Diploma Thesis

# QUALITY OF VISION AND COMPLICATIONS WITH THE I-CARE PHAKIC IOL

Submitted by

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Graz, April 2009

## *Affidavit*

*Herewith I, Sophie Plainer, declare that I have written the present diploma thesis fully on my own and without any assistance from third parties.*
*Furthermore, I confirm that no sources have been used in the preparation of the thesis other than those indicated in the thesis itself.*

Graz, April 2009

Sophie Plainer

# Preface

During the last years, the implantation of phakic intraocular lenses for correction of ametropia has gained importance. Especially for higher refraction errors, where corneal procedures pose a risk for iatrogen keratektasia, pIOL implantation is a very suitable treatment option. [1,2,3]

There are many different types of pIOLs, which have been optimized in design and material to guarantee better vision and safety. Thus long-term outcomes of many lenses have not been evaluated.

The I-CARE phakic intraocular lens (Corneal, France) was implanted at the University-Eye Clinic Graz in the time between 2003 to 2006. There are two short-term studies about this pIOL [4,5] and their conclusion was that this lens model has a high level of efficacy and safety as well as a stable and predictable refractive outcome.

Now, almost 6 years after the first I-CARE lens was implanted, the aim of this study is to evaluate the long-term outcomes of this lens type.
Although the pIOL is no longer being implanted, the results of the study are relevant as there are still many patients with an implanted I-CARE lens today.

## Acknowledgement

I am particularly grateful to my supervisor Univ.-Doz. Dr. med. Navid Ardjomand for giving me the opportunity to work in the interesting field of Ophthalmology. He made a lot of efforts to support me in writing this thesis.

Furthermore I want to thank Univ.-Prof. Dr. Andreas Wedrich, Ass.-Prof. Dr. med. Bertram Vidic and all employees of the University Eye Clinic who helped and supported me in any way.

Finally I want to mention my parents and my two sisters. Thank you for encouraging me in an incredible way during the whole six years of my studies.

# Abstract

**Purpose:** To evaluate visual quality and postoperative complications of myopic patients, who underwent I-CARE anterior chamber phakic intraocular lens implantation in the period between 2003 and 2006. The aim is to estimate – in a retrospective study – whether the I-CARE lens is an appropriate treatment for patients with high myopia or not.

**Patients:** Data of 29 eyes of 16 patients (6 female, 10 male) was analyzed. The average follow up was 3.41 years (from 0.38 to 5.23 years)

**Results:** Visual acuity increased and the average BCVA rose from 0.74 preoperatively to 0.94 one year postoperatively with a mean refractive error of -0.40D. The BCVA stayed almost stable during the observation period. Uncorrected visual acuity after one year was 0.63 and also remained stable over the years.

Of all complications, endothelial cell loss was the most frequent and most serious. Preoperatively, all patients had normal endothelial cell numbers. The mean endothelial cell density loss in the first year was 2.03%, 9.05% after 2 years, 16.06% after 3 years, 21.44% after 4 years and 27.91% after 5 years. In 4 eyes, the decrease of endothelial cell density was serious and the pIOL had to be explanted.

In 17 cases, the pIOL rotated at least 10°, with the average rotation being 33°. Decentration of the pIOL appeared in 8 eyes and 12 eyes showed a mild pupil ovalisation.

Immediately postoperatively, 2 patients suffered from an excessive IOP rise up to more than 40mmHg which lead to an Urrets-Zavalia Syndrome in one case.

**Conclusion:** Although the implantation of the I-CARE phakic-IOL resulted in a stable and predictable refractive outcome, it has failed as a safe method for the correction of high myopia due to the constant decrease of the endothelial cell density over the years.

# Kurzdarstellung

**Zielsetzung:** Die Sehqualität und postoperativen Komplikationen von Patienten, denen im Zeitraum zwischen 2003 und 2006 an der Universitäts-Augenklinik Graz eine I-CARE phake Intraokularlinse implantiert wurde, wurden evaluiert.
In dieser retrospektiven Studie soll abgeschätzt werden, ob die Linse ein geeignetes Behandlungsverfahren für hohe Myopie ist.

**Patienten:** Daten von 29 Augen von 16 Patienten (6 weiblich, 10 männlich) wurden analysiert. Die durchschnittliche Beobachtungszeit lag bei 3,41 Jahren (von 0,38 bis 5,23 Jahren)

**Ergebnisse:** Es kam zu einem deutlichen Anstieg der Sehqualität, wobei sich der korrigierte Visus von 0,74 präoperativ auf 0,94 nach dem ersten postoperativen Jahr verbesserte und weitgehend stabil blieb, bei einem mittleren Refraktionsfehler von -0,40D. Der unkorrigierte Visus lag nach dem ersten Jahr bei 0,63 und blieb ebenfalls in der gesamten Beobachtungszeit stabil.
Von allen beobachteten Komplikationen war der Endothelzellverlust die häufigste und schwerwiegendste. Der mittlere Endothelzellverlust im ersten Jahr betrug 2,03%. Nach 2 Jahren erreichte er bereits 9,05%, 16,06% nach 3 Jahren, 21,44% nach 4 Jahren und schließlich lag er bei 27,91% nach 5 Jahren. In 4 Augen nahm die Endothelzelldichte dermaßen stark ab, dass die pIOL explantiert werden musste. Zusätzlich drehte sich in 17 Fällen die pIOL im Auge um mindestens 10°, die mittlere Rotation betrug 33°. Eine Dezentration war in 8 Augen zu beobachten und eine leichte Ovalisierung der Pupille trat in 12 Fällen auf.
Unmittelbar postoperativ erlitten 2 Patienten einen starken Anstieg des Augendrucks, was in einem Fall zur Ausbildung eines Urrets-Zavalia-Syndroms führte.

**Schlussfolgerung:**
Obwohl die Implantation der I-CARE Myopielinse zu stabilen und vorhersagbaren refraktiven Ergebnissen führt, stellt sie vor allem aufgrund des anhaltenden Endothelzellverlusts keine sichere Methode zur Myopiebehandlung dar.

# Index

# 1 INTRODUCTION

## 1.1 Ocular anatomy

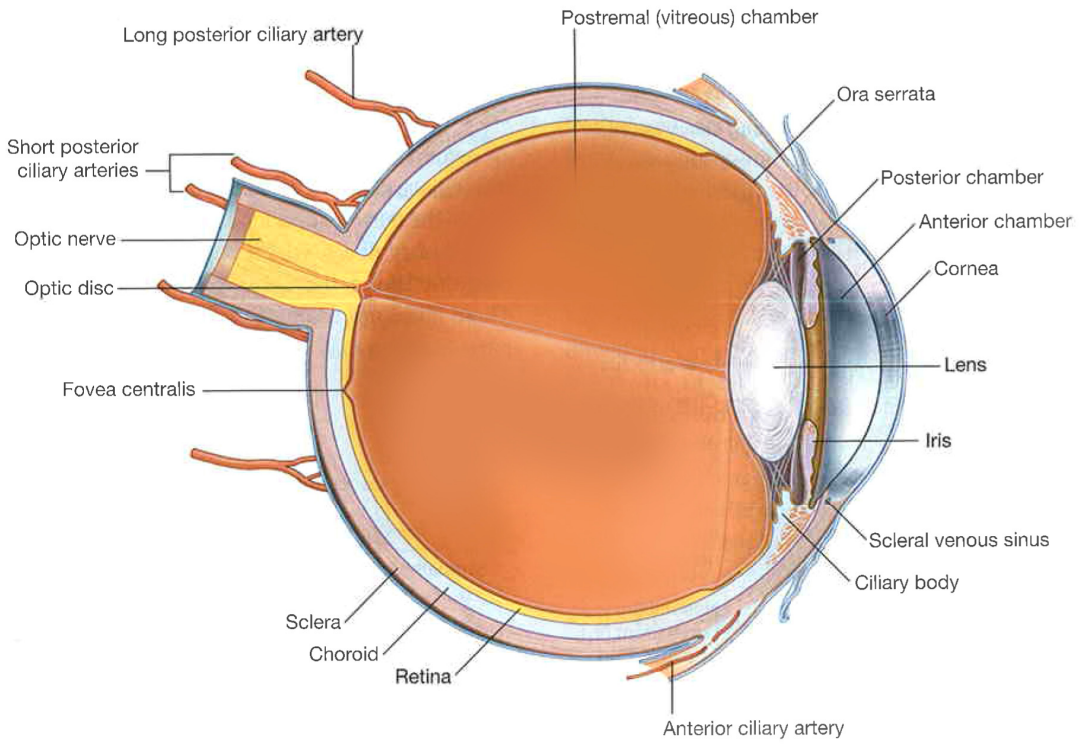



*Figure 1:* Schematic diagram of the human eye

### 1.1.1 Cornea

The cornea as the clear, transparent part of the anterior eye, is an amazing biological structure. Its optical properties are due to the highly ordered collagen, which allows light energy to pass through and, combined with its specific shape, it has the ability to bend or to refract incoming light rays. As the major focusing element of the eye, the cornea (or principally the interface between air and tear film) is responsible for about two-thirds of the eye's converging power. [6]

It is innervated by sensory nerves of the ophthalmic division of the trigeminal nerve. Because of the high density of nerves the cornea is a very sensitive organ and injuries of the corneal epithelium lead to severe pain. The thickness of the central cornea is about 500 microns. To the periphery, the corneal thickness increases to an average of 1200 microns at the limbus. The anterior surface has

an average radius of 7.8 mm while the radius of the posterior surface is about 6.7 mm. This difference enables 43 diopters of convergence lens power. [6]

The epithelium, Bowman's layer, stroma, Descemet's membrane and endothelium form the five layers of the cornea:

The corneal epithelium is a nonkeratinized, stratified squamous epithelium on a basal lamina. To this basement membrane, the basal cells are attached, which are responsible for regeneration and followed by wing cells. Surface cells form the third layer of the epithelium. The apical surface of these cells is very irregular since it is covered with microvilli, but the corneal tear film creates optical smoothness. Damages of the corneal epithelium are resurfaced very rapidly. [6]

Posterior to the basal lamina of the epithelium, there is the Bowman's layer or membrane. It is acellular, made up of unorganized collagen fibres and glycosaminoglycans and forms 2% of the overall corneal thickness. The posterior part of the Bowman's layer merges with the major component of the cornea – the corneal stroma. It constitutes about 90% of the corneal thickness and is dominated by collagen type I. Stromal transparency is granted by the regular architecture of the collagen fibres. Keratocytes are responsible for synthesizing the new collagen/proteoglycan matrix. [6]

The fourth layer is the Descemet's membrane. It forms the basement membrane of the corneal endothelium and, due to accumulation of material, this layer increases in thickness over the years. [6]

Endothelial cells are hexagonal cells and play a very important role in maintaining corneal transparency. The single layer of cells forms a permeability barrier between anterior chamber and corneal stroma. Endothelial cells let nutrients pass from the aqueous humor into the cornea and with energy-dependent pump processes, the endothelial cells are able to pump out fluids and dehydrate the stroma. Stromal hydration has to be kept at a low level to provide corneal transparency. About 10 microlitres of fluid are pumped back into the aqueous humor every hour. Damage to the endothelium or a loss of a significant number of cells lead to corneal edema and consequently to a reduction of corneal transparency. Soon after birth, these cells lose their mitotic activity and can only be replaced by migration or enlargement of existing cells to cover a greater surface area. At the time of birth the endothelial cell density is

3500-4000 cells/mm²; a cornea of an adult has 1400-2500 cells/mm². A minimum density of 400-700 cells/mm² is necessary to maintain a normal endothelial function. Otherwise the pump function is not sufficient, leading to a corneal edema. Deviation from the normal hexagonal shape of the cells, such as pleomorphism or polymegatism, is a sign for corneal stress. [6, 7, 8]

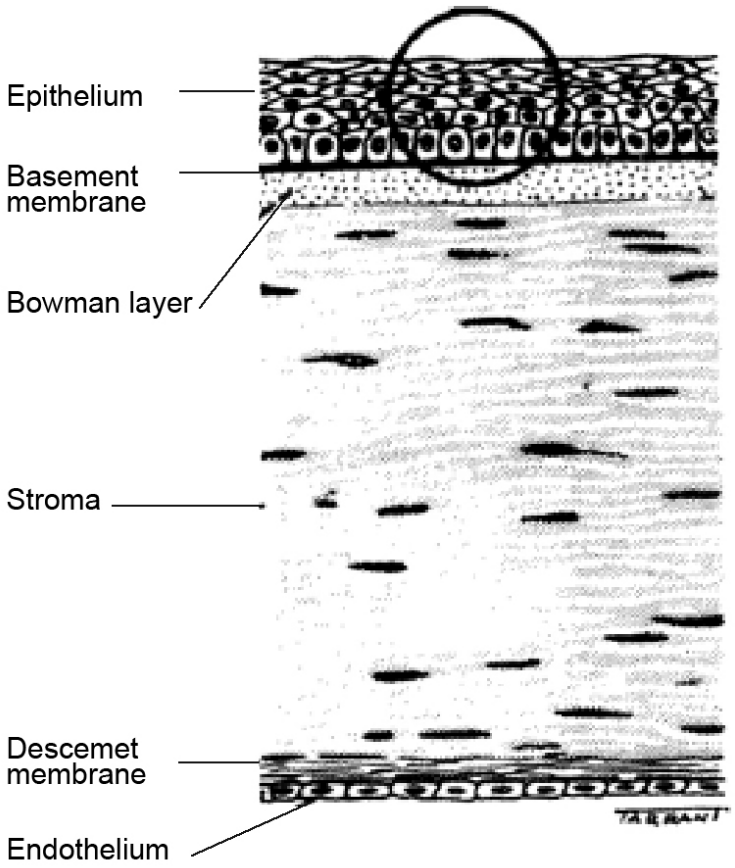



*Figure 2*: Anatomy of the Cornea

### 1.1.2 Iris

The iris is the most anterior anatomic compartment of the uvea. It can be defined as a musculovascular diaphragm with the pupil being its central opening. Consisting of two antagonistic muscles, the sphincter iridis and dilatator pupillae, it controls the pupillary diameter. Regulating the amount of light that enters the eye is important to gain a maximum of visual acuity but also for retinal protection. The autonomic nervous system innervates the iris muscles. Sympathetic fibres control the dilatator muscle while parasympathetic fibres are responsible for the contraction of the pupil.

The anterior surface consists of many crevices and crypts and has no endothelium. Collagen, mucopolysaccharides, melanocytes and non-pigmented cells are part of the stroma. The two layer iris pigment epithelium forms the posterior surface.
The quantity of iridial pigmentation defines the color of the eye. [6]

### 1.1.3 Ciliary body

The cross section of the ciliary body, which is located between the iris and ora serrata of the retina, is triangular. The ciliary body is divided in two segments: the anterior pars plicata and the posterior pars plana.
Accomodation and production of aqueous humor are its major functions.
Ciliary zonules connect the ciliary body with the crystalline lens.
Contraction of the ciliary body diminishes the tension of the ciliary zonules, which enables the lens to raise its curvature, causing accommodation as a result. The many ciliary processes of the pars plicata offer a large surface area for the secretion of aqueous humor. [6]

### 1.1.4 Lens

The transparent crystalline lens is positioned in the posterior chamber just behind the iris and the pupil and in front of the vitreous body. It has the ability to refract rays of light to be focused on the retina. The lens has a biconvex shape and a diameter of 4 to 5 millimetres from the anterior to the posterior pole. It is completely surrounded by a capsule and consists of a central nucleus. Fibres form the main part of the lens, synthesized by the lens epithelium, which lies under the anterior part of the capsule.
Tension and relaxation of the ciliary zonules allow the lens to increase or reduce its convexity. Thus it can focus on objects in variable distances. This ability of accommodation stays upright before an age of about 40. After this age, the lens loses its elasticity and its diameter stays almost constant, a condition known as presbyopia. [6]

### 1.1.5 Anterior chamber and aqueous humor

The anterior chamber is the “fluid-filled space inside the eye between the iris and the innermost corneal surface” [9].

To the front, it is bordered by the corneal endothelium, in the periphery by the chamber-angle with the trabecular network and to the back by the front side of lens and iris [8].
To keep the eyeball distended, it is filled with intraocular fluid to keep up a constant pressure. Intraocular fluid can be divided into vitreous body and aqueous humor. The vitreous body lies in the space behind the lens, whereas the aqueous humor flows in front of the lens, between the posterior and anterior chamber. [10]

Because cornea, lens and trabecular meshwork are avascular, the aqueous humor can be considered as a blood substitute for these structures, providing oxygen and the necessary nutrients. Aqueous humor is produced by the nonpigmented epithelium of the ciliary process through the mechanism of active secretion into the posterior chamber. The normal production rate is about 150 microlitres/hour. [8]

Through the pupil, the aqueous humor enters the anterior chamber and reaches the angle between the cornea and the iris. From this place it continues to flow through the trabecular meshwork and reaches the canal of Schlemm. The canal of Schlemm finally leads into the extraocular veins. A constant balance between production and outflow of aqueous humor is necessary to maintain a stable intraocular pressure. [10]

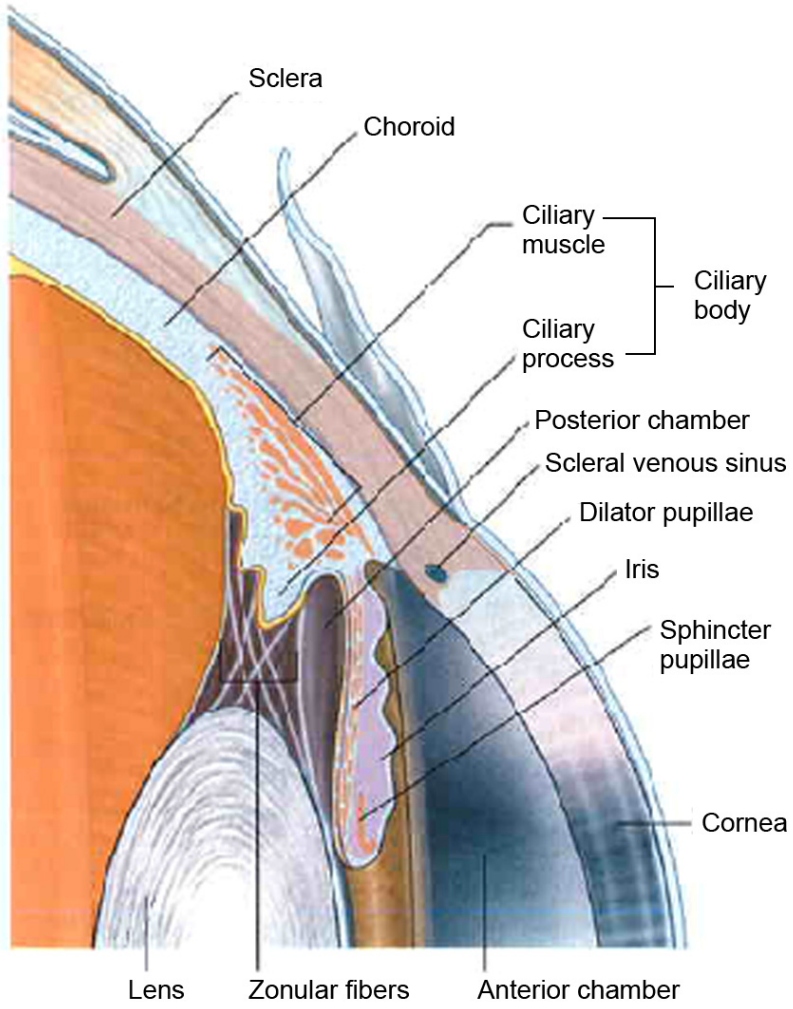



*Figure 3:* Structures of the anterior eye

## 1.2 Myopia

Myopia or short-sightedness is a refractive error of the eye, where close objects can be seen sharply whereas distant objects appear blurred. In myopic eyes, the light rays are not focused on the retina, which is necessary for a clear image, but in front of it. However, if an object is near enough, its image can be focused. If it comes closer it can still be kept in focus with the mechanism of accommodation. The limiting point for clear vision is the far point. [10]

Myopia can be classified into axial myopia, which is due to an increased axial length of the eye, and refractive myopia, which is caused by alteration of a refractive element of the eye such as the cornea or the crystalline lens. [11]

A change of the bulbus' length of 1 mm equates to a myopia of 3 diopters [12].

According to its clinical appearance, myopia can be classified into different forms: [11]

Myopia simplex:
Starting by the age of 10 to 12, this kind of myopia usually does not increase past the age of 20 and reaches up to 6 diopters.

Myopia benigna progressiva:
Stabilizing at the age of 30, this kind of myopia comes up to 12 diopters.

Myopia maligna (progressiva) is a disease with constant progression and often hereditary.

Apart from age-related dysfunctions of the eye, myopia is the most frequent ocular disease. It is estimated at a percentage of 35 in adolescents [11]. 23 Studies of 19 different countries were averaged. Some industrial nations in the Far East even show percentages of 80-90 [11]. The prevalence of high myopia, described as more than 6.00 diopters or considered as a bulbus length of more than 26 mm, is estimated from 1% to 4% in general population [13].
The aetiology is still unknown. Accumulation in families leads to the assumption that myopia is genetically determined. Sections in chromosomes that contain genes correlating with high myopia have been localized. [11]
People who suffer from high myopia do not only have a loss of visual acuity; they are also more susceptible to severe ocular abnormalities. The risks for developing glaucoma, chorioretinal abnormalities such as retinal detachment, chorioretinal atrophy and lacquer cracks as well as optic disc abnormalities are increased [14]. Compared to general population, cataract development is 4 times more frequent in highly myopic patients [15]. The detection and treatment of these complications is essential in the management of high myopia.

## 1.3 Conservative treatment of myopia

Whereas in former times myopia was generally treated with glasses, there are several options for its treatment today and it is the ophthalmologist's duty to find the most adequate way to treat his/her patients. Especially for cases of high

myopia, this task can be a very challenging one and individual solutions for the needs of each patient have to be found.

### 1.3.1 Spectacles

Basically, concave spherical lenses that diverge incoming light rays are used for correction [10]. Spectacles are a cheap option and easy to handle. But as the strength of the glasses increases, more and more problems arise. Because the image on the retina gets smaller with the amount of diopters, full visual acuity cannot be achieved with strong glasses [16]. Additionally, the glasses gain in weight whereas the quality of optical imaging decreases. For high myopic patients, spectacles lead to significant optical aberrations [16]. Cosmetic reasons leading to patients refusing to wear glasses should be mentioned as well.

### 1.3.2 Contact lenses

Some of these disadvantages can be avoided by the use of contact lenses, e.g. they have only a small effect on the size of the object that a person sees through the lens [4]. Compared to glasses, contact lenses turn with the eye and provide a wider field of clear vision [10].

Another advantage is a better correction of vision in people who show an irregularly shaped cornea [10].

However, the handling of contact lenses is more time-consuming and requires hygienic manipulation. Especially for very highly myopic people, it can be difficult to cope with contact lenses and some do not tolerate them at all.

Other drawbacks are associated with overwear, infection, giant papillary conjunctivitis, warpage, and vascularisation of the cornea [16].

If conservative methods do not bring the desired results or pose a handicap in everyday life, surgery is an option.

## 1.4 Refractive surgery

Refractive surgery can be performed to correct common vision disorders such as myopia as well as hyperopia and astigmatism. Due to media attention and extensive advertising, especially for laser refractive surgery, it attracts the interest

of a lot of people. However, not every person with a refractive error is a good candidate for refractive surgery.

The currently most important corneal procedure is probably laser-in situ-keratomileusis (LASIK), besides photorefractive keratectomy (PRK), laser assisted subepithelial keratomileusis (LASEK) and Epi-LASIK, which are also in use. More invasive surgical procedures should be discussed subsequently, namely clear lens extraction and of course the implantation of phakic intraocular lenses (pIOLs).

The history of refractive surgery reaches back to the end of the 19$^{th}$ century with the basic idea of changing corneal shape to alter its refraction. The first approaches were based on corneal incisions, mainly to correct astigmatism and later also for the correction of myopia. In the 1960s, Jose Barraquer did pioneer work by inventing keratomileusis and lamellar procedures to alter the corneal curvature. [17]

The change from incisional to laser ablative procedures was a remarkable step in the development of refractive surgery, made possible by the invention of the excimer laser. Nowadays, due to the availability of wavefront aberrometry, not only sphere and cylinder errors, but even higher order aberrations can be laser corrected. [17]

### 1.4.1 LASIK

The main principle of LASIK is excimer laser ablation under a lamellar corneal flap. This corneal flap can either be created with a microkeratome by using an oscillating blade or with a newer femtosecond laser. At its hinge, the flap is folded back, exposing the corneal stroma so that the preprogrammed excimer ablation can be performed. After irrigation of the stromal bed, the flap is finally repositioned. Sutures are not necessary, because the relative dehydration of the cornea, created by endothelial cells, stabilizes the corneal flap. [17, 18]

### 1.4.2 Surface ablation

Excimer laser ablation of the most anterior part of the cornea, the so-called surface ablation, is the basic principle of PRK, LASEK and Epi-LASIK.

These three methods are different in the way the epithelial layer is handled. In PRK the epithelium is removed completely, leading to a large epithelial defect, whereas the original epithelial sheet is repositioned after ablation in LASEK and Epi-LASIK. In any case, a bandage contact lens is required for postoperative protection. [17]

Both LASIK and surface ablation methods have advantages and disadvantages. The improvement of uncorrected visual acuity is faster in LASIK. Additionally, there is less pain or postoperative discomfort, improved stability and predictability. Risks for complications are mostly flap-related.
Surface ablative procedures avoid these flap-related complications and leave a larger residual bed to preserve the biomechanical strength of the cornea. However, they present the disadvantage of a slower and more painful recovery. Especially an ablation through the Bowman's layer can result in stromal haze and scarring. [17]

An article published in the Cochrane Database Syst. Rev. in 2006 compares LASIK and PRK and shows a faster visual recovery of patients treated with LASIK but a comparable effectiveness of both methods [19].
In another meta-analysis of the same year, LASIK appears to show a level of efficacy and safety superior to those of PRK [20].

What all corneal refractive procedures have in common is their irreversibility and their limitations related to the correction of higher ranges of refractive errors where corneal stability becomes a problem with the danger of corneal ectasia. For patients who cannot be treated adequately with laser ablation, surgical procedures which leave the corneal plane intact – like clear lens extraction or pIOL implantation – become an option.

### 1.4.3 Clear lens extraction

Clear lens extraction (CLE), which is also known as refractory lensectomy (RLE), refers to the process of removing the natural crystalline lens, usually by phakoemulsification techniques, and substituting it with an intraocular lens (IOL) [21]. Especially for young people, the major disadvantage of this method is the loss of accommodation [3].

Furthermore, there are risks for posterior chamber opacification and retinal detachment [3, 21]. It is likely that the popularity of clear lens extraction increases with the introduction of multifocal IOLs, which would solve the problem of losing accommodation [21].

## 1.5 Phakic intraocular lenses

Another treatment option for myopia is called phakic IOL implantation. This term refers to the placement of a supplementary IOL between the cornea and the lens.
Phakic IOL implantation is gaining importance for highly myopic patients, where excimer laser ablation cannot guarantee a certain corneal thickness, which is necessary to prevent iatrogen corneal ectasia. Thus pIOLs enlarge surgical options, especially for patients with refractive errors of more than -10 diopters or more than +5 diopters. [3]

Used especially for highly myopic patients, phakic IOL Implantation presents a number of advantages: [2]

1) The crystalline lens can keep its function and possible side effects of the CLE are avoided.
2) The high quality of the lens implant surfaces maintains and can even improve the natural properties of the eye's optical system to improve the quality of the retinal image.
3) pIOLs are removable and exchangeable, providing reversibility to the preoperative situation.
4) pIOLs provide a predictable result, which is immediately stable, because the refractive outcome is less dependent on healing processes. If necessary, the refractive outcome can be amended with corneal surgery.

However, phakic IOLs have their own drawbacks. One of the major disadvantages of pIOL implantation is the potential risk of an intraocular procedure such as endophthalmitis and sympathetic ophthalmia that can theoretically appear, as well as induced astigmatism [2, 16].
Another concern is the fixation of the pIOL inside the eye. Whereas iris-claw-lenses touch the mid-peripheral iris, angle-fixated-lenses are in contact with chamber angle structures and the peripheral iris. Posterior chamber pIOLs are placed between the crystalline lens and the iris. The pIOLs can cause alteration or

damage to all adjacent structures leading to severe complications. These complications include the loss of corneal endothelial cells, iris ovalisation caused by ischemia or entrapment, a chronic uveitis, pupillary bloc glaucoma, pigment dispersion syndrome and cataract. [2, 16]

The history of phakic intraocular lenses goes back to the 1950s, when they were introduced by Baron [22, 23], Barraquer [24] and Strampelli [25].

The first lens was implanted by Baron in France. It was made of PMMA and had such a steep anterior curve that corneal endothelial contact and resulting complications were inevitable. [7]

A flatter lens with a three-point-fixation was designed by Strampelli in Italy. Compared to Baron's lens, it minimized the contact between lens and corneal endothelium and it was the prototype of many anterior chamber lenses. Barraquer also adapted this design in Spain. [7]

Nevertheless, many complications appeared with all these early models of anterior chamber lenses, such as frequent corneal decompensation, pseudophakic bullous keratopathy, corneal opacification, angle recession, intraocular pressure rise, hyphema because of erosion of gonio-structures, inflammation with anterior synechiae, pupil distortion, sectoral atrophy of the iris and movements of the lenses with decentration of the optics [2, 7].

Besides the design problems, poor manufacturing quality was responsible for these complications, because sharp, rough edges led to chafing of the anterior chamber structures [7].

As a consequence, many of the implants had to be removed, pIOL implantation got a bad reputation and the pioneering phase ended [2].

The reintroduction of pIOL implantation began in the late 1980s by the use of angle-supported lenses by Baikoff and Joly [26] and the use of iris-fixated lenses by Fechner and co-authors [27].

As the related complications of the second generation pIOLs were less severe and frequent [2], pIOL implantation became more and more popular. From this time on, many pIOL types differing in design and material appeared on the market.

The first model of an angle supported AC-PIOL was the Baikoff ZB (Domilens, Lyon, France) in 1986. It was replaced by the ZB5M (Domilens) in 1990. The improved design was supposed to increase the distance between corneal endothelium and the pIOL. [28]

The I-CARE lens itself is a hydrophilic acrylic monobloc lens, fixated in the chamber angle.

An example for a well established iris-claw lens is the Artisan lens by Ophtec, Groningen, Netherlands. It is also known as Verisyse when distributed by Advanced Medical Optics, Santa Ana, CA, USA. Its major advantage is the long track record compared to other lenses [2]. Many of them have been redesigned, altered or abandoned several times and therefore little literature about every single type of pIOL is available.

Posterior chamber pIOLs were used throughout the 1990s. Due to the bad long term results, they faced considerable criticism and are no longer commercially available in Europe. Severe complications of PC-PIOLs, mainly caused through the intraocular positioning between iris and crystalline lens, subcapsular cataract, pupillary block, narrow angle glaucoma, iridocyclitis and pigment dispersion syndrome [3]. Corneal decompensation was also reported [2].

Electron-microscopical examinations have proven that the manufacturing of the modern pIOLs considering surface quality is good. Irregularities and roughness of the surfaces have been minimized over the years, guaranteeing a long-term acceptance and a minimized risk of intraocular inflammation. [29]

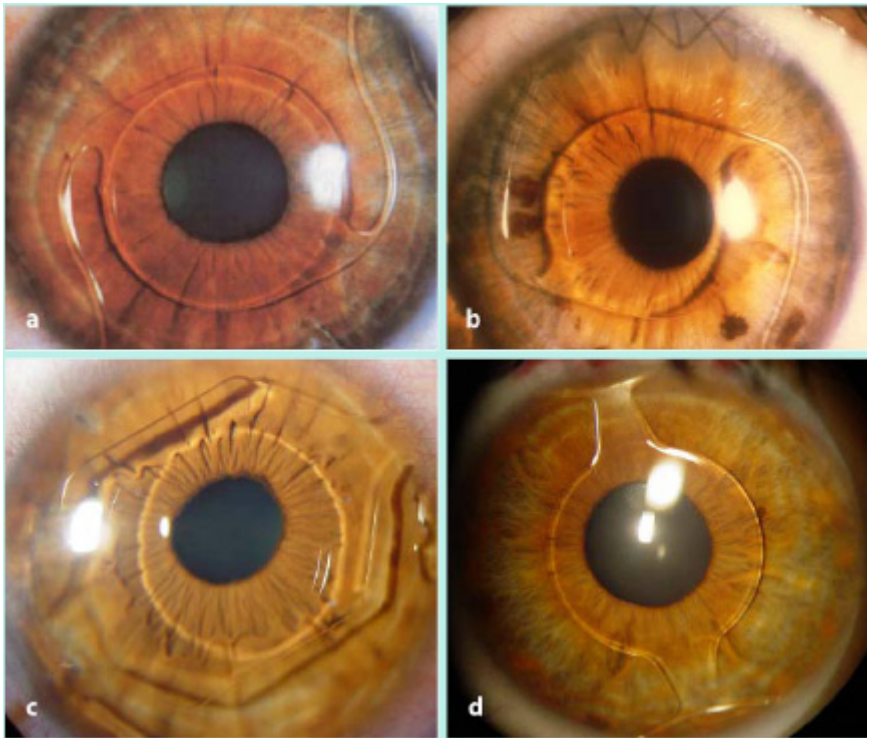



*Figure 4:* Angle supported AC-PIOLs in situ
a) NuVita MA20 b) ZSAL-4 (Morcher) c) I-CARE (Corneal) d) AcrySof (Alcon)

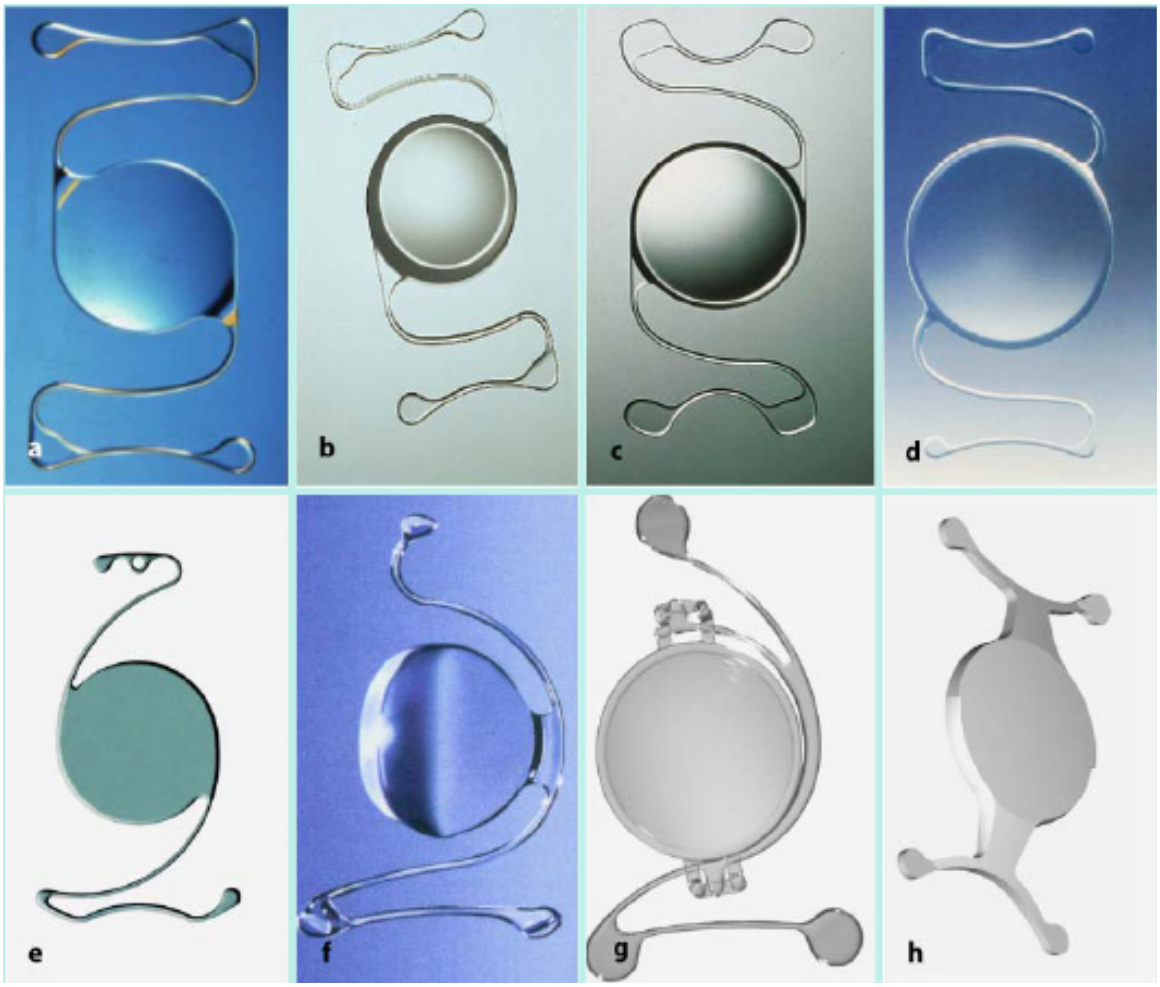



*Figure 5:* Evolution of the angle supported AC-PIOLs:

Legend:

a) Baikoff ZB (Domilens)
b) Baikoff ZBM5 (Domilens)
c) NuVita MA20 (Bausch & Lomb)
d) Phakic 6 (Ophthalmic Innovations Int.)
e) ACRIOL (Soleko)
f) Vivarte (Ciba)
g) Kelman Duet (Tekia)
h) Acrysof (Alcon)

# 2 MATERIALS AND METHODS

## 2.1 Patients

Data of 16 patients (6 female, 10 male) who underwent I-CARE phakic intraocular lens implantation in the period between 2003 and 2006 was analyzed, resulting in a total of 29 eyes with an I-CARE lens.

After the implantation the patients were recommended to go to check-up examinations one month postoperative, three month postoperative and then in intervals of 6 month or 1 year, depending on the individual situation of the patient.

The check-ups contained a slit lamp examination, an endothelial cell count (Noncon Robo clinical specular microscope, Konan), measurement of intraocular pressure, photo documentation and – since 2007 – the generation of Scheimpflug images with the Pentacam. From the Scheimpflug images, the anterior chamber depth, the distance between the Cornea and the pIOL and the distance between pIOL and the crystalline lens were measured. These values were correlated with the number of endothelial cells.

*Table 1:* Patient demographics

| Demographic | Value | |
|---|---|---|
| Number of patients (eyes) | 16 | (29) |
| Bilateral cases (%) | 13 | |
| Sex, n (%) | | |
| Female | 6 | (37.5) |
| Male | 10 | (62.5) |
| Age (y) (at time of implantation) | | |
| Mean | 37.5 | |
| Range | 28.0 to 53.2 | |
| Ocular parameters (D) | | |
| Spherical equivalent | | |
| Mean | -11.24 | |
| Range | -5.50 to -21.00 | |
| Implanted IOL Power (D) | | |
| Mean | -11.47 | |
| Range | -7.00 to -16.00 | |

The average follow up was 3.41 years, ranging from 0.38 to 5.23. The number of eyes evaluated was: 1 month (29 eyes), 1 year (17 eyes), 2 years (20 eyes), 3 years (16 eyes), 4 years (10 eyes), 5 years (5 eyes).
At the time of pIOL implantation, the average age of the patients was 37.5 years (ranging from 28.0 to 53.2).

## *2.2* I-CARE lens

The I-CARE lens is a phakic intraocular lens developed by Corneal, France, and it is used to treat highly short-sighted or hyperopic patients.

It is a hydrophilic acrylic monobloc lens with four independent feet to provide a wide contact surface in the angle support. This is supposed to help preserve the iridocorneal angle and iris structures due to smaller forces emerging under compression. The diameter of the lens' optic is 5.75 mm and it is available with an overall diameter from 12 mm to 13.5 mm in increments of 0.5 mm.

Strengths range from minus 20 to plus 10 diopters, in steps of 0.25 diopters. The refractive index of the optic is 1.46. The geometrical shape of the lens was chosen to provide a larger mid-peripheral distance between the corneal endothelium and the convex-concave optic of the lens.

Size and dioptric power of the lens were calculated with a software available on the Corneal homepage by considering refraction, anterior chamber depth and keratometry. [2, 3, 8, 30]

*Figure 6:* The I-CARE lens

## 2.3 Implantation

Candidates for the implantation were patients with no major general diseases, who presented a stable myopia for at least two years. The PIOL implantation had to be indicated, which means that the patients either suffered from contact lens problems or refused glasses due to cosmetic reasons. Anterior chamber structure and depth had to be normal and an endothelial cell number of at least 2500 cells/mm² was necessary. The patient's Retina had to be intact, a presurgical laser coagulation was performed, if indicated, and a minimum age of 20 years was required. The patients of the study had an average age of 38 (28 to 52).

The surgery was performed during retrobulbar or general anaesthesia.
Two hours before the operation, the pupil was contracted with miotic eyedrops (2% pilocarpine). To reach the anterior chamber, where the lens would be positioned, a corneal tunnel and a paracenthesis were made. Miovisin (Farmigea, Italy) was administered and the anterior chamber was filled with a viscoelastic solution (Oculocrom, Cromapharma or Aelor, Pfizer) to maintain a deep anterior chamber and protect the endothelial cells. The next step was the implantation of the foldable I-CARE lens. The average strength of the implanted lenses was -11.47 diopters (from -7.00 to -16.00) with an average length of the implant of 12.88 mm (12.00 to 13.50).
In the injector, the lens was folded with its four feet bent under the optic, after the injection, it unfolded itself in the anterior chamber. After correct positioning of the lens' feet, the viscoelastic solution was removed with a Simcoe-irrigation-aspiration-cannula and the anterior chamber was filled up again with saline. The corneal incision was self sealing and in most cases stitches were not necessary; tightness of the incisions was checked with flourescein drops. Finally dexamethason-ointment was administered.

In order to prevent a severe postoperative rise of the intraocular pressure a prophylactic iridotomy was performed in 19 of 29 cases (65.5%) either a few days preoperative as Nd:YAG-Laser Iridotomy or during the operation itself. The iridotomies were positioned between 11 and 1 o'clock under the upper lid.

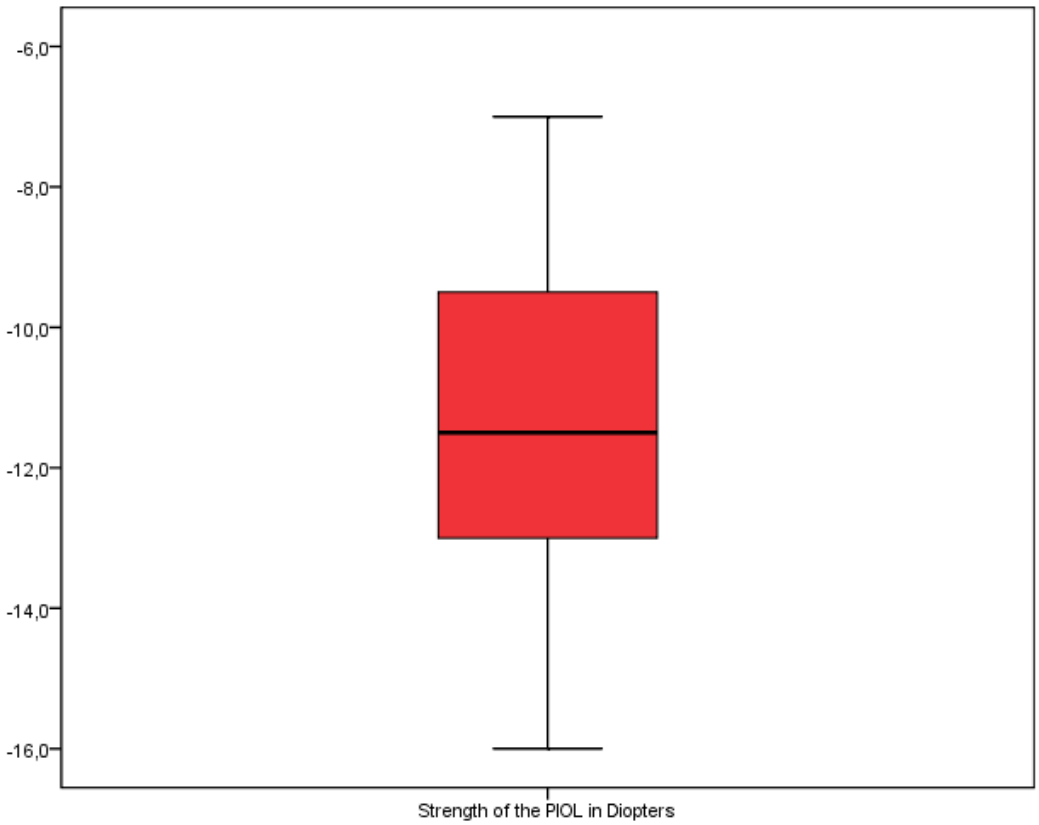



*Figure 7:* Average IOL power in diopters

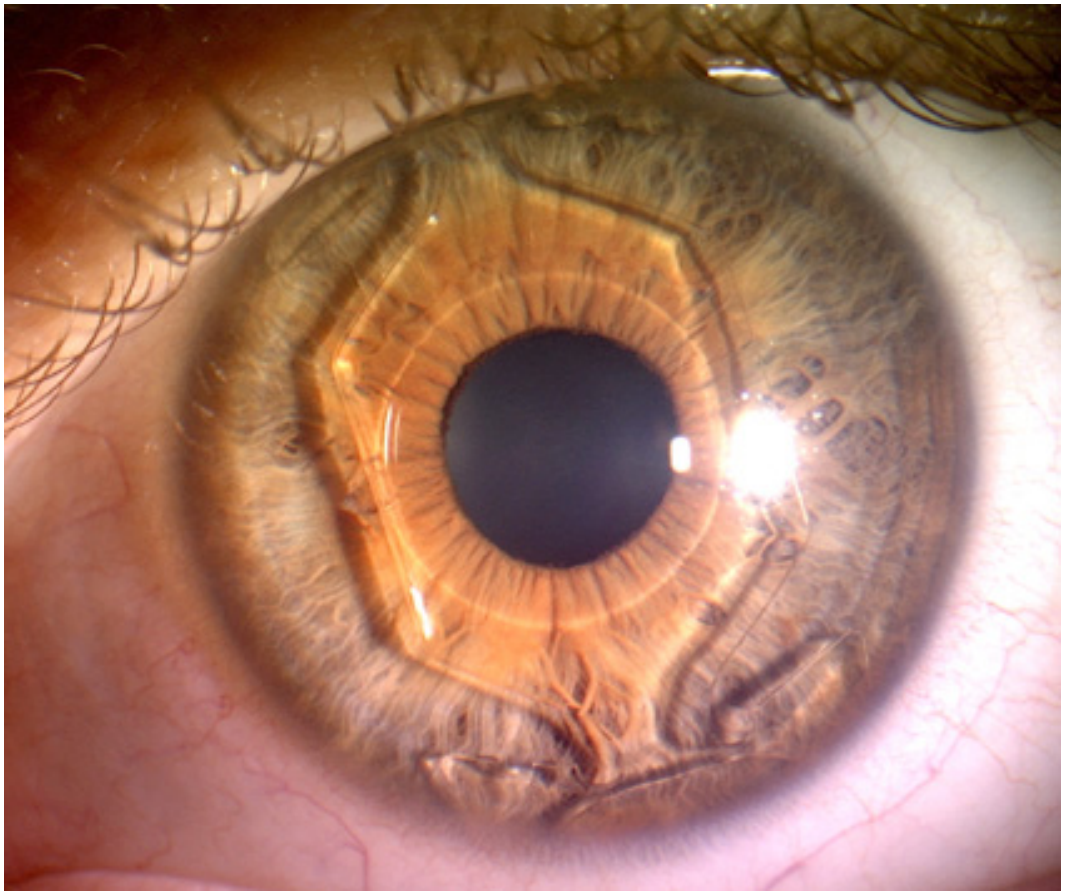


*Figure 8:* I-CARE lens in situ

## 2.4 Pentacam

The Pentacam (Oculus/Wetzlar) is a fast rotating Scheimpflug camera (180°). With computer assisted reconstruction of 12 to 50 exposures it gives information of all important structures of the anterior part of the eye. [8]

The distance from the inner corneal surface to the pIOL, from the pIOL to the front side of the crystalline lens as well as the anterior chamber depth (distance between inner corneal surface and front side of the crystalline lens) were measured from Scheimpflug images generated with the Pentacam.

Corneal topography provided by the Pentacam was used to quantify surgically induced astigmatism, whereas recently created topographical maps were compared with preoperatively generated topograms by Orbscan Version 3.12 (Bausch & Lomb).

## 2.5 Statistics

The data was analyzed statistically with SPSS 17.0 (SPSS, Chicago, Illinois). The mean +/- the standard deviation were calculated for the acquired data (visual acuity, refraction, endothelial cell count, anterior chamber depth, intraocular pressure) and a minimum and a maximum were defined. A Student-T-Test was performed (Paired Samples T-Test or Independent Samples T-Test) and a p-value of 0.05% was defined for statistical significance. Outcomes were compared and illustrated with box plots.

# 3 RESULTS

## 3.1 Visual quality

### 3.1.1 Best corrected visual acuity

Preoperatively, spherical equivalent of the refractive error ranged from -21.00 to -5.50D, average -11.84D. The average BCVA increased from 0.74 (from 0.40 to 1.25) preoperatively to 0.76 at the time of discharge from the hospital two or three days after surgery. The refraction error ranged from -1.50D to +1.50D. One month postoperatively, the mean BCVA increased further to 0.88 (from 0.50 – 1.25) with a refractive error between -3.00D to +0.50D. After one year, BCVA was at 0.94 (from 0.50 to 1.25) with refraction errors between -2.25D and +0.50D. Two years after surgery, BCVA increased to 0.98 (from 0.80 to 1.25). The spherical equivalent of the refraction error was between –2.00D and +1.00D. In the third year of the follow-up, values were similar, with a BCVA of 0.95 (from 0.80 to 1.25) and the refraction error ranged from 0.00D to -0.50D. In the fourth year, a small decrease in visual acuity became apparent. The mean BCVA amounted to 0.90 (from 0.63 to 1.25) with a refraction error between 0.00D and -1.25D. In the fifth year, a further decrease to a BCVA of 0.80 showed up. The spherical equivalent of the refraction error was between 0.00D and -1.50D.

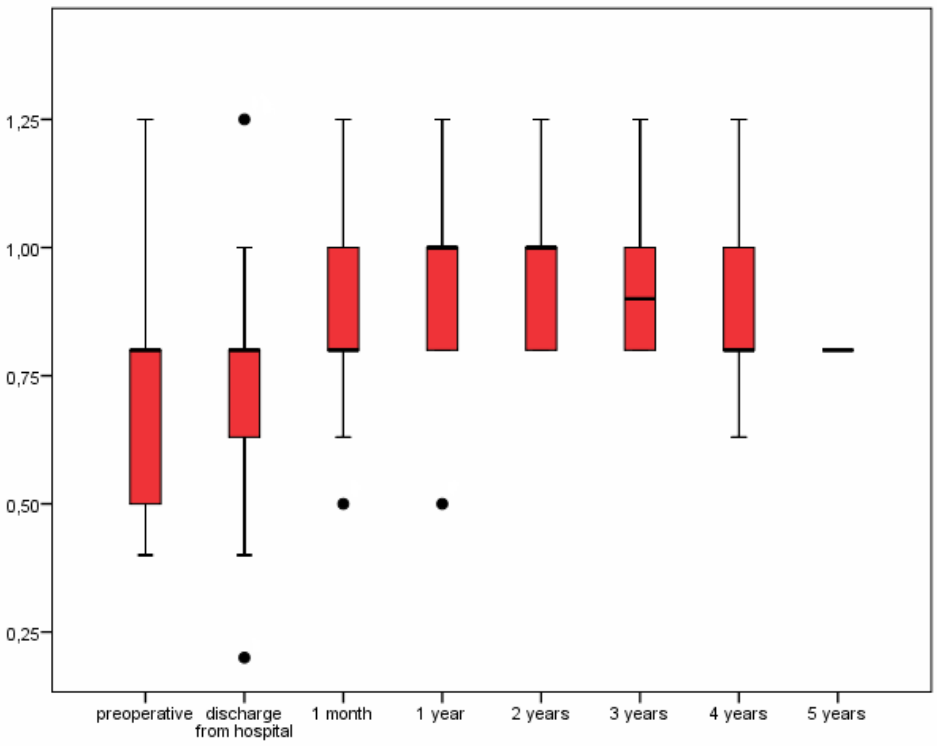



*Figure 9:* BCVA over the years

### 3.1.2 Uncorrected visual acuity

Due to the high refraction errors of the patients in this study, the preoperative UCVA was not determined.

At the time of discharge from the hospital two or three days after pIOL implantation, uncorrected vision was 0.62 (from 0.20 to 1.25). After one month, the uncorrected vision increased to 0.67 (from 0.40 to 1.00).

One year after surgery, the mean uncorrected vision was 0.63 (from 0.20 to 1.25) and after two years, it increased to 0.70 (0.50 to 1.00). The UCVA stayed almost stable in the third year, with an average of 0.69 (from 0.50 to 1.25).

In the fourth year, a small decrease in visual acuity was seen. Uncorrected vision was on average 0.67 (from 0.32 to 1.00).

In the fifth year a further decrease to an average uncorrected vision to 0.54 (from 0.32 to 0.80) showed up.

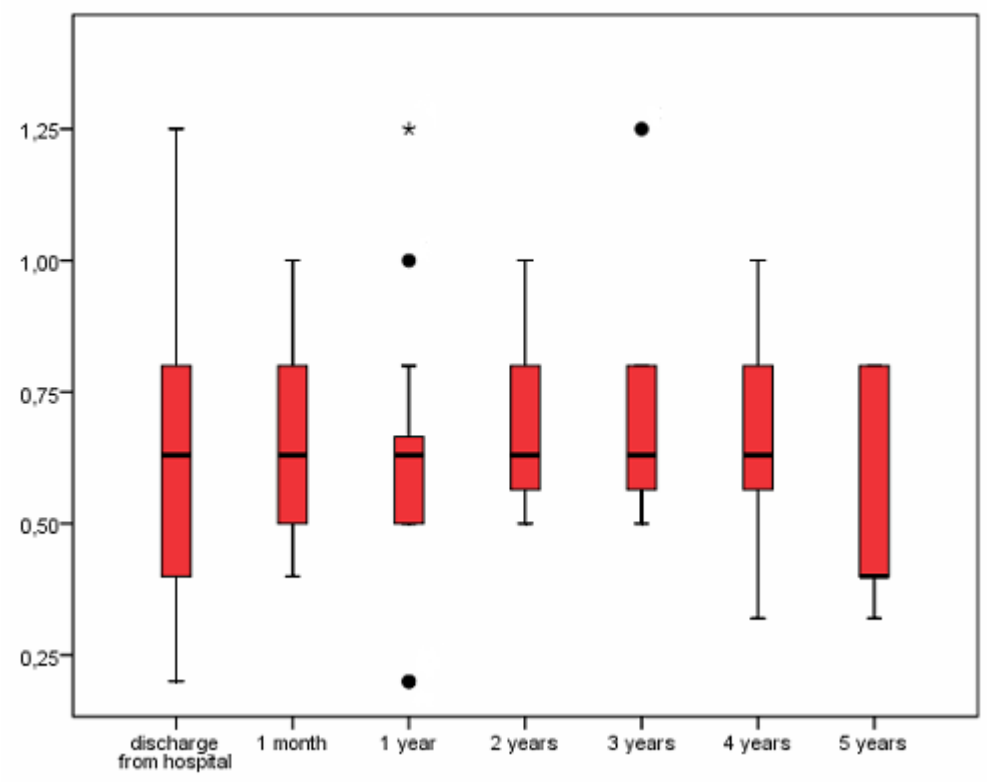



*Figure 10:* UCVA at different times after implantation

### 3.1.3 Halos

Especially in the beginning some patients (37.5%) reported halos. The halos appeared particularly during night time. However, most of the patients were not bothered by them, only two desired medical treatment (Alphagan).
In general, all patients were satisfied with the visual outcome.

## 2.2 Intraocular pressure

Immediately postoperatively, 2 patients suffered from an excessive IOP rise up to more than 40 mmHg.
One of those patients developed an Urrets-Zavalia Syndrome. He showed a postoperative intraocular pressure of 45 mmHg, which also lead to a corneal edema. The pressure normalized after medical treatment, the IOP remained stable (between 10 and 20 mmHg) and the corneal edema recovered slowly. Nevertheless, the pupil remained fixed and dilated and the patient suffered from photophobia.

Over the years, 2 patients developed a slightly increased IOP, but there is no evidence that this was related to the implanted pIOL.
The rest of the patients showed normal IOP values between 10 and 21 mmHg.

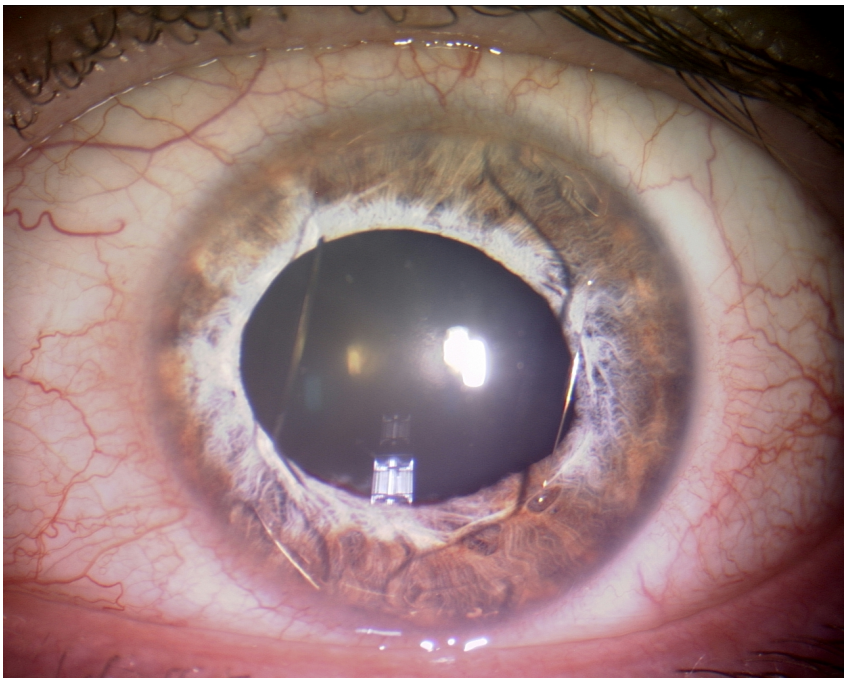


*Figure 11:* Eye with I-CARE pIOL and Urrets-Zavalia Syndrome

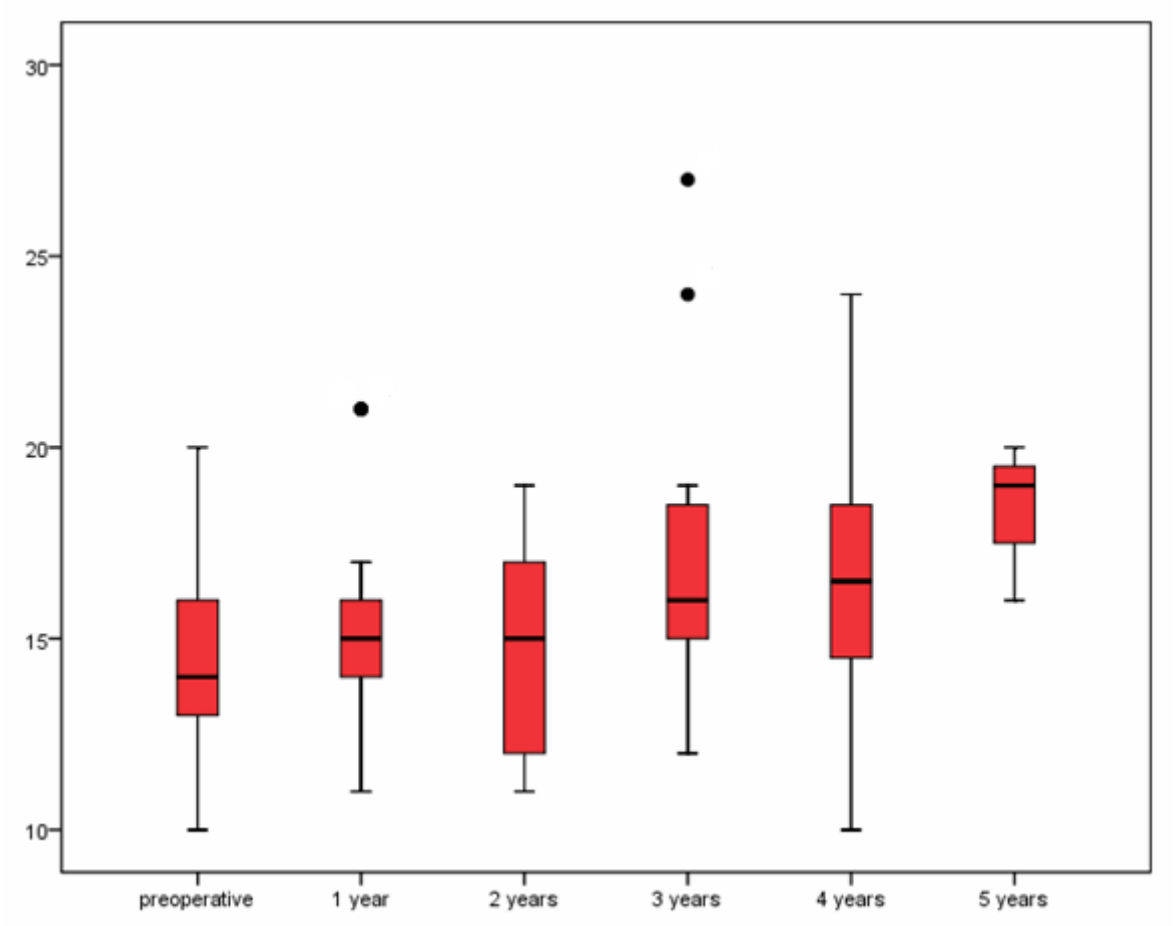



*Figure 12:* Intraocular pressure preoperative and over the years in mmHg

## *2.3* Endothelial cell count

Preoperatively, all patients had normal endothelial cell numbers between 2500 cells/mm² and 3000 cells/mm², averaging at 2752 cells/mm².

The mean endothelial cell density loss in the first year was 2.03 %, with a density of 2696 cells/mm². Endothelial cell changes in the first year were not statistically significant. To the second year, endothelial cell density decreased by 9.05% with a statistically significant difference compared to the preoperative values (p=.014). After three years, the average density was 2310 cells/mm² (from 1324 – 3164). In the fourth year, the rate had decreased by 21.44% to an average cell number of 2040 (from 800 to 2785). The decrease in the following year was 8.23% with a final endothelial cell number of 1984 (from 530 to 3030) after 5 years.

The total endothelial cell loss over the whole follow-up period of 5 years was 27.91%.

In 4 eyes, the decrease of endothelial cell density was so high that the pIOL had to be explanted, whereas in one of those cases a beginning corneal decompensation/bullous keratopathia showed up.

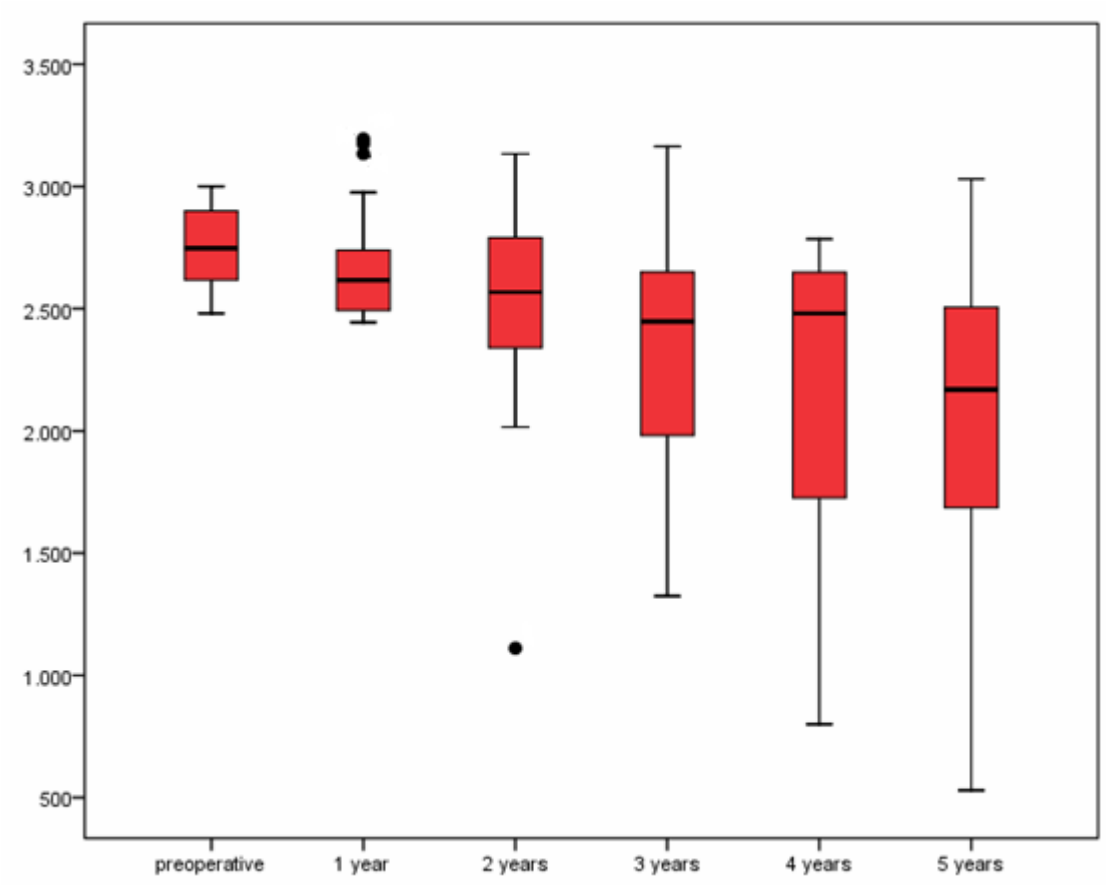
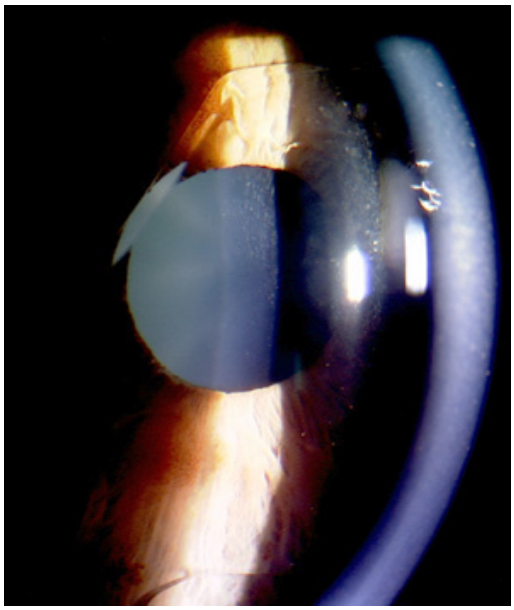
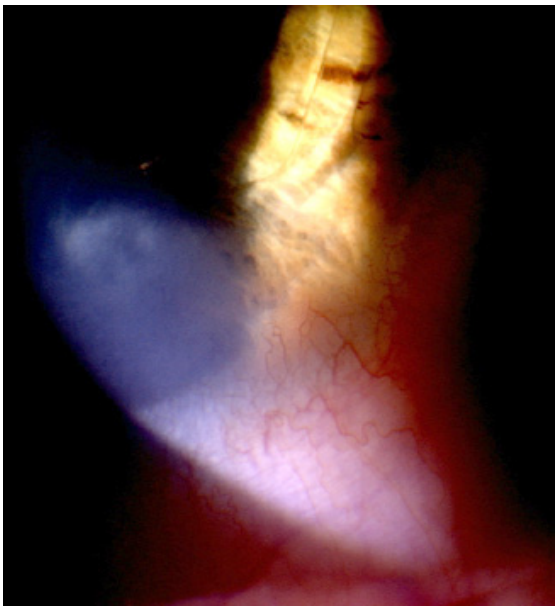



*Figure 13:* Endothelial cell density per mm² over the years

*Table 2*: Endothelial cell density per mm² over the years

| | N | Minimum | Maximum | Mean | Std. Deviation |
|---|---|---|---|---|---|
| preoperative | 27 | 2481 | 3000 | 2752,41 | 165,856 |
| 1 year | 17 | 2444 | 3194 | 2696,29 | 259,936 |
| 2 years | 20 | 1111 | 3134 | 2502,70 | 430,212 |
| 3 years | 16 | 1324 | 3164 | 2310,19 | 504,646 |
| 4 years | 11 | 800 | 2785 | 2162,36 | 693,031 |
| 5 years | 5 | 530 | 3030 | 1984,20 | 949,177 |





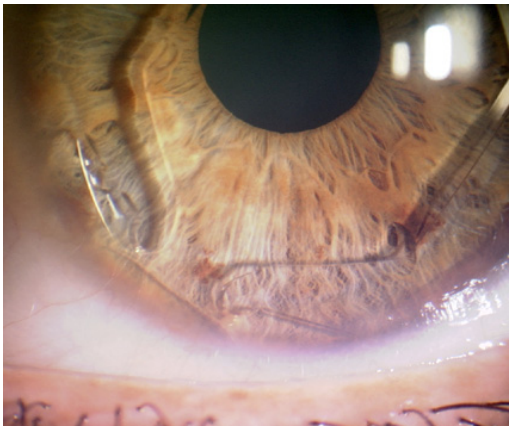


*Figure 14*: Eye with I-CARE pIOL and beginning corneal decompensation at different magnification levels

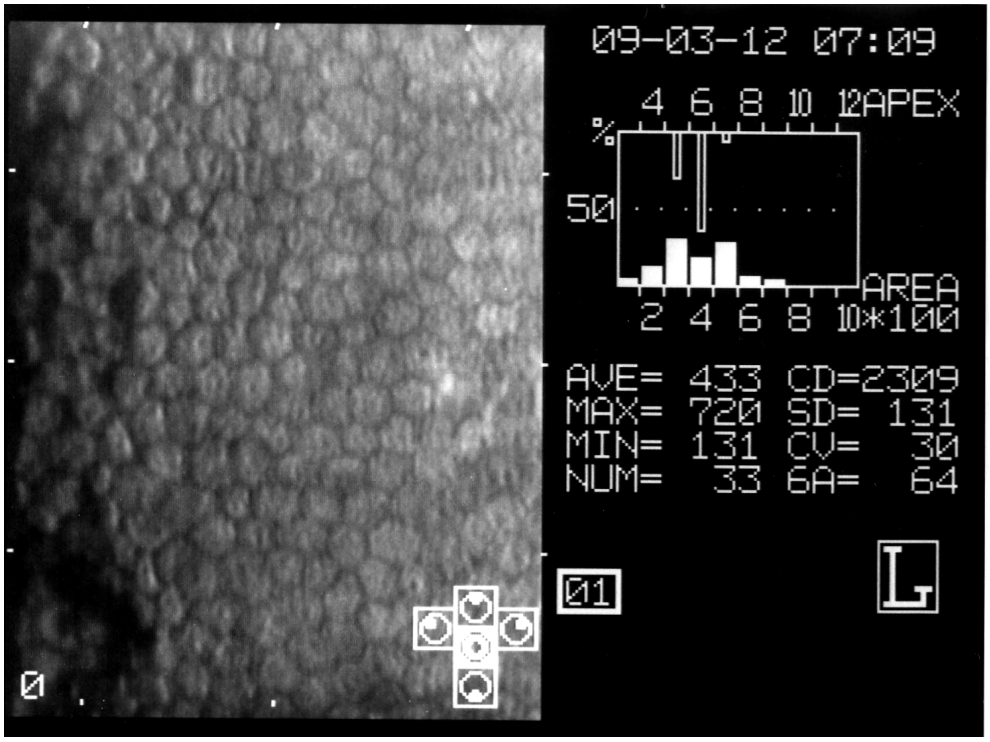



*Figure 15:* Specular microscopy of a patient with I-CARE pIOL: normal corneal endothelium with hexagonal cells; ECD = 2309 cells/mm²

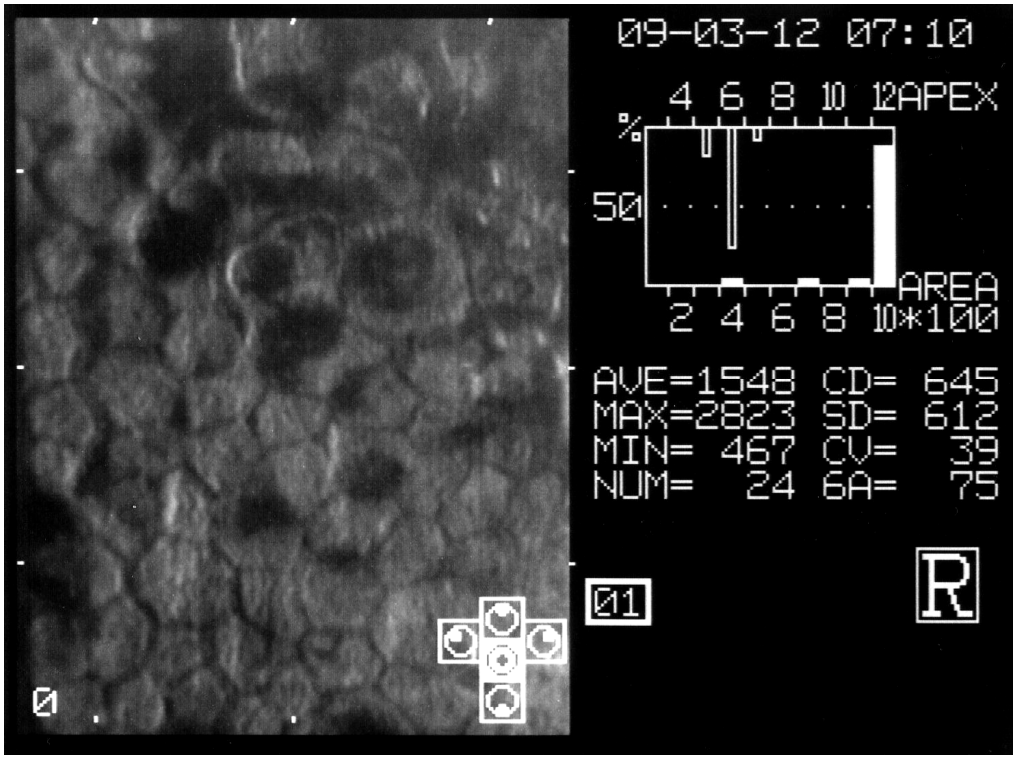



*Figure 16:* Specular microscopy of the patient's contralateral eye: less and enlarged endothelial cells 18 month after I-CARE pIOL explantation, ECD = 645 cells/mm²

## 2.4 Anterior chamber depth

The average distance between corneal endothelium and the front face of the pIOL was 1523 micrometres (ranging from 1170 to 1990) at the end of the study.
The distance between the pIOL and the crystalline lens was on average 1431 micrometres (ranging from 990 to 2000).

The average anterior chamber depth was 3254 micrometres (ranging from 2940 to 3780).

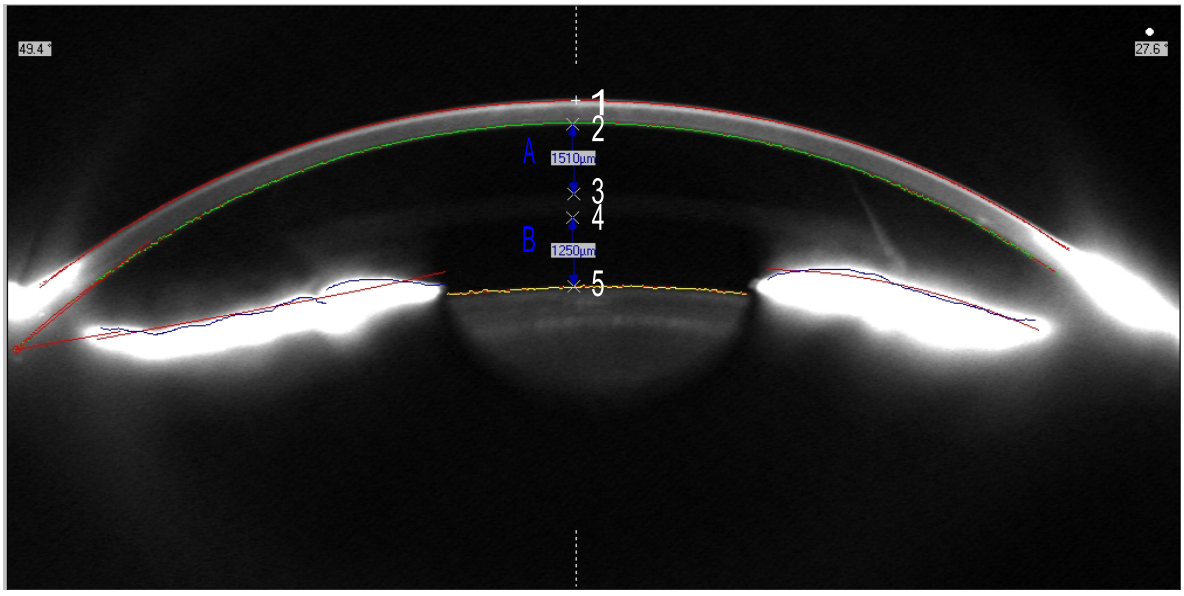



*Figure 17:* Scheimpflug image of the anterior chamber with implanted pIOL

Legend:

1 Outer corneal surface
2 Inner corneal surface
3 Front face of the pIOL
4 Back side of the pIOL
5 Front face of the crystalline lens

A Distance between inner corneal surface and front face of the pIOL
B Distance between back side of the pIOL and front face of the crystalline lens

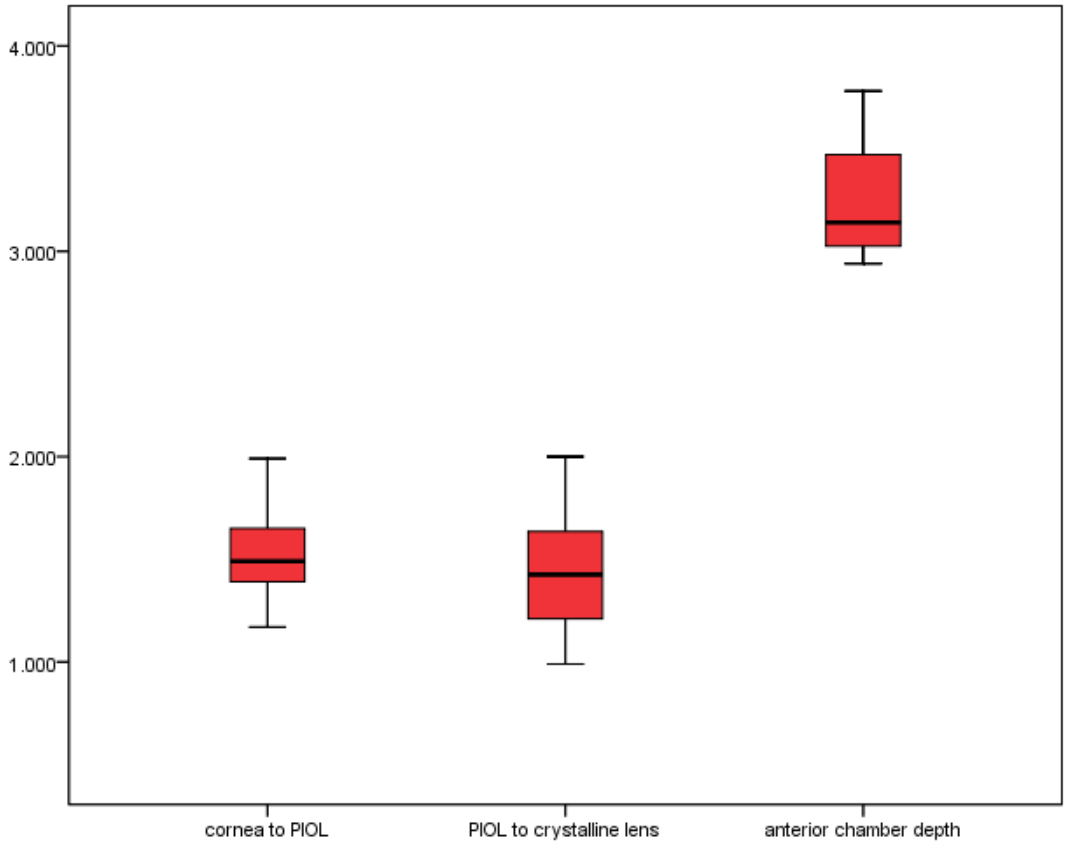



*Figure 18:* Measured distances from the Scheimpflug images

Legend:

1. Distance between inner corneal surface and front face of the pIOL
2. Distance between back side of the pIOL and front face of the crystalline lens
3. Anterior chamber depth: from inner corneal surface to front face of the crystalline lens

## 2.5 Rotation and decentration

In 17 cases (58.6%) the pIOL rotated at least 10°, the average rotation was 33°. Slight decentration of the pIOL appeared in 8 eyes, whereas none of these patients complained about photopsia.

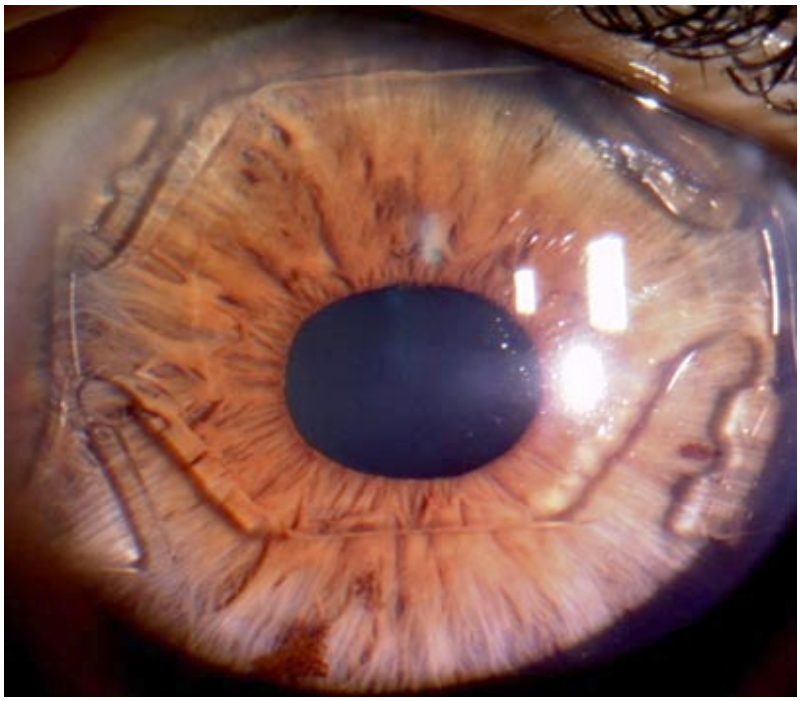


*Figure 19*: Eye with rotated I-CARE pIOL

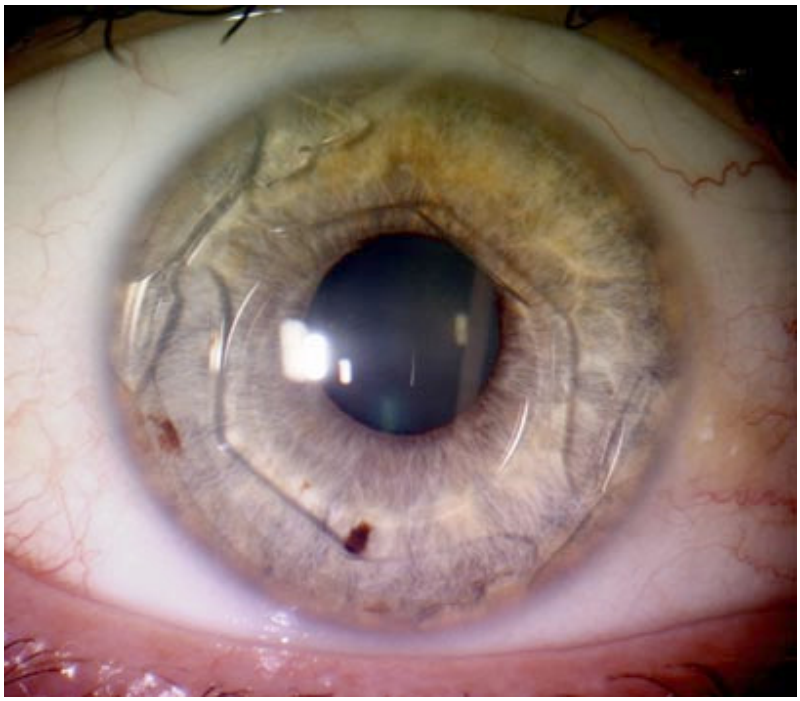


*Figure 20:* Eye with decentrated I-CARE pIOL

## 2.6 Pupil ovalisation

12 eyes (41.4%) out of 29 showed a mild pupil ovalisation. Severe cases of pupil ovalisation were not seen and no explantations had to be made due to this complication.

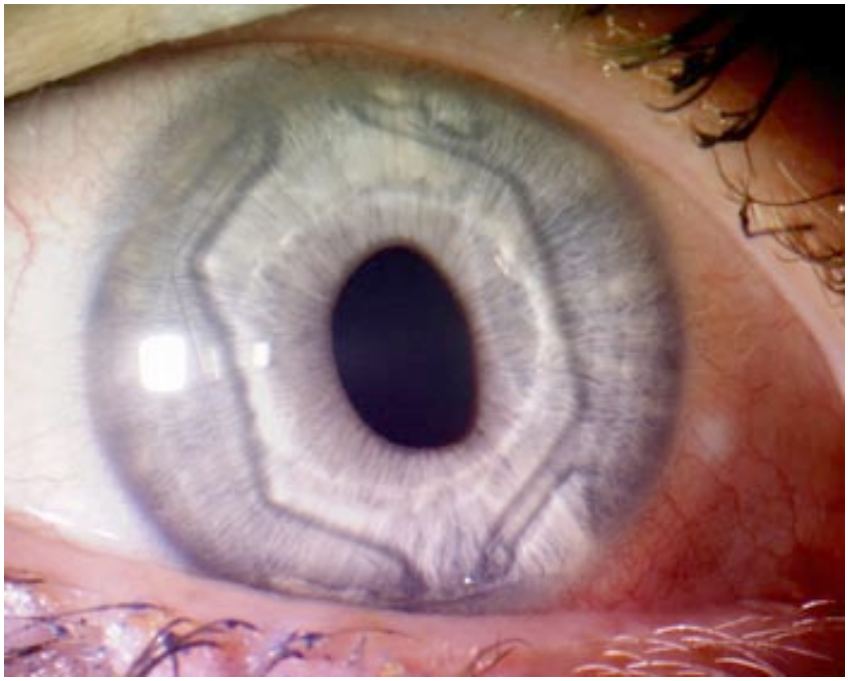


*Figure 21:* Eye with pIOL in situ and slight pupil ovalisation

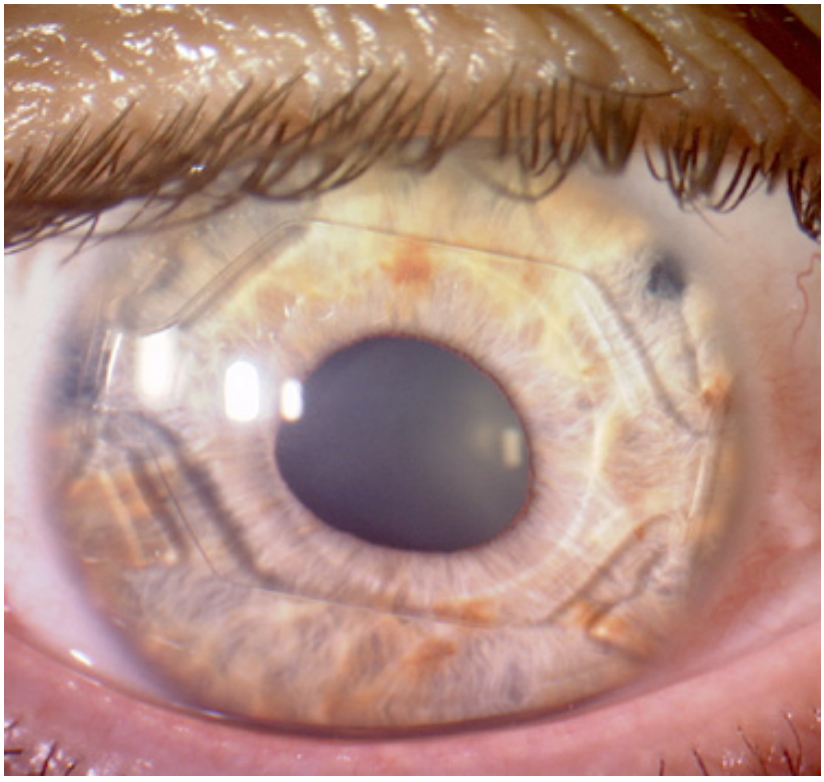


*Figure 22:* Eye with rotated pIOL and slight pupil ovalisation

## 2.7 Astigmatism pre- and postoperative

Preoperatively, the average astigmatism amounted to 1.34 diopters (ranging from 0.40 – 2.90 diopters).

Postoperatively, the average astigmatism was 1.40 diopters (ranging from 0.20 to 2.60 diopters), with the latest corneal topograms being evaluated.

There was no statistically significant difference between pre- and postoperative astigmatism (p= .43).

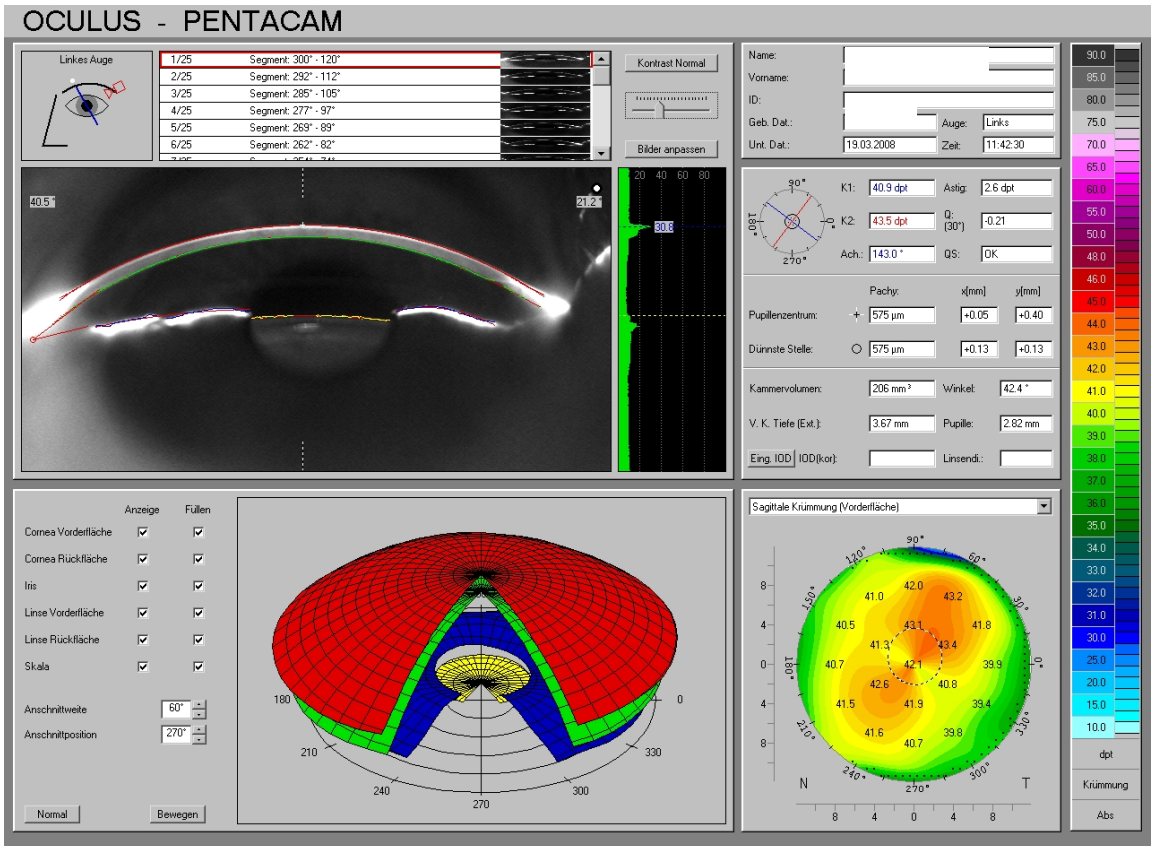



*Figure 23:* Corneal topogram created by Pentacam: Astigmatism of 2.6 diopters at 143 degrees

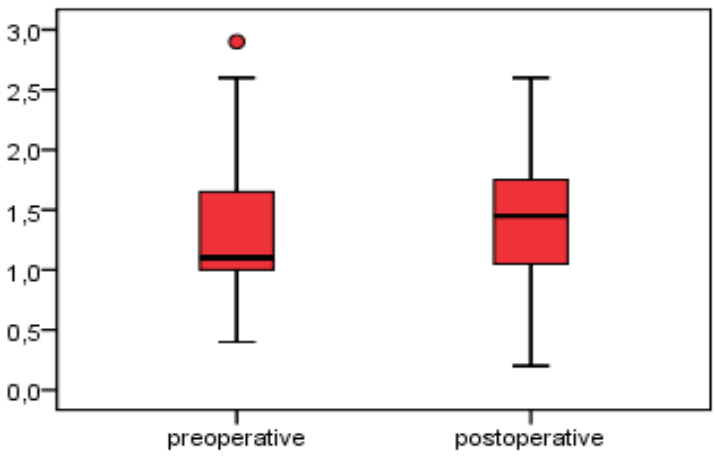



*Figure 24*: Astigmatism pre- and postoperative

## 2.8 Outcome differences between men and women

The I-CARE lens was implanted in 6 female patients (12 eyes) and 10 male patients (17 eyes). Different outcomes between both groups were not expected. However, all 4 explantations due to severe endothelial cell loss had to be made in female patients, whereas one patient underwent pIOL explantation on both sides and two other patients on one side.

A comparison of the average endothelial cell count over the years shows similar results preoperatively and in the first two years after implantation. From the third postoperative year on, a higher decrease of endothelial cell density for women was found.

*Table 3:* Average ECC of men and women over the years in cells/mm²

| sex | preoperative | 1 year | 2 years | 3 years | 4 years | 5 years |
|---|---|---|---|---|---|---|
| women | 2675 | 2774 | 2583 | 1965 | 1501 | 1108 |
| men | 2798 | 2609 | 2437 | 2518 | 2411 | 2568 |

However, the available data for each group is limited. An Independent Samples T-Test was performed, in which the difference in endothelial cell density after three years between men and women was not statistically significant (p= .061). Nor was it after four (p= .18) or five years (p= .20).

The distance between corneal endothelium and front surface of the lens was similar in both groups; 1550 (from 1170 to 1830) in the female and 1515 (from 1170 to 1990) in the male group.

Rotation seemed to be more frequent and severe in women. The lens rotated in 80% of the eyes of female patients, in average 43° (from 0° to 90°). On the contrary, 64.29% of the male patients' eyes showed a rotation of the pIOL, on average by 26° (ranging from 0° to 90°).

# 4 DISCUSSION

First of all, it must be pointed out that there is very little literature concerning the I-CARE pIOL. Apart from two polish studies by Gierek-Ciaciura and coauthors [4, 5] with a maximum follow-up of twelve months, only a case report [31] concerning endothelial cell loss after pIOL implantation could be found. Long term results are not available yet, thus they should be presented and discussed subsequently and compared with other anterior chamber lenses in use, especially the well-established and frequently implanted Artisan lens (Ophtech; Verisyse, AMO) which is also currently being implanted at the University-Eye-Clinic Graz.

Other foldable angle supported AC-PIOLs from the same material (hydrophilic acrylate) are, for example, the Vivarte (Ciba Vision) and Kelmann Duet (Tekia, Inc.) lens. They have already been recalled from several European countries. Also, the use of the I-CARE lens was recently prohibited by French regulatory agencies [32]. Presently, no angle-supported AC-PIOL has FDA approval; however, the new Acrysof angle-supported pIOL (Alcon Laboratories, Texas, USA) is currently undergoing FDA trials [33]. Promising results about this lens have been reported in clinical studies [28].

## 4.1 Advantages and disadvantages of pIOL implantation over other surgical techniques

Several potential benefits have been described in the use of AC-PIOLs, especially for the correction of high myopia [2, 3, 33]. They include the ability to correct higher levels of myopic refraction errors, excellent refractive accuracy without loss of accommodation, improvement of UCVA and BCVA and reversibility.

The disadvantages are related to complications such as endothelial cell loss, pupil ovalisation, induced astigmatism, glaucoma and chronic subclinical inflammation [33]. Additionally, the potential risks of intraocular surgery must be mentioned [28]. Other challenges may arise from the correct power [28] and size calculation [31].

## 4.2 Visual acuity

There are several studies showing that pIOL implantation leads to a stable and predictable refractive outcome [4, 5, 34, 35]. It could also be demonstrated that the visual outcomes after pIOL implantation in patients with moderate or high myopia are superior over other refractive surgeries, in particular when it comes to visual quality and contrast sensitivity [28]. Magnification of the retinal image through the pIOL additionally leads to improvement of the BCVA [1].

Also in this study about the implantation of I-CARE phakic IOL for the correction of high myopia, a stable improvement of the BCVA was found. The average BCVA increased from 0.74 (from 0.40 to 1.25) preoperatively to 0.88 (from 0.50 – 1.25) one month postoperatively.

The increase in BCVA from the preoperative to the postoperative situation is related to a magnification effect of the pIOL in comparison with the use of spectacles, which produce a smaller image on the retina [34]. The diminution that results from the minus glasses is proportional to their refractive strength [4]. Thus especially highly myopic patients benefit from pIOL implantation. Various authors report about this effect [35, 36, 37].

One year after surgery, the BCVA of the patients in this study was 0.94 (from 0.5 to 1.25) with a mean spherical equivalent of the refraction error of -0.40 (between -2.25D and +0.50D). 26 eyes (89.65%) were in a range of +/- 1D at this time. Gierek-Ciaciura and coauthors reported 85% of the patients in the range of +/- 1D after 6 months [5] and 100% after one year [4] with the same lens. Their study included 20 eyes of 12 patients.

The average uncorrected visual acuity was 0.63 (from 0.20 to 1.25) 1 year postoperatively compared to a postoperative UCVA of 0.7 in the study of Giereck-Ciaciura and coauthors [4].

A study with the Artisan/Verisyse lens by Moshirfar and coauthors with a two-year follow-up reported a mean SE of -0.53D with 84% of patients in an interval of +/- 1.0D of the intended correction at the end of the observation period [34].

The two-year results of this study are comparable and even better with an average spherical refraction error of -0.21D; 85% of the patients remained within +/-1.0D.

In the third year of the follow-up values were similar with a BCVA of 0.95 (from 0.80 to 1.25) and an uncorrected visual acuity of 0.69 (0.50 – 1.25). Refraction error reached from 0.00D to -0.50D.
In the fourth year, a small decrease in visual acuity was noticed. The mean BCVA was 0.90 (from 0.63 to 1.25) with a refraction error between 0.00D and -1.25D. Uncorrected vision was on average 0.67 (from 0.32 to 1.00). In the fifth year, a further decrease to a BCVA of 0.80 and to an average uncorrected vision of 0.54 (from 0.32 to 0.80) was found. The spherical equivalent of the refraction error was between 0.00D and -1.50D. Even though there was a small decrease in visual acuity in the fourth and fifth year of the study, the last measured BCVA was still better than the preoperative BCVA.

## 4.3 Halos

6 patients (37.5 %) reported halos – particularly during night time. While most of them were not bothered by them, two got medical treatment (Alphagan). Over time, the occurrence of halos disappeared in some patients and in general, all patients were satisfied with the visual outcome.
The occurrence of halos is mainly caused by the edge of the pIOL's optic. A larger optic diameter would reduce the incidence of halos, but the size of the optic is limited in order to avoid contact between corneal endothelium and the pIOL [30].
A possible explanation for this phenomenon is the change of the pupil shape after pIOL implantation. This can induce higher orders of aberrations, which lead to the occurrence of halos. [34]
Moshirfar et al. also describes glares and halos as the most common complication of the Verisyse lens. They appeared in 6% of the patients after one month and in 3% after 2 years. [34]

## 4.4 Endothelial cell loss

Due to the high rate of corneal decompensation after implantation of the early phakic IOLs, preservation of the corneal endothelium is still one of the major aspects in pIOL implantation [3].

In this study, endothelial cell loss was also the major problem and the only reason which lead to explantations of the pIOL.

The decrease was much greater than the annual physiological cell loss of 14 cells/mm² [38] or 0.6+-0.5% per year [39].

Primarily, endothelial cells were sacrificed during the implantation procedure by manipulation in the anterior chamber [2, 40]. The amount depends on the surgeon's experience and lies between 2.1% and 7.6% [2]. The decrease of endothelial cell density during the first year of this study was only 2.03%. This implies that the primary surgical trauma is not to blame for the severe ECC loss.

In their study about the I-CARE lens, Gierek-Ciaciura and co-authors [5] report a mean endothelial cell density loss of 6.12% after the first postoperative year.

Elevation of the intraocular pressure in the early postoperative period also minimizes endothelial cell density [41] and the pIOL implantation may cause a chronic inflammation of the anterior chamber, which is another mechanism for a decrease of endothelial cell density [42], but none of the patients in this study showed signs of inflammation.

The bigger concern was the endothelial cell loss during the postoperative period, caused by transient contact between pIOL and endothelium [31]. To avoid this contact, a certain distance between corneal endothelium and the thickest part of the pIOL of at least 1.5 mm is recommended. This is the critical mid-peripheral distance [2, 3]. Extensive eye rubbing is discussed as another possible reason for intermittent contact and consequently endothelial cell loss [3, 31].

In a study by Menezo et al. [43], a correlation between endothelial cell loss and anterior chamber depth respectively pIOL thickness was found. The smaller the anterior chamber depth or the thicker the pIOL, the higher the endothelial cell loss was found to be. In the same article, an annual check-up examination including endothelial cell count is recommended.

In this study, the central distance between corneal endothelium and the anterior surface of the anterior chamber lens was 1523 micrometres (ranging from 1170 to

1990) at the end of the observation period. In 11 cases (out of the remaining 20) the clearance was lower than 1.5 mm.

Another possible mechanism for ECC loss is a permanent contact between peripheral corneal endothelium and the haptics of the pIOL, especially if the haptics are positioned incorrectly or if the shape of the pIOL is inadequate [44].

However, the transient contact between the pIOL optic and the corneal endothelium seems to be the main risk factor.

In comparison to the distance between cornea and pIOL, the distance between the pIOL and the crystalline lens was on average 1431 micrometers (ranging from 990 to 2000). This leads to the assumption of a vaulting of the pIOL after implantation in some cases.

Compared to the results of a study by Kohnen and co-authors [45], where also the median distance from the central corneal surface to the front face of the pIOL was measured, the distances in this study were much smaller. Artisan, Artiflex I and Artiflex II lenses were analyzed in the study and the mean distances after one year were in the range of 2.50 mm to 2.64 mm.

In another article by Kohnen and coauthors [30], a minimum anterior chamber depth of 3.0 mm and a minimum endothelial cell count of 2000 cells/mm² are defined as a requirement for any pIOL implantation.

J. Coullet et al. blame oversizing for the excessive vaulting of the lens with a consequent endothelial cell loss and furthermore a slight pupil ovalisation. Three cases of I-CARE pIOL explantation are described in the same article. [31]

Another study which analyzed 100 cases of angle-supported AC-PIOL explantations suggests that an excessive vaulting of the lens together with a relatively large optic diameter contributes to the endothelial cell damage [15]. However, different types of AC-PIOLs were analyzed there.

In this study, explantations had to be made in 4 eyes of 3 patients. All showed a massive decrease of the endothelial cell number between 49% and 79% compared to the preoperative endothelial cell count. In one case, a beginning bullous keratopathy was already visible and another patient developed a transient corneal edema during/after explantation which declined afterwards. For the rest, the explantations were performed without complications.

Although the mean endothelial cell density loss in the first postoperative year showed no statistically significant differences between patients who got an I-CARE

pIOL and those who received a Verisyse lens [4], results were very different after the second and the following postoperative years. In this study the endothelial cell density decreased 9.05% from preoperative to the second year, whereas a study with a two-year follow-up of patients with an implanted Verisyse lens showed a decrease of only 6.49% compared to the total preoperative endothelial cell count [34]. A study of Benedetti and co-authors [46], who made a five-year study about endothelial changes after Verisyse pIOL implantation, reported an endothelial cell loss of 4.7% after two years.

Table 4 compares these five-year results of Benedetti with the Verisyse lens [46] with the long-term results of this study.

*Table 4:* Long-term endothelial changes with Verisyse and I-CARE AC-PIOL

| | Mean ECD preoperative (cells/mm2) | EC loss after 1 year | EC loss after 2 years | EC loss after 3 years | EC loss after 4 years | EC loss after 5 years |
|---|---|---|---|---|---|---|
| Verisyse | 2616 | 3.5% | 4.7% | 6.7% | 8.3% | 9.0% |
| I-CARE | 2752 | 2.03% | 9.05% | 16.06% | 21.44% | 27.91% |

An interesting fact is that after the first year the results of the I-CARE lens are comparable to or even better than those of the Verisyse lens. However, already in the second year, the results of the two lenses diverge: while the EC loss with the Verisyse lens was 1.2% from the first to the second year, the I-CARE lens showed a massive EC loss of 7.02%. From the second year on, the annual EC loss with the I-CARE lens was at least 5.38%, with a maximum ECD decrease of 7.01% from the second to the third year. In comparison, the maximum annual ECD decrease with the Verisyse lens from the first year was 2%.

At the end of the observation period, the ECD loss in this study was more than three times higher than the five-year results with the Verisyse lens.

## 4.5 Sizing of the pIOL

According to the assumptions of Coullet and coauthors [31], a correct overall size of the pIOL is essential to avoid postoperative complications.

If the selected pIOL is too small, it can rotate or decentrate, which can lead to light sensations caused by the edge of the optic. On the other hand, a pIOL that is too large can cause deformation of the iridocorneoscleral structures and consequently lead to chronic progressive iris retraction, pupillary ovalisation and partial atrophy of the iris. [3]

Determining the appropriate size is difficult, because it depends on the internal diameter of the anterior chamber, the angle-to-angle distance, which cannot be measured directly with the usual equipment [47]. The size of the I-CARE lens was calculated with a software available on the Corneal homepage and was based on white-to-white measurement.

However, several authors consider white-to-white measurement as inappropriate for pIOL sizing [30, 4, 31].

An analysis of cadaver eyes shows that the vertical white-to-white distance correlates with the angle-to-angle distance, whereas in the horizontal measurement, no correlation was found [47]. The same authors recommend ultrasound biomicroscopy (UBM) and another high frequency ultrasound system to measure accurate angle-to-angle distances. Also, intraoperative measurement with a specific device is mentioned as a less subjective method than white-to-white measurement.

Alió [1] describes intraocular callipers and other surgical devices for intraoperative sizing of pIOLs as inaccurate and unsuitable for precise IOL sizing.

The measured results differ with the applied force on the calliper, the amount of viscoelastics in the anterior chamber, the centering of the calliper's end etc. [3].

A recent publication by Tehrani and co-authors [48] presents a software tool where phakic intraocular lens position can be simulated preoperatively by the use of high-resolution Scheimpflug imaging (Pentacam, Oculus Optikgeraete GmbH, Germany). It is available for the rigid iris-fixated Artisan lens (Ophtech; Verisyse, AMO) and its foldable model (Artiflex/Veriflex).

The program selects the most appropriate IOL and helps the surgeon with defining the optimum position and axis alignment of the pIOL. All distances to proximate structures of the eye are calculated.

The anterior chamber depth decreases over the years and consequently leads to reduced distances between the corneal endothelium and the pIOL. With the new software, even the aging process can be simulated. Thus the new software contributes to the reduction of future complications. [48]

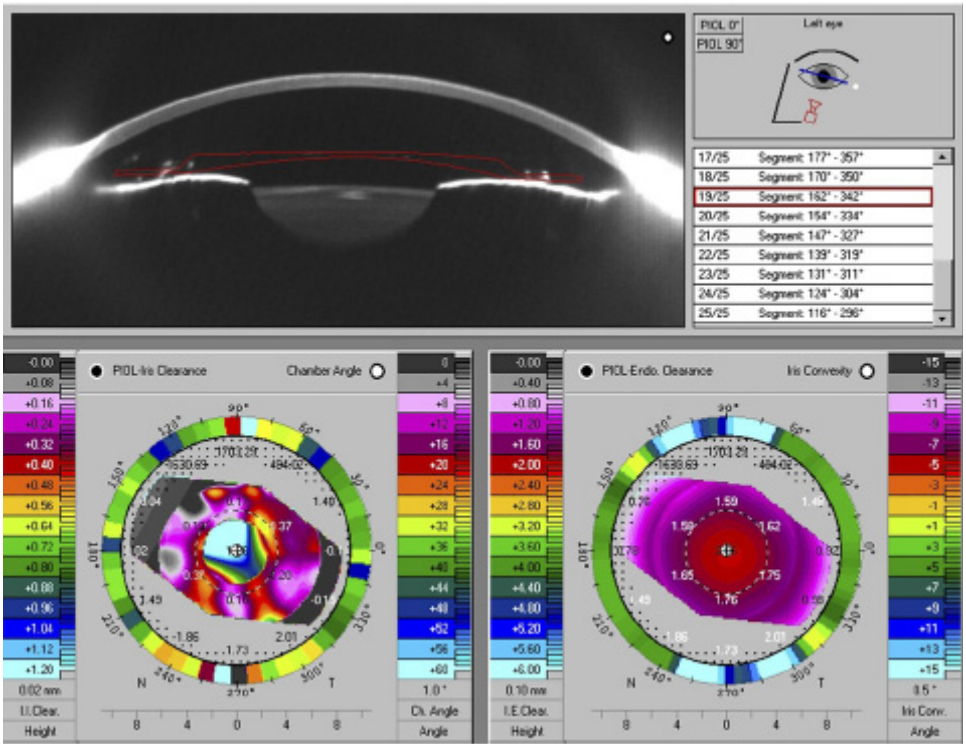



*Figure 25:* Preoperative anterior chamber image with simulation of postoperative pIOL position

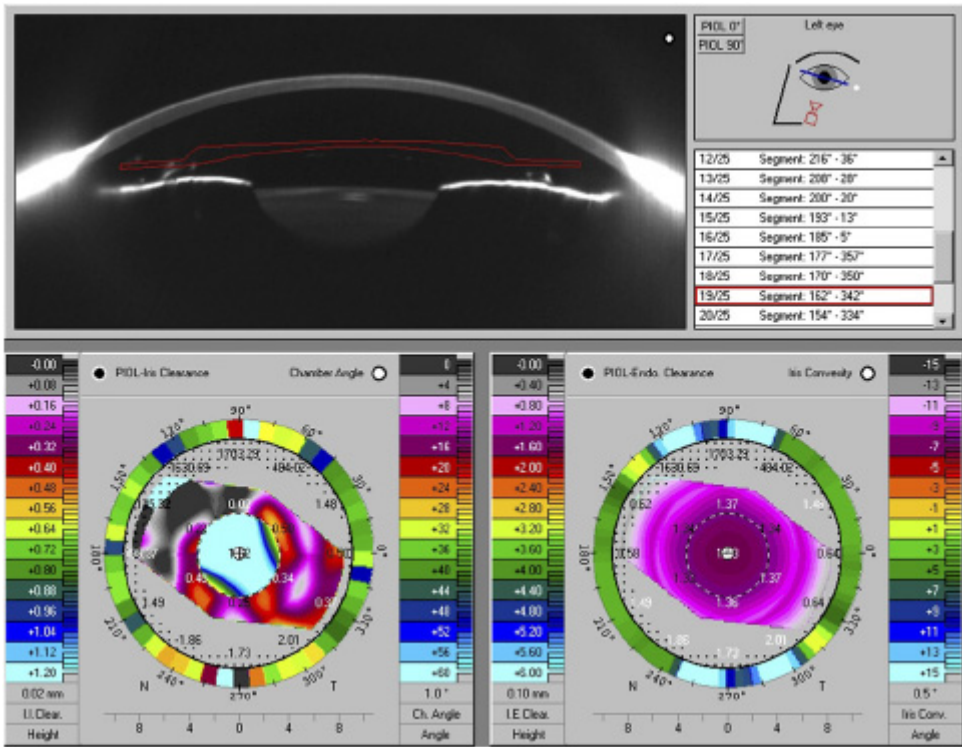



*Figure 26:* Simulation of pIOL position after 30 years

## 4.6 Pupil ovalisation

An analysis of complications with anterior chamber pIOLs by Alió and co-authors [40] reported that pupil ovalisation is a frequent finding in patients with AC-PIOLs.
Kohnen and co-authors [30] also declare pupil ovalisation as a typical complication of angle supported AC-PIOLs. In the same article, a mechanism is described, in which the positioning of the pIOL haptics leads to a chronic progressive ovalisation in direction of the haptics in many cases.
Dick and Tehrani [3] blame inappropriate sizing for ovalisation of the pupil.
In this study, 12 eyes (41.4%) out of 29 showed a mild pupil ovalisation.
No pupil ovalisation was extending beyond the edge of the pIOL optic and therefore no explantations had to be made for this complication.
In comparison, Alió et al. [40] report a slight pupil ovalisation in 10.3% of 263 eyes. A severe pupil ovalisation appeared in 5.9%, which lead to the explantation of the pIOL in two cases.

## 4.7 Rotation and decentration of the pIOL

As previously described, inadequate sizing and consequent implantation of a too small pIOL are blamed for rotation and decentration of the pIOL.
In this study, there were 17 cases in which the pIOL rotated at least 10°. The average rotation was 33°.
Slight decentration of the pIOL appeared in 8 eyes, but none of these patients complained about photophobia.
The only two available studies about the I-CARE lens from Gierek-Ciaciura et al. [4,5] do not report about rotation or decentration at all, but they mention that the white-to-white distance is not the ideal method for calculation of the lens' diameter.
In a study about the angle supported NuVita MA20 (Bausch & Lomb) lens by Allemann et al. [49], 80% of the implanted lenses rotated more than 15° during a period of 2 years.
Baumeister and co-authors [50] compared the position of an angle-supported pIOL (NuVita, Bausch & Lomb), and iris-fixated pIOL (Artisan, Ophtech) and a ciliary sulcus implanted myopic pIOL (Staar ICL) by means of Scheimpflug photography.

They demonstrated that the iris-fixated pIOL has the best positional stability of all examined pIOL types.

## 4.8 Cataract

In a study of Alió and co-authors, where the reasons for explantation of angle supported anterior chamber pIOLs were analyzed, cataract was the most frequent cause for explantations. [15] They report that the mean age for cataract surgery is 65 years in highly myopic patients and that previous surgeries might increase the speed of cataract development. If a patient develops cataract, the ametropia can be corrected during cataract surgery and the use of the AC-PIOL is no longer necessary. The oldest patient at the end of this study was 57 years and showed no signs of beginning cataract in his last check-up examination. Another patient showed an incipient cataract shortly after pIOL implantation. However, the pIOL of this patient had to be explanted due to an excessive loss of endothelial cells.

As angle supported phakic anterior chamber lenses are separated from the lens through the iris, cataract development is not one of the typical complications. Besides, highly myopic patients have an increased risk for cataract, which makes it more difficult to distinguish between myopia- and IOL-induced cataract formation. [30]

In another study by Alió et al. [40], 9 cataract (3.4%) surgeries were performed during a period of 7 years. 263 eyes were analyzed in the study.

## 4.9 Acute and chronic glaucoma

Pupillary block glaucoma after pIOL implantation is a rare complication and appears to be more frequent if the pIOL is implanted in the posterior chamber than after implantation in the anterior chamber [51].

An atonic pupil or the so-called Urrets-Zavalia Syndrome appears after IOP rise, caused by e.g. pupillary block or incomplete removal of viscoelastics during the pIOL implantation [3].

The Urrets-Zavalia Syndrom was defined by A. Urrets Zavalia [52] in 1936. He described a fixed, dilated pupil, iris atrophy and secondary glaucoma as a distinct clinical entity originally following penetrating keratoplasty in keratoconus.

The Urrets-Zavalia Syndrome is often irreversible and not responsive to pharmacological treatment. The pathomechanism is a severe increase of the IOP followed by a sudden ischemia, which paralyses the M. sphincter pupillae. This leads to a wide, fixed pupil without direct or indirect light reaction. Consequences are optical sensations such as glare and halos caused by the edge of the optic. For prevention, a complete removal of viscoelastics and iridotomy are essential. In general, an iridotomy or neodym:YAG iridotomy should be performed during or before implantation of a phakic IOL, independent of the pIOL type and position. [3] Ardjomand et al. [53] also show the importance of iridotomy/iridectomy before pIOL implantation.

Additionally, antiphlogistics containing steroids should be avoided, because they can cause a steroid-induced rise of the IOP, especially in myopic eyes. [3, 30]

Although this complication appears rarely, there were two patients in this study who suffered from an excessive IOP rise to more than 40 mmHg immediately postoperatively. One of them developed an Urrets-Zavalia Syndrome, even though a prophylactic neodymium:YAG iridotomy was performed one day preoperatively.

In the study of Moshirfar et al. [34], one out of 85 eyes developed a postoperative IOP rise. They also suspect that remaining ophthalmic viscosurgical device was responsible for the IOP spike.

Over the years, 2 patients developed a slightly increased IOP, but there is no evidence that this was related to the implanted pIOL.

The fact that the glaucoma rate is more frequent in myopic eyes is well known [14].

## 4.10 Chronic subclinical inflammation

Due to the proximity of implanted pIOL and iris, the possibility for acute or chronic intraocular inflammation arises. As the optic is positioned immediately in front of the iris, the pupillary motion may lead to irritation of iris tissue through intermittent contact or friction. [30]

In this study, no patients showed signs of inflammation.

In literature, individual cases of inflammation can be found. For example, Alió et al. [40] reported an acute postoperative iritis in 4.56% with angle supported AC-pIOLs (ZB5M/ZSAL-4).

## 4.11 Induced astigmatism

Surgically induced astigmatism was a particular problem with rigid AC-PIOLs, which required a long incision for implantation [33].

These lenses usually had a PMMA optic and incision length was between 5 and 6mm. Since foldable pIOL models have been introduced, incisions have become smaller and as a result, induced astigmatism has become less frequent. [30]

As the I-CARE lens is a foldable hydrophilic acrylic lens that requires only a small corneal tunnel for implantation, induced astigmatism was not a problem.

Preoperatively, the average astigmatism was 1.34 diopters (ranging from 0.40 – 2.90 diopters).

Postoperatively, the average astigmatism was slightly higher and amounted on average to 1.40 diopters (ranging from 0.20 to 2.60 diopters), with the latest created corneal topograms being evaluated.

There was no statistically significant difference between pre- and postoperative astigmatism (p= .43).

## 4.12 Other complications

There are reports of severe, vision-threatening complications after phakic intraocular lens implantation in literature. Fortunately, they occur very rarely and in this study, there were no cases of vitreous hemmorage [54], retinal detachment [55, 28], choroidal neovascularization [28] or panophthalmitis [56].

## 4.13 Differences in outcome between men and women

Against the expectation of an equal outcome for men and women, results seem to be different.

Especially from the third postoperative year on, the average endothelial cell count was lower in the eyes of female patients and also, all four explantations of the pIOL were performed in women.

However, the distance between corneal endothelium and front surface of the lens, which is thought to be one of the most important factors for preservation of the corneal endothelial cells [2, 3], was equal.

There are no studies that provide information about different outcomes of I-CARE pIOL implantation between men and women.

An article published by Coullet et al. [31] describes three cases of I-CARE explantation due to severe endothelial cell loss. A woman underwent explantation on both eyes. The second patient was a man, who had the pIOL explanted on one eye. The same patient reported frequent eye rubbing. The authors came to the conclusion that the main risk factor for severe endothelial cell loss appears to be intermittent contact between the pIOL optic and the cornea.

# 5 CONCLUSION

Concerning the refractive outcome, the implantation of the I-CARE pIOL lead to excellent results because both - BCVA and UCVA - increased and remained stable during the whole observation period.

The implantation itself was characterized by a high level of safety. All surgeries were uneventful, except in one eye, which developed an Urrets-Zavalia-Syndrome despite preoperative Nd:Yag-Laser iridotomy.

Postoperatively, some patients reported the occurrence of halos, especially at night, but in general, all patients were satisfied with the visual outcome.

Nevertheless, the I-CARE pIOL failed as a safe method for the correction of high myopia due to frequent and severe complications in the follow-up period. The most serious complication was the constant decrease in endothelial cell density over the years, which lead to beginning corneal decompensation in one case and to 4 pIOL explantations in total. Further preventive explantations are likely to be necessary in the future.

Furthermore, mild pupil ovalisation occurred in many cases, as well as rotation, decentration and vaulting of the I-CARE lens in the anterior chamber, which endangers the corneal endothelium. All these clinical features can be linked with incorrect sizing of the pIOL and the following intermittent contact between lens and inner corneal surface [3, 31]. The calculation of the pIOL size was based on white-to-white measurement, which is considered as inappropriate [4, 30, 31]. Nowadays, there are very accurate methods for anterior chamber measurements e.g. Scheimpflug imaging or high frequency ultrasound systems [45, 47] and they are also more widely available. These new methods enable precise pIOL sizing and therefore the majority of the complications which appeared with the I-CARE lens will be avoided.

Since the I-CARE pIOL is no longer implanted, full attention has to be paid to patients who still carry those lenses. Signs for severe and ongoing endothelial cell loss have to be diagnosed early enough and preventive pIOL explantation or replacement with an optimally sized lens have to be considered to evade further reduction of endothelial cells and corneal decompensation.

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# List of figures

**Figure 25:** Preoperative anterior chamber image with simulation of postoperative pIOL position. Available from: Tehrani M, Schaefer M, Koeppe J, Dick HB. Preoperative simulation of postoperative iris-fixated phakic intraocular lens position and simulation of aging using high-resolution Scheimpflug imaging. J Cataract Refract Surg 2007; 33: page 12

**Figure 26:** Simulation of pIOL position after 30 years. Available from: Tehrani M, Schaefer M, Koeppe J, Dick HB. Preoperative simulation of postoperative iris-fixated phakic intraocular lens position and simulation of aging using high-resolution Scheimpflug imaging. J Cataract Refract Surg 2007; 33: page 14

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## Glossary and abbreviations

| | |
|---|---|
| AC | anterior chamber |
| AC-PIOL | anterior chamber phakic intraocular lens |
| BCVA | best corrected visual acuity |
| CLE | clear lens extraction |
| D | diopters |
| EC | endothelial cell |
| ECC | endothelial cell count |
| ECD | endothelial cell density |
| FDA | U.S. Food and Drug Administration |
| ICL | implantable contact lens |
| IOL | intraocular lens |
| IOP | intraocular pressure |
| LASIK | laser in situ keratomileusis |
| LASEK | laser assisted subepithelial keratomileusis |
| Nd:YAG | neodymium-doped yttrium aluminium garnet |
| PC | posterior chamber |
| PC-PIOL | posterior chamber phakic intraocular lens |
| pIOL | phakic intraocular lens / phake Intraokularlinse |
| PMMA | Polymethylmethacrylat |
| PRK | photorefractive keratectomy |
| RLE | refractory lens exchange |
| SE | spherical equivalent |
| UBM | ultrasound biomicroscopy |
| UCVA | uncorrected visual acuity |

# Project schedule

**Winter 07**

- Choosing a topic in Mugthesis
- Contacting supervisor
- Devising a concept and formulating an appropriate title
- Submitting concept form to Medical University

**Spring/ Summer 08**

- Selection of all patients with I-CARE pIOL implanted at the University Eye Clinic
- Contacting patients and arranging check-up examinations
- Aquiring data
- Literature search
  via pubmed and (Online-) Library of Medical University Graz
  key words: I-CARE, phakic IOL, high myopia, endothelial cell loss, Urrets-Zavalia Syndrome

**Autumn 08**

- Completing data
- Statistical analysis of data
- Writing the abstract

**Autumn/Winter 08**

- Writing the thesis with regular feedback by the supervisor
- Presentation of the results at the 13th ESCRS Winter Meeting in Rome, Italy by Univ-Doz. Dr. N. Ardjomand

**Spring 09**

- Presentation of the results at the *50. Jahrestagung der ÖOG* in Bad Ischl, Austria by Sophie Plainer

# CURRICULUM VITAE, 2009

Sophie Plainer
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Date of Birth: 04.04.1985
Place of Birth: Salzburg
Nationality: Austria

EDUCATION:

| | |
|---|---|
| October 2008 | Started with third term, Trainee Year at Trauma Surgery University Clinic Graz, Internal Medicine, LKH West Graz and currently at University Eye Clinic Graz |
| July 2008 | Completion of the second term |
| since October 2004 | Medical studies at Medical University Graz |
| October 2003/04 | Medical studies at Medical University Innsbruck until completion of first term |
| 1999 – 2003 | High School, Bundesoberstufenrealgymnasium Neumarkt am Wallersee<br>Matura (qualification for university entrance) in subjects Math, German, English, Physics und Music |

EXPERIENCE:

**Work Experience:**

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|---|---|
| July 2008 | Medical Clerkship in Emergency Medicine, exchange program, HUCA, Oviedo, Spain – 4 weeks |
| June 2008 | Medical Clerkship in Cardiology, Innere Medizin 2, LKH Salzburg – 4 weeks |
| March/April 2008 | Medical Clerkship in Internal Medicine, KH der Barmherzigen Brüder, Salzburg – 2 weeks |
| September 2007 | Medical Clerkship in Gynecology and Obstetrics, LKH Salzburg – 3 weeks |
| July 2007 | Medical Clerkship in Ophthalmology, exchange program, CEM „Dr. Rafael Lucio“, in Xalapa, Mexico – 4 weeks |
| August 2006 | Medical Clerkship in Internal Medicine, Innere Medizin 1, LKH Salzburg - 3 weeks |
| July 2006 | Medical Clerkship in Ophthalmology, LKH Salzburg - 2 weeks |
| August 2005 | Medical Clerkship in Surgery, LKH Salzburg - 4 weeks |
| July/August 2004 | Internship at a nursing home in Seekirchen a. W., Salzburg, 6 weeks |

**Jobs:** various jobs at a book trade, textile logistics company, restaurant, nursery home

**Languages:**

| | |
|---|---|
| German | mother tongue |
| English | fluently |
| Spanish | good |
| Latin | qualification in Latin |

**Computer literacy:**

| | |
|---|---|
| Software: | Microsoft Office (Word, Excel, PowerPoint), SPSS, Mac OSX, Photodraw |
| Hardware: | PC, Mac, Scanner, Printer |

**Miscellaneous:**

B driving licence, typewriting

INTERESTS**:**

playing piano, music, photography, reading

Sports: running, hiking, slacklining, cycling
Travel experience: different European countries, USA, South Africa, Ghana, Cuba, Mexico, India