–11</sup> Because several studies have shown that endothelial cell loss after intraocular surgery continues at a higher rate than the normal age-related cell loss rate,<sup>12,13</sup> safety with regard to the corneal endothelium is even more important in the pediatric age group than in adult patients. Only a few studies have been published on the corneal endothelium after IOL implantation in children, and only 3 of these were published in the last 10 years.<sup>14–20</sup> For this reason, we performed a retrospective follow-up study on the corneal endothelium in children with monocular traumatic aphakia, corrected with an Artisan lens. We compared the endothelial cell parameters in the injured eye to those in the normal eye of the same patient and correlated the amount of cell loss in the injured eye compared with the normal eye to the length of the scar of the original traumatic corneal perforation. We also compared these results with endothelial cell counts in children with an Artisan aphakia lens in only 1 eye after cataract extraction for monocular congenital cataract, without a history of trauma.

### MATERIALS AND METHODS

We retrospectively studied the charts of 10 patients, 3 girls and 7 boys, who were operated on for unilateral penetrating ocular injury requiring cataract extraction under

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the age of 14 years and who also underwent Artisan lens implantation, either at the time of the primary surgery or as a secondary procedure. All 10 eyes underwent cataract extraction (CE) through irrigation and aspiration at the time of surgical repair of the corneal laceration. Five of 10 patients received a standard Artisan aphakia lens: 1 patient during the primary surgical procedure and in the remaining 4 as a secondary procedure. Surgical technique of implantation of an aphakia Artisan IOL is similar to the technique in phakic Artisan IOL implantation and has been described elsewhere.<sup>1,2,4-9</sup> The other 5 patients received an individually designed iris-fixated Artisan lens with a colored iris diaphragm to treat photophobia caused by traumatic partial aniridia or traumatic mydriasis and aphakia: the custom-made Artificial Iris Implant. In 6 of these 10 patients with unilateral traumatic cataract, photographs of the central corneal endothelium were available of both eyes: these patients were included in the study. Clinical results and complications in these patients are described in Table 1.

The Artificial Iris Implant was designed using an anterior-segment photograph of the affected eye and information from the surgeon indicating the preferred location of the "claws" because atrophic iris tissue is not suitable as fixation site (see Fig. 1 for an example of an eye with an Artisan Artificial Iris Implant). Both the standard aphakia IOL and the artificial iris implant are made of polymethyl methacrylate (PMMA) material; the standard aphakia IOL is totally transparent, and in the Artificial Iris Implant, the central optic part is transparent. For the peripheral part, a choice can be made between 4 colors: black, blue, green, and brown. The pigment is molecularly bound in the PMMA. The size of all Artisan aphakia IOLs used in patients in this study was 5 × 8.5 mm, 5 mm being the diameter of the optic. The smallest diameter of the Artificial Iris Implants varied from 6 to 8.5 mm; the largest diameter was 8.5 mm. Diameter of the optic was 4 mm. All IOLs were implanted through a corneoscleral incision with a size corresponding to the smallest diameter of the IOL. The claws each were fixated (or "inclavated") by grasping a piece of midperipheral iris and

pulling it into the claw by special toothed forceps or by using a bent needle to push some iris tissue into the claw. The forceps or bent needle was introduced into the eye through separate side ports and not through the main incision. Healon was used in all cases. No additional iris sutures were used. Implanting the Artisan Artificial Iris Implant requires more skill than implanting a standard Artisan aphakia IOL because it is mandatory to avoid excessive manipulation of the iris in these already severely damaged eyes and to avoid atrophic parts of the iris in placing the claws.

The endothelial photographs were made with a non-contact auto-focus SP2000P specular microscope (Topcon Corp., Tokyo, Japan), after an average follow-up period of 10.5 years after IOL implantation. All images were analyzed using Imagenet 2000 software (Topcon Corp.). Using this program, the cell borders were corrected interactively by 1 of the authors (M.T.P.O.) before endothelial cell parameters were computed.

We wanted to know whether the size and location (central or not central) of the corneal laceration was related to the amount of endothelial cell loss in these eyes. The size of the corneal scar had been measured in all eyes at a follow-up visit by aligning the slit beam of the slit lamp to the corneal scar and using the slit length indication on the Haag Streit BQ slit lamp (Bern, Switzerland) to estimate the size of the scar. The location of the scar was documented by drawings in the charts, and in most cases, was documented by anterior-segment photography as well.

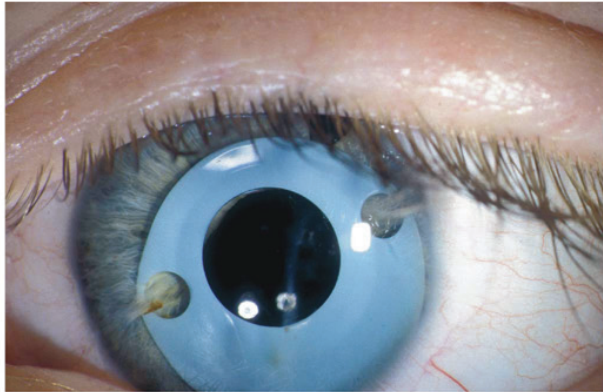
We also wanted to find out whether the endothelial cell loss should be attributed to the presence of the Artisan lens or to the original trauma and the subsequent repair surgery, including lens aspiration. Therefore, we retrospectively examined the endothelial photographs of 3 children who were operated on for unilateral congenital cataract in our clinic at a mean age of 2.7 years and received an Artisan aphakia lens, with a mean follow-up of 9.5 years after lens implantation (see Fig. 2 for an example of an eye of a child with a standard Artisan aphakia IOL). All patients were operated on by the same surgeon (N.G.).

TABLE 1. Patient Characteristics

Patient	Sex	Eye	Type of Artisan Aphakia Lens	Age at CE (yr)	Interval Between CE and IOL Implantation (yr)	Follow-Up Period After IOL Implantation (yr)	Location of Scar (Central or Not Central)	BSCVA	Other Procedures Besides IOL Implantation
1	M	OS	Standard aphakia	5.6	0.2	14.7	Not central	20/100	RD surgery (4 times)
2	M	OS	Standard aphakia	8.8	0.8	8.5	Central	20/30	YAG laser of vitreous strand
3	F	OD	Standard aphakia	10.3	0	8.0	Not central	20/100	No
4	M	OS	Custom-made with colored artificial iris	7.7	5.1	12.5	Not central	20/30	No
5	M	OS	Custom-made with colored artificial iris	6.3	2.9	10.6	Not central	20/200	No
6	M	OS	Custom-made with colored artificial iris	6.9	2.8	8.3	Not central	20/100	IOL refixation (after partial dislocation due to blunt trauma)
Mean ± SD				7.6 ± 1.7	2.0 ± 2.0	10.5 ± 2.7			

F, female; M, male; CE, cataract extraction; IOL, intraocular lens; BSCVA, best spectacle-corrected visual acuity; RD, retinal detachment; HM, hand motion.





**FIGURE 1.** Example of an eye with an Artisan artificial iris implant: left eye of patient 4.

Endothelial cell loss was estimated by comparing central endothelial cell density (CECD) of the operated eye with CECD of the normal, nonoperated eye at the last follow-up visit.

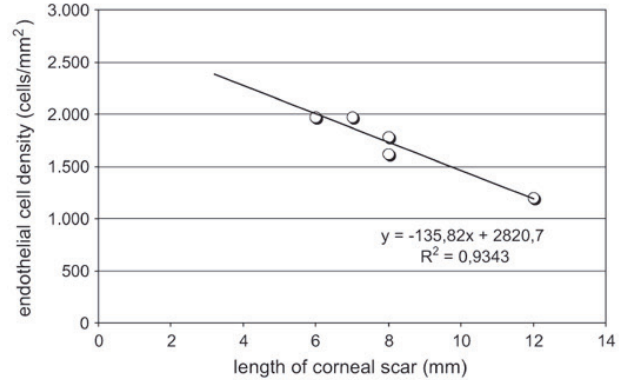
For statistical analysis, the paired Student *t* test was used to compare endothelial cell densities and parameters between the operated and unoperated eyes in each group. To find a possible correlation between length of the corneal perforation and corneal cell loss, we performed linear regression analysis.

### RESULTS

In 6 of 10 patients with an Artisan lens for traumatic aphakia, endothelial photographs were made at the last follow-up visit, with a mean follow-up period of 10.5 years after lens implantation. Details of these 6 patients can be found in Table 1. In 3 other patients of the total group of 10 patients, the cornea of the operated eye was clear at the last follow-up



**FIGURE 2.** Typical appearance of an eye with the standard Artisan aphakia IOL.



**FIGURE 3.** Central endothelial cell density and length of corneal scar.

visit, with a mean follow-up period of 10.8 years after IOL implantation, except for the corneal scar resulting from the trauma, but endothelial photographs were not taken. In the remaining patient, endothelial photographs could not be made because of the development of calcific band keratopathy, 3 years after the original trauma.

The 6 eyes with an Artisan lens for traumatic aphakia and a clear cornea, in which endothelial photography was performed at the last follow-up visit, showed a substantially lower endothelial cell count than the normal fellow eyes. These trauma eyes had a substantial mean endothelial cell loss of 41% (range: 22%–58%) compared with the normal fellow eye. At the last follow-up visit, no significant difference was found in mean endothelial cell loss (compared with the normal eye) between the eyes with a custom-made Artisan Iris Implant lens (42%) and the eyes with a standard Artisan aphakia lens (40%).

Endothelial cell loss was related to the size of the wound. For the calculation of a possible correlation between size of the corneal laceration and central endothelial cell density, we excluded 1 eye with a central corneal perforation and a central endothelial cell density of 1349 (cell loss of 53%), because a lower cell density next to the site of the perforation than away from the perforation was observed by Kletzky et al.<sup>21</sup> In the remaining 5 eyes, a strong negative correlation between endothelial cell density and length of the corneal scar was found (Fig. 3).

In the eyes operated on for unilateral congenital cataract, no significant endothelial cell loss was found when the operated eyes were compared with the nonoperated fellow eyes (Table 2). The endothelial morphologic parameters, coefficient of variation of cell size, and percentage of hexagonal cells showed no statistical difference between the operated and unoperated eyes in all groups.

### DISCUSSION

In the management of pediatric traumatic aphakia, several treatment options exist in the absence of adequate capsular support: the use of a contact lens, an angle-supported anterior-chamber IOL, a sulcus-sutured lens, and the Artisan



**TABLE 2.** Endothelial Cell Parameters

	Patients Operated on for Unilateral Congenital Cataract		Patients Operated on for Traumatic Cataract	
	Operated eye	Unoperated eye	Operated eye	Unoperated eye
N	3	3	6	6
Mean age on date of IOL implantation (yr)	2.7	NA	9.5	NA
Mean follow-up time (yr)	9.5	NA	10.5	NA
Range (yr)	4.7–14.5	NA	8.0–14.7	NA
Mean endothelial cell density (cells/mm <sup>2</sup> )	3,323	3,165	1,647*	2,799
Range	2,875–3,679	2,980–3,386	1,197–1,967	2,542–2,894
SD	410	205	322	133
Mean % cell loss, compared with unoperated eye	–6	NA	41	NA
Range	–23 to 15	NA	22–58	NA
Coefficient of variation of cell size	27	26	29	25
% Hexagonal cells	74	73	70	64

\*Cell density difference between operated and unoperated eye is statistically significant ( $P \leq 0.005$ , Student *t* test).  
IOL, intraocular lens; NA, not applicable.

lens. The Artisan lens is an iris-fixated lens that recently received US Food and Drug Administration (FDA) approval for the correction of high ametropia in the phakic eye. In The Netherlands and elsewhere, an iris-fixated lens of similar design has been widely and successfully used for more than 10 years for the correction of aphakia in the absence of capsular support. This is the first long-term follow-up study on the impact on the corneal endothelium of this lens for this indication in children.

Only a few studies have been published that include reports on endothelial cell loss after surgery for traumatic cataract after perforating ocular injuries. In a paper by Kletzky et al,<sup>21</sup> mean endothelial cell loss in the injured eyes of 12 patients compared with the uninjured eyes was 58% near the wound versus 46% away from the wound. The age of the 12 patients was not mentioned, and follow-up ranged from 3 months to 3.4 years after repair of the corneal laceration and lensectomy. None of the patients received an IOL. The authors found a strong positive correlation between size of the corneal laceration and endothelial cell loss. In our study, we measured only central corneal endothelial cell parameters. Mean endothelial cell loss in the eyes with an Artisan lens compared with the uninjured eyes was on average 41%: in 1 eye with a central perforation, the cell loss was 53%, and in the remaining eyes, it was 38% on average, after a mean follow-up of 10.5 years. We also found a strong correlation between size of the corneal laceration and central endothelial cell density in the 5 eyes in which the scar was not in the center of the cornea. The eye with the highest endothelial cell loss (58%) also had the largest perforation: 12 mm (limbus to limbus). Roper-Hall et al<sup>22</sup> measured cell loss in 7 patients that had lens surgery for traumatic cataract varying from 3.5% to 72.5% (mean: 32%) compared with the normal eye with a follow-up of approximately 2 years. Churchill et al<sup>19</sup> measured endothelial cell loss compared with the other eye in 3 children with relatively small corneal perforations (eg, caused by a pin) and traumatic cataract after a mean follow-up of 9 years and found a mean cell loss of 30%. Kora et al<sup>15</sup> found a mean cell loss of 44% in

5 eyes of children with traumatic cataract, mean age 9.9 years, with a mean follow-up of 6.8 years after implantation of a posterior-chamber IOL. One further patient in that study received an angle-supported anterior-chamber IOL at the age of 14 and showed 70% cell loss after 8 years of follow-up.

We were surprised to find no difference in endothelial cell density between eyes with the Artisan aphakia IOL and eyes with the Artificial Iris Implant, because a larger corneoscleral incision is usually necessary for implantation of this device.

In 1 of 4 children of whom endothelial photographs were not available, the cornea developed calcific band keratopathy 3 years after artificial iris IOL implantation in an eye that experienced an extensive perforating trauma with a wound including the whole corneal diameter and extending into the sclera, iris, and lens. This eye also developed secondary glaucoma, necessitating surgical intervention. We speculate that this eye suffered from persistent low-grade inflammation, causing the calcific band keratopathy. Persistent low-grade inflammation is common after perforating trauma and is, in our opinion, not related to this type of IOL.

Unfortunately, an age-matched group of patients with an Artisan aphakia IOL in 1 eye, but without perforating injury, was not available. In the group of 3 children that were operated on for congenital cataract and received an Artisan aphakia IOL, cell densities in the unoperated eyes were higher than in the uninjured eyes of patients in the trauma group. This finding is not surprising, given the difference in mean age (2.7 vs. 9.5 years) of the patients in both groups and the relatively large influence of age on cell density in children.<sup>23,24</sup> Mean cell density in the operated eyes in the patients in the congenital cataract group was not different from that in the unoperated eyes. This finding is remarkable because, in adults, a cell loss of at least a few percent after cataract surgery is usual even with modern techniques.<sup>13,25–27</sup> In children, Basti et al<sup>14</sup> found a mean cell loss of 6.5% in 18 eyes of children operated on for congenital cataract at a mean age of 9.3 years and a follow-up period of 6 to 9 months, and Kora et al<sup>15</sup> found a mean cell loss



of 6% after a mean follow-up of 4 years after implantation of a posterior-chamber IOL in 6 eyes of children with congenital cataract, operated on at a mean age of 11.3 years. Lifshitz et al<sup>20</sup> recently reported on the corneal endothelium of 2 children, 4 and 12 years of age, after Artisan aphakia IOL implantation after lens extraction for a subluxated lens. After a follow-up of 8 months, they also did not find any endothelial cell loss in the operated eyes compared with the unoperated eyes. The corneal endothelium in children may be more resistant to surgical damage than the endothelium in adults. We feel that this finding needs confirmation in a larger group of patients, and it may not be applicable to phakic IOL implantation in children, where the distance of the IOL to the corneal endothelium is smaller because of the presence of the natural lens.<sup>28</sup> However, we may conclude that the Artisan aphakia lens in any case does not seem to cause excessive endothelial cell loss compared with other studies of traumatic aphakia corrected with a contact lens or posterior-chamber IOL. The substantial cell loss in eyes after surgery for traumatic cataract seems to be caused primarily by damage caused by the perforating trauma and the repair surgery.

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## 11.5 Penetrating keratoplasty combined with posterior Artisan iris-fixated intraocular lens implantation.

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### ABSTRACT.

**Purpose:** To present a new surgical technique combining penetrating keratoplasty and open-sky posterior iris fixation of the Artisan® iris-claw intraocular lens (IOL) for treatment of pseudophakic bullous keratopathy in a case series of five patients. **Methods:** A graft diameter of 8.25 mm was chosen. The formerly implanted angle-supported IOL was removed. The IOL was enclosed, entrapping a fraction of the mid-peripheral iris within the haptics whilst being held firmly with the implantation forceps. The corneal button was sutured to the recipient bed with 10-0 nylon sutures. A specular microscope was used for making an endothelial cell count. Patients underwent an ultrasound biomicroscope (UBM) scan before and 6 months after surgery and postoperative macular oedema was assessed by optical coherence tomography (OCT). The minimum follow-up was 12 months. **Results:** Visual acuity (VA) improved in all five cases (mean best corrected VA was 0.4 postoperatively versus 1.28 preoperatively). No complications were noted. The mean endothelial cell density obtained after 1 year was 1508 cells/mm<sup>2</sup>. The UBM study showed a deep anterior chamber and an open iridocorneal angle of 360 degrees in all cases.

**Conclusion:** The implantation of the Artisan device behind the iris better preserves the anatomy of the anterior segment with respect to the iridocorneal angle.

**Key words:** Artisan – bullous keratopathy – penetrating keratoplasty – ultrasound biomicroscope (UBM) – surgical technique

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### Introduction

We present a new surgical technique combining penetrating keratoplasty and open-sky posterior iris fixation of

the Artisan® (Verisyse™, AMO, Mougins, France) iris-claw intraocular lens (IOL) for the treatment of pseudophakic bullous keratopathy in five

patients. This surgical technique was designed to respect anterior segment anatomy as closely possible; the ideal position for the IOL after extracapsular cataract extraction is behind the iris plane. We confirmed that the anterior segment anatomy was preserved with our technique (normal anterior chamber depth and wide iridocorneal angle) by systematically examining patients postoperatively with the ultrasound biomicroscope (UBM) (Zeiss-Humphrey, Le Pecq, France) developed by Pavlin et al. (1991).

This technique was effective in our series of five patients, who presented with major bullous keratopathy induced by cataract surgery associated with anterior chamber angle-supported IOL implantation, but with no history of macular cystoid oedema.

### Materials and Methods

Each patient underwent a UBM scan and systematic ophthalmological examination the day before surgery. Best corrected visual acuity (BCVA) and intraocular pressure (IOP) (measured with a contact Goldman applanation tonometer) were noted. The surgical procedure was performed under sub-Tenon's anaesthesia in two cases and under general anaesthesia in three cases. All operations were performed by the same surgeon (PD). All patients



underwent corneal trephination with the Hanna trephine. The recipient's corneal button was then cut out with scissors. A graft diameter of 8.25 mm was chosen (8 mm for the recipient bed). In all patients, removal of the angle-supported IOL implanted previously was followed by complementary anterior vitrectomy. In two cases, this was associated with synechiolysis of the angle. Iridoplasty was performed in one case to centre the pupil. After the intracameral injection of acetylcholine (to constrict the pupil to facilitate centering), an Artisan IOL was implanted as described in Figs 1 and 2. The lens was rotated into the desired position (haptics at 3 o'clock and

9 o'clock). The IOL was enclosed, entrapping a fraction of the mid-peripheral iris within the haptics whilst being firmly held with the Artisan implantation forceps. The donor's corneal button was then sutured to the recipient bed with 10-0 nylon sutures. All patients received topical dexamethasone and neomycin four times per day for 1 month after the operation. This treatment was tapered over the following 4-6 months. It is to be noted that neomycin is only necessary for a short time after surgery, and may induce bacterial resistance. However, dexamethasone alone is not widely available in France, so we had to use the combination of dexamethasone + neomycin in our protocol. After 6 months, each patient was re-examined. Best corrected VA and IOP were noted and compared to preoperative data. The graft clarity was assessed by slit-lamp examination. Endothelial cells were counted with a contact specular microscope (EM-1000; Tomey, Erlangen, Germany). All patients underwent a UBM scan 6 months after surgery and postoperative macular oedema was assessed by optical coherence tomography (OCT) (OCT 3; Zeiss-Humphrey).

## Results

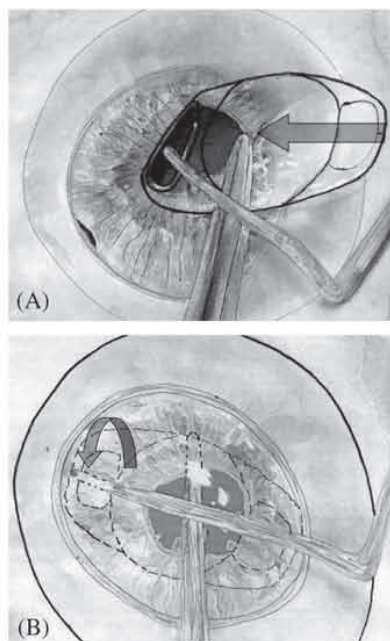
All five patients were followed at least for 12 months. The pre- and postoperative (6 months after surgery) data are summarized in Table 1. The mean age of our patients at the time of surgery was 79.6 years. Visual acuity improved noticeably in all cases (mean BCVA was 0.4 6 months postoperatively versus 1.28 preoperatively). In all cases, VA remained stable for the entire follow-up period. No complications were noted in this preliminary series; in particular, we observed no cases of IOL dislocation. No patient presented postoperative cystoid macular oedema on OCT scans. Slit-lamp examination showed that all grafts were clear after 6 months and that the anterior chamber was quiet in all patients. The mean endothelial cell density obtained after 6 months was 1487 cells/mm<sup>2</sup>. The UBM study showed a deep 'neo' anterior chamber (depth measured between the upper face of the IOL and the endothelium) and an open iridocorneal angle of

360 degrees in all cases. The clipping zone of the haptics was clearly visible along the 3 o'clock to 9 o'clock axis, provoking a depression in the iris plane. There was no contact between the IOL and the endothelium, or between the haptics and the ciliary body. Pigmentary dispersion that might have been anticipated, due to possible rubbing between the iris and the anterior face of the IOL, was not observed postoperatively.

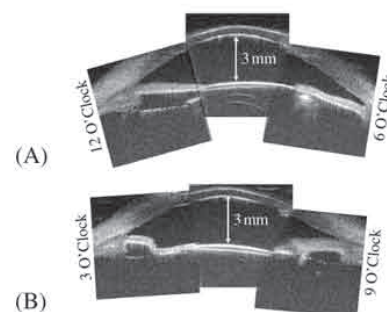
The mean IOP was lower after surgery (15.6 mmHg versus 19.2 mmHg the day before surgery). Longterm follow-up showed that these data tended to remain stable over time.

## Discussion

Patients who develop bullous keratopathy following cataract surgery with anterior chamber angle-supported IOL implantation typically require penetrating keratoplasty, due to the lack of a better technique. The first steps of this procedure give the surgeon access to the anterior segment via the open-sky approach. This facilitates IOL explantation, anterior vitrectomy, synechiolysis, pupilloplasty and IOL implantation. Once the former IOL has been removed, the surgeon may leave the patient aphakic. Aphakia may be corrected postoperatively by a gas-permeable contact lens that will help correct keratoplasty-induced astigmatism. In our experience, older patients have



**Fig. 1.** Schematic representation of the open-sky posterior Artisan IOL enclavation procedure. (A) The Artisan IOL (polymethylmethacrylate with a convex concave profile) is inserted with the implantation forceps and slid through the pupil area; a Sinsky-type manipulating instrument is used to recline the iris sphincter gently. (B) The IOL is now behind the iris plane. While the IOL is maintained horizontally with the forceps, centred over the pupil, with the haptics positioned at 3 o'clock and 9 o'clock, the iris is entrapped using the Sinsky-type manipulating instrument (arrow), by applying gentle pressure over it through the slotted centre of the lens haptic. A sufficient amount of iris tissue must be delivered through the haptic slot to create a fold to ensure lasting lens stability and to prevent it from moving into the vitreous. The Sinsky-type manipulator is then retracted, taking care not to damage the iris surface.



**Fig. 2.** Postoperative composite picture of three longitudinal axial UBM echograms of the Artisan IOL implanted under the iris in patient no. 2. (A) The IOL appears hyperechogenic with marked backscatter effect. The anterior chamber is deep (3 mm). (B) On the 3 o'clock/9 o'clock plane, the clipping zone of the haptics is clearly visible, provoking a depression of the iris plane. (A) and (B) demonstrate that the iridocorneal angle is wide (360 degrees).



**Table 1.** Demographic, preoperative and postoperative data for patients 1–5.

Patient	Sex	Age (years)	Eye	Preop VA IM	Preop VA Snellen	Postop VS IM	Postop VA Snellen	Preop IOP	Postop IOP	OCT ME	Clarity	Endothelial cell count per mm <sup>2</sup> at 6 months	Endothelial cell count per mm <sup>2</sup> at 1 year
1	F	88	OD	1.5	20/630	0.5	20/63	18	15	–	4	1535	1600
2	F	87	OD	1.5	20/630	0.4	20/50	22	17	–	4	1655	1645
3	M	82	OS	1.3	20/400	0.5	20/63	19	12	–	4	1380	1435
4	M	76	OD	0.8	20/125	0.1	20/25	20	19	–	4	1320	1300
5	M	65	OS	1.3	20/400	0.5	20/63	17	15	–	4	1545	1560
Mean		79.6		1.28		0.4		19.2	15.6		4	1487	1508

Preop VA IM = preoperative visual acuity measured in logMAR (log of the minimum angle of resolution). It states the visual acuity in absolute terms and makes the calculation of a mean visual acuity possible.

Postop VA IM = postoperative visual acuity measured in logMAR.

Data also appear in Snellen acuity (Preop VA Snellen)/(Postop VA Snellen).

Preop IOP = preoperative intraocular pressure.

Postop IOP = postoperative intraocular pressure.

OCT ME = detection of macular oedema with ocular coherence tomography.

difficulty in dealing with contact lens care, and permanent lens wear is not advisable on a corneal graft. Although recently developed angle-supported IOLs seem to be less harmful to the corneal endothelium than their predecessors, they are still not ideal (Hara 2004). Their iridocorneal angle fixation inevitably leads to endothelial cell loss and bullous keratopathy. The learning curve for implanting transcleral sulcus sutured IOLs, especially during open-sky surgery, is long and steep. Their complications include chronic inflammation, IOL–iris contact, pigment dispersion, high aqueous flare, vitreous incarceration and BCVA loss due to cystoid macular oedema (Dadeya et al. 2003). Current-generation refractive, iris-fixed, anterior chamber IOLs, such as the Artisan, leave enough space between themselves and the endothelium to avoid harming the endothelium in phakic and aphakic eyes with genuine uncut corneas (Budo et al. 2000). Artisan IOLs are placed inside the anterior chamber and clawed onto the mid-peripheral iris. They have previously been used in combination with keratoplasty for the surgical management of aphakic bullous keratopathy (Kanellopoulos 2004) and for the correction of high myopia after penetrating keratoplasty (Moshirfar et al. 2004). Although penetrating keratoplasty usually creates irregular astigmatic patterns (Karabatsas et al. 1999), we found that when the Artisan IOL is clipped to the iris the iridocorneal angle is closed significantly and the anterior chamber becomes shallow. These

findings are consistent with our UBM findings obtained with a preliminary series of eight patients grafted and implanted according to classic Artisan protocol. The implantation of the Artisan IOL in the anterior chamber modified the parameters defined by Pavlin & Foster (1992) (angle-opening distance, iridocorneal angle, anterior chamber depth). This led us to implant the Artisan device behind the iris. We hoped that this would better preserve the anatomy of the anterior segment. Intraocular pressure values may have decreased postoperatively because the anatomical iridocorneal angle was respected. The absence of contact between the endothelium and the IOL explains the good cellular density noted in all cases after 6 months. The BCVAs obtained with our technique after 6 months are similar to those published in a previous series in which patients were treated with a combination of penetrating keratoplasty and anterior over-the-iris Artisan IOL clipping (Kanellopoulos 2004). The absence of contact between the IOL and the ciliary body, and of postoperative aqueous flare in the anterior chamber, seem to have preserved patients from loss of BCVA by cystoid macular oedema. Our technique also offers the advantage of being compatible with the newly developed posterior lamellar keratoplasty techniques (Melles et al. 2000). Posterior clipping in an aphakic eye is still possible even in the absence of open-sky access.

However, the technique has to be modified in the absence of open-sky access: a non-penetrating pre-incision

measuring 6.2 mm at 12 o'clock is followed by a corneal incision to allow the introduction of the Artisan device in the anterior chamber after injection of a viscoelastic substance. Two paracenteses of 1.2 mm (one beginning at 2 o'clock and one at 10 o'clock) will be needed for enclavation, as is the case for classic Artisan implantation in phakic eyes (Budo et al. 2000). Once inside the anterior chamber, the IOL is rotated to the 3 o'clock/9 o'clock position. Using the enclavation forceps, it must be slid behind the iris as previously described. The iris entrapment technique does not differ from that used in open-sky surgery, but the Sinsky manipulator is introduced through the paracenteses.

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