Diploma Thesis

Quality assessment of iris-fixated anterior chamber lens implantation

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Affidavit

Hereby I, Thomas Falb, declare that I have written this diploma thesis fully on my own without any assistance of third parties.
Furthermore I declare that I haven't used any other sources than those cited and that all explanations copied directly or in their sense are marked as such.

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Abstract

Purpose: To assess the intraoperative complication risks and the rate of secondary surgical interventions' necessity of iris fixated intraocular lens implantation for the correction of refractive errors or aphakia.

Material and Methods: Retrospective, single-center data analysis of patients who underwent iris fixated intraocular lens implantation. Data was acquired through the intranet of the Medical University of Graz Eye Clinic and the log books. Data of 327 implantations in 233 patients from 2005 to 2012 was reviewed. Mean follow-up period was 4.30 years, ranging from 0.45 up to 8.39 years. Main outcome measures were intraoperative complications (intraocular haemorrhage, early ocular hypotension, pupil ovalization and decentration, immediate luxation or decentration of the lens, and corneal haze) as well as the rate of needed reoperations for reasons like disenclavation or the need of explantation.

Results: Intraoperative complications occurred in 19 out of 327 cases (5.81%). Intraocular haemorrhage occurred 9 times (2.75%), immediate decentration or luxation of the lens 5 times (1.53%), pupil ovalization or decentration 3 times (0.92%), and ocular hypotension and corneal haze 1 time each (0.31%). Secondary surgical intervention was performed after 20 implantations (6.12%), whereas in 4 cases (1.22%) follow-up surgery had to be performed a second time. Reasons for secondary surgical intervention were disenclavation of the lens (22 cases, 6.73%), 1 case of endophthalmitis (0.31%) and 1 case of corneal wound leakage (0.31%) with the necessity of secondary suturing.

Conclusion: Iris fixated intraocular lens implantation provides a safe way of treating refractive errors and cases of aphakia without adequate capsular support in terms of intraoperative complications and secondary surgical intervention rate.

Kurzdarstellung

Zielsetzung: Die Sicherheit der Implantation von irisfixierten Intraokularlinsen wurde in Hinsicht auf intraoperativer Komplikationen und Auftreten von Reoperationsindikationen kontrolliert.

Material und Methoden: Es wurde eine retrospektive, monozentrische Datenanalyse durchgeführt. Inkludiert wurden alle Patienten bei denen eine irisfixierte Intraokularlinse im Zeitraum von 2005 bis 2012 implantiert wurde. Die Daten wurden mittels des Intranet und der Operationsbücher der Augenklinik der medizinischen Universität Graz erhoben. Die durchschnittliche Nachbeobachtungszeit betrug 4.30 Jahre, mit einem Minimum von 0.45 und einem Maximum von 8.39 Jahren. Zielgrößen waren intraoperative Komplikationen (intraokulare Blutung, frühe okulare Hypertension, Pupillenovalisierung oder -dezentrierung, sofortige Luxation oder Dezentrierung der Linse und Hornhauttrübung) sowie die Anzahl der durchgeführten Revisionen aufgrund von Lösungen der Linse oder der Notwendigkeit einer Explantation.

Ergebnisse: Intraoperative Komplikationen traten in 19 von 327 Fällen (5.81%) auf. Intraokulare Blutungen traten 9-mal (2.75%), sofortige Dezentrierung oder Luxation der Linse 5-mal (1.53%), Pupillenovalisierung oder -dezentrierung 3-mal (0.92%) und okulare Hypotension sowie Hornhauttrübung jeweils 1-mal (0.31%) auf. Reoperationen wurden in 20 Fällen (6.12%) durchgeführt, wobei in 4 Fällen (1.22%) eine zweite Reoperation durchgeführt wurde. Gründe für Reoperationen waren Luxationen der Linse (22 Fälle, 6.73 %), 1 Fall von Endophthalmitis (0.31%) und 1 Fall von Durchlässigkeit der kornealen Inzision (0.31%) mit der Notwendigkeit einer Sekundärnaht.

Conclusio: In Hinsicht auf intraoperative Komplikationen und Reoperationsnotwendigkeit ist die Implantation irisfixierter Intraokularlinsen eine verhältnismäßig sichere Möglichkeit Refraktionsfehler und Aphakie (bei Augen ohne intakten Kapselapparat) zu beheben.

Acronyms

D	Diopters
WTR	with-the-rule
ATR	against-the-rule
LASIK	laser in situ keratomilieusis
PRK	photorefractive keratectomy
LASEK	laser subepithelial keratomilieusis
IOL	intraocular lens
pIOL	phakic intraocular lens
FDA	Food and Drug Administration
ICL	implantable collamer lens
PRL	phakic refractive lens
PMMA	polymethylmethacrylate
SIA	surgically induced astigmatism
BSCVA	best spectacle corrected visual acuity

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1 INTRODUCTION

Refractive errors are widely spread throughout world population. Different methods to correct myopia, hyperopia and astigmatism exist. Most common is the correction by means of spectacles or contact lenses. Among the surgical procedures to correct refractive errors, the keratorefractive procedures are currently the most frequently used. However, if laser refractive surgery is not possible, phakic intraocular lens implantation poses a safe and effective alternative way of treatment. Iris fixated lenses have another indication in aphakic eyes without adequate capsular support.

The implantation of current models of iris fixated lenses is the main subject of this study.

2 OCULAR ANATOMY

2.1 Cornea

The cornea is the translucent front part of the eye and the first anatomical structure passed by light within the axis of vision. At its edge the cornea is attached to the sclera with the limbus in between. It is of elliptical shape with diameters of approximately 12 mm horizontally and 11.5 mm vertically. The thickness of the cornea changes from its central area to the edge, from approximately 0.52 mm at the central up to 1 mm at the limbus (1,2).

The average radius of the cornea's anterior surface is 7.8 mm whereas the average radius of its posterior surface is 6.5 mm, which makes its form spherical. Due to this specific shape, and the difference between the index of refraction of air (1.0) and water (1.33), it has a refractive power of approximately 43 D, which are about two-thirds of the eye's optical power (1).

To provide its transparency, the cornea contains no blood vessels. Nutrition is provided through the lacrimal fluid, the aqueous humor and the blood vessels of the conjunctiva that are closest to the cornea. Because of the lack of blood vessels the risk of rejection after corneal transplantation is pretty low compared to transplantation of other organs (2,3).

The cornea has the highest density of innervation within the human body. Its sensible innervation is provided by the ophthalmic divison of the trigeminal nerve (V1). Due to the high density of sensible nerve endings, injuries of the cornea are extremely painful (3,4).

Five different layers form the cornea: Epithelium, Bowman's membrane, stroma, Descemet's membrane and endothelium.

The epithelium of the cornea is a multi-layered noncornified squamous epithelium. It consists of 5 to 6 layers. The superficial layer consists of plate-shaped cells. Beneath the superficial cells there are 2-3 layers of wing cells. As the inner part of the epithelium there is a sole-layer of basal cells on a basement membrane. The

surface of the superficial cells is formed by microvilli and microplicae, which increase the surface area and the adherence of mucine and the lacrimal fluid (1,4).

Beneath the corneal epithelium is Bowman's layer, also called Bowman's membrane. It contains no cells, consists mostly of collagen fibres and is the thickened superficial layer of the condensed stroma. Upon getting damaged the Bowman's layer cicatrizes (4).

The stroma, as the main part of the cornea, with a diameter of approximately 500 microns, makes up to 90% of its total thickness. It consists mostly of regular arranged collagen fibers (Type I and III) and has a low cell density. Between the collagen fibers there are keratocytes interconnected to strengthen and maintain the collagen fibers (1,2).

Underneath the stroma there is Descemet's membrane. It's the basement membrane of the cornea's endothelial cells and is composed of collagen type VIII and laminin (1,2).

The fifth layer of the cornea is the endothelium. It's formed by a single layer of hexagonal cells, which are post-mitotic. Due to that, endothelial cell-loss can only be comprehended by the left-over cells through flattening and dispersion. The physiological function of the endothelium is that of a permeability barrier between the stroma and the aqueous humor. Nutrients may slip through whereas fluids are actively pumped out of the stroma and into the aqueous humor. This process is of utmost importance to provide the transparency of the cornea. If the endothelial cell density is lower than 500 cells/mm² the endothelium can't provide proper function. This will result in an oedema and a loss of transparency of the cornea. The normal endothelial cell density of an adult is approximately 2,500 cells/mm² (1,2,4).

2.2 Iris

The iris, together with the ciliary body and the choroid, is a part of the uvea. It is a thin circular diaphragm and contains the pupil as its central opening. On its peripheral edge it's attached to the ciliary body, the central edge lies nearly upon the lens. The area where the iris connects to the ciliary body is called sulcus ciliaris. The iris mostly consists of melanocytes, connective tissue and blood

vessels. The iris also divides the anterior segment of the eye into the anterior and the posterior chambers (1,2).

By adjusting the pupil's size the iris is able to regulate the amount of light passing through. For this purpose it contains two muscles, the parasympathetic iris sphincter muscle and the sympathetic iris dilator muscle. The iris sphincter muscle consists of circular arranged smooth muscle cells and is located next to the pupil, whereas the iris dilator muscle is built up of radially arranged smooth muscle cells and is located in front of the posterior pigment epithelium (1,2).

The stroma and pigmented epithelial cells form the two layers of the iris. The stroma is the superficial part and consists of melanocytes, vessels, non-pigmented cells, collagen fibres, and hyaluronic acid. The posterior surface is formed by two layers of strongly pigmented cells which prevent the light from passing (1,2).

2.3 Ciliary body

The ciliary body is the middle part of the uvea, located between the iris and the choroid. Its cross-sectional area is of triangular shape. A distinction is made between two different parts, namely the pars plicata and the pars plana (1,2).

The pars plicata is the anterior part of the ciliary body that connects to the iris. It contains the parasympathetic ciliary muscle, which is responsible for accommodation. Contraction of the ciliary muscle relieves the zonula fibres and therefore causes the lens to become more spherical. On the other hand, relaxation of the ciliary muscle strains the zonula fibres, which results in a flattening of the lens. Through this, accommodation is possible. The surface area of the pars plicata is greatly increased by the ciliary processes. The pars plana has a flat surface and connects to the choroid with the ora serrata as a junction in between (1-3).

Both, the pars plicata and the pars plana, are covered by a two-layered pigmented epithelium. The non-pigmented epithelium secretes the aqueous humor, whereas most of it is produced at the pars plicata due to its larger surface area (1-3).

2.4 Crystalline lens

The crystalline lens is a transparent structure positioned right behind the iris' pupil and in front of the vitreous body. It is completely embedded in a capsule which is connected to the ciliary body by zonula fibres. It's of biconvex arched shape, whereas the posterior surface is stronger bended. In an adult the lens' diameter is approximately 10 to 12 mm. The thickness is about 4 mm, from anterior to posterior pole, but due to accommodation it changes constantly. The lens' refraction power largely depends on the state of accommodation and is about 20 D if distant objects are focused (2,3).

Four main parts form the lens: the lens capsule, the lens epithelium, the cortex and the nucleus. Lens capsule and nucleus consist of crystalline fibres which are formed by the lens epithelium. The lens contains neither nerves nor blood vessels, therefore gets nourished by the aqueous humor (2).

Tension and relaxation of the ciliary muscle control the accommodation, but it's only possible due to the lens' own elasticity. As one is growing older, the lens loses its elasticity and by the age of sixty to sixty-five the ability of accommodation is completely gone. The loss of accommodation due to the loss of the lens elasticity as a result of aging is a condition known as presbyopia (2).

2.5 Iridocorneal angle, trabecular meshwork and Schlemm's canal

The iridocorneal angle is a space in the anterior chamber, limited by the iris and the cornea. It contains Schwalbe's line, the trabecular meshwork and Schlemm's canal as most important anatomical structures.

Schwalbe's line is the border between Descemet's membrane and the trabecular meshwork. With a spongy structure, consisting of connective tissue and trabeculocytes, the trabecular meshwork is permeable for the aqueous humor. However, due to their contractile ability, the trabeculocytes are able to affect the amount of aqueous humor that gets drained (1,4).

Through the trabecular meshwork the aqueous humor reaches Schlemm's canal, a circular channel quite similar to lymphatic vessels. From there the fluid pours into the anterior ciliary veins (1).

2.6 Anterior chamber, posterior chamber and aqueous humor

The anterior chamber gets limited by the posterior surface of the cornea, the iridocorneal angle, the iris and, in the area of the pupil, by the anterior pole of the lens. The smaller posterior chambers' borders are the posterior surface of the iris, the sulcus ciliaris, the zonula processes and fibers, the anterior surface of the vitreous body and the lens' surface (2).

The aqueous humor is secreted by the ciliary epithelium in the posterior chamber and helps to keep up the internal pressure of the eyeball. It also provides the cornea and the lens with proper nutrition. About 2 microliters per minute are floating from the posterior chamber to the anterior chamber through the pupil (2).

3 AMETROPIA

To provide a clear image, the eye has to focus the incoming light on to the retina. Ametropia, also known as refractive error, occurs if the eye's focus is either in front or beyond the retina. This is caused by a discrepancy between the eye's anteroposterior diameter and its refractive power. There are three different kinds of refractive errors: Myopia, hypermetropia and astigmatism (5).

3.1 Myopia

Myopia, also known as short-sightedness, is a condition in which close objects may be seen clear whereas distant objects seem blurry. The myopic eye is either too long or its refractive power is too large. As a result, the focal point is in front of the retina while the eye focuses distant objects. A distance of 1 mm from the focal point to the retina equals a myopia of about 3 D. (2,3,5).

A myopia caused by an elongated anteroposterior diameter is also known as “axial myopia”, whereas the term “index myopia” refers to a myopia caused by an increased refractive power (5).

Axial myopia is further divided into myopia simplex and myopia magna. Myopia simplex starts around the age of 10 and progression stops until the age of 20. The progression of myopia simplex correlates with the growth of the body in general (2,6). The myopia magna is, in contrast to the myopia simplex, a disease, often transmitted recessively. In myopia magna the axial length of the eyeball increases continually, usually resulting in high levels of myopia with a spherical equivalent of -6 D and higher (3).

The prevalence of myopia is approximately 30%, whereas only 2.5% of persons with myopia have a high myopia of more than -6 D (2).

The extension of the axial length of the eye does not only result in myopia, but leads to more complications namely an increased risk to open angle glaucoma, choroidal and retinal atrophy, retinal detachment, lacquer cracks and staphyloma. Therefore, frequent checks are highly recommended in patients with high myopia (5,7).

3.2 Hypermetropia

Hypermetropia, also known as hyperopia or far-sightedness, occurs if the focal point of the eye is beyond the retina. This is a result of a reduction of either the axial length or the eye’s refractive power, whereas the reduced axial length is by far the more common cause. As far as accommodation is still possible, the eye may adapt to hyperopia. While a young person may easily adapt to a hyperopia of 4 D at far distance, in a distance of 33 cm another 3 D of refractive power would be required. As example, reading at close distance would require an accommodation of 7 D which over time will most likely cause troubles such as headache, stinging eyes, fatigue, blepharoconjunctivitis and blurred vision. This symptom complex is also known as asthenopia (1-3).

Due to the constant accommodation, the ciliary muscle of young hyperopic people is not able to relax completely even if the defective vision would be corrected by a

plus lens. This degree of hypermetropia can only be revealed after medical induced paralysis of accommodation and is referred to as latent hyperopia, whereas the percentage of hypermetropia that may be detected without cycloplegia is known as manifest hyperopia. The overall amount of hyperopia, combining both latent and manifest hyperopia, is called total hyperopia (2,3).

3.3 Astigmatism

Astigmatism occurs if two perpendicular meridians of the cornea have different refractive powers. As a result, the cornea's surface is not spherical and the light rays are not focused onto one point, but rather onto a line. Mostly the vertical meridian is steeper than the horizontal meridian. Thus it is called "with-the-rule" (WTR) astigmatism, whereas "against-the-rule" (ATR) astigmatism refers to a situation in which the horizontal meridian is the steepest. If the principal meridian lies more than 20° from 90° or 180° it is called oblique astigmatism. WTR astigmatism is thought to be a result of the constant pressure of the upper eyelid onto the cornea (1-3,5).

Furthermore astigmatism may be classified due to the refractive error of the meridians. A distinction is made between simple, compound and mixed astigmatism. Simple and compound astigmatism may either be myopic or hyperopic. On simple astigmatism one meridian is emmetropic and the perpendicular meridian shows the refractive error, whereas with compound astigmatism both meridians together are either myopic or hyperopic but with different extents of refractive error. If one meridian is either myopic or hyperopic and the perpendicular meridian is the opposite, it is referred to as mixed astigmatism (2).

WTR and ATR astigmatism as well as oblique astigmatism are all forms of regular astigmatism, because in these cases the principal meridians are perpendicular to each other. However, there is also irregular astigmatism, where diverse areas of the cornea differ greatly in terms of refractive power, usually due to an irregular surface as a result of scarring or keratoconus (2,5).

4 CONSERVATIVE TREATMENT OF REFRACTIVE ERRORS

Since the refractive power of ametropic eyes is either insufficient or excessive in relation to the axial length, or in the case of astigmatism, that differs between different meridians, a correction with lenses of suitable positive or negative refractive power is a possible treatment.

4.1 Spectacles

Nowadays spherical glasses with a convex anterior surface and a concave posterior surface, which provide the same focal point in every viewing direction, are used for the correction of myopia and hyperopia. They may provide a convergent or a divergent power. For the correction of astigmatism, cylindrical lenses are used, which bend light only in one meridian, while having no or different refractive power in the perpendicular meridian. Bifocal, trifocal or progressive lenses provide an option of treating ametropia together with a loss of accommodation. These lenses show different refractive powers in different areas. The upper part of the lens is used for distant viewing, therefore has more negative or less positive refractive power than the lower part, which is used for close viewing. In other words, the lower area of the lens has an extra near addition of positive optical power (2,3).

4.2 Contact lenses

Contact lenses are an alternative way to correct refractive errors conservatively. They are placed on the surface of the cornea and adhere to it. Due to their firmness, they are divided into “rigid” and “soft” lenses. Rigid lenses are smaller than the cornea. They should rest upon the cornea loosely, so that each blink of the eye is able to move them and to refresh the tearfilm beneath. However due to their rigidness they provide an advantage in correction of astigmatism and keratoconus. Soft contact lenses have a better permeability but they are less effective in terms of astigmatism. Both types, rigid and soft lenses, are made of synthetic material (2,3,5).

However, contact lenses don't suit to every patient. Especially for older people, the insertion of the contact lens may prove to be too difficult. Furthermore, contact lenses need a hygienic handling, otherwise they might lead to infection and even to corneal ulceration. In some professions, which, for example, include working with dust or steam, they are no good alternative in correcting refractive errors (2).

5 REFRACTIVE SURGERY

The objective of refractive surgery is the correction of myopia, hyperopia and astigmatism. This can be achieved by manipulating the refractive power of the eye, either by altering the corneal shape, inserting a corrective intraocular lens or exchanging the lens with an artificial lens.

Current options in refractive surgery may be divided mostly into laser refractive surgery and the insertion of phakic intraocular lenses. In laser refractive surgery the correction of the refractive error is achieved by modifying the corneal shape. It was established within the 1980's due to the introduction of the excimer laser. Today's most common procedures are the photorefractive keratectomy (PRK), laser stromal in situ keratomilieusis (LASIK), laser subepithelial keratomilieusis (LASEK), and the epikeratome based LASIK namely Epi-LASIK, whereas LASIK may be seen as the most popular laser refractive procedure (1,5,8).

The first phakic intraocular lenses were implanted in the 1950's. During the 1980's and the 1990's the development of surgical techniques and intraocular lenses themselves was progressing, however due to an unacceptable high complication rate many pIOLs had to be withdrawn from the market (9).

5.1 Excimer laser refractive surgery

With the introduction of the excimer laser, refractive surgery made a huge progress in terms of precision and reliability. The first excimer laser based operation was performed by Theo Seiler in 1985 on a blind eye after removing the epithelium mechanically (1).

The different excimer laser refractive procedures may be divided into two groups: The superficial procedures (PRK, LASEK, Epi-LASEK) and the lamellar excimer laser surgery (LASIK, Femto-LASIK) (1,8).

With PRK the first effective laser based procedure of refractive surgery was introduced in the 1980's, followed by LASIK in 1990, which replaced the PRK as the predominant refractive procedure due to its lower complication rate (5,10,11). However, the superficial procedures were developed further, thus PRK was followed by LASEK and Epi-LASIK (1).

5.1.1 Superficial ablation procedures

The basic principle of all superficial procedures is the reshaping of the anterior stromal surface of the cornea with the excimer laser, and thereby altering its refractive power, after removing its epithelium. The method of the epithelial removal is to distinguish the different surgical procedures. An important advantage to LASIK is the fact that the superficial procedures are less restricted by the cornea's thickness. On the other hand the postoperative pain is more severe and it takes more time for patients who undergo superficial ablation to achieve their visual acuity than it takes for patients who undergo LASIK (5,8,12). The superficial procedures are able to correct refractive errors from +3 D to -8 D and up to 6 D of astigmatism (13).

The method first invented was the PRK. During PRK the epithelial layers get separated from the Bowman's layer by mechanical debridement and get discarded. For reducing the postoperative pain a bandage contact lens is inserted (12). Still this procedure may be considered as the most painful even if the difference between PRK and LASEK is not great (14-16).

In LASEK the epithelial sheet is carefully removed and preserved with assistance of alcohol application. After the ablation of the stroma, the epithelial sheet is replaced and a bandage lens is inserted. Compared to PRK, LASEK is considered to be less painful with a faster visual recovery (1,5,12).

In Epi-LASIK the epithelial sheet gets removed mechanically by use of an epikeratome. An advantage of Epi-LASIK is the avoidance of alcohol and therefore

a better viability of epithelial cells. However, the Epi-LASIK is the most expensive of the surface ablation procedures (1,5,17).

5.1.2 Lamellar laser refractive surgery

Lamellar laser refractive surgery mostly refers to LASIK. In LASIK surgery the ablation of the stroma is done after producing a partial-thickness lamellar corneal flap with a microkeratome and folding it back. After the reshaping of the stroma, the corneal flap then is replaced. The flap attaches to the stromal bed due to adhaesion, therefore a suture is not necessary (1,2,18). Compared to the surface ablation methods, LASIK shows a faster visual recovery and less postoperative discomfort (2,19). However, this surgical method bears the risk of flap-related complications, such as incomplete flap, free cap, thin flap, buttonhole flap, dislodged flap, flap striae and of course corneal perforation (5,20). Nowadays the corneal flap may also be formed by the use of a femtosecond laser. This surgical procedure is thus known as Femto-LASIK. The Femto-LASIK has a lower complication rate and a higher variability of flap-parameters (1).

LASIK shows good results for the correction of refractive errors of +3 D to -8 D and up to 5 D of astigmatism (13). After removing the corneal flap the residual thickness of the stroma should be at least 250 µm. Considering the flap thickness and the depth of ablation by the excimer laser, LASIK should not be performed on a cornea with a minimal depth less than 500 µm (21).

5.2 Refractive lens exchange

The extraction of the crystalline lens followed by the implantation of an intraocular lens into the capsular bag, known as refractive lens exchange, is also a way to correct ametropia. The crystalline lens gets removed by the use of the phacoemulsification technique, similar to cataract surgery in an early stage. The lens exchange causes a loss of accommodation, therefore it is only recommended in patients with either myopia or hyperopia and coexisting presbyopia. Further major complications are retinal detachment, secondary cataract, rupture of the capsular bag, and a low risk of endophthalmitis (1,22).

5.3 Phakic intraocular lenses

The implantation of phakic intraocular lenses was first done in the 1950's. However, due to insufficient technology and inadequate surgical knowledge, the complication rate was too high and therefore the first generation of phakic IOLs was bound to fail. Continuous research and development lead to a new generation of phakic intraocular lenses with excellent efficacy, predictability and safety (9,23).

The implantation of a phakic intraocular lens (pIOL) is an alternative to laser eye surgery or refractive lens exchange, especially in treating moderate to severe myopia. But myopia isn't the only indication for the implantation of phakic intraocular lenses. There are also models for correction of hyperopia, astigmatism and aphakia. Excimer laser eye surgery may be the more common way of treating lower refractive errors, but it is restricted by the cornea's thickness and the risk of iatrogenic keratectasia (9,24). Phakic intraocular lenses provide a way of treating high refractive errors, and, if needed, can be combined with refractive laser surgery to treat even higher refractive errors. The implantation of a pIOL may be used for the correction of myopia of -3 D and hyperopia of +2 D at least. However, it is recommended for myopia of more than -6 D and hyperopia more than +3 D. The available refractive power of the current models, with a FDA or CE authorization, ranges from -2 to -23.5 D for myopia, and from +1 to +22 D for hyperopia (9,13).

The implantation of phakic intraocular lenses has several advantages. As the crystalline lens is preserved, the eye maintains its accommodation ability. Since the optical limits of the pIOL exceed the limits of the eye itself, an improvement of the retinal image may be achieved. Compared to corneal procedures or the refractive lens exchange, the implantation of a phakic intraocular lens is potentially reversible. Because the optical outcome is less affected by healing processes, it is highly predictable especially with the possibility of further adjusting the optical power with fine-tuning corneal surgeries (25-27).

Phakic intraocular lenses do also have disadvantages. Complications may be the result of the anesthesiological methods, the intraocular surgical procedure or the phakic IOL itself. They may occur either during the operation or afterwards. Major

complications due to anaesthesia are retrobulbar haemorrhage, penetration of the globe, allergic reaction to the anaesthetic or accidental injection into the optic nerve, which may cause cardiovascular problems and even respiratory paralysis, but has rarely been observed (24,26).

General perioperative complications in phakic iris-fixated lens implantation are quite similar to the complications in cataract surgery. Possible intraoperative complications are a loss of intraocular pressure due to an excessive leakage through the corneal tunnel incision, prolapse of uveal tissue through the incision and Descemet's detachment. Hyphema may either occur during the operation or postoperatively. Surgically induced astigmatism as a result of the corneal incisions is also a well-known postoperative complication (28).

Since the implantation of a phakic IOL is an invasive procedure, it bears the risk of developing postoperative endophthalmitis (1,24,26). With the additional prophylactic use of intracameral cefuroxime the incidence of postoperative endophthalmitis following cataract surgery may be reduced below 0.08% (29). However, only one case of endophthalmitis after implantation of a phakic intraocular lens has been reported (30). Another inflammatory complication of phakic IOL implantation is the toxic anterior segment syndrome, which is always culture negative and usually improves with steroid treatment (31,32).

Specific complications are caused by the phakic intraocular lenses themselves. The range of complications is quite similar despite the different pIOL designs, though they might differ in incidence rates. Major complications would be the corneal endothelial cell loss, surgically induced astigmatism (SIA), pupil ovalization, iris retraction, optical aberration, haze, glare, pigment dispersion, intraocular lens deposits, intraocular pressure evelation, intraocular lens rotation, chronic inflammation or uveitis, cataractogenesis, and retinal detachment. There is also the possibility of incorrect power or upside-down implantation of the phakic intraocular lens (1).

Due to their placement in the anterior eye segment, phakic intraocular lenses are currently categorized into three different groups: angle-supported anterior chamber lenses, iris-fixated anterior chamber lenses and posterior chamber lenses.

5.3.1 Angle supported phakic intraocular lenses

The angle supported phakic intraocular lenses are implanted into the anterior chamber in front of the pupil, with their haptics resting in the chamber angle and providing the lens' stability within the eye. Today's angle supported lenses are foldable to reduce the size of the needed corneal incision, and therefore reduce the risk of developing surgically induced astigmatism. Current models with either FDA- or CE- approval are the Kelman Duet and the AcrySof Cachet (1,9).

5.3.2 Iris-fixated phakic intraocular lens

The iris-fixated lenses, also known as iris-claw lenses, are implanted into the anterior chamber. The lens is hold in place through enclavation of the midperipheral iris stroma by the haptics. The first iris-claw lens was the "lobster claw" lens invented by Jan Worst in 1978. There are currently two types of iris-fixated lenses, the rigid and the foldable lenses. The rigid models are the Artisan-pIOL and the Verisyse-pIOL, which are both made of polymethylmethacrylate (PMMA) and are identical in design. The foldable models are the Artiflex-pIOL and the Verisyse-pIOL. Their haptics are rigid and made of PMMA whereas their optic consists of polysiloxane and therefore is flexible. The foldable models require a smaller incision, and therefore bear less risk of developing surgical induced astigmatism (1,9,26).

Figure 1: Artisan/Verisyse phakic intraocular lens.

Figure 2: Artiflex/Veriflex phakic intraocular lens.

5.3.3 Posterior chamber phakic intraocular lens

The specific complications of phakic anterior chamber lenses lead to the development of posterior chamber lenses. Due to the implantation behind the iris, the risk of endothelial cell loss and corneal haze should be reduced. There are currently two different models approved by the FDA and/or the CE, the implantable collamer lens (ICL) and the phakic refractive lens (PRL). The foldable ICL is implanted through a 3 mm corneal incision using a microinjector and its haptics are positioned in the sulcus ciliaris (1,9). The PRL is also foldable but needs a corneal incision of 3.2 mm in size. It theoretically floats in front of the lens upon a layer of aqueous humor, having no contact to the anterior capsule or the crystalline lens itself. It also should not exert force onto the ciliary structures (33). However, due to its lack of fixation, the PRL is not absolutely rotation-stable and therefore not always suitable for correcting astigmatism (9).

6 STUDY

6.1 Purpose

Phakic intraocular lens implantation is an alternative way for treating refractive errors. Different kinds of placement (anterior or posterior chamber) or fixation (angle-supported or iris-fixated) as well as many different types of lenses have been developed. Overall, they show good results in terms of safety and visual outcome. However, most studies focus on visual outcome only. The intraoperative risks and complications, as well as the frequency of events which need secondary surgical intervention, are not frequently analysed.

To provide extended information about possible side effects and outcomes to the patients, the exact percentages were evaluated in a retrospective study.

This study evaluates all cases of iris-fixated intraocular lens implantation at the Eye Clinic of the Medical University of Graz during the period 2005 to 2012 and focuses on the occurrence of intraoperative complications and events with the necessity of secondary surgical intervention.

6.2 Materials and Methods

6.2.1 Data collection and statistical analysis

Records from patients, who underwent iris-fixated phakic intraocular lens implantation of Artisan-, Artisan pediatric-, Verisyse-, Artiflex-, Veriflex-pIOL were reviewed by the use of the Eye clinic's intranet. All implantations from 2005 to 2012 (8 years) at the Eye Clinic of the Medical University of Graz were reviewed, resulting in a total number of 327 implantations in 233 patients. Main outcome measures were intraoperative complications, such as intraocular haemorrhage, early ocular hypotension, pupil ovalization and decentration, immediate luxation or decentration of the lens, and corneal haze. Furthermore the rate of needed reoperations for reasons like repositioning or the need of explantation, were evaluated. The exact refractive power and the diameter of the optics of the implanted pIOLs were acquired from the log-books.

Data concerning date of birth, gender, date of primary iris-fixated pIOL implantation (at the Medical University of Graz Eye Clinic), side on which surgery was performed, type of phakic intraocular lens (including a distinction between spheric or toric lens), optical diameter of the lens, refractive power of the implanted pIOLs, and method of implantation (classic or retropupillary fixated) was collected in a spreadsheet in Microsoft Excel 2003 (Microsoft Corporation). Further evaluation and statistical analysis were made with Microsoft Excel 2010 (Microsoft Corporation) and SPSS 20 (SPSS, Chicago, Illinois).

Correlations were assessed through Pearson's correlation. To evaluate possible differences in terms of complication or reoperation risks between rigid and flexible types of iris-fixated pIOL, cross tables were created and chi-square tests were performed.

For the further evaluation of the refractive power of toric lenses, the spherical equivalent was calculated. This caused cases of quarter diopters, which actually shouldn't exist because the implanted lenses are only available in 0.5 increments. Still, they were listed to ensure the accuracy of the study.

Follow-up period was ending at 01/06/2013, ranging from 0.45 up to 8.39 years with a mean follow-up of 4.30 years.

6.2.2 Rigid iris-fixated phakic intraocular lenses (Artisan, Verisyse)

The Artisan-pIOL (Ophtec BV, Groningen, The Netherlands) and the Verisyse-pIOL (Abbott Medical Optics. Inc. Abbott, IL, USA) are single piece phakic intraocular lenses consisting of PMMA, which makes them rigid. Their haptics are claw-shaped and are diametrically opposed. The lens is fixated by enclavation of the iris by the haptics. Several models exist for the correction of myopia, hyperopia, astigmatism and aphakia (9,26).

Different models for the correction of myopia are currently available. They differ in the diameters of the optics and in the range of refractive power.

- Model 206 has a 5.0 mm optical zone and its refractive power ranges from -3.0 to -23.5 D.
- Model 204 has a 6.0 mm optical diameter and its refractive power ranges from -3.0 to -15.5 D. Both models are available in 0.5 D increments in their range of refractive power.
- Model 203 is available or the correction of hyperopia. With an optical zone of 5.0 mm it provides a refractive power between +1.0 to +12.0 D also in 0.5 D increments.
- The toric model ranges from +12.0 to -23.5 D in terms of refractive power, with an additional cylinder at 0 or 90 degrees, with refractive power ranging from +1 to +7 D. Both values are available in steps of 0.5 D. The toric model's optical diameter is 5.0 mm. The overall length of all models is 8.5 mm (9).
- For the correction of aphakia there is an individual model, namely the Artisan aphakia, with an overall diameter of 8.5 mm and an optical diameter of 5.4 mm. Its dioptric power ranges from +2.0 D to +30.0 D in 1.0 D increments, whereas from +14.5 D to +24.5 D it is also available in 0.5 D increments (34).

- Additionally for small eyes, like in children, there is the Artisan pediatric aphakia lens with a smaller optical diameter of 4.4 mm and an overall diameter of either 6.5 or 7.5 mm. The range of dioptric power is similar to the Artisan aphakia (34).

6.2.3 Foldable iris-fixated phakic intraocular lenses (Veriflex)

- The Veriflex-pIOL (Abbott Medical Optics. Inc. Abbott, IL, USA) consists of a flexible hydrophobic polysiloxane optic and the rigid haptics made of PMMA. Due to the foldability of the optical part, the Veriflex lens can be inserted through an incision of only 3.1 mm, even though the optical diameter is 6 mm, if unfolded. The available refractive power ranges from -2 to -14.5 D in 0.5 increments (9).
- The Artiflex-pIOL is also a foldable iris-fixated phakic intraocular lens, identically in construction to the Veriflex-pIOL, but produced by Ophtec BV (Ophtec BV Groningen, The Netherlands).

6.2.4 Implantation of rigid iris-fixated anterior chamber lenses

The implantation is performed in retrobulbar, parabulbar or general anaesthesia. For the implantation of the Verisyse- or Artisan-pIOL a corneal or sclerocorneal tunnel of either 5.2 mm or 6.2 mm, depending on the diameter of the chosen model, is made at 12 o'clock. Two paracenteses are created, usually at 10 o'clock and 2 o'clock. To protect the anterior surface of the crystalline lens miosis is induced by injecting acetylcholine chloride into the anterior chamber. To prevent the anterior chamber from collapsing, it is filled with a viscoelastic medium (methyl cellulose, Healon GV). The pIOL then is inserted into the anterior chamber and rotated into a horizontal position, with the optic lying in front of the pupil. By the use of an enclavation needle, the iris is pushed into the haptics. After the correct position is checked, the viscoelastical device is removed and saline is inserted to uphold the intraocular pressure. To prevent an increase of the intraocular pressure due to a pupillary block, a peripheral iridotomy is made either during surgery or before surgery by means of the Nd:YAG-laser. If sutures are necessary, a 10-0 nylon suture is usually used.

The rigid phakic intraocular lenses may also be implanted retropupillary, as a way of treating aphakia in cases of posterior capsular rupture. If implanted retropupillary, the pIOL is centered behind the pupil before acetylcholine chloride is injected and the enclavation is performed (35).

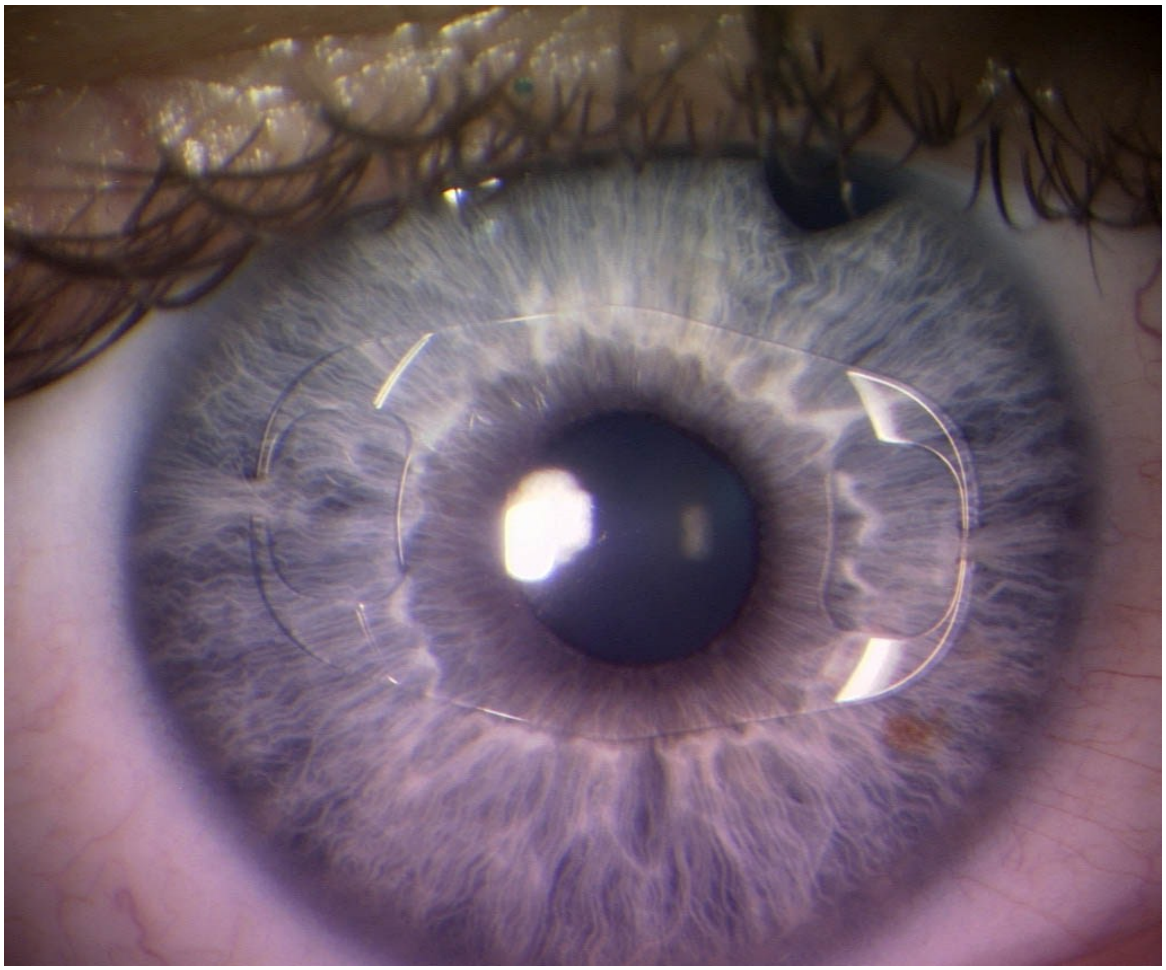

Figure 3: Artisan/Verisyse lens in situ.

6.2.5 Implantation of flexible iris-fixated phakic intraocular lenses

The implantation of flexible iris-fixated pIOLs is quite similar to the implantation of their rigid counterpart. The main difference is the way of inserting the pIOL. Due to their flexibility, a smaller corneal insertion of 3.1 mm is sufficient. The lens itself is inserted by the use of a specially designed spatula. A second difference is the way of grasping the pIOL while bringing it into the right position. While the rigid lenses are grasped at the edge of the optic, the flexible pIOLs are grasped at the base of the haptic (9).

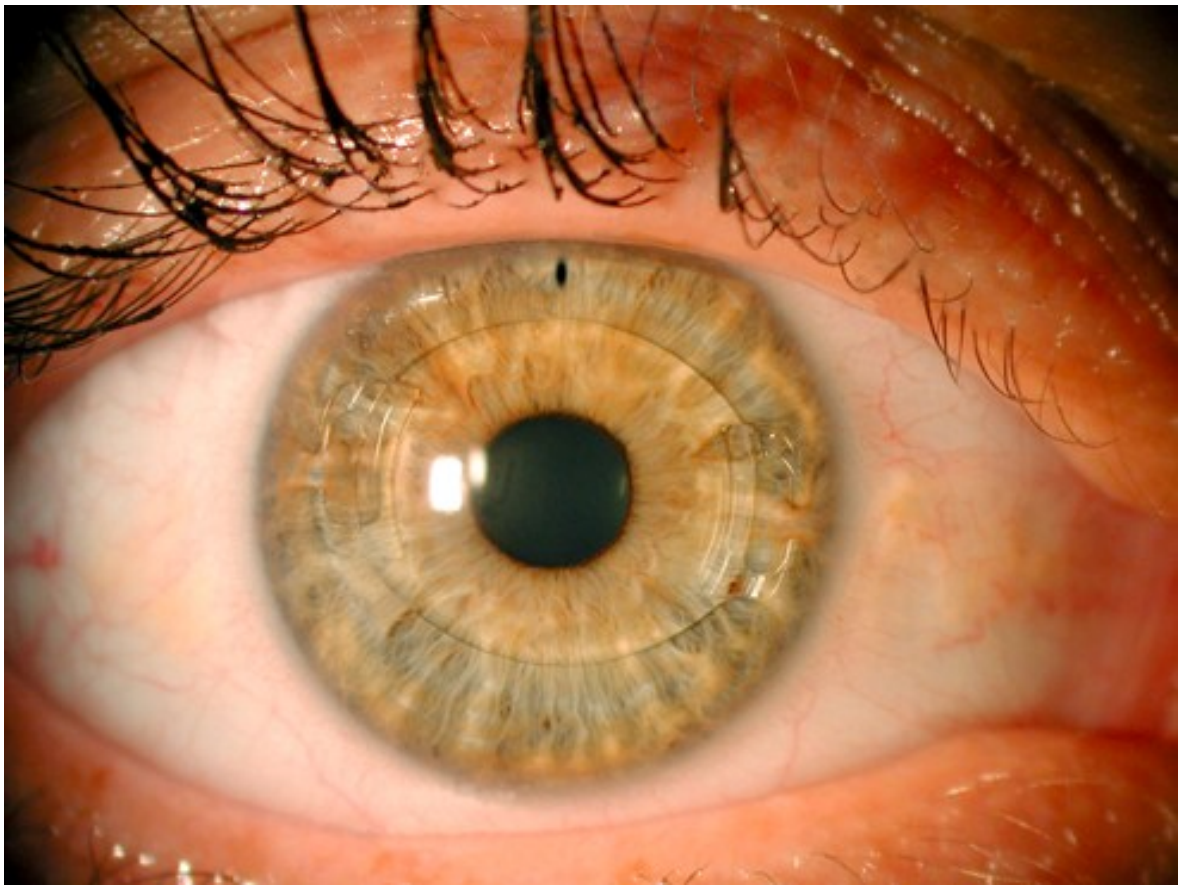

Figure 4: Artiflex/Veriflex lens in situ.

6.3 Results

6.3.1 Patients demographics

Data of 233 patients who underwent phakic IOL implantation from 2005 to 2012, was reviewed, resulting in a total number of 327 cases of phakic IOL implantation. Of these 233 patients, 123 (52.8%) were male and 110 (47.2%) were female (Figure 1). However, referring to the total number of surgeries, 162 (49.5%) were performed on male patients, while 165 (50.5%) were performed on female patients (Figure 2). The age at the time of surgery was ranging from 2 to 97 years, with a mean age of 43.55 years (Figure 3).

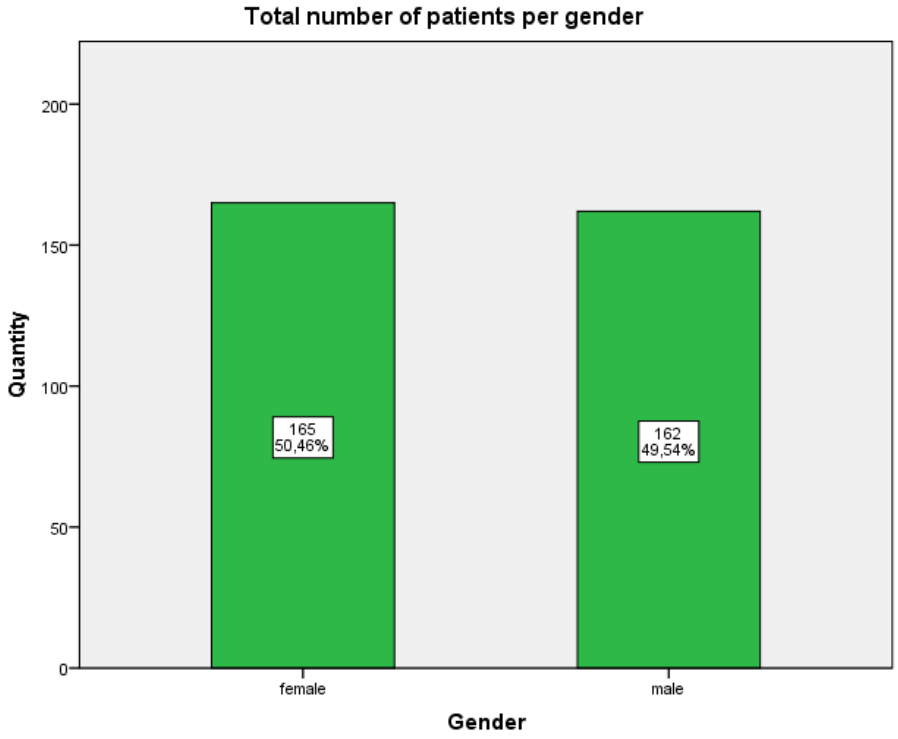

Figure 5: Patients per gender.

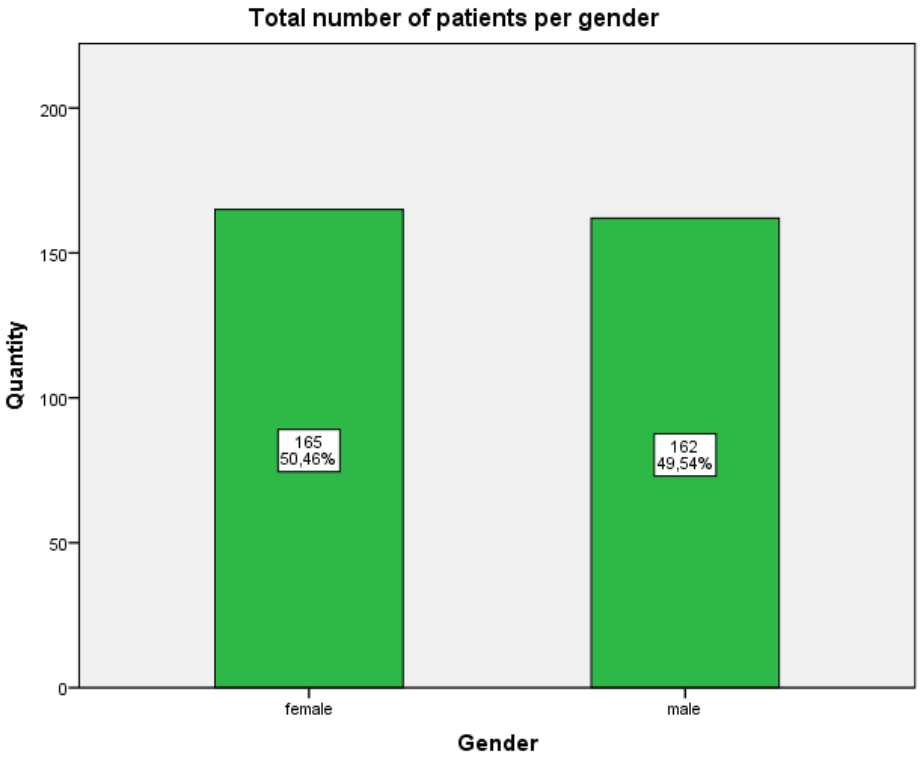

Figure 6: Implantations per gender.

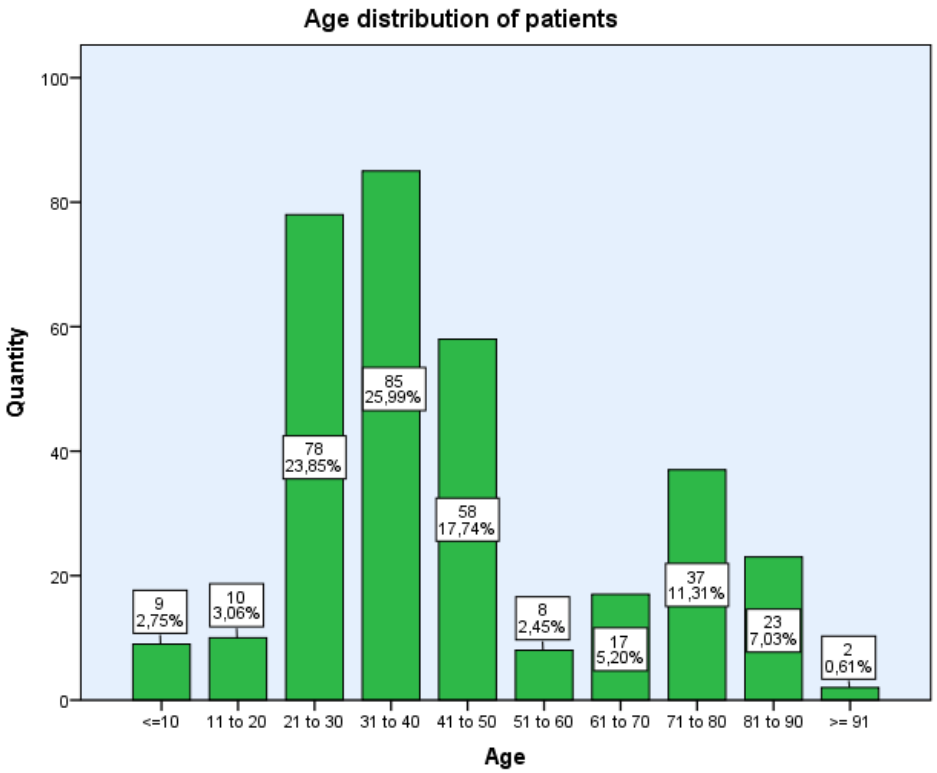

Figure 7: Age distribution of patients.

6.3.2 Frequencies of implantation of the different pIOL types and implantation methods

A total number of 327 phakic iris-fixated intraocular lenses were implanted. Of those 327 lenses, 7 (2.1%) were Artisan-, 15 (4.6%) were Artiflex-, 5 (1.5%) were Artisan pediatric-, 196 (59.9%) were Verisyse- and 104 (31.8%) were Veriflex-pIOLs (Figure 4).

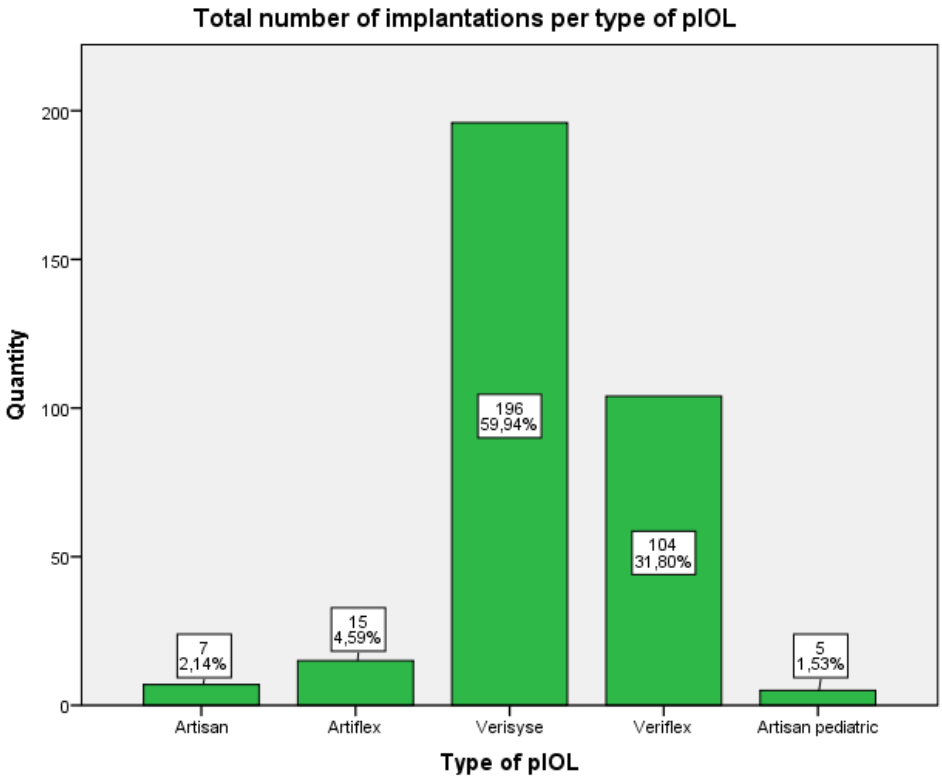

Figure 8: Total number of implantations per type of pIOL

In 312 (95.4%) out of 327 cases, the implanted lens was a spherical lens. Toric lenses were implanted in 15 cases (4.6%).

Retropupillary implantation was performed in 90 (27.5%) cases, of those 87 were Verisyse- and 3 were Artisan pediatric-lenses. No retropupillary implantations were performed with other types (Figure 5).

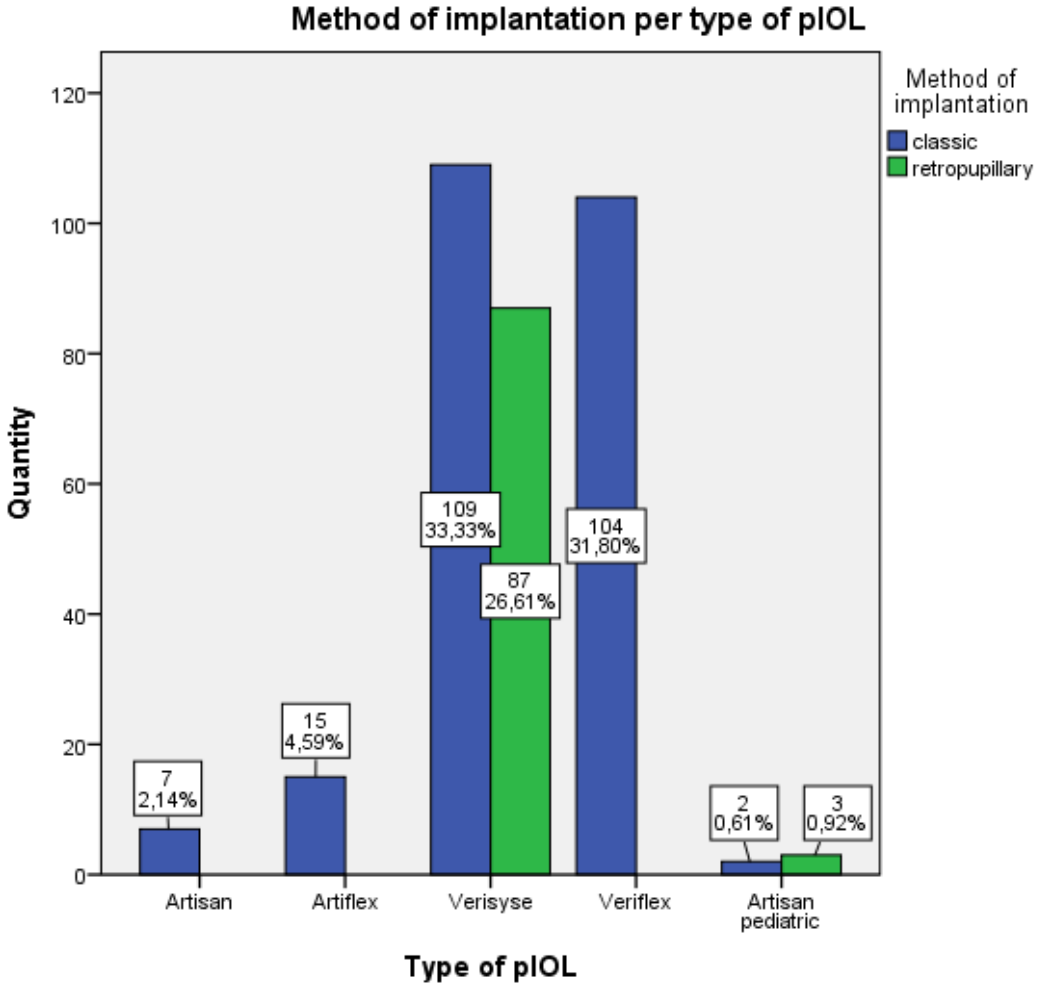

Figure 9: Method of implantation per type of pIOL

Furthermore, the total number of implantations in myopic and in hyperopic eyes was evaluated. Phakic intraocular lenses were implanted in 200 (61.2%) cases of myopia, and in 127 (38.8%) of hyperopia. Of those 127 pIOLs, 120 (94.5%) were models for the correction of aphakia and 7 (5.5%) were phakic models. The refractive power of implants for myopia was ranging from -6.0 D to -22.5 D, with a mean refractive power of -11.3 D. Refractive power of lenses implanted to correct hyperopia or aphakia was ranging from + 5.0 D to +30.0 D with a mean refractive power of +18.8 D. The total number of implantations per refractive power of the phakic IOLs may be seen in Figure 6 and Figure 7.

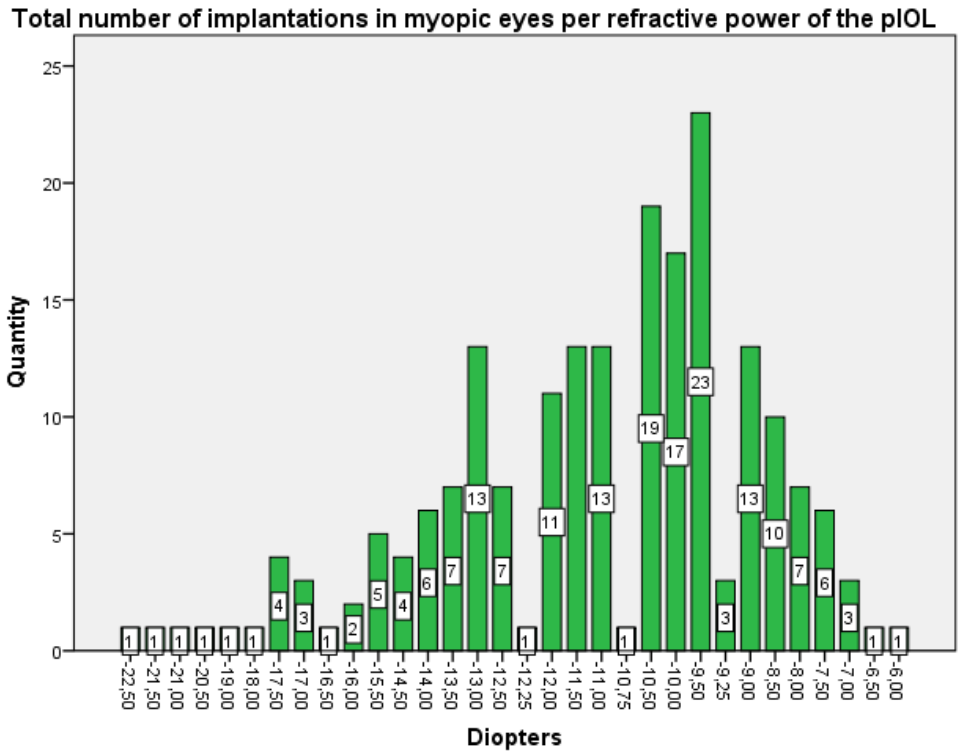

Figure 10: Total number of implantations in myopic eyes per refractive power.

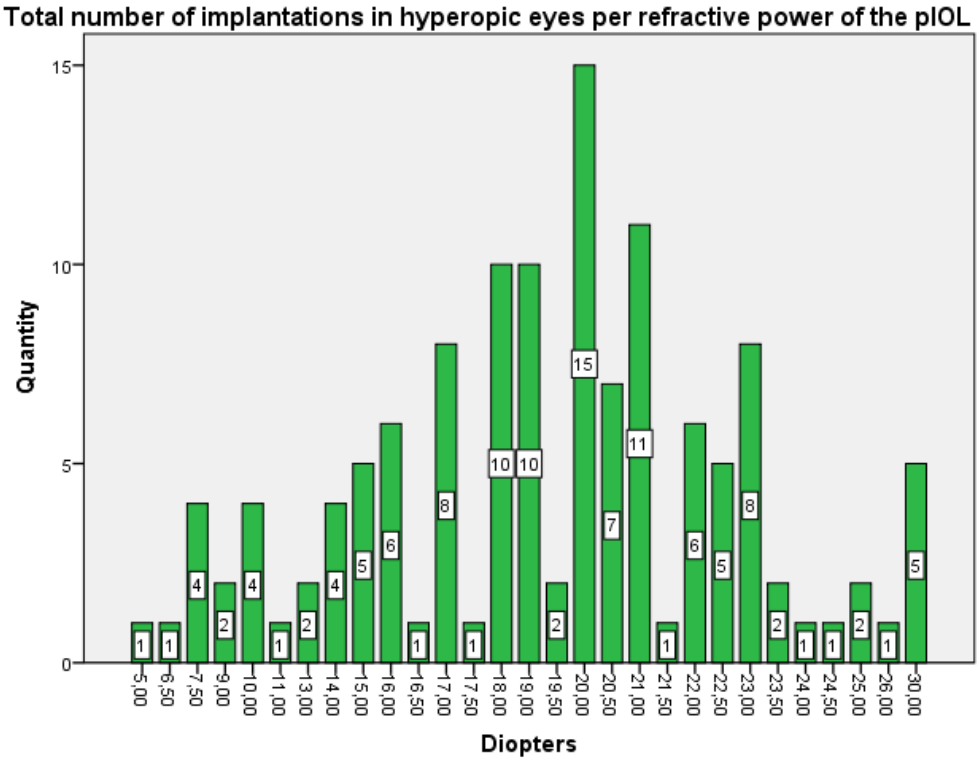

Figure 11: Total number of implantations in hyperopic eyes per refractive power

6.3.3 Indications

Iris-fixated anterior chamber lenses where either implanted to correct refractive errors or aphakia in cases with insufficient capsular support. For the correction of aphakia different models are used, as explained above. Those models, namely the Artisan/Verisyse aphakia and Artisan pediatric aphakia where implanted either classical or retropupillary.

Out of 327 implantations in total, 207 (63.3%) where performed for the correction of refractive errors, whereas 120 (36.7%) had aphakia as indication.

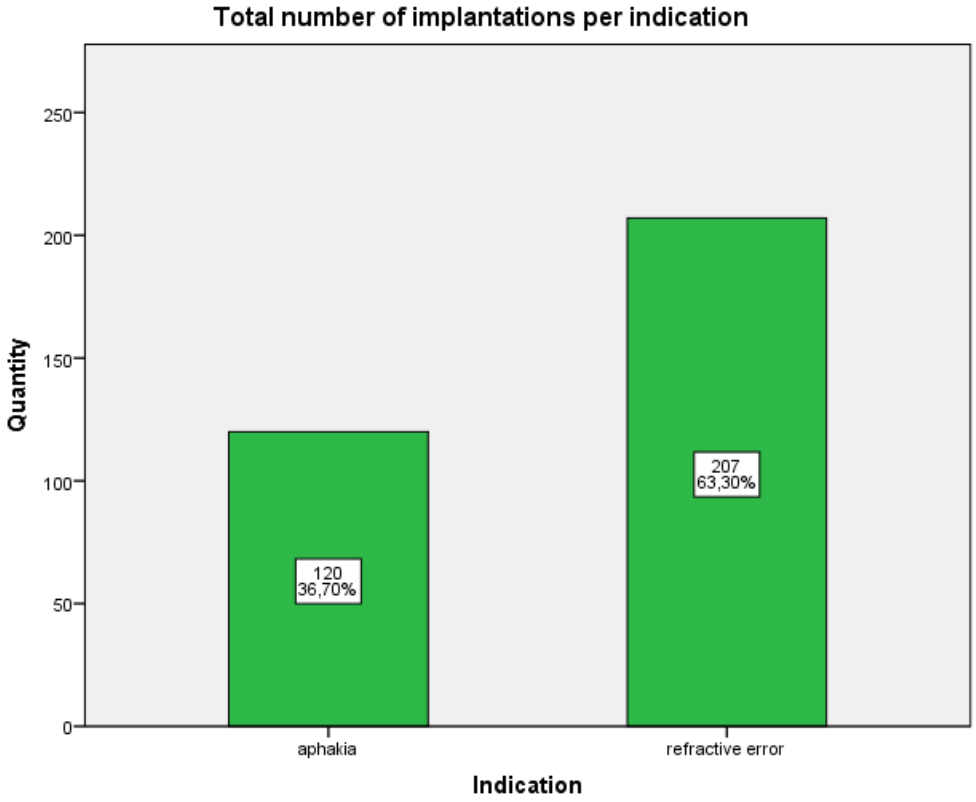

Figure 12: Total number of implantations per indication.

6.3.4 Intraoperative Complications

Because iris-fixated intraocular lenses are sometimes implanted during cataract surgery in case of insufficiency of the capsular bag or the zonular fibres, complications such as rupture of the zonular fibres or the capsular bag and

prolapse of the vitreous body were attributed to cataract surgery, and therefore were not listed.

In total, intraoperative complications attributed to iris-fixated intraocular lens implantation occurred in 19 out of 327 cases (5.81%), 9 in male and 10 in female patients, compared to 308 implantations (94.19%) without any intraoperative complications regarding iris-fixated pIOL implantation.

Relevant haemorrhage was reported in 9 (2.75%) cases. In all cases the source of haemorrhage was the iris. In 8 out of 9 cases the cause was the iridotomy, in 1 case the haemorrhage occurred after enclavation of the iris into the haptic. If necessary the hyphäma was treated by rinsing the anterior chamber, otherwise it was further observed.

Decentration or ovalization of the pupil was reported in 3 cases (0.92%). Ocular hypotension only occurred once (0.31%). Immediate decentration or luxation of the lens was reported in 5 cases (1.53%). If the decentration of the lens was severe, the lens got relocated and refixated. If the surgery was advanced and the dislocation was not severe, no further interventions were performed.

One case of corneal haze during surgery was reported (0.31%).

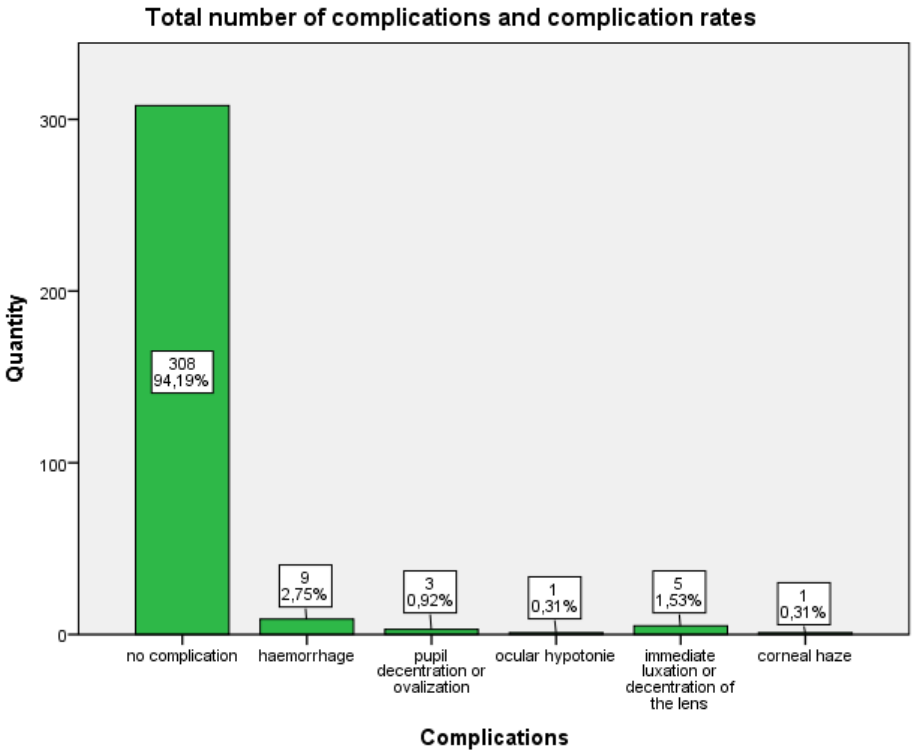

Figure 13: Total number of each complication and complication rates

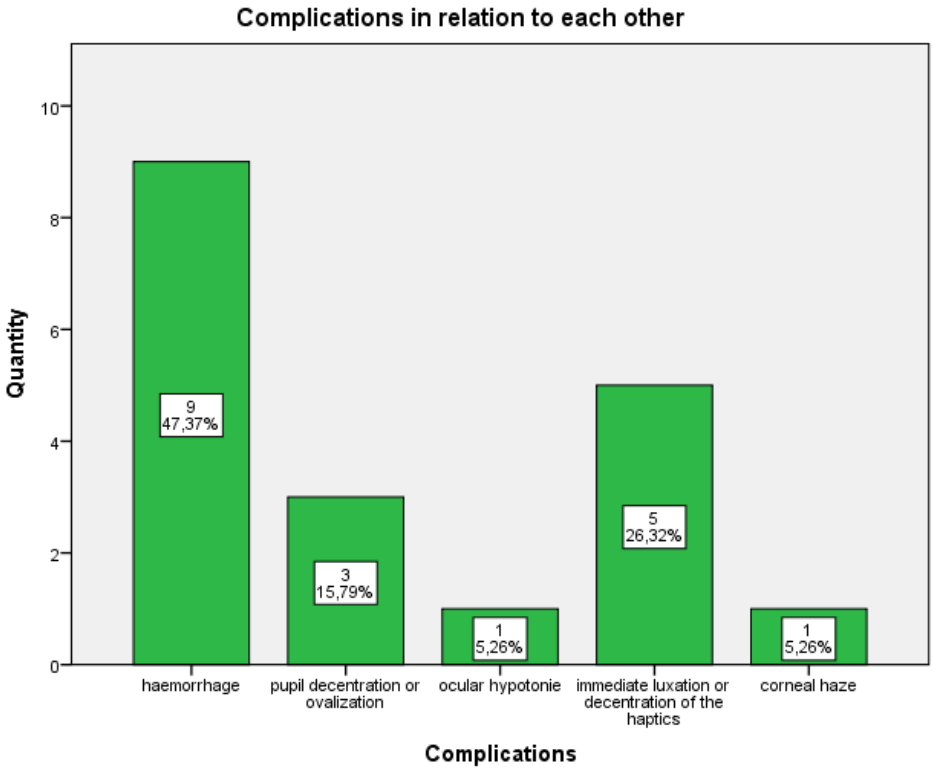

Figure 14: Occurrence of each complication in relation to each other

6.3.5 Secondary surgical intervention

Out of 327 implantations, 20 (6.12%) needed follow-up surgery, whereas in 4 cases (1.22%) interventional surgery was performed twice, resulting in a total number of 24 reoperations. Indications for follow-up surgery were disenclavation of the lens (in 17 cases or 5.20%), the need of explantation (6 cases or 1.83%), and in one case (0.31%) the need of secondary suturing of the cornea. Reasons for explantation where either luxation of the lens with unsuccessful attempt of repositioning (5 cases or 1.53%) or in one case (0.31%) the development of postoperative endophthalmitis.

The interval between the primary implantation and the first reoperation ranged from the same day (in case of the secondary suturing of the cornea) up to 6.76 years, with a mean interval of 1.50 years. Referring only to disenclavation of the lens as indication for secondary surgery, the interval was ranging from 3 days up to 6.76 years, with a mean interval of 1.50 years, too.

In 4 (1.22%) cases, a second reoperation was necessary. The indications for a second reoperation always were dislocations of the pIOLs. In 2 cases reenclavation was successfully performed, in the other 2 cases the lenses had to be exchanged. The interval between the first and the second reoperation was ranging from 42 days up to 5.61 years, with a mean interval of 2.15 years. Figure 10 shows the total count of reoperations per postoperative year.

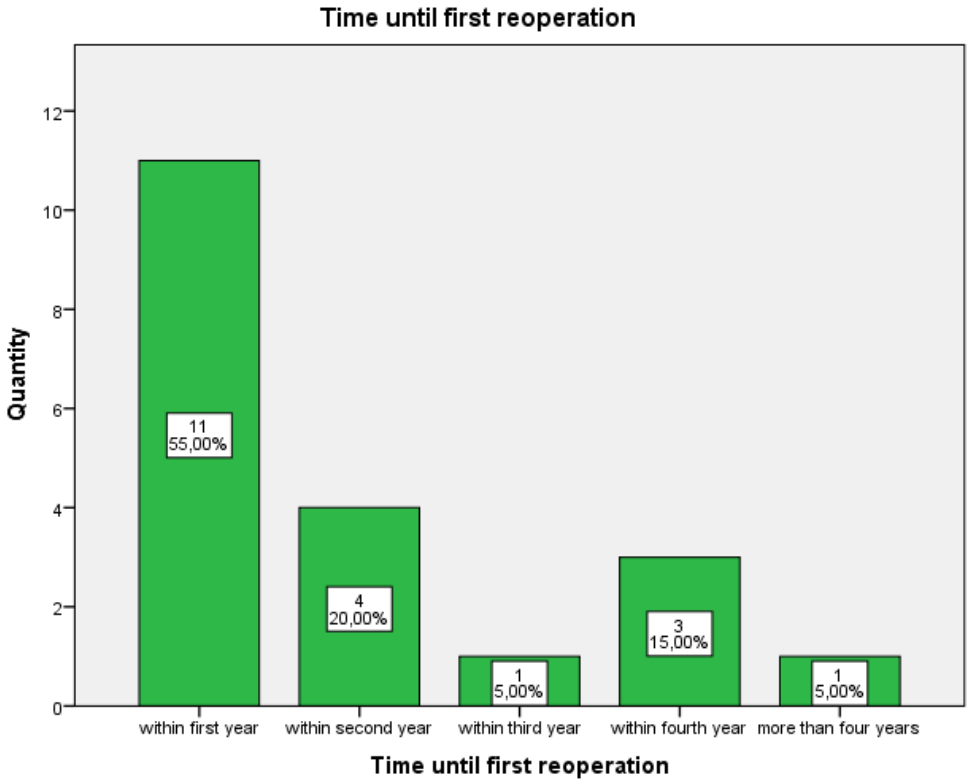

Figure 15: Total number or reoperations per postoperative year.

Based on these results, the risk for events that require follow-up surgery occurring for the first time would be 3.4 % within the first, 1.2 % within the second, 0.3% within the third, 0.9 % within the fourth year and another 0.3 % after the fourth year.

6.3.5.1 Reoperation rate and method of implantation

Out of the total number of 327 implantations, 237 (72.5%) were performed with the classic procedure, whereas in 90 cases (27.5%) the lens was implanted retropupillary. Seventeen (7.2%) of those classical implantations needed one follow-up surgery, and 3 (1.3%) needed follow-up surgery twice. Three (3.3%) out of the retropupillary implantations needed at least one follow-up operation and in 1 (1.1%) case reoperation had to be performed twice.

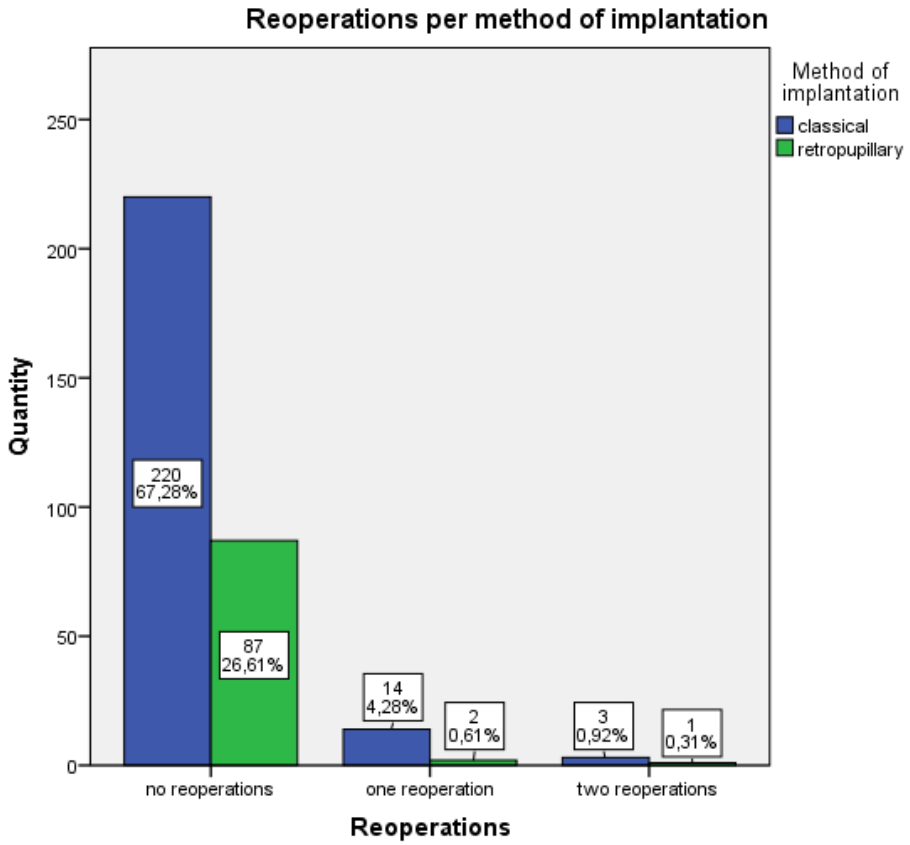

Figure 16: Reoperations in total, percentage refers to total number of implantations.

6.3.6 Statistical analysis

6.3.6.1 Correlations

Suspected correlations between refractive power of the implanted lens, age and risk of complications or rate of reoperations were determined. Significant correlations were found between age and complication occurrence, age and reoperation necessity, and between refractive power and complication rate. There was no significant correlation between refractive power and reoperation necessity.

The correlation was positive for age and complication occurrence with a correlation coefficient of r = +0.18 (n=327, p=0.001). The correlation between refractive power and complication occurrence was also positive, with a correlation coefficient of r = +0.26 (n=327, p=0.001).

The correlation between age and reoperation necessity was negative, with a correlation coefficient of r = -0.18 (n=327, p<0.001).

6.3.6.2 Cross tabulation

Out of 327 implanted iris-fixated pIOLs in total, 208 (63.6%) were rigid and 119 (36.4%) were flexible subtypes. Within the rigid pIOL group, intraoperative complications occurred in 16 cases (7.7%), whereas 2 cases (1.7%) of intraoperative complications occurred in the flexible pIOL group. The difference is statistically significant (p=0.022).

Complications * Type of pIOL Cross tabulation

			Type of pIOL		Total
			rigid	flexible	
Complications	no complications	Count	192	117	309
		Percentage within type of pIOL	92,3%	98,3%	94,5%
		Percentage within total number	58,7%	35,8%	94,5%
	complications occured	Count	16	2	18
		Percentage within type of pIOL	7,7%	1,7%	5,5%
		Percentage within total number	4,9%	0,6%	5,5%
Total number		Count	208	119	327
		Percentage within type of pIOL	100,0%	100,0%	100,0%
		Percentage within total number	63,6%	36,4%	100,0%

Table 1: Cross tabulation of complication occurrence and type of pIOL.

Within the rigid pIOL group, secondary surgical intervention was necessary in 13 cases (6.2%) once and in 2 cases (1.0%) twice. In the flexible pIOL group 1 reoperation was necessary in 3 cases (2.5%) once, and twice in 2 cases (1.7%). There was no statistically significant difference between the groups (p=0.28).

Reoperations * Type of pIOL cross tabulation

			Type of pIOL		Total
			rigid	flexible	
Reoperations	no reoperations	Count	193	114	307
		Percentage within type of pIOL	92,8%	95,8%	93,9%
		Percentage within total number	59,0%	34,9%	93,9%
	one reoperation	Count	13	3	16
		Percentage within type of pIOL	6,2%	2,5%	4,9%
		Percentage within total number	4,0%	0,9%	4,9%
	two reoperations	Count	2	2	4
		Percentage within type of pIOL	1,0%	1,7%	1,2%
		Percentage within total number	0,6%	0,6%	1,2%
Total number		Count	208	119	327
		Percentage within type of pIOL	100,0%	100,0%	100,0%
		Percentage within total number	63,6%	36,4%	100,0%

Table 2: Cross tabulation of reoperation occurrence and type of pIOL

6.4 Discussion

Iris-fixated phakic intraocular lenses provide an alternative way of treating refractive errors and aphakia, with good results in terms of efficacy and safety (36,37), especially in moderate to high refractive errors. The possibility of implanting iris-fixated intraocular lenses retropupillary offers a good way of treating aphakia in eyes without capsular support (35,38). Gonnermann et al. (39) also describe good visual outcome with favorable complication rate after retropupillary implantation of iris-fixated phakic intraocular lenses in children. In terms of safety and efficacy the implantation of phakic intraocular lenses seems to be equal to laser refractive surgery. In contrast to cases of myopia, some studies even describe better results in best spectacle corrected visual acuity (BSCVA) and visual quality with pIOL implantation (40-43).

Compared to other types of phakic intraocular lenses, the iris-fixated as well as angle supported pIOLs might even have a slightly better visual outcome in terms of contrast sensitivity than posterior chamber pIOLs (44). However, it must be mentioned, that there aren't many studies which compare the different types of phakic intraocular lenses to each other.

Also, only a few studies include intraoperative complications of phakic intraocular lens implantation and in most of the studies which do, the small number of cases often results in a complete absence of intraoperative complications. Most authors focus on the postoperative course including visual outcome and postoperative complications such as corneal endothelial cell loss, surgical induced astigmatism, elevation of intraocular pressure and so forth.

With a percentage of 2.75% (9 out of 327), haemorrhage was the most frequently observed intraoperative complication in our case series. In 8 out of 9 cases the bleeding occurred as result of the iridotomy, and only once was it caused by the enclavation of the lens. In their study of 2005, Budo et al. (45) describe the occurrence of relevant haemorrhage in 1.9% of implantations. The source of haemorrhage is not further explained. In addition, iridotomy was not listed in their surgical procedure chapter. In 2006, Gierek-Ciaciura et al. (46) reported haemorrhage from iris tissue in one of their 20 Verisyse implantations (5.0%).

Immediate pupil decentration or ovalization occurred in 0.92% (3 cases) of the implantations in our case series. Maloney et al. (37) report pupil irregularities in 9.27% (14 out of 151) at the first postoperative day, continuously decreasing down to 1.2% after 6 months. Stulting et al. (47) report a pupil ovalization incidence of 13.0% (86 out of 660 implantations) at the first postoperative day, also continuously decreasing down to 1.7% after 4 to 6 months and 0.4% after 3 years. Because pupil ovalization or decentration are most likely caused by asymmetrical fixation of the pIOL and therefore by the force that pulls on the iris, it may seem logical that the ovalization is a continuous process which increases in the early postoperative course and decreases later on. This might explain the different percentages of pupil ovalization and decentration incidence between this study and studies which evaluated at the first postoperative day.

Decentration or luxation of the lens or one of the haptics occurred in 5 cases (1.53%) in our case series. Decentration was not always accompanied by luxation of one haptic, thus reenclavation was not always essential. In 3 out of 5 cases reenclavation was not necessary. None of those 5 cases required follow-up surgery at the University Eye Clinic Graz. Budo et al. (45) evaluated difficulties in centering, enclavation and fixation of the lens. Difficulties with centering the lens occurred in 0.4% of their 518 cases. Difficulties with enclavation or fixation of the lens occurred in 0.2% each. In a study of Stulting et al. (47), the authors report of only 1 case out of 662 patients (0.2%), who underwent Verisyse or Artisan lens implantation, in which intraoperative lens repositioning was necessary.

In our study, one case (0.31%) of ocular hypotony during surgery was reported. Ocular hypotony is most likely the result of leakage through the corneal incision. However, most studies don't report intraoperative ocular hypotony. Rüfer et al. (48) compared cases of retropupillary implantation of Artisan or Verisyse lenses with and without penetrating keratoplasty. They analyzed perioperative complications within the first postoperative week. The group without penetrating keratoplasty consisted of 10 cases of retropupillary pIOL implantation. In this group, 2 cases (20%) of ocular hypotony occurred. Due to the rather small study population and the difference in time of evaluation, the results are not directly

comparable. Gonnermann et al. (35) also report hypotony in the first postoperative week in 7 out of 137 cases (5.1%) of retropupillary Artisan/Verisyse implantation.

Corneal haze, which already occurred during surgery, was reported in one case (0.31%) in a patient with Fuchs endothelial dystrophy in our case series. Corneal edema after anterior segment surgery is a rather common complication. Maloney et al. (37) report occurrence of corneal edema after Artisan implantation in 11 out of 151 (7.3%) implantations at the first postoperative day, ranging from mild to moderate severity. Stulting et al. (47) report corneal edema in 128 out of 660 cases (19.4%) on the first postoperative day. However, the fact that those studies evaluated at the first postoperative day and not during the operation, restricts the comparability.

Secondary surgical intervention might be necessary in cases of repositioning after decentration or luxation (traumatic or non-traumatic), explantation in cases of inflammatory response, power calculation error, halos, significant loss of corneal endothelial cells, cataractogenesis, pigmentary dispersion, dense lens deposits, pupil ovalization, pupil decentration, intraocular pressure elevation, retinal detachment or lens rotation especially in patients with toric lenses (24). In our studies' population, secondary surgical intervention had to be performed in 20 out of 327 cases (6.12%) at least once. In 4 cases (1.22%) follow-up surgery was performed twice. Secondary surgical reoperation was performed in 22 cases of disenclavation or luxation of the lens, 1 case of endophthalmitis and 1 case of postoperative wound leakage. The time interval between primary surgery and first secondary surgical intervention ranged from the same day up to 6.76 years, with a mean interval of 1.50 years. The interval between the first and the second reoperation was ranging from 42 days up to 5.61 years, with a mean interval of 2.15 years.

Disenclavation or luxation of the implanted iris-fixated phakic intraocular lenses was the most common indication for secondary surgical intervention, with a total number of 22 cases of disenclavation (6.73%), resulting in either repositioning or lens exchange as secondary surgical intervention. Budo et al. (45) reported necessary repositioning of decentered lenses in 5 out of 249 cases (2.0%). Replacement of the pIOL had to be performed 8 times (3.2%), although the

reasons for the replacement were not listed. Seven (2.8%) pIOLs had to be removed, but only 2 (0.8%) due to disenclavation. In both cases the cause was an ocular trauma. Other causes for secondary surgical intervention were repositioning of an iris prolaps or correcting astigmatism with PRK, both performed in 1 case (0.4 %) each. No secondary intervention due to inflammation or wound leakage was reported. The study evaluated implantations between September 1991 and October 1999 (8 years) and was published in 2000. The time distances between the primary implantations and the secondary interventions were not reported. Follow-up was specified between 6 months and 3 years. However, it is not explained if cases of secondary surgery were evaluated which happened 3 years after primary implantations but within the studies' duration of implementation. In the study of Stulting et al. (47), 1179 pIOL implantations were reviewed. Lens explantation due to inflammatory response was reported in 3 cases (0.25 %). The authors reported lens exchange due to inadequate surgical fixation in 2 cases (0.17 %) and lens reattachment for the same reason in 5 cases (0.42%). Follow-up was 3 years at most. The distance between primary implantation and secondary surgical intervention was not evaluated. Maloney et al. (37) reported wound leak in 6 out of 151 cases (4.0%) on the first postoperative day. However, they did not mention secondary suturing of the cornea or any other way of treatment.

Significant correlations were found between age and complication occurrence, refractive power and complication occurrence and between age and reoperation necessity in our case series. The correlation between age and complication occurrence was positive with a correlation coefficient of $r = +0.18$ ($n=327$, $p=0.001$), meaning that the higher the age was at the time of pIOL implantation the higher the risk for intraoperative complications. The correlation between refractive power and complication occurrence was also positive with a correlation coefficient of $r = +0.26$ ($n=327$, $p=0.001$). The negative correlation between age and reoperation necessity ($r = -0.26$, $n=327$, $p<0.001$) implies that less reoperations had to be performed the older the patients were at time of implantation. However, the negative correlation between age and reoperation rate may be caused by a possibly reduced follow-up period in elderly patients due to other health problems. Furthermore, it has to be recalled that correlations do not imply causation.

The comparison between rigid and flexible pIOL subtypes in terms of complication rates revealed a statistically significant difference. The risk of intraoperative complications occurring was lower for implantation of flexible iris fixated intraocular lenses. This might be because of the gentler surgical procedure. However, one should keep in mind that rigid pIOL models are frequently used to correct aphakia during complicated cataract surgery, which may naturally lead to a higher rate of complications.

The inequality in follow-up periods and the retrospective nature are limitations to this study. The inequality in follow-up periods limits the significance of the secondary surgical intervention rates. Compared to a prospective study design, the retrospective design is inferior in terms of accuracy. Another limitation is the data acquiring through computer databases. While searching for implantations of the different iris fixated intraocular lens subtypes, the records with a typing error in the term searched for were naturally missed. The single-center nature of this study may pose another limitation. Strengths of this study were the rather high sample number and the high mean follow-up period as well as the limited number of surgeons (2 in total).

Further investigations for reasons of non-traumatic disenclavation and time to disenclavation without apparent reason are suggested.

6.6 Conclusion

Implantation of iris fixated anterior chamber lenses poses a good way of treating refractive errors and aphakia in eyes without adequate capsular support. This study showed good results in terms of intraoperative safety and a low rate of secondary surgical intervention necessity, comparable to related studies (37,45,47).

In terms of intraoperative safety they may be well compared to other common procedures of refractive surgery. However, major postoperative complications such as retinal detachment, endothelial cell loss, chronic inflammation or uveitis, cataractogenesis, surgical induced astigmatism, elevation of intraocular pressure, glare and halos have not been part of this study.

Due to the limitations of this study, further investigations concerning causes of disenclavation and time interval to disenclavation are suggested.

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