The Artisan Lens:
Effects on Vision Quality, the Corneal Endothelium and Vision-Related Quality of Life

Ruchi Saxena

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De Artisan lens:
Effect op de kwaliteit van de visus, het corneale endotheel
en de visus-gerelateerde kwaliteit van leven

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Chapter 1

General Introduction

1.1 Refractive Errors

Refractive errors are the most frequent disorders of the eye[1]. In the ideal refractive state, *emmetropia*, an image is focused directly on the retina, resulting in the perception of a sharp image in a healthy visual system (Figure 1.1.1). Such eyes do not require glasses or contact lenses to see sharply. Most eyes, however, have some degree of refractive error, although correction is not always required.
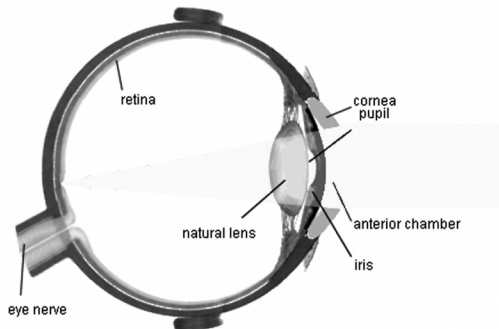
Figure 1.1.1 The Emmetropic Eye
(Courtesy of Ophtec BV)

In *myopia* (nearsightedness), the image appears focused anterior to the retina, producing a sharp image at near and a blurred image at distance (Figure 1.1.2). A concave lens (minus Diopter) is required to sharpen the image. The reverse is true in *hypermetropia* (also known as hyperopia or farsightedness), where the image is projected posterior to the retina, producing a blurred image at near and a sharper image at distance (Figure 1.1.3). A convex lens (plus Diopter) is required to produce a clear image. *Astigmatism* (cylindrical error) is the result of two different refractive powers between two perpendicular meridians (Figure 1.1.4). A cylindrical correction can correct this problem. Extreme cases of all these refractive errors can cause severe visual loss. *Anisometropia* is the presence of two significantly different refractive errors. In these situations, simple spectacle correction is not always suitable due to *aniseikonia* (different sized images) resulting from the different powers in the lenses; other options such as contact lenses or surgery can then be considered. When refractive errors and anisometropia are not corrected aptly, diminished binocular vision and/or amblyopia could result.

Refractive error is not static. Newborns are normally born hypermetropic (approximately +2.0 D) and emmetropise quickly to plano between 4 and 6 years of age. Lack of emmetropisation can lead to hypermetropia[2].
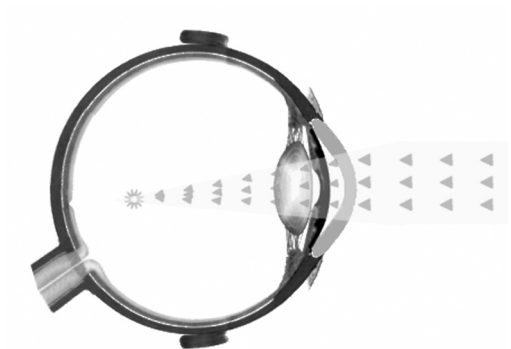
Figure 1.1.2 The Myopic Eye
(Courtesy of Ophtec BV)
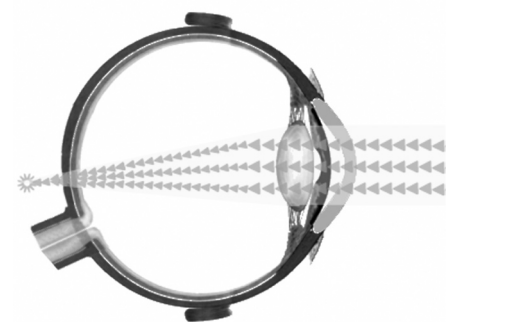
Figure 1.1.3 The Hypermetropic Eye
(Courtesy of Ophtec BV)

Figure 1.1.4 The Astigmatic Eye
(Courtesy of Ophtec BV)

Myopia generally has its onset around puberty, although in pathologic myopia, negative refractive error is found earlier. Myopization can continue slowly until about the age of 30. The development of cataract in older individuals can cause rapid myopization, however some patients become more hypermetropic.

Myopia is the most common form of refractive error, being most frequent in Asia[3]. It has been described as having reached epidemic proportions in South East Asia, where studies among schoolchildren have found a prevalence of 81% in Taiwan, 73% in Singapore and 62% in rural China[4-6]. Frequencies are lower in other Eastern countries, attaining 54% in Jordan, between 20 to 37% in India and Pakistan, 33% in Turkey and 3.4% in Iran[7-12]. It is less common in Europe, with 11.9% in Finland, 13% among Polish schoolchildren and 33% among the Danes[13-16]. Although there definitely appear to be large differences in the frequency of myopia around the world, population comparisons are hampered by the diverse criteria used to define refractive errors, the specific population groups being studied (such as registered schoolchildren and military recruits), different age groups and whether cycloplegic drops are used for the determination of refractive error[17].

Myopia is generally divided into two categories, simple myopia (between –1.0 and –6.0 D) and pathologic myopia (more than –6.0 D). Complications as a result of pathological myopia abound. Patients run a higher risk of severe visual loss through retinal detachment, myopic chorioretinal degeneration, cataract and open-angle glaucoma[18-34]. The chance of such complications occurring is greater as the severity of myopia increases, although even eyes with simple myopia are not completely immune.

Animal experiments have been able to induce myopia through exposure to flashing lights or continuous illumination, form deprivation, lid suture, or goggling eyes with translucent lenses or lenses with different myopic refractive errors[35-50]. Most of these models imply that a visual feedback mechanism based on blurred images on the retina are fundamental to increases in axial length, and hereby the development of myopia. However, accelerated axial length increase can also be observed if the optic nerve has been severed[51]. Thus, the cause of myopia still remains elusive.

Many studies have revealed the highly hereditary nature of myopia. Twin studies on high myopia have shown a greater concordance among monozygotic twins than dizygotic twins[52,53]. So far, 15 loci associated with myopia have been established (MYP 1-15) although to date, no consistent associated genes have been found[54-68]. Still, different inheritance patterns between simple myopia and pathologic myopia have been implicated[68-72]. Genetic links in myopia could partially explain the dissimilar distribution of refractive errors amongst different ethnicities. The Baltimore Eye Survey found that 28.1% of adult urban subjects of European descent (living in the Baltimore area) were myopic, as opposed to 19.4% of African Americans[73]. Examinations of children of different ethnic backgrounds living in the same area have also found similar distributions[74,75].

Still, genes are not the only factor associated with refractive error; environmental aspects also appear to have a part in its development[76,77]. The effects of environment become apparent when studying individuals of similar ethnic backgrounds living in different places. Saw *et al.*, observed that Chinese, Malay and Indian children living in Singapore expressed significantly more myopia than their ethnic counterparts residing in Kuala Lumpur, Malaysia[78]. Pertinent risk factors for nearsightedness have been found, whereby near work is considered the greatest; a study examining monozygotic and dizygotic twins and their reading habits was able to find a significantly higher concordance in myopia among monozygotic twins with comparable reading habits[79]. Furthermore, adult-onset myopia is most common in individuals who are involved in intensive near work, such as microscopists, carpet weavers and workers using visual display terminals[80-82]. Near work is thought to have perpetrated the rise of myopia in urban Asia, where school-age children are becoming increasingly younger, leading to longer periods of near work at a younger age[4,73,83-91]. Animal experiments have been able to confirm the association between near focus and myopization found in humans [5, 92-98]. Moreover, a consistent correlation has also been found between both levels of education and intelligence with myopia, although both these factors may be associated with the greater amount near work among these individuals[5,16,77,88,89,99-102]. Urban areas display significantly more myopia than rural areas, although yet again, this could be confounded by higher levels of education (and thus near work) among urban dwellers[77,86,100,103-105].

Nearsightedness is further associated with introvert personalities and a decreased chance of developing schizophrenia[106,107]. These relationships are not necessarily associated with the visual environment of the individual, but more with the chemical and genetic relationships of myopia with these traits. According to some studies, myopia is also significantly more common among women[10,13,107-110].

The role of light exposure and the physical effects of melatonin associated with myopia remain contentious[94,95,107,111-119]. Still, outdoor activity has been shown to protect against myopia[11,120]. While one could surmise that this could be caused by less accommodation during sport, indoor sport activities do not appear to prevent nearsightedness[120].

Hypermetropia is a less common refractive error and unlike myopia, more common among Caucasians[121]. Studies have shown frequencies of 28% in Finland, 27.4% of Malays residing in Singapore, 27.1% in Pakistan, 16.6% in Iran, 9.9% in the United States and 9.8% among South Indians 3.6%[1,8,12,13,100,122]. A limited number of family studies have shown that inheritability of hypermetropia exists[53,123-125]. In individual populations, hypermetropia shows a U-shaped distribution, with higher incidences among prepubescent children and then again among older individuals without cataract[13,121,126,127].

Hypermetropia is much more often associated with amblyopia, decreased stereovision and strabismus, and can hereby pose a threat to the young eye. Also, the smaller ocular structures associated with hypermetropia makes hypermetropic eyes more prone to vision threatening acute and chronic angle closure glaucoma among older patients[128-131].

Animal experiments show a propensity towards hypermetropia among restrained animals and with the use of convex or hypermetropic lenses[37,44-47,49,132]. Similar to myopia, the exact physiological events leading to hypermetropia are unknown, however it appears to be caused by changes in axial length and corneal flattening[44, 45].

Outdoor activity induces hypermetropic tendencies, in direct contrast to the near work associated with myopia[120]. Furthermore, farsightedness is more common among individuals with a lower socio-economic status[133,134]. Surveys have also determined a higher frequency of hypermetropia among youngsters with developmental delays[135-138]. Also, hypermetropia is associated with extrovert personalities, as opposed to introvert personalities among myopes[106].

Recent attempts at slowing the progression of myopia among children with ocular distillation of pirenzepine, a selective M1 muscarinic receptor antagonist, have been mildly successful. Still, pirenzepine has yet to halt myopization altogether[139-141]. Until refractive errors can be prevented effectively, we are simply left with the option to correct them with spectacles, contact lenses or surgery.

1.2 A Brief History of Correcting Refractive Error

1.2.1 Glasses and Contact Lenses

For centuries, people have been trying to correct ametropia. Before the invention of lenses, scholars would be hired to read to those who no longer could read due to their vision. Others would use containers filled with water to magnify their scripts. In 1000 AD, "reading stones" (magnifying glasses passed over reading materials) were used by monks to allow for studying scriptures. The first documented use of spectacles was either in Florence or Pisa, Italy where two convex lenses were used to magnify images[142,143]. With the advent of Gutenberg's printing press in 1476, demand for spectacles increased throughout Europe[143,144]. Initially, there were single handheld lenses, which were then adapted to two lenses connected at in the middle, held with one hand. Nearly 350 years later, Benjamin Scarlett, a London optician, finally designed spectacles that were suspended on both ears[143].

The renowned inventor, Benjamin Franklin, has been accredited with the creation of "double spectacles", which have evolved into the bifocals of today[142]. The basis of efficiently grinding several lenses at once, although significantly altered, was originally created by John Marshall of London, England[145].

The first rough blueprints of the contact lens are accredited to da Vinci, Descartes, de la Hire and Young[146,147]. Contact lenses were first implemented independently near the end of the nineteenth century by three different inventors[146]. The French ophthalmologist Eugéne Kalt created contact lenses from the bottom of glass test tubes to counterbalance the severe astigmatism in keratoconus in 1888. The same year, Adolf Eugen Fick, a German physiologist, described the use of afocal contact lenses to counteract the optical effects of corneal distortions. Months later, the German physician August Müller, presented his dissertation on scleral contact lenses with a refractive power, based on experiments to correct his own myopia of -14.00 D[148]. Due to occurrence of severe corneal edema, Müller became disparaged with his idea and left Ophthalmology to pursue Orthopedic Surgery. Otto Himmler, a renowned maker of microscopes, manufactured these first glass-blown contact lenses for both Müller and Fick at a respective 4 and a whopping 38 Deutschmark price tag at his factory in Berlin[149]. The more current corneal contact lenses of today were invented by Kevin Tuohy in 1948. Professor Otto Wichterle of Prague patented a centrifugal casting machine to produce lenses of hydroxyethylmethacrylate and glycol diester (hydrogel) in 1961. These lenses were much more comfortable than the polymethyl methacrylate (PMMA) hard lenses which were in use at the time. In 1972, these "soft lenses" were introduced to the larger public by Bausch & Lomb[146]. Unlike glasses, contact lenses do not diminish retinal size with increasing myopia nor do they reduce visual fields[148]. Furthermore, they are lightweight and virtually invisible.

Currently, contact lenses have many different ophthalmic applications, such as keratoconus, aniseikonia, color blindness, ocular deformity and diplopia[150-164]. More frivolous applications also exist, such as changing ones eye color with the notoriously troublesome colored contact lens[160,162,163,165-168]. Nowadays, contact lenses are fabricated from a variety of materials and offer comfortable long-term wear and excellent refractive correction for 125 million people worldwide[146,169]. Still, microbial keratitis, often associated with corneal hypoxia and poor patient hygiene, dry eye and the development of contact lens intolerance, allergy and giant papillary conjunctivitis remain drawbacks of this form of refractive correction[146,170-175].

1.2.2 Refractive Surgery

The idea of reducing corneal curvature to correct myopia has existed for centuries. The ancient Chinese apparently slept with sandbags over their eyes in order

to flatten their corneas. In the 19th century, Dr. J. Ball introduced small mallet that would flatten the cornea through the eyelid[176]. Luckily, today's more refined innovations have taken over these rudimentary techniques.

1.2.2.1 Refractive Keratotomy

Dr. Lans, from Leiden, the Netherlands corrected astigmatism in rabbits using the methods of keratectomy, keratotomy and thermoplasty in 1898. In 1933, Tokyo's Dr. Sato discovered that the astigmatism of his keratoconus patient decreased after breaks in the Descemet membrane. This led him to perform radial incisions in the anterior and posterior corneas of nearly 700 patients between 1951 and 1959. The formation of bullous keratopathy due to his toying with the corneal endothelium eventually led him to abandon this practice[176-179].

The Radial Keratotomy (RK) procedure was introduced by several Russian eye surgeons in the early 1970s, the most renowned being Svyatoslav Fyodorov[176-178]. The procedure creates a flattening of the central cornea by incising the epithelial and stromal layers of the midperipheral cornea. The six steps to the procedure are as follows: 1. administration of appropriate anesthesia; 2. accurate marking of the visual axis; 3. marking the appropriate sized optical zone; 4. measuring the corneal thickness; 5. accurately setting the depth of the blade so as to be as close to the Descemet membrane as possible; and 6. making a predetermined number of corneal incisions (usually eight) to adequately flatten the cornea[178]. Problems associated with RK include overcorrection and progressive hypermetropic shift, diurnal fluctuations, corneal perforation and a lack of stability due to different wound healing patterns among patients of different age, whereby younger patients endure more refractive regression[177,180-183].

Until the mid 1990s, RK was the most common procedure to correct myopia in the United States, having been performed by approximately 10% of ophthalmologists[177]. Its popularity diminished with the advent of the more refined excimer laser techniques.

1.2.2.2 Excimer Laser Treatments

The excimer ("excited dimer") laser uses a 193 nm argon fluoride excimer laser to reshape the anterior corneal stroma through a procedure known as photoablation[179,183,184]. The laser was originally used to etch silicone computer chips in the 1970s by IBM[185]. Dr. Steven Trokel and Rangaswamy Srinivasan first described its use on the eye in 1983 to reshape freshly enucleated cow eyes. They wrote that the benefit, apart from its great precision, was that there was no damage

to the neighboring tissue nor was there any sign of tissue disorganization[186]. Dr. Seiler from Germany, was the first to use it on a functioning human eye in 1987[176]. In 1988, John Marshall, along with Stephen J. Koons and Charles R. Munnerlyn, described the Photorefractive Keratectomy (PRK) procedure in rabbit eyes[187]. The Food and Drug Administration (FDA) approved its use on human eyes in the United States in 1995[188].

Currently, there are three main forms of excimer laser treatments available: PRK, Laser in situ Keratomileusis (LASIK), and Laser-Assisted Sub-Epithelial Keratectomy (Laser Epithelial Keratomileusis or LASEK). PRK was the first to be performed; during this procedure, the corneal epithelium is first removed and the laser treatment then takes place on the stroma. Thanks to Pallikaris of Greece and Buratto of Italy, who combined PRK with Jose Barraquer's invention, the microkeratome, LASIK was born. It was first carried out in 1989 by Pallikaris[176]. This procedure entails the making of a stromal flap of 8 – 10 mm diameter and 100 to 180 μm thickness with a microkeratome, the laser procedure, and then the replacement of the flap immediately thereafter. It allows for a nearly painless procedure, minimal haze and faster visual rehabilitation than PRK, although current technology allows for similar visual results between both[188-190].

LASIK can correct higher refractive errors than PRK, although flap-related complications, which can be quite troublesome, can occur[191-195]. The femtosecond laser is the newest innovation in LASIK, allowing for thinner, more precise flaps with fewer complications, with comparable visual outcomes[30,188,196,197]. Other serious complications associated with LASIK are corneal ectasia, corneal perforation, diffuse lamellar keratitis, interface debris and epithelial ingrowth[188,195,198-200].

LASEK was independently introduced by Dimitri Azar and Massimo Camellin in 1999. It combines both the PRK and LASIK procedures. Diluted ethanol is used to create an epithelial flap (like in PRK), which is replaced on the eye after ablation takes place (like LASIK). Postoperative pain, haze and visual rehabilitation are less bothersome than with PRK, but more problematic than with LASIK[201].

All excimer laser procedures can be associated with postoperative keratitis, dry eye and visual disturbances such as starbursts and halos[188,195,202-205]. Currently, LASEK and PRK are indicated for low to moderate myopia, whereas LASIK is indicated for moderate to high myopia up to -10.0 D.

1.2.2.3 Phakic Intraocular Lens Implantations and the Artisan Lens

Several different Phakic Intraocular Lens (pIOLs) are available today – from anterior chamber angle-supported and iris-fixated lenses to posterior chamber lenses.

English ophthalmologist Dr. Harold Ridley (1906-2001) invented the first intraocular lens. He had observed polymethylmethacrylate (PMMA) splinters that would occasionally become lodged in the eyes of World War II Fighter pilots after returning from missions did not lead to ocular inflammation. This inspired him to create an intraocular lens made of PMMA which he placed in an eye after a cataract operation in 1949. These first "top secret" experiments were an absolute failure – not only did he render his first patient highly myopic (-14.0 D), the up to 108 mg weight of the lens was so heavy that it would often tumble into the vitreous cavity behind[206-208]. Initially, Ridley was not appreciated by his peers, however he eventually went on to receive numerous prestigious awards and was knighted by Queen Elizabeth II in 2000[206].

Since Ridley's pioneering work, many different pseudophakic lenses were created. Strampelli, Dannheim, Baron and then Barraquer were some of the first to design phakic IOLs to correct high myopia in the 1950s. These angle-fixated lenses led to many serious complications, such as extreme endothelial cell loss and Uveitis-Glaucoma-Hyphema Syndrome (UGH-Syndrome), leading many of these lenses to be explanted[208,209]. Georges Baikoff finally published work on his angle-fixated phakic IOL in 1991, which was adapted to prevent severe endothelial cell loss. Still, the new lens was also unable to escape the considerable side-effects of iridopathy, pupil ovalization, low-grade uveitis, peripheral synechiae and sectorial atrophy of the iris[209].

Figure 1.2.1 Prof.Dr. J. Worst
(Courtesy of Ophtec BV)

Prof. Dr. Jan Worst of Groningen, the Netherlands felt that the angle-fixated pIOLs would always be problematic due to the contact of the haptic with the tissue of the anterior chamber (Figure 1.2.1). After observing his compatriot Cornelius Binkhorst's innovation, the "pupil fixation" lens, which stayed partially in place

thanks to pilocarpine to avoid lens luxation in mydriasis, he had an epiphany. He devised a PMMA lens that could be fixated to the iris stroma - this would deter the need for chronic eye drop use and would avoid the problems associated with angle-fixated lenses. He also believed that this prototype would not affect pupil dynamics[208,210]. After several different models, Worst finally invented the Iris-Claw lens, a lens which simply could be clamped onto the midperipheral iris without interfering with the iris's mechanical function of pupil dilation. Variations of the lens were initially used in high volume to correct aphakia in Pakistan and India. In 1980, Professor Worst implanted an opaque version of the lens in the eye of a phakic patient suffering from diplopia. Years later, the eye remained un-inflamed with a clear cornea and a clear lens[208,211]. This last lens provided the basis for the Iris-fixated phakic IOL, which was initially implanted into the eyes of a highly myopic (-20 D) female patient by Dr. Paul Fechner of Germany[208]. Worst and Fechner eventually went on to implant a series of these biconcave "Worst-Fechner" lenses with 5.0 mm optics with very reasonable refractive results. However endothelial cell loss was a cause for concern, leading to the development of a convex-concave lens to increase the distance between the lens and the corneal endothelium (Figures 1.2.2 and 1.2.3)[212-216].

Many studies proved that the Artisan lens led to safe and efficacious results[217-221]. Multicenter studies for the Artisan lens to correct moderate to high Myopia have shown postoperative best corrected visual acuity (BCVA) of 20/40 (legal visual acuity required to drive in most countries) in at least 93.9% of the eyes, with postoperative uncorrected visual acuity 20/40 in at least 76.8% of eyes[222-225]. At present, the lens is available between -1.0 to -23.5 D (0.5 increments)[226].
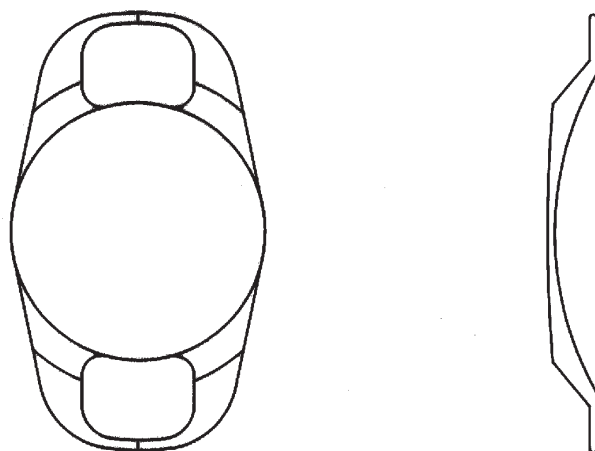
Figure 1.2.2: The Convex – Concave design of the Artisan lens, Model 206, 5.0 mm optic (Courtesy of Ophtec BV)
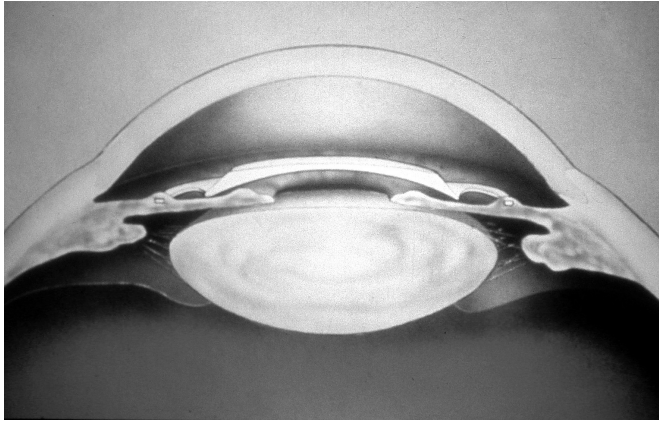
Figure 1.2.3: The lens is located in the anterior chamber, between the iris and the cornea. The crystalline lens is visible behind the iris. (Courtesy of Ophtec BV)

Studies have shown superior visual results and contrast sensitivity with the Artisan lens than LASIK for the correction of high myopia (greater than -9.0 D). Also, when compared to different phakic IOL types, there is minimal to no cataract formation[227-232]. The surface of the lens has also been studied by electron micrograph, revealing a smooth plane with few irregularities[233]. Still, complaints of glare and haloes remain, although these can be minimized with the Artisan Model 204 lens (with a 6.0 mm optic), available in 0.5 D increments between -1.0 and -15.5 D (Figure 1.2.4)[214,226,234].
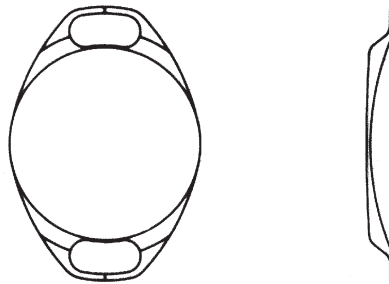
Figure1.2.4: Artisan lens, Model 204, 6.0 mm optic
(Courtesy of Ophtec BV)

The Artisan lens for hypermetropia was first implanted in 1992. The lens is available in 0.5 D increments for corrections between +1.0 and +12.0 D[226]. Studies have demonstrated safe and predictable results. Pop did a study comparing clear lens extraction and the Artisan hypermetropic lens and concluded that although visual results between the two were comparable, the Artisan hypermetropic lens

is more suitable for young high hypermetropes so that their accommodation may remain intact[235]. Nevertheless, pigment dispersion due to the small size of the eye remains a problem with this lens[236].

Since the development of the toric Artisan Lens in 2001, astigmatic hypermetropic or myopic patients, and patients with keratoconus can also be treated with an intraocular lens[237-239]. Unlike the regular Artisan lens, the axis of enclavation is of particular importance with the toric Artisan lens[238,240,241]. Studies have proven that this lens is stable once implanted in the eye, which is of substantial importance, as postoperative movement of the lens would cause a change in the astigmatic correction[242]. Both the toric and myopia lens can be used with relatively good visual results in eyes undergoing or having undergone penetrating keratoplasty, implantation of Intacs, after radial keratotomy or in eyes with Pellucid Marginal Degeneration[217,234,243-247].

The Artiflex lens was introduced in 2003 (Figure 1.2.5). It is constructed with Polysiloxane with PMMA haptics and is available to correct myopia between −2.0 to −12.0 D. The foldability of the lens permits smaller incisions and the use of a suture is not necessarily required[226]. Thanks to this trait, the Artiflex leads to less postoperative induced astigmatism, less spherical aberrations and faster visual rehabilitation than the original Artisan lens[248,249]. Cisneros-Lanuza noted small refractile glistenings on many of the Artiflex lenses, although they did not appear to affect visual acuity or patient satisfaction[250].
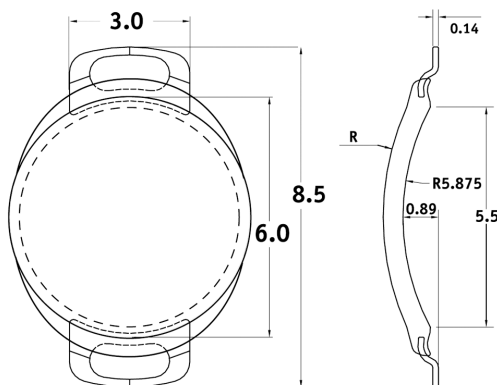
Figure 1.2.5: Artiflex lens, 6mm optic
(Courtesy of Ophtec BV)

The location of the Artisan lens, in the anterior chamber between the iris and the cornea, has always led to concerns regarding the safety of the innermost cell layer of the cornea, the corneal endothelium (Figure 1.2.3). This single layer of hexagonal cells serves to dehydrate the cornea and is not capable of regeneration

(Figures 1.2.6 a and b). A significant loss of these cells can lead to cornea guttata and corneal decompensation. Despite changes to a convex-concave form, endothelial cell loss has remained a concern with this lens[220,222,251-253]. Although rare, corneal decompensation has been documented[254]. Benedetti noted that endothelial cell loss was especially significant in the first two postoperative years, suggesting operative trauma as the cause of cell loss[255]. Tehrani advocates injecting a bolus of a high viscosity ophthalmic viscosurgical device after the lens has been brought into the anterior chamber and before enclavation, to give added protection to the endothelium during the implantation procedure[256]. Though some endothelial damage is certainly due the implantation procedure, it is unlikely to be the only cause of endothelial cell loss. Eyes with Artisan lenses have been found to display endothelial cell loss faster than the natural rate of 0.6% per year[255,257]. Nevertheless, ultrasound and Scheimpflug studies have yet to demonstrate direct contact between the pIOL and the endothelium cell layer. Furthermore, the lens demonstrates stability in the anterior chamber, although it has been found to move forward during accommodation[258-262]. Kohnen was able to demonstrate that the Artiflex lens has a significantly greater distance to the endothelium than the Artisan lens, perhaps allowing for more safety against endothelial cell loss[263].

a

b
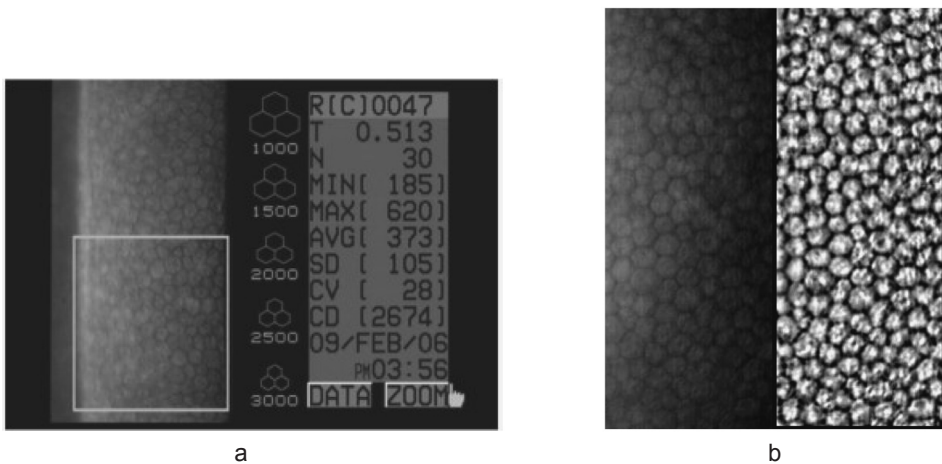
Figures 1.2.6.a. An example of an endothelial cell count measurement, b. an image of endothelial cells and a computer-generated depiction to allow for easier counting using the Topcon SP-2000 Specular Microscope (Topcon, Tokyo, Japan).

Most likely, there are other, as yet unknown factors that affect the interaction between the Artisan lens and the loss of cells in the endothelium. Other recorded, yet infrequent, complications associated with the Artisan lens include: traumatic dislocation, pigment dispersion, myopic shift, cataract, rise in intraocular pressure, endophthalmitis and retinal detachment[236,252,264-270]. Chronic anterior chamber

reaction is rare, although perhaps more common among the Artiflex model of this lens[259,271,272].

Artisan Lens-power calculations are performed using the Van der Heijde formula, taking into account spectacle refraction, corneal power and the depth of the anterior chamber[208]. Nonetheless, residual refractive error is relatively common after pIOL implantation. This can be corrected with the use of glasses or contact lenses as the anterior part of the eye is left unaffected. More gregarious surgeons combine this technique with the excimer laser to correct the remaining ametropia[251,273-275].

1.3 Quality of Life

Refractive surgical procedures have become nearly "everyday" procedures. Unlike other common operations such as cataract operations or hip replacement, refractive surgery is nearly always performed in healthy eyes. In fact, most refractive procedures consider a diseased eye as a contraindication to surgery. Generally, studies regarding refractive surgery techniques evaluate the following aspects: best corrected visual acuity (BCVA), uncorrected visual acuity (UCVA), postoperative refractive error (Predictability), Stability of the postoperative refractive error, Safety (% eyes with loss of 2 or more lines of BCVA), Efficacy (% eyes with UCVA 20/20), Safety Index (mean postoperative BCVA / mean preoperative BCVA) and Efficacy Index (mean postoperative UCVA / mean preoperative BCVA)[276]. Although these evaluations are critical to determine the medical success of an intervention, positive objective results do not necessarily mean that a patient is pleased with the results. Patient-oriented parameters such as patient satisfaction and quality of life (QOL) can add a new dimension in evaluating success in such procedures, allowing new insights on subjective improvements owing to the technique, as well as side-effects and complaints surrounding it. Clinical experience certainly provides awareness on many of these questions, however quantifying these issues is more concrete. Quantification is especially useful considering that eye specialists have been found to underestimate the quality of life of their patients[277,278]. Stein *et al*., found that ophthalmologists overestimated the QOL of patients with respect to cataract and macular disease, yet slightly underestimated QOL of patients with glaucoma[277]. Quality of life measurements can lend insight into the effects of disease on patients and can also allow more understanding as to how a certain treatment has helped.

The World Health Organization defines the Quality of Life as: "An individual's perception of their position in life, in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards, and concerns. It is a broad ranging concept, affected in a complex way by the person's physical health, psychological state, level of independence, social relationships,

and their relationship to salient features of their environment[279].

Currently, there are two main approaches to quantify QOL:

1.3.1 Choice Based Evaluation Methods

The Time Trade-Off Method is based on the scenario where a patient is asked how many years of his remaining life he is willing to trade-off for perfect health/ vision/hearing etc. The Utility-Method is a calculation based on the Time Trade-Off Method, where 0.0 indicates the worst possible health and 1.0 indicates the best possible health. For example, a patient who is expected to live for 20 years and is willing to trade 4 of these years for perfect vision will have a Utility Index of 20/20 - 4/20 = 16/20 = 0.8). The Standard Gamble Method asks the patient how much of a risk he or she would be willing to take to allow for perfect health, considering that the treatment which would lead to the cure could lead to either perfect health or to death. The Utility Index for someone willing to take a 60% risk of death for the chance of perfect health would be 1.0 - 0.6 = 0.4. Quality-Adjusted Life-Years (QALYs) combine both the quantity and quality of life produced by a medical intervention. It is a product of life expectancy and a measure of the quality of the remaining life-years. A QALY places a weight on time in different health states. A year of perfect health is worth 1.0; however, a year of less than perfect health life expectancy is worth less than 1.0. Death is considered to be equivalent to 0.0, however, some health states may be considered worse than death and have negative scores (based on Utility Indices). For example, if a patient is to survive for one year on Treatment A in moderate health, his QALY will be 1 year x 0.5 = 0.5. However, if the patient were to undergo Treatment B and would live for 1 year and 3 months, and be in excellent health, his QALY would be 1.25 x 1 (excellent health) = 1.25. A patient not receiving any treatment would survive 6 months with severe pain and suffering. The QALY would then be 0.5 (years) x -0.6 (approximately) = -0.3. These numbers would then be used in cost-utility analysis to see which treatment is the most beneficial and provides the lowest cost per QALY[280,281]. The advantage of these methods is that they can be easily compared with different diseases and also among the diverse medical subspecialties. However, they are not very descriptive, and allow for little added data information[282].

1.3.2 Standardized Questionnaires

Standardized Quality of Life surveys also exist. Examples are the 36-Item Short-Form Survey (SF-36), Nottinham Health Profile, Symptom Rating Scale, The Sickness Impact Profile and The Quality of Well Being Scale[277,283]. The World

Health Organization (WHO) even has their own questionnaire, the WHOQOL-BREF survey, available in at least eight different languages[279]. Such scales, in their innate generality, allow for easy comparison among different disease states, allowing a broad spectrum of disorders to be compared to one another. They are, however, generally difficult to translate into utility indexes, making them somewhat impractical to apply into clinical practice[284]. Still, QOL questionnaires give plenty of descriptive information about problems that a patient can experience due to a disorder.

In Ophthalmology, however, general health QOL questionnaires are of limited use, as they provide little to no information on vision-related QOL[277,282]. Fortunately, several different surveys have been developed to study the Quality of Life in patients with ocular disease[285,286]. The National Eye Institute introduced the Visual Functioning Questionnaire (NEI-VFQ-25) in 1998. It consists of 25 questions with an appendix containing another 12. There are 12 subscales; General Health, General Vision, Ocular Pain, Near Activities, Distance Activities, Social Functioning, Mental Health, Role Difficulties, Dependency, Driving, Color Vision and Peripheral Vision. The questionnaire is scored from 0 to 100, where 0 is the worst possible score and 100, the best. The mean score of subscales 2 to 12 equal the total score. The subscale General Health is used as a control variable and does contribute to the total Score. This survey was originally designed for patients of different ages with chronic eye disease such as diabetic retinopathy and CMV retinitis[287-289]. However, it has been used to study a broad range of ocular ailments, such as uncorrected refractive error, age-related macular degeneration, macular holes, optic neuritis and retinal vein occlusion[290-294]. Predictably, all these surveys found that these patients had a significantly lower vision-related quality of life than their counterparts without eye disease. Of importance, however, is that this research was able to chart which specific problems were being encountered by patients with eye disease, and what areas of their lives were being affected by it.

Another questionnaire that has arisen of late is the Refractive Status and Vision Profile (RSVP). It consists of 58 questions in the following eight subscales: Concern, Expectations, Physical / Social Functioning, Driving, Symptoms, Optical Problems, Glare, Problems with Corrective Lenses. Patients rate how much difficulty they have with activities using glasses, contact lenses or neither. The raw, non-missing scores (from 1 to 5) are converted to a 0 to 100 scale, where 0 is the best possible score and 100 the worst. When a patient chooses more than one method of correction (glasses or contact lenses), the one with the highest score (lowest quality of life) is used. The total score is then calculated by averaging all non-missing un-weighted subscales. This questionnaire was specifically developed for use among ametropic patients[295].

Rose and Takashima studied the effects of myopia on the quality of life. Both found that patients with high myopia express a lower QOL. This was not only related to higher costs, but also to the psychological, practical and cosmetic issues associated with higher degrees of myopia[296,297]. Castanon Holguin also found that there were also cosmetic issues among younger patients with myopia. Older children, and children residing in more populated areas were more likely to demonstrate trepidation about the appearance of glasses or about being teased, thus affecting their compliance with spectacle wear[298].

To date, many studies regarding postoperative satisfaction and subjective outcomes after refractive surgery have been done. These studies have all shown satisfaction with uncomplicated refractive surgical procedures, whereby the degree of satisfaction often correlated with postoperative problems such as haze and night vision disturbances[299-307]. In 2007, a comparative study was published regarding the Quality of Life among three different groups: Emmetropes, Myopes using contact lenses or glasses and Former Myopes who had undergone refractive surgery. They found that Emmetropes and the Refractive Surgery patients had comparable QOL results, and that the Myopes had significantly lower QOL scores[308]. With the exception of two studies, however, none compared preoperative and postoperative results of the same individual patients[302,307]. So far, no study has looked at QOL before and after surgery, and compared these results with individuals not seeking refractive surgery.

1.4 Goals of this Thesis

The first part of this thesis aims to evaluate objective results of the Artisan lens. The first study discusses the effects of incision-induced astigmatism and the effects of planned versus actual positioning of the Toric Artisan pIOL on postoperative astigmatism. The second study analyzes the visual results and safety of the Artisan lens for hypermetropia. As mentioned previously, hypermetropic eyes are especially sensitive due to their small size, possibly making them prone to complications not witnessed in myopic eyes implanted with the Artisan lens. Thirdly, the long-term effects of the Artisan lens on the corneal endothelium are assessed. The relationship between endothelial cell loss and the depth of the anterior chamber is evaluated.

The second part of this thesis considers the subjective results of patients with myopia in the form of Quality of Life scores. In Chapter 5, satisfied contact lens wearers are asked to complete both the RSVP and NEI-VFQ-25 questionnaires. The relationship of their scores in relation to their degree of myopia is examined. Chapter 6 analyzes the QOL scores of patients undergoing either excimer laser

procedures or implantation of the Artisan lens. Patients are given both the RSVP and the NEI-VFQ-25 questionnaires before treatment and then again two and twelve months postoperative. The Quality of Life scores are then compared with each other and with contact lens wearers not seeking refractive surgery (from the aforementioned work in Chapter 5), to determine: 1. If the Quality of Life improves after refractive surgery 2. If patients seeking refractive surgery have poorer preoperative QOL scores than individuals not seeking refractive surgery and 3. If the QOL scores of operated (and thus nearly emmetropic) patients are higher than myopic contact lens wearers not seeking refractive surgery.

The third part of this thesis looks at unique uses of the Artisan lens. Chapter 7 involves a case of a child with severe anisometric amblyopia. Due to problematic issues with contact lenses, an Artisan lens is implanted in the highly myopic eye. The postoperative outcomes are discussed. Chapter 8 is a report on five patients having undergone cataract extraction in one eye and, due to the resulting anisometropia, an Artisan lens implantation in the other eye. Patients completed two postoperative RSVP questionnaires, one in relation to each eye. The results of the two are then compared.

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Part 1:

Objective Results:
Clinical Analysis of the Artisan Lens

Chapter 2

The Influence of Incision-Induced Astigmatism and Axial Lens Position on the Correction of Myopic Astigmatism with the Artisan Toric Phakic Intraocular Lens

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Purpose

To evaluate postoperative astigmatism with regard to incision-induced astigmatism and deviation in axial alignment with the use of preoperative limbal marking with the Javal keratometer in eyes implanted with the Artisan toric phakic intraocular lens (IOL).

Design

Prospective nonrandomized trial.

Participants

Fifty-four eyes of 33 patients with myopia (mean= –9.67 diopters [D]) and astigmatism (mean= –3.44 D).

Intervention

The enclavation site was marked on the limbus using the Javal keratometer. The Artisan toric phakic IOL was implanted according to the axis marked on the limbus. Follow-up was a minimum of 6 months.

Main Outcome Measures

Safety index, efficacy index, predictability, safety, and vector analysis of total refractive correction were determined. The effects of axis misalignment and incision-induced astigmatism on the final refractive error were evaluated.

Results

At 6 months after surgery, the safety index was 1.29±0.29 and the efficacy index was 1.04±0.35. Mean spherical equivalent subjective refraction reduced from -11.39±4.86 D before surgery to -0.38±0.57 D at 6 months. Sixty-seven percent of eyes were within 0.50 D of attempted refraction and 89% were within 1.00 D. Mean preoperative cylinder was 2.92±1.60 D at 91.4°. At 6 months, the mean cylinder was 0.28±0.54 D at 174.3°. No eyes lost 2 or more lines of best-corrected visual acuity at 6 months. Eighty-three percent of eyes achieved uncorrected visual acuity of 20/40 and 28% achieved 20/20. Vector analysis of total surgically induced astigmatism revealed a mean cylindrical change of 3.21±1.71 D. Average axis misalignment was 0.37±5.34°. The mean incision-induced astigmatism was 0.74±0.61 D at 0.2°.

Conclusions

Implantation of the myopic toric IOL leads to safe, efficacious, and predictable results. The level of unpredictability caused by minor axis IOL misalignment has minimal effects on the residual refractive error. The procedure of axis alignment with the Javal keratometer seems to be an accurate method of marking the eye for toric IOL implantation. Incision-induced astigmatism can result in an overcorrection of the cylinder. A systematic undercorrection of -0.50 D for attempted cylindrical outcome could result in an achieved correction closer to emmetropia.

Achieving emmetropia or other desired refractions is challenging when spherical ametropia is combined with astigmatism. Keratorefractive procedures with an excimer laser have proven to be accurate for the treatment of mild to moderate myopia combined with astigmatism[1]. Among higher refractive errors, however, such procedures can lead to flap complications and irreversible weakening of the cornea and problems associated with small optical treatment zones[2,3]. Over the last few years, studies on diverse phakic intraocular lenses (IOLs) have demonstrated satisfactory results in the correction of high ametropia[4-6].

The Artisan toric phakic IOL (Ophtec, Groningen, The Netherlands) can be used for the combination of ametropia and astigmatism. It is an iris-fixated anterior chamber implant of Perspex CQ-UV polymethyl methacrylate with ultraviolet filtration (Ophtec). Its overall diameter is 8.5 mm with an optical zone diameter of 5.00 mm. The myopic toric Artisan IOL is available in half-diopter (D) increments with a cylindrical power up to 7.5 D and a spherical power from –3.0 to –23.5 D. Two models of toric phakic IOLs are available to allow lens insertion on the correct axis through a superior or temporal incision, according to the surgeon preference. In models A and B, the axis runs through the claws at 0° and 90°, respectively.

Several incision types can be used: corneal, corneoscleral, limbal, or scleral tunnel incisions[5]. Several studies published recently on the outcome of the toric phakic IOL have demonstrated satisfactory results[7-10]. The Artisan lens also has been shown to be rotationally stable[8,11]. However, a drawback of the lens is that it requires an incision of 5.2 to 5.5 mm. This incision can induce corneal astigmatism.

Precise enclavation of the lens is paramount. Especially in higher degrees of astigmatism, minimal misalignment greatly reduces the corrective value of the lens. Approximately one third of the cylindrical correction is lost if the IOL is rotated 10° off the axis[12]. Some surgeons mark the intended axis of enclavation on the iris with the argon or yytrium–aluminum–garnet laser[7]. Although this procedure seems to be accurate, laser burns can cause inflammatory reactions, iris bleeding, or endothelial cell loss[13,14]. Because laser burns must be placed at least 1 week before lens implantation, they also create logistical problems. Furthermore, laser burns may disappear into the iris folds after enclavation, which preclude the evaluation of accurate lens position. Other surgeons use a digital image system in which the axis is projected on the iris. This image can be used during surgery to find the correct lens position. At our center, the intended position of enclavation is marked on the corneal limbus using the Javal keratometer (Haag Streit, Bern, Switzerland) directly before anesthesia.

In this single-center prospective study, we evaluated the safety, efficacy, and predictability of the toric Artisan myopia phakic IOL. We further assessed the

influence of accurate axis lens placement using corneal markings with the Javal keratometer, and studied the effect of astigmatism induced by corneoscleral incisions on the total surgically induced refraction.

Patients and Methods

Fifty-four consecutive eyes of 33 patients receiving toric phakic IOLs were enrolled in this prospective study. Lens implantations were performed by one surgeon (GL) between January 2000 and January 2004. Inclusion criteria consisted of the following: (1) general good health; (2) a minimum of 18 years of age; (3) stable refraction for a minimum of 1 year; (4) astigmatism more than 1.5 D combined with myopia; (5) absence of ocular pathological features; (6) endothelial cell count more than 2000 cells/mm^2; (7) anterior chamber depth more than 3.0 mm (including corneal thickness); (8) mesopic pupil size limited to 5.0 mm or less, although larger pupils were included after informing the patients about the increased risk of haloes and glare. Institutional ethics committee approval and informed consent in accordance with the Helsinki Declaration was obtained for each patient.

Before preoperative examination, patients were requested to discontinue contact lens wear for a minimum of 14 days to avoid the possibility of contact lens-induced corneal warpage. The examination included best spectacle-corrected visual acuity (BSCVA) in Snellen notation, slit-lamp biomicroscopy, endothelial cell count (Topcon SP-2000-P), keratometry (autokeratometer, Topcon KR 7000P), A-scan immersion biometry, applanation tonometry, measurement of mesopic pupil diameter (Colvard pupillometer), and indirect ophthalmoscopy. Furthermore, objective refraction was measured with cyclopentolate hydrochlorate 1.0% eyedrops to exclude any accommodative error in subjective refraction. If large differences were found between the 2 refractive errors, subjective refraction was measured again and used to calculate the power of the lens. The power of the IOL, including the intended axis of enclavation, was calculated according to the Van der Heijde formula[15]. Model A was implanted in 53 eyes and model B in 1 eye.

When subjective and corneal astigmatism coincided, intended axes were marked before surgery onto the corneal limbus with a surgical marker guided by the reflected images of the Javal keratometer. If the subjective and corneal astigmatism differed, the cornea was marked on the basis of the subjective measurements, using the reflected image as a reference point. Myotic drops (pilocarpine 4%) were administered to prepare the iris for lens fixation. Surgery was performed with retrobulbar anesthesia (41 eyes of 26 patients) or general anesthesia (13 eyes of 7 patients), according to the patient needs.

A corneoscleral bevelled incision of 5.5 mm was made at the steep meridian and 2 paracenteses were placed 8 mm apart at either side. The anterior chamber was opened and filled with viscoelastic fluid (Healon, AMO, Santa Ana, CA) to maintain its depth and to protect the endothelium. After introduction of the lens into the anterior chamber with holding forceps (Ophtec REF D02-70), it was positioned onto the desired axis and then fixed onto the midperipheral iris stroma with a disposable enclavation needle. A slit iridotomy was performed at approximately 12 o'clock to prevent pupillary block glaucoma; thereafter, the viscoelastic material was irrigated manually[5]. The incision was closed with a 10-0 nylon running suture. Tobramycin 0.3% eye ointment was administered once directly after surgery. Postoperative treatment included ketorolac and dexamethasone 0.1% eyedrops 4 times daily for 4 weeks. If both eyes were to be operated on, the interventions were separated by a minimum of 2 weeks.

Follow-up examinations were scheduled at 1 day, 1 week, 1 month, 2 months, 6 months, and 1 year after surgery, and on a yearly basis thereafter. Postoperative examinations included slitlamp biomicroscopy, endothelial cell count (from 6 months after surgery), keratometry, applanation tonometry, subjective and objective refraction, uncorrected visual acuity (UCVA) and BSCVA. Within the first 6 postoperative weeks, the suture was dissected or removed if it created undesirable corneal astigmatism. After 6 weeks, the suture was removed if it caused discomfort or had loosened. At the 1-month follow-up, the Javal keratometer was used to determine the postoperative IOL axis alignment. Axis misalignment was defined as the difference between intended and achieved axis. The postoperative IOL position was measured by paraxial illuminating the IOL and projecting the Javal reflections between the claws of the IOL. This was done without prior knowledge of the intended axis of implantation (MB). Furthermore, patients were asked if they experienced haloes or glare. All data were collected prospectively from patient charts.

Statistical Analysis

To analyze BSCVA, UCVA, safety index (mean postoperative BSCVA / mean preoperative BSCVA), and efficacy index (mean postoperative UCVA / mean preoperative BSCVA), Snellen visual acuity first was converted into logarithm of the minimum angle of resolution notation to calculate the mean and then transformed back to the geometric mean Snellen visual acuity. Refraction was calculated with vector analysis[12]. The astigmatism vector levels were estimated using the mixed model analysis of variance (SAS software; SAS Institute, Cary, NC). The model accounts for a possible inclusion of 2 eyes of 1 patient.

Cylindrical refractions were transformed into double-angle vectors and rectangular

coordinates as described by Holladay *et al*[12]. The double-angle vector plots chart the cylinders horizontally (parallel, x-coordinates) and vertically (orthogonal, y-coordinates). After calculation, the horizontal and vertical components were transformed back to cylindrical notation. Total surgically induced refractive change in astigmatism was calculated with the use of vector analysis using cylindrical subjective refraction results[12].

Incision-induced astigmatism was defined as the vector of the change that occurred based on preoperative and postoperative keratometry values. This was calculated by first averaging the incision-induced astigmatism of each individual eye after 2 months to correct for measurement errors. In this analysis, eyes in which additional operations were performed after implantation were excluded. Furthermore, the single eye with a model B lens implantation also was excluded, because the incision was on the flat axis.

Comparison of data between preoperative and postoperative periods were performed with the Student *t* test for paired data using a level of significance of *P*=0.05. Changes between preoperative and postoperative periods and differences between postoperative periods also were analyzed using mixed-model analysis of variance using a level of significance of *P*=0.05.

Results

Patient Population

All 54 eyes of 33 patients were followed-up for a minimum of 6 months. At 1 year, follow-up data were available for 45 eyes of 27 patients, and at 2 years, data were available for 20 eyes of 14 patients. Mean follow-up was 17.1±11.4 months. Twenty-three of the 33 patients were female (69.7%). Mean age was 39.5±2.0 years (range, 19–57 years). Average axial length was 27.34±0.27 mm (range, 23.72–32.54 mm), and average anterior chamber depth was 3.66±0.31 mm (range, 3.18–4.32 mm). Mesopic pupil diameter averaged 4.7±0.9 mm (range, 3.0 –7.0 mm).

Visual Acuity and Refraction

Preoperative refractive measurements, along with the postoperative spherical equivalent of subjective refraction, UCVA, BSCVA, and percentages of eyes within ±1.00 D or ±0.50 D of emmetropia at 6 months, 1 year, and 2 years are presented in Table 1. The deviation of the achieved spherical equivalent correction from attempted spherical equivalent correction at 6 months is presented in Figure 1.

	Preoperative	Postoperative		
	(54 Eyes, 33 Patients)	**6 months** **(54 Eyes, 33 Patients)**	**12 months** **(45 Eyes, 27 Patients)**	**24 months** **(20 Eyes, 14 Patients)**
SE (mean) ± SD (D)	*−11.39 ± 4.86*	*−0.38 ± 0.57*	*−0.44 ± 0.62*	*−0.44 ± 0.51*
Range (SE)	*(−2.13 to −25.63)*	*(−2.25 to +0.75)*	*(−2.75 to +0.50)*	*(−2.13 to 0.00)*
Mean vectorial astigmatism (D) × axis	*2.92 ± 1.60 × 91.4°*	*0.28 ± 0.54 × 174.3°*	*0.23 ± 0.54 × 173.9°*	*0.26 ± 0.43 × 175.4°*
Mean UCVA ± SD		*0.72 ± 0.28*	*0.70 ± 0.28*	*0.75 ± 0.26*
Mean BSCVA ± SD	*0.71 ± 0.23*	*0.88 ± 0.23*	*0.85 ± 0.25*	*0.94 ± 0.25*
± 1.00 D of emmetropia (%)	*—*	*88.9*	*90.7*	*95.0*
± 0.50 D of emmetropia (%)	*—*	*66.7*	*65.1*	*70.0*
Loss ≥ 2 lines BSCVA	*—*	*0*	*1 (2.2%)*	*0*
Gain ≥ 1 line BSCVA	*—*	*40 (74.1%)*	*33 (73.3%)*	*14 (70.0%)*

Table 1: Preoperative and Postoperative Refractive Results: BSCVA = best spectacle corrected visual acuity; D = diopters; SE = spherical equivalent refraction; SD = standard deviation; UCVA = uncorrected visual acuity.

Average BSCVA improved significantly after implantation from 0.71±0.23 before surgery to 0.88±0.23 at 6 months (*P*<0.001). A gain of 1 or more BSCVA lines was seen in 74.1% of the eyes at 6 months. The safety index after 6 months and 1 year was 1.29 and 1.26, respectively. The efficacy index was 1.04 at 6 months and 1.02 at 1 year. Eighty-three percent of eyes achieved a UCVA of 20/40 and 28% achieved 20/20.
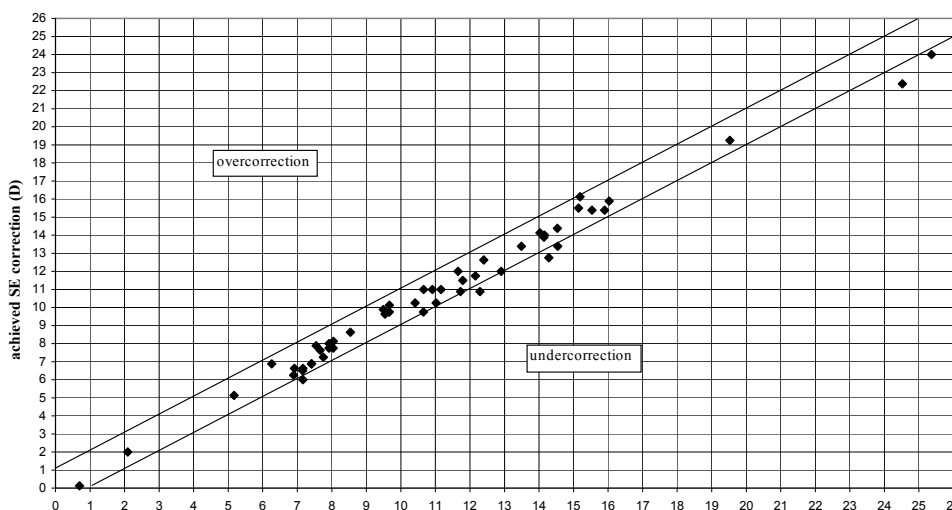
Figure 1. Plot of attempted spherical equivalent versus achieved subjective spherical equivalent at 6 months after surgery. D = diopters; SE = spherical equivalent.

Surgical and Incision-Induced Astigmatism

The mean preoperative astigmatism using vector analysis was -2.91±1.66 D for the horizontal component (x-axis) and -0.15±1.54 D for the vertical component (y-axis), equivalent to a cylinder of 2.92±1.60 D at an axis of 91.4°. A double-angle minus cylinder plot of preoperative subjective cylinder is presented in Figure 2. At 6 months, the total surgically induced refractive change was 3.21±1.71 D at an axis of 0.3°. Based on the amount of cylindric correction of the implanted IOL, average attempted cylindric outcome was -0.14 D at 180°. Mean achieved postoperative astigmatism at 6 months was +0.28±0.57 D for the x-axis value and -0.06±0.51 D for the y-axis value, translating to a cylinder of +0.28±0.54 D at a mean axis of 174.3° (Fig 3). There was no significant difference in postoperative astigmatism between follow-up periods (*P*=0.13 for the x-axis value and *P*=0.84 for the y-axis value).

Keratometric data did not change significantly after 2 months, even if suture removal took place after this period (Fig 4). The mean incision-induced astigmatism was +0.74±0.61 D at a mean axis of 0.2°. Taking into account incision-induced astigmatism, mean expected cylindrical outcome changed from –0.14 D at 180° to +0.60 D at 180°.
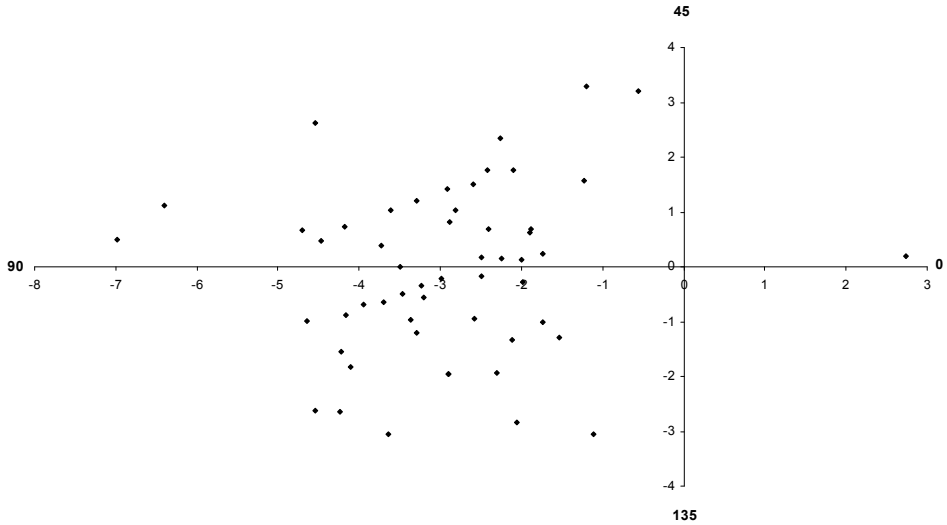
Figure 2. Double-angle plot of minus cylinder of subjective preoperative refraction.
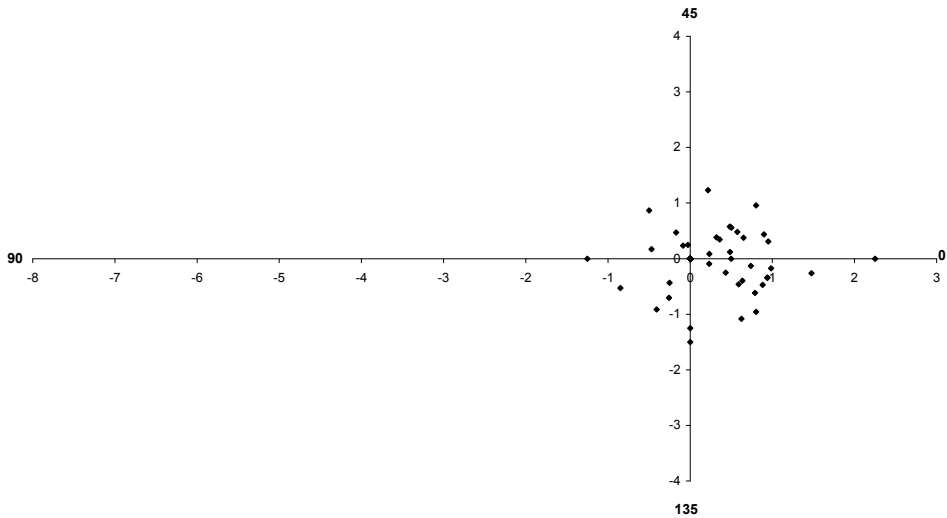
Figure 3. Double-angle plot of minus cylinder of subjective refraction 6 months after surgery.

Axis Misalignment

The mean difference between achieved and intended lens axis alignment was 0.37±5.34° (range, -13 to +14°). The mean absolute deviation was 4.15±3.34°. Axis misalignment is presented in Figure 5. An IOL with a -7.0 D cylinder was repositioned owing to a residual cylinder of -1.75 D at 130°, in combination with an axis misalignment of 8°. After IOL realignment, a cylinder of -0.50 D at 65° remained. Two eyes with cylindrical corrections of -2.00 and -3.00 D, respectively, had axis misalignments of more than 10°. No subjective residual astigmatism was seen in the first eye, despite an axis deviation of 14°. A deviation of -13° from the target axis in the second eye resulted in a residual subjective cylinder of -1.00 D.

The average (absolute) spectacle cylindrical error as a result of axis misalignment was 0.16±0.12 D. When the known axis deviation for each lens was accounted for, the attempted cylindrical correction of -0.14 D at 180° changed marginally to -0.15 D at 180°.
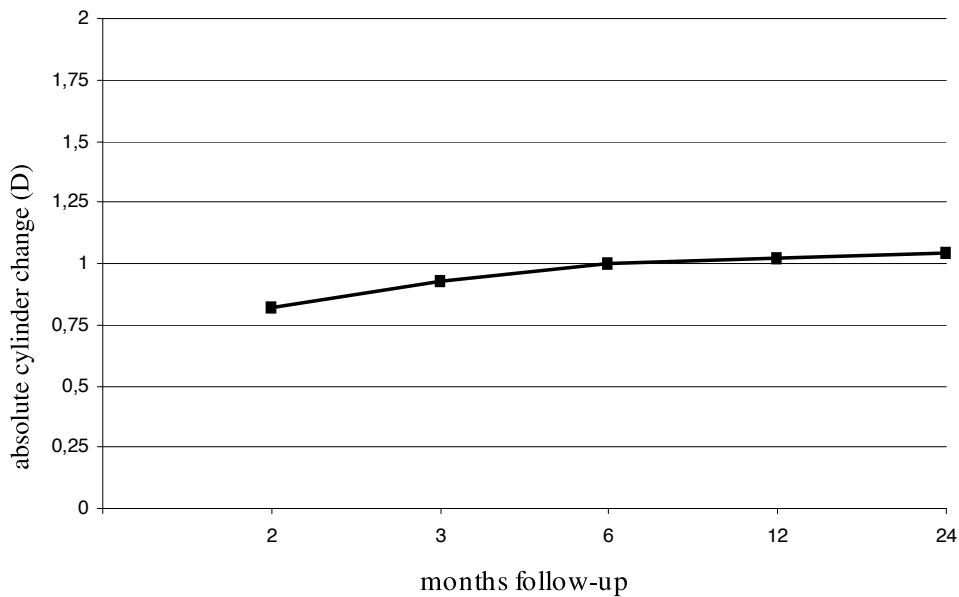
Figure 4. Graph showing the mean absolute incisional-induced astigmatism in diopters (D) at different follow-up periods.

Endothelial Cell Loss

The mean preoperative endothelial cell count was 2724±388 cells/mm^2 (range, 1577–3463 cells/mm^2). Mean postoperative endothelial cell count was 2779±458 cells/mm^2 (range, 1658–3784 cells/mm^2) at 6 months, 2783±475 cells/mm^2 (range, 1658–3591 cells/mm^2) at 1 year, and 2717±356 cells/mm^2 (range, 2249–3344 cells/mm^2) at 2 years and did not significantly differ from mean preoperative values (*P*>0.45).
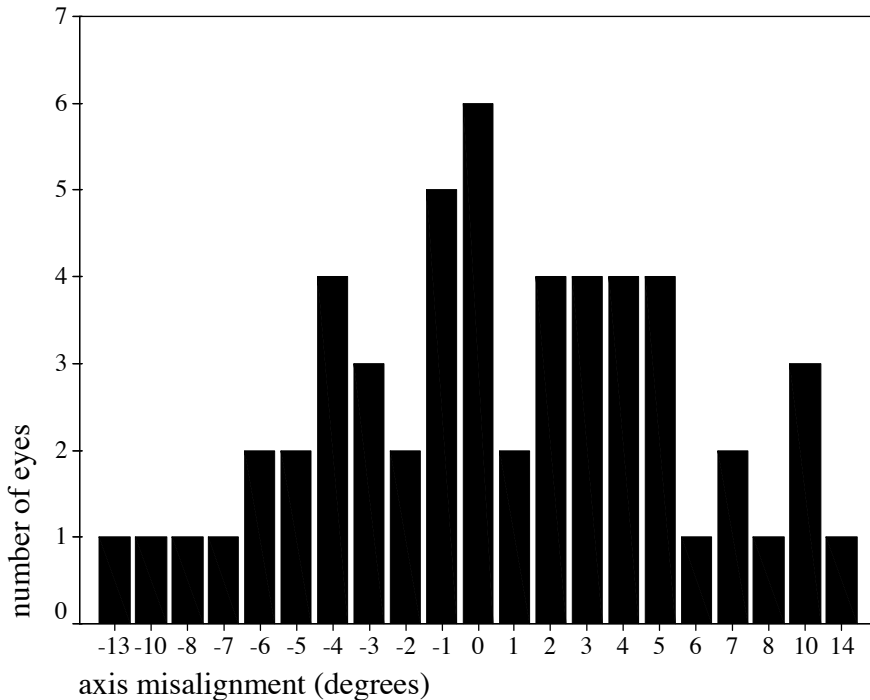
Figure 5. Bar graph showing the postoperative deviation in attempted axis of enclavation per eye.

Complications

Intervention was uneventful in all patients. One patient experienced a wound leak after suture removal at 1 week, requiring resuturing of the incision. One patient, with a preoperative asymptomatic retinal break treated with argon laser, experienced a retinal detachment 10 days after surgery. At 1 year of follow-up, the BSCVA in this eye was 0.40, compared to 0.50 before surgery.

The mean preoperative intraocular pressure was 15.3±3.4 mmHg. Seven eyes experienced a temporary intraocular pressure higher than 21 mmHg within the first month of surgery (range, 22–30 mmHg), although this normalized in all eyes after discontinuing topical corticosteroids. The mean postoperative intraocular pressure (15.7±3.4 mmHg) did not differ significantly from preoperative values (*P*>0.25).

One eye in the study experienced a significant loss of lines after cataract developed 1 year after surgery. Visual acuity decreased from 0.4 before surgery to 0.2 after surgery. We are not aware of any surgically induced reason for the development of the cataract.

No pigment dispersion or pupillary block occurred in any eye during follow-up. Seven of the 33 patients noted having more difficulty with haloes or glare. One of these patients had a mesopic pupil size larger than 5 mm. All patients were satisfied with the outcome of surgery. No patient considered removal of the lens.

Discussion

The safety, efficacy, and predictability of phakic toric Artisan lens implantation for the correction of myopia and astigmatism in this study were high. Although the toric Artisan lens was investigated in a large European study, the effect of axis misalignment and incision-induced astigmatism on the final outcome was not analyzed[7]. Based on our calculations, mean intended astigmatism correction ought to have been -0.14 D. However, our study demonstrated a slight overcorrection of +0.28 D. By analyzing the effect of incision-induced astigmatism, we found that an against-the-rule astigmatism of 0.74 D could be introduced by making a 5.5 mm incision on the steep axis. This induced astigmatism also can result after cataract surgery[16,17]. Taking the latter into account, the expected cylinder outcome should have been a 0.60 D overcorrection. Instead, we observed an overcorrection of only 0.28 D. To evaluate if this discrepancy was a result of axis misalignment, we also analyzed its effect on the refractive outcome. We found an absolute axis deviation of 4.15±3.34°, comparable with the results of Tehrani et al[8]. Because rotation of the lens has not been observed as a result of its firm fixation onto the midperipheral iris stroma, axial misplacement of an iris-claw lens must be caused by incorrect alignment of the lens during the surgical procedure. Because proper surgical alignment of the IOL is a prerequisite for the success of toric phakic IOL implantation, a precise method of axis marking is critical. Although most surgeons use preoperative laser iridotomies to mark the axis, we used limbal marking with the Javal keratometer in this study. This method does not incur the risk of intraocular inflammation and also can be practical, because

marking can take place immediately before surgery, avoiding extra patient visits. One disadvantage of this method, however, is that the markings can fade or disappear during preoperative preparation of the eye. We encountered this in 1 eye, resulting in an enclavation 14° from the intended axis of implantation. Another lens required realignment after developing a subjective postoperative cylinder of -1.75 D. The effect of the misalignment on the final cylindrical outcome, however, was minimal. The mean attempted cylindrical outcome changed marginally from -0.14 D at 180° to -0.15 D at 180° when the known axis error for each lens was accounted for. Both the incision-induced astigmatism and axis misalignment could not fully explain the discrepancy between the expected and achieved cylindrical corrections. Fixed factors such as the lens only being available in half-diopter increments and a calibration error of ±0.3 D of the lens itself could have influenced the achieved correction. Also, our data are based on subjective refraction only. Our impression is that patients tend to experience less astigmatism than was objectively observed[10]. We do not have a good explanation for this interesting phenomenon.

Refractive results in this study however, were predictable and efficacious and resembled those achieved by LASIK in lower degrees of myopia and astigmatism[1]. Approximately 90% of the eyes in our study were within 1.00 D of emmetropia. These data compare favorably those of LASIK for moderate to high myopia and astigmatism, where studies report 41% to 76% of eyes being within the same range[1,18–22]. LASIK, however, tends to result in lower predictability among higher refractive errors[23,24]. The large amount of stromal tissue ablated with the excimer laser in these higher degrees of myopia and astigmatism also predisposes eyes to corneal ectasia and associated visual problems[25]. Clear lens extraction with toric IOL implantation is another option for such eyes. Studies have shown that clear lens extractions carry a higher risk of retinal detachment and further result in the loss of accommodation in younger patients[26]. Moreover, rotational stability may be a problem with toric IOLs in the capsular bag[27]. Compared with LASIK or clear lens extraction, the correction of moderate to high myopia with astigmatism seems to be safer and more predictable with the implantation of phakic IOLs. Furthermore, unlike excimer laser procedures, the eye is not affected by the amount of refractive correction. Posterior chamber IOL implantation requires a smaller incision (3.2 mm) compared with the toric Artisan lens (5.5 mm)[28–30]. However, reports on phakic toric posterior chamber IOLs for the correction of myopia combined with astigmatism currently are limited[31]. The potential for cataractogenesis and pigment dispersion with posterior chamber IOLs is also a crucial long-term concern, as is the potential for postoperative lens rotation[27,32,33]. One patient in this study also experienced a cataract, although it is unclear if this was the result of the intraocular surgery.

In our study, 70% or more of the cases exhibited a gain of 1 or more lines of BSCVA. Such improvements in visual acuity also have been reported in other studies and have been attributed to the increase in the size of the retinal image compared with spectacle correction[34–36].

Successful correction of myopia and astigmatism with a toric phakic IOL depends on several variables. In this study, we report not only the accuracy of the refractive results, but also the refractive contribution of the deviation between intended and achieved axis of implantation and the input of incision-induced astigmatism. We believe that understanding these parameters will allow greater insight into toric phakic IOL implantation.

In conclusion, toric myopic Artisan lens implantation leads to highly predictable, effective, and safe results. Marking the enclavation site for toric phakic IOL implantation with the use of the Javal keratometer seems to be a safe and reliable method. Accounting for incision-induced astigmatism could increase predictability further. To compensate for this, a systematic undercorrection of -0.50 D for attempted cylindric outcome is advised when using a corneoscleral incision of 5.5 mm.

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Chapter 3

Three-year Follow-up of the Artisan Phakic Intraocular Lens for Hypermetropia

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Purpose

We report the postoperative results of the Artisan Hyperopia phakic intraocular lens.

Design

Prospective, nonrandomized trial.

Participants

Twenty-six eyes of 13 self-selected patients with refractive error ranging from +3.00 to +11.00 diopters (D).

Intervention

Patients with hypermetropia were implanted with the Artisan Hyperopia phakic IOL. Mean follow-up was 22.4 months (range 3–36 months).

Main outcome measures

Predictability, stability, efficacy, loss of best spectacle-corrected visual acuity, and complications.

Results

At six months, 90.9% (20 of 22 eyes) were ±1.00 D of intended correction and 81.8% (18 eyes) were ±1.00 D of emmetropia. The mean spherical equivalent was stable within 0.25 D during the entire 3-year follow-up period. Twenty-four eyes (92.3%) had a postoperative best spectacle-corrected visual acuity of 0.50 or better at all of their individual follow-up examinations. No patient lost 2 or more lines after the procedure. There was a significant negative correlation between anterior chamber depth and endothelial cell loss. Two patients experienced posterior synechiae with pigment deposits in both eyes. One of these patients had convex irides and underwent implant removal within 2 years with a consequent clear lens extraction and posterior chamber lens implantation.

Conclusions

Implantation of the Artisan Hyperopic lens leads to accurate and stable refractive results with no significant loss of vision. More attention should be paid to convex irides and shallow anterior chambers during the preoperative screening to avoid unnecessary complications.

High hyperopia has proven to be a challenge to correct. Procedures with the excimer laser have shown great potential, although many authors find that they are only safe in cases of low to moderate hyperopia[1-5]. Thanks to the introduction of phakic intraocular lenses (IOL), however, correcting higher degrees of farsightedness has now become possible.

Phakic IOLs can be an attractive alternative to other types of refractive interventions, such as refractive keratectomy, LASIK, and photorefractive keratectomy. Studies on diverse phakic IOLs have demonstrated that visual results are stable and predictable[6-11]. The Food and Drug Administration currently is undergoing clinical trials for several different types of hyperopic and myopic phakic IOLs (unpublished), although some of these lenses are already being used in clinical settings outside the United States[6-8,12].

One of these phakic IOLs is the Artisan Myopia lens (model 203W; Ophtec, Groningen, The Netherlands), first used clinically in 1986. The competency of this lens was scrutinized during the European multicenter study, with refractive errors ranging from −5.00 to −20.00 diopters (D)[6]. The authors concluded that the lens was safe, stable, efficacious and predictable. The first clinical implant of the Artisan Hyperopia lens took place in 1992. In this single-center investigation, we analyzed the predictability, stability, and visual acuity results of this phakic IOL, as well as its possible effect on the corneal endothelium and its rate of complications in hyperopic patients.

Materials and Methods

Intraocular Lens

The Artisan Hyperopia lens is an iris-fixated anterior chamber implant made of ultraviolet-absorbing clinical quality polymethyl methacrylate, Perspex CQ-UV. The lens is vaulted to allow maximum clearance between itself and the cornea and the crystalline lens. It has a 5-mm diameter optic with a total length of 8.5 mm and an absolute height of 1.00 mm. It is available in half-diopter increments between +1.00 and +12.00 D.

Patients

Twenty-six eyes of 13 patients (5 female and 8 male) were fitted with the Artisan Hyperopia lens implant between May 1996 and June 2000 at Erasmus MC in Rotterdam, The Netherlands. Patient age ranged from 28 to 59.5 years,

the average being 43.6 years. Preoperative spherical refraction averaged +6.80±1.97 D (standard deviation; range, +3.00 – +11.00 D), with an astigmatism of −0.67±0.52 D (range, −1.75 – 0.00 D). The mean best spectacle-corrected visual acuity (BSCVA) was 0.86±0.59 and ranged between 0.1 and 1.5. Four amblyopic patients had a BSCVA of 0.5 and less in one eye each. The mean axial length was 21.22±0.79 mm (range, 19.47 – 22.66 mm), and the anterior chamber depth average was 3.25±0.25 mm (range, 2.87–3.69 mm). Four eyes (3 patients) had an anterior chamber depth of less than 3.00 mm.

All procedures were performed consecutively by the same surgeon (GL). Inclusion criteria for the intervention consisted of the following: age more than 18 years, absence of ocular pathologic features or abnormality, general good health, BSCVA more than 0.1, endothelial cell count more than 2000 cells/mm^2, anterior chamber depth more than 2.6 mm (first 15 months, eight patients) then 3.0 mm, fixed pupil size less than 5.0 mm, no surgical difficulty at the time of implantation that may increase the potential for complications.

Each patient was informed about the investigative nature of the procedure and signed a detailed informed consent form in accordance with the Helsinki Declaration.

Intervention

Preoperative examination included a complete slit-lamp examination, endothelial cell count (Topcon SP2000-P; Tokyo, Japan), keratometry, applanation tonometry (Haag Streit; Bern, Switzerland), and A-scan biometry (Alcon; Irvine, California, USA). The objective and subjective refractions were measured with and without cyclopentolate hydrochlorate 1.0% eye drops. Both the uncorrected visual acuity (UCVA) and the BSCVA were measured (Snellen). The IOL power calculations were determined using the Van der Heijde formula[6].

One day before surgery, patients were requested to apply gentamicin (Genta Mytrex Tramedico, Weesp, The Netherlands) ointment in the eye. Each patient received an eyedrop of pilocarpine 4% on the morning of surgery and 30 minutes before surgery. The intervention was performed under complete anesthesia until mid June 1998 (both eyes of six patients). Thereafter, surgery was carried out with local retrobulbar anesthesia, using 5 ml of mepivacaine with hyaluronidase (Hyason) and applying pressure with the Honan balloon (Organon, Oss, The Netherlands) for a minimum of 10 minutes. The second lens implantation of each patient took place 2 to 4 weeks after the first.

Surgical procedure followed standard protocol. Corneoscleral beveled incisions of 5.5 mm were made at 12 o'clock and another two paracenteses were placed at 10 and 2 o'clock. The anterior chamber was opened and introduced with viscoelastic fluid (Healon) to maintain its depth. After implantation with the use of forceps (model D02-72, Ophtec, Groningen, The Netherlands), the lens was fixed onto the iris with an enclavation needle (model OD125, Ophtec). At the end of the operation, a slit-iridotomy was performed at 12 o'clock, the corneoscleral wounds were closed with a running suture (Ethilon 10.0), and the viscoelastic material was manually irrigated.

Follow-up examinations took place 1 day, 1 week, 1 month, 3 months, 6 months, and 12 months after surgery, and on a yearly basis thereafter. Patients with complications were examined more frequently. To be included in this study, patients required a minimum 3-month follow-up. Patients were contacted by mail with an appointment date to ensure completeness of follow-up. One patient died after 2 years and thus was lost to follow-up.

For any given comparison of preoperative and postoperative data, the preoperative average included only the group of eyes depicted in the given postoperative period. To evaluate the stability of the procedure more precisely, we also separately analyzed eight eyes that were present at every examination for all 3 years.

Postoperative examinations included slit-lamp biomicroscopy, applanation tonometry, manifest refraction, UCVA, and BSCVA. Postoperative specular microscopy was performed at every follow-up after 3 months. All data were collected prospectively from patient charts during follow-up examinations by the ophthalmologists (GL and ML) and their assistants.

Both eyes of each patient were analyzed separately. We performed regression analysis and t tests ($P = 0.05$) using the SPSS statistical program. To analyze BSCVA and UCVA results, Snellen visual acuity was first converted into logarithm of the minimum angle of resolution notation to calculate the mean and then transformed back into Snellen visual acuity.

Results

Mean follow-up was 22.4 months per patient. All 26 eyes were followed-up for 1 month, 21 eyes for 3 months, 22 for 6 months, 17 for 1 year, 15 for 2 years, and 10 for 3 years (Table 1). Eight eyes with a 3-year follow-up attended every examination. Average preoperative measurements are noted in Table 1 along with postoperative spherical equivalent, BSCVA, UCVA, and endothelial cell counts.

Refraction

The preoperative subjective spherical equivalent ranged from +3.00 to +11.00 D, with a mean of +6.80±1.97 D (standard deviation). The average spherical equivalent was −0.16±0.61 D at 1 month after surgery, −0.04±0.78 D at 3 months, and −0.08±0.74 D at 6 months. At 1, 2, and 3 years after surgery, the averages were −0.03±0.71 D, −0.15±0.89 D, and +0.10±0.85 D, respectively (Fig 1 and Table 1). One eye with no evidence of cataract or other pathologic features changed more than 1.00 D in refraction between 1 month and 3 years.

At 6 months, 13 eyes (59.1%) were ±0.50 D of intended correction and 19 eyes (86.4%) were within ±1.00 D (Fig 2). There was a significant correlation between intended and achieved correction ($R = 0.87$; $P < 0.0005$). Thirteen eyes (59.1%) were corrected within ±0.50 D of emmetropia, and 18 eyes (81.8%) were corrected within ±1.00 D. All eyes were within ±2.00 D of intended correction and emmetropia throughout the investigation. Four eyes required lenses stronger than what was available (from +12.50 to +14.70 D). Five other eyes would have benefited from half-diopter incremented lenses, which were not being manufactured at the time of surgery, so that the intended refraction of 2 eyes was −0.50 D and the intended refraction of 3 eyes was +0.50 D. Three eyes whose preoperative refraction was more than +12.00 D achieved a final refraction of more than +1.00 D. There were no correlations between predictability and the following: preoperative refraction, axial length, anterior chamber depth, and endothelial cell counts.

The spherical refraction of the four patients who attended every check-up averaged −0.22±0.76 D after 1 month, −0.23±0.86 D at 3 months, −0.09±0.72 D at 6 months, −0.11±0.72 D at 1 year, −0.27±0.99 D at 2 years, and −0.05±0.85 D at 3 years (Fig 1).
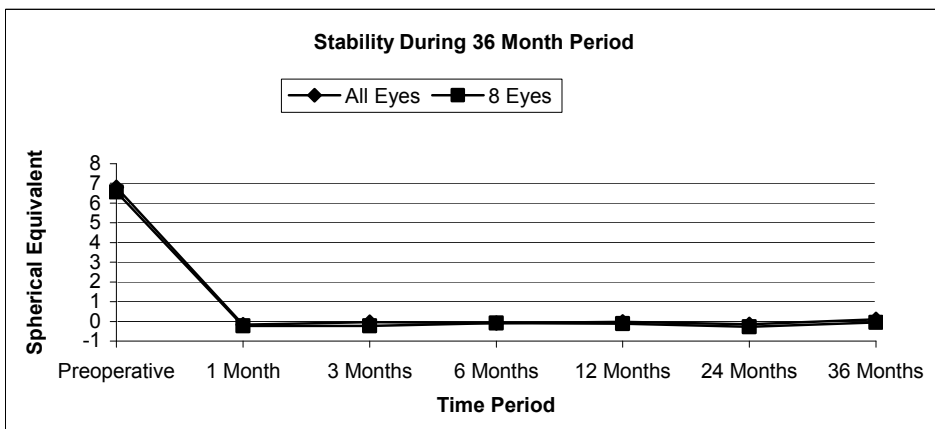
Figure 1. Stability in 3-year period postoperative refraction over a 3-year period (n = 21 at 3 months, n = 22 at 6 months, n = 17 at 12 months, n = 15 at 24 months, n = 10 at 36 months).

Visual Acuity

Mean preoperative BSCVA was 0.86±0.59. After surgery, the average BSCVAs were 0.86±0.67 at 1 month, 0.82±0.65 at 3 months, 0.87±0.67 6 months, 0.82±0.27 at 1 year, 0.82±0.59 2 years, and 0.75±0.52 at 3 years (Table 1). There were no significant differences between the preoperative and postoperative BSCVAs.

Postoperative BSCVA was unchanged or better in 80.8% of the eyes (21 eyes) at 1 month, 85.7% (18 eyes) at 3 months, 86.4% (19 eyes) at 6 months, 82.4% (14 eyes) at 1 year, 80.0% (12 eyes) at 2 years, and 50.0% (5 eyes) at 3 years. Figure 3 shows the number of Snellen lines gained and lost at 6 months and 3 years after surgery. No eyes lost 2 or more lines throughout our investigation.

A BSCVA of 0.50 or better was achieved by 92.3% of the eyes (24 eyes) at 1 month, 95.2% (20 eyes) at 3 months, 95.5% (21 eyes) at 6 months, and 94.1% (16 eyes) at 1 year. In the second year, 93.3% (14 eyes) could see equal to or better than 0.50, and 80.0% (8 eyes) could see equal to or better than 0.50 in the third year (Table 1). A BSCVA of 1.00 or better was achieved by 73.1% of the eyes (19 eyes) at 1 month, 57.1% (12 eyes) at 3 months, 50% (11 eyes) at 6 months, 58.8% (10 eyes) at 1 year, 60.0% (9 eyes) at 2 years, and 40.0% (4 eyes) at 3 years.
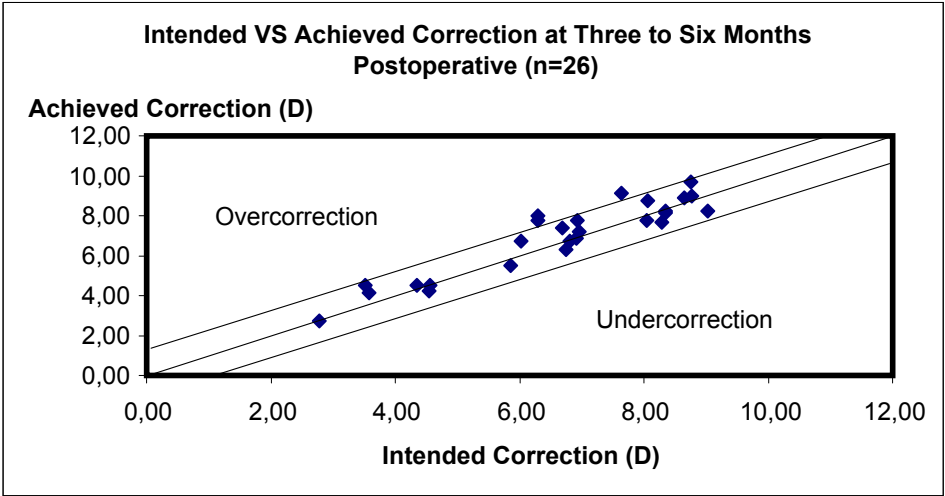
Figure 2. Intended versus achieved correction 6 months after the implantation of the Artisan Hyperopia phakic intraocular lens in 22 eyes.

Gain and Loss of Snellen Lines
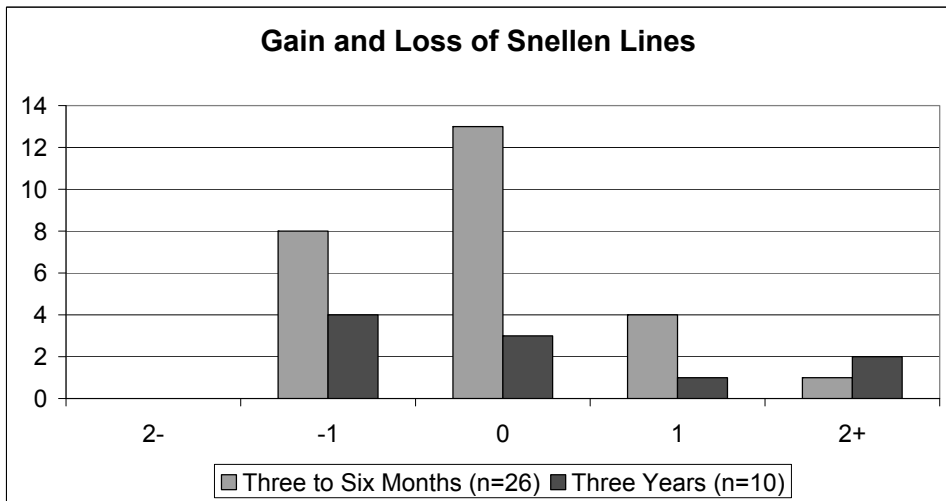
Figure 3. Gain and loss of Snellen lines change in best spectacle-corrected visual acuity after implantation of the Artisan phakic intraocular lens (model 203W; Ophtec, Groningen, The Netherlands). There were no significant loss of Snellen lines (loss of two or more lines) throughout the investigation.

The average UCVA was 0.73±0.68 at 1 month, 0.66±0.66 at 3 months, 0.65±0.65 at 6 months, 0.63±0.62 at 1 year, 0.59±0.60 at 2 years, and 0.58±0.57 at 3 years. There were no significant differences in UCVAs among the different time periods (Table 1).

Six months after surgery, 20 eyes (90.9%) could see 0.50 or better uncorrected, and 5 eyes (22.7%) could see 1.00 or better.

Endothelium

Up to and including the first year after the procedure, we noted gains in the postoperative corneal endothelial counts ranging from 1.0% to 3.8%. After 2 years, there was a decrease of 8.5% from the mean preoperative cell count, and there was a decrease of 11.7% after 3 years. There was a significant loss of endothelial cells between the 3-year postoperative endothelial cell count and 1-month and 1-year postoperative cell counts, even when we corrected for different patient groups ($P < 0.05$). However, there were no significant differences between the preoperative and any of the postoperative results. We found a significant negative correlation between endothelial cell loss and the depth of the anterior chamber at 3 months ($P < 0.05$) and 2 years ($P < 0.01$).

	Preoperative n=26	1 Month n=26	3 months n=21	4-6 Months n=22	1 Year n=17	2 Years n=15	3 Years n=10
Refractive Error (SE)	+6.80 ± 1.97	-0.16 ± 0.61	-0.04 ± 0.78	-0.08 ± 0.74	-0.03 ± 0.71	-0.15 ± 0.89	+0.10 ± 0.85
Range of Refractive Error	+3.00 to +11.00 D	-1.25 to +1.25 D	-1.75 to + 1.63 D	-1.50 to +1.38 D	-1.50 to +1.13 D	-2.00 to +1.00 D	-1.50 to +1.25 D
BSCVA	0.86 ± 0.59	0.86 ± 0.67	0.82 ± 0.65	0.87 ± 0.67	0.82 ± 0.27	0.82 ± 0.59	0.75 ± 0.52
UCVA	-NA-	0.73 ± 0.68	0.66 ± 0.67	0.65 ± 0.65	0.63 ± 0.62	0.59 ± 0.60	0.58 ± 0.57
BSCVA 0.5 or higher	92.3%	92.3%	95.2%	95.5%	94.1%	93.3%	80.0%
Mean postoperative BSCVA **Mean preoperative BSCVA**	-NA-	1.00	0.99	1.06	1.06	1.01	1.05
Mean postoperative UCVA **Mean preoperative BSCVA**	-NA-	84.7	0.80	0.79	0.81	0.73	0.77
Endothelial Cell Count	2749 ± 348	2946 ± 334	2804 ± 375	2858 ± 462	2965 ± 305	2611 ± 472	2471 ± 372

Table 1. Preoperative and Postoperative Results of Refraction, Visual Acuity and Endothelial Cell Count:
BSCVA = best spectacle-corrected visual acuity; SE = spherical equivalent; UCVA = uncorrected visual acuity.

Although a trend toward this was also present in the other time periods, results were not significant. Before surgery, there was no correlation between the endothelial cell count and anterior chamber depth (P = 0.45).

Complications

Two patients experienced posterior synechiae and pigment cell deposits on the crystalline lens of both eyes 2 weeks after surgery. Patient 1, 49 years of age, experienced no clinical symptoms and remained stable all 3 years (Fig 4).

Patient 2, 59.5 years of age, experienced posterior synechiae at nearly all clock hours with a fixed pupil size of 2.5 mm. She described her vision as "like looking though a pinhole," although her BSCVA remained at 1.00 (Fig 5). She chose to have the lenses removed, and underwent clear lens extractions in both eyes; the first eye 4 months after the initial intervention, and the second after 2 years.

None of the 13 patients reported halos or glare in either eye.
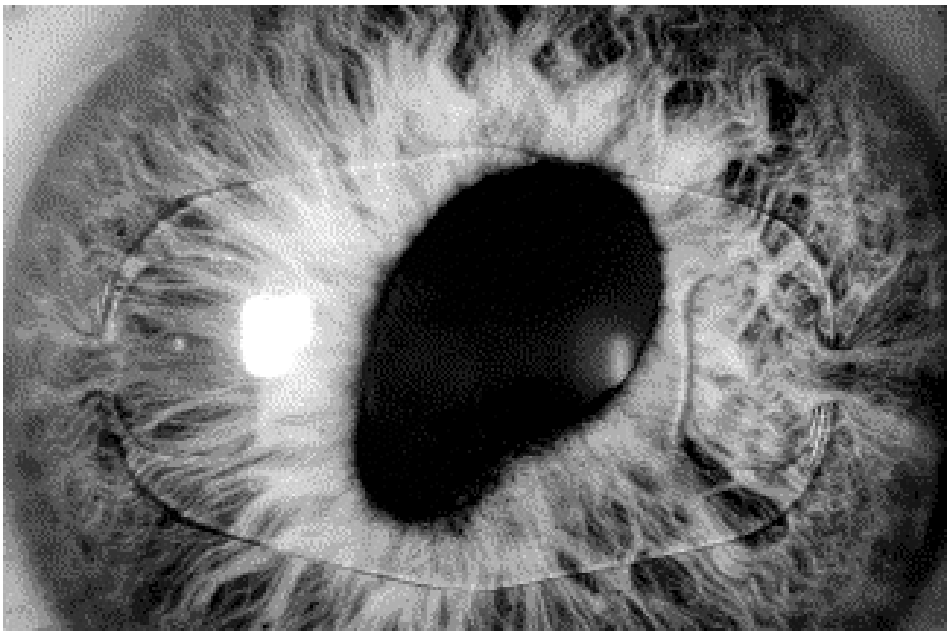
Figure 4. A dilated pupil with pigment dispersion on the crystalline lens and posterior synechiae from 4 o'clock to 5 o'clock and again from 7 o'clock to 11 o'clock.
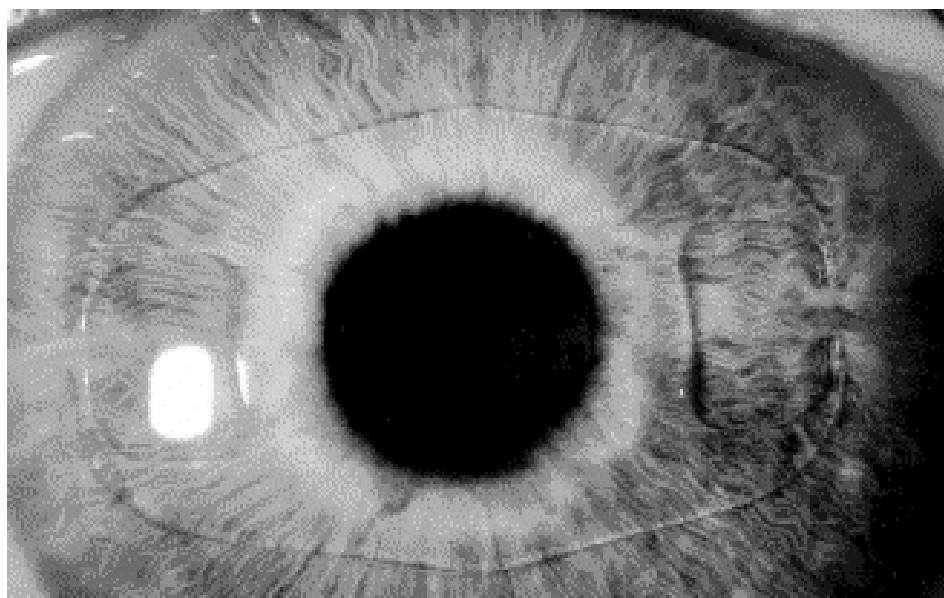
Figure 5. Pigment dispersion on the crystalline lens and posterior synechiae encircling the pupil. This patient subsequently underwent implant removal and a clear lens extraction and thereafter, a posterior chamber lens implantation in both eyes.

Discussion

We achieved a predictability of 88.5% (23 of 26 eyes) within 1.00 D of intended correction. Only 2 eyes of a patient (1.79 D and 1.45 D of overcorrection) and a single eye of another patient (1.49 D of overcorrection) were not within ±1.00 D of intended correction. The individual overcorrected in both eyes did have the longest axial length and the third deepest anterior chamber from all the patients; however, neither of these factors nor a ratio thereof showed a correlation with predictability. We believe, therefore, that other yet unknown factors may play an important role in determining the postoperative refractive outcome.

Compromises in correction are a general problem encountered with all lens implants. In our case, the Artisan lens is produced minimally in half-diopter increments and up to a maximum of +12.00 D. Nine of 26 eyes were not fitted with lenses that would have ideally corrected their vision. The 4 eyes that required lenses stronger than that available were the most undercorrected (postoperative spherical refraction between +0.63 and +1.38 D). Patients requiring corrections of smaller increments had to settle for a minor overcorrection or undercorrection. Nonetheless, at 6 months, 20 of the 22 eyes (90.9%) requiring lenses up to +12.00 D saw within ±1.00 D of emmetropia.

The mean spherical equivalent remained within 0.25 D during the 3 years of follow-up. However, because not all patients were present at each of the examinations and their follow-up was not of equal length, we decided to examine 8 eyes of 4 patients who were present at every follow-up examination. The greatest difference we found among this group was 0.22 D between years 2 and 3. Three of the 8 eyes (3 of 4 patients) increased in refraction (two from −1.00 to −0.50 D and one from emmetropia to +0.75 D). One of these patients, however, did not experience a reduction in visual acuity in the same time frame. A longer follow-up may be required to determine the cause of this change.

All but a single patient had a postoperative BSCVA 0.5 or higher until the third year of the investigation, when the BSCVA of another patient dropped from 0.5 to 0.4 (from a preoperative 0.5). The one patient who remained at less than 0.5 throughout the investigation was amblyopic. Her preoperative BSCVA was 0.1 and improved to 0.2 after phakic IOL implantation.

The mean postoperative BSCVA at every examination period was better than the mean preoperative BSCVA, indicating that, on average, the Artisan Hyperopia phakic IOL improved the BSCVA. Comparing the mean postoperative UCVA to the preoperative BSCVA led to less positive results and indicated that many patients still benefited from glasses or contact lenses after acquiring the implant. As mentioned before, ideal corrections were hampered by the availability of the lens of the exact corrective error. More importantly, however, is that hyperopic patients experience a smaller image size when their refraction is corrected, thereby limiting postoperative BSCVA improvement. This may explain why patients implanted with the Artisan lens for myopia saw, on average, better without correction after surgery than they did before surgery with correction and that the hyperopic patients did not[6-8].

The Artisan lens maintains a relatively favorable position in the eye. As long as the anterior chamber is deep enough, the lens keeps a healthy distance from the corneal endothelium and avoids the posterior chamber completely. Still, anterior chamber implants do run the risk of damaging the corneal endothelial layer, mostly through intraoperative trauma or through rubbing of the eyes. There were no significant differences between preoperative and postoperative endothelial cell counts in our study, even after correcting for different groups of patients. Nevertheless, our investigation did indicate a loss of 11.7% after 3 years. Even after correcting for a naturally occurring decrease of 0.6% a year, endothelial cell loss remained high (10.1% after 3 years), indicating that endothelial cell loss remains a cause for concern. Also, we found a significant negative correlation between endothelial cell loss and the anterior chamber depth at 3 and 24 months, although not at any other period. The increased loss of cells in shallower anterior chambers may have been the result of the endothelium undergoing more trauma during the implantation process and thereafter, although the inconsistencies

among the different periods and in the endothelial counts themselves indicate that further investigation is required. Nevertheless, we propose that a minimum anterior chamber depth of 3.0 mm be incorporated in the inclusion criteria, instead of the current 2.6 mm recommended by the manufacturer. Fechner et al made same recommendation when studying a similar iris-fixated lens and further suggested a minimum anterior chamber depth of 3.5 mm in younger patients, considering that the depth decreases with increasing age[11,14]. This may prevent endothelial damage during surgery and the complications mentioned above.

The most serious complication we encountered was the appearance of pigment deposits on the crystalline lens of both eyes of two patients, along with posterior synechiae. We found that the asymptomatic patient, patient 1, had convex irides. The constant contact of the lens with the iris could have created the complication. We could not find a satisfactory explanation for the synechiae of patient 2 because ophthalmologic examination showed no further abnormalities and surgery had proceeded without any complications. The anterior chamber depths and axial lengths of their eyes were at neither extremes of the ranges measured within our group of patients. Patient 1 had an anterior chamber depth of 3.30 mm in both eyes and an axial length of 20.60 and 21.20 mm in the left and right eye, respectively. Patient 2 had an anterior chamber depth of 3.00 mm in both eyes with axial lengths measuring 21.10 and 21.40 mm in the respective left and right eyes. The only common factor between the 2 patients is that they were both operated under general anesthesia; however, four other patients with the same form of anesthesia did not experience this complication. During the American Food and Drug Administration trials of the same lens, 2 of the 14 eyes taking part in the study experienced analogous problems. Furthermore, an eye had a fibrin pupillary membrane 6 weeks after surgery. These complications were ascribed mainly to the implantation procedure (unpublished). These findings emphasize that special care should be taken to avoid disturbing the internal structures of the eye during surgery and that careful preoperative screening is required with hyperopic eyes, which tend to be smaller, have shallow anterior chambers, and have a higher frequency of convex irides. After we began regarding convex irides as a contraindication, we no longer encountered such complications. We also advise that iris abnormalities, such as convex irides, likewise be considered contraindications for anterior chamber lenses in general.

Conclusions

The Artisan Hyperopic phakic IOL provides predictable, stable, and efficacious results in patients with high degrees of refractive error, with minimal loss of BSCVA. Strict patient screening is necessary to prevent complications. Further study on long-term complications, endothelial cell loss, and stability with a greater number of eyes is required.

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Chapter 4

Long-Term Follow-up of Endothelial Cell Change After Artisan Phakic Intraocular Lens Implantation

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Objective

To report endothelial cell densities (ECDs) and their correlation to anterior chamber depth (ACD) after implantation of the Artisan intraocular phakic lens.

Design

Prospective observational case series.

Participants

Three hundred eighteen eyes of 173 myopic patients treated with the Artisan iris-fixated phakic intraocular lens (IOL).

Methods

Eyes with an ACD ranging between 2.89 and 4.50 mm were implanted with the Artisan phakic IOL. Endothelial cell density measurements were performed preoperatively and at each follow-up examination using a noncontact specular microscope.

Main Outcome Measures

Endothelial cell density (cells per square millimeter).

Results

Follow-up ranged between 1 (82 eyes) and 7 years (13 eyes) (mean, 35.3±20.7 [standard deviation] months per eye). After 3 years, there was a significant loss in ECD ($P≤0.03$). At 5 years, mean observed endothelial cell loss was 8.3% (5.3% corrected for a natural endothelial cell loss of 0.6% a year). Endothelial cell density loss remained progressive throughout our follow-up period. After 3 years, a significant negative correlation between ACD and endothelial cell loss was revealed ($P≤0.03$). Patient age, gender, refractive error, incision size, and side of the eye were not correlated to ECD loss. All corneas remained clear throughout the study.

Conclusion

After 3 years, a significant ECD loss was revealed. This ECD loss was significantly negatively correlated to the ACD. We therefore suggest that eyes just meeting the minimum ECD requirement have greater ACDs to compensate for possible greater endothelial cell loss and that patients with shallow anterior chambers have higher ECDs. Artisan phakic lens implantation in young eyes narrowly meeting the minimum criteria of endothelial cell density (2000 cells/mm^2) and ACD (2.6 mm) should perhaps be reevaluated, due to longer exposure to higher rates of endothelial cell loss.

The Artisan lens was first introduced by Worst in 1978 for aphakic eyes under the name Iris Claw. In 1986, refractive surgeons began to implant the iris-fixated lens in phakic myopic eyes. Thereafter, developments also led to lenses for the correction of hyperopia and mixed astigmatism. More recently, a foldable version of the lens, the Artiflex, was introduced. Multicenter clinical trials have demonstrated that these lenses are safe and have a high efficacy[1-3]. However, from the time of its use, there have been concerns that this anterior chamber (AC) lens could damage the endothelial cell layer due to its close proximity to the cornea[4-5]. In fact, an earlier biconcave model was modified to a convex–concave lens for this reason[6]. The manufacturer advises the use of the Artisan lens only in eyes with an endothelial cell density (ECD) > 2000 cells/mm^2 and an AC depth (ACD) > 2.6 mm (from the corneal epithelium to the crystalline lens). Furthermore, patients are advised not to rub their eyes after lens implantation, as possible warping of the peripheral cornea may cause the endothelial cell layer to rub against the intraocular lens (IOL). Still, most studies have not revealed significant endothelial cell loss, although most had relatively short follow-ups[3,7-9]. Our previous research in hyperopic patients demonstrated an inversely proportional relationship between the ACD and endothelial cell loss in our 3- and 12-month follow-ups[10].

In this study, we examine the long-term relationship between ACD and endothelial cell loss in myopic eyes.

Materials and Methods

The following inclusion criteria were used in this study: ACD > 2.6 mm; ECD > 2000 cells/mm^2; pupil (in scotopic light conditions) < 6 mm; stable refractive error for a minimum of 1 year; no corneal, iris, or pupil abnormalities; and general good health. Eyes having undergone more than one operation were excluded from analysis after their subsequent procedure.

Preoperative examinations included subjective and objective refractive error with and without cyclopentolate 1.0% eyedrops, best-corrected visual acuity (Snellen), Javal keratometry, applanation tonometry, slit-lamp examination, fundus examination, and ECD. The ACD (distance between corneal epithelium and crystalline lens) and axial length were measured by A-scan immersion biometry using OcuScan (Alcon, Irvine, CA). The results from the ultrasound with the highest and straightest peaks from 10 different measurements (with a standard deviation of ≤7) were used. All ECD measurements were performed on an SP-2000P unit (Topcon, Tokyo, Japan). These were based on photographs of the central cornea. Between 1996 and 2002, these consisted of the average of 2 manual ECDs where the center of a minimum of 50 cells was marked (center or dot technique). If there was a large difference between the 2 counts,

another ECD measurement would be performed. After 2002, we used automated measurements with the retracing method by means of the IMAGEnet software program (Topcon), with the same specular microscope[11]. All complete cells on the image were used to measure the cell density. The value of 0.6% per year was used to estimate natural endothelial cell loss[12].

Each patient was informed about the procedure and signed a detailed informed consent form in accordance with the Helsinki Declaration. The lens power was calculated using the van der Heijde formula. All lens implantations were performed according to protocol by one experienced surgeon (GPML)[10]. We received approval from the institutional review board/ethics committee of our institution for this study.

Statistics

We used paired Student's *t* tests to test for differences between preoperative and postoperative endothelial cell densities. A mixed model analysis of variance was applied to determine a relationship between endothelial cell loss and ACD, correcting for the factors age, gender, left or right eye, refractive error (higher power IOLs are thicker), and lens type (Artiflex, 5.0 mm, and 6.0 mm). Spatial correlation structure of the repeated measurements within an eye was employed. SAS for Windows software (SAS Institute, Cary, NC) and SPSS statistical software (version 11.0, SPSS Inc., Chicago, IL) were used for data analysis.

Results

Patient demographics are listed in Table 1. Three hundred eighteen eyes implanted with the Artisan Myopia Claw Lens of 173 patients with a minimum follow-up of 1 year were included. Patients were operated between February 1997 and September 2004. Mean follow-up was 35.3±20.7 months per eye. Patients were excluded from the study after they had undergone lens exchange (n = 5), cataract extraction (CE) (n = 4), or retinal detachment surgery (n = 1) or experienced a pupillary block glaucoma (n = 1). The surgeon (GPML) chose to include one eye with an ECD of 1993 cells/mm^2 (which narrowly missed the inclusion criteria) after conferring with the patient. Data of some of these eyes have been published in previous reports[2,3,8].

Patient Population (318 eyes, 173 patients)	
Age (years)	*38.5 ± 10.1 (range 18 – 61)*
Male	*34.1 %*
Mean Spherical Refractive Error (Diopters)	*-12.25 ± 4.20 (range –1.00 to –23.50)*
Mean Anterior Chamber Depth (mm)	*3.70 ± 0.30 (range 2.89 to 4.50)*
Mean preoperative Endothelial Cell Density (cells / mm^2)	*2817 ± 356 (range 1993 to 3979)*
Type of Lens (number) 5.0 mm	*152 (57 toric)*
6.0 mm	*149*
Artiflex	*17*

Table 1. Patient Population Demographics (318 Eyes, 173 Patients)

Table 2 shows the endothelial cell loss between 3 months and 7 years postoperatively. There is an initial yet insignificant rise in endothelial cells in the first postoperative year. Endothelial cell loss was significant from 3 years onwards, also when corrected for an expected natural cell loss of 0.6% per year[12].

Figures 1-8 display the relationship between ACD and ECD, corrected for patient age, refractive error, gender, left or right eye, and lens type. After 3 years, a significant negative correlation was revealed.

All corneas remained clear throughout our follow-up period. There were no significant differences in endothelial cell loss between the 3 different lens types (Artiflex, 5 mm, and 6 mm require incisions of 3.2, 5.2, and 6.2 mm, respectively). Age and gender of the patient and refractive error of the lens (difference in lens thickness) did not show a correlation with endothelial cell loss, nor did the side of the eye.

Discussion

In our study, we found a significant endothelial cell loss in our patient population starting at 3 years after implantation of the Artisan iris-fixated phakic IOL. Endothelial cell loss in our population, 8.3% (5.3% when correcting for natural loss), was relatively higher than that of other studies[13-16]. However, some of these studies had a relatively shorter follow-up[13, 14, 16]. Additionally, similar to other reports, there was an initial yet insignificant increase in cells the first postoperative year[1, 7, 10, 16]. Though we did not account for this preoperatively, we believe that the increase in ECD may have been caused by endothelial cell migration from the peripheral to the central cornea after contact lens discontinuation by some of our patients, although this pattern of cell distribution has been disputed[17-19]. Moreover, ECD measurements have been found to be less accurate immediately postoperatively[20]. The size of the incision did not appear to play a role in cell loss,

Time Period	Number of eyes	Mean Endothelial Cell Density (Cells / mm² ± SD)	Mean Endothelial Cell Density Change (Cells / mm² ± SD)	Mean Observed Percentage Endothelial Cell Density Change	Mean Expected Percentage ECD Change in an un-operated eye with 0.6% cell loss/year	Mean Observed – Expected ECD Change
Preoperative	318	2817 ± 356	NA	NA	NA	NA
3 months	220	2856 ± 385	-34 ± 269	+1.9	-0.2	+2.1
6 months	248	2848 ± 425	-37 ± 296	+1.7	-0.3	+2.0
1 year	250	2813 ± 426	-7 ± 290	+0.5	-0.6	+1.1
2 years	168	2777 ± 376	42 ± 327	-0.8	-1.2	+0.4
3 years	122	2729 ± 342	96 ± 406*	-2.2	-1.8	-0.4
4 years	69	2616 ± 307	291 ± 502*	-6.5	-2.4	-4.1
5 years	51	2581 ± 293	285 ± 501*	-8.3	-3.0	-5.3
6 years	28	2560 ± 270	380 ± 608*	-9.1	-3.5	-5.5
7 years	13	2451 ± 256	557 ± 805*	-12.6	-4.1	-8.5

Table 2. Mean Endothelial Cell Density (ECD) and Standard Deviation (SD) over 7 Years: NA = not applicable. t test, preoperative versus postoperative, P≤0.03.

Figure 1. Relationship between anterior chamber depth and endothelial cell loss (preoperative endothelial cell density [ECD] − postoperative ECD) per patient at 6 months postoperatively (n = 248). Mixed model analysis of variance (*P*>0.05) is corrected for patient age, refractive error, gender, left or right eye, and lens type.

Figure 2. Relationship between anterior chamber depth and endothelial cell loss (preoperative endothelial cell density [ECD] − postoperative ECD) per patient at 1 year postoperatively (n = 251). Mixed model analysis of variance (*P*>0.05) is corrected for patient age, refractive error, gender, left or right eye, and lens type.

Figure 3. Relationship between anterior chamber depth and endothelial cell loss (preoperative endothelial cell density [ECD] − postoperative ECD) per patient at 2 years postoperatively (n = 168). Mixed model analysis of variance (*P*>0.05) is corrected for patient age, refractive error, gender, left or right eye, and lens type.

Figure 4. Relationship between anterior chamber depth and endothelial cell loss (preoperative endothelial cell density [ECD] − postoperative ECD) per patient at 3 years postoperatively (n = 122). Mixed model analysis of variance (*P* = 0.03) is corrected for patient age, refractive error, gender, left or right eye, and lens type.

Figure 5. Relationship between anterior chamber depth and endothelial cell loss (preoperative endothelial cell density [ECD] − postoperative ECD) per patient at 4 years postoperatively (n = 69). Mixed model analysis of variance (P = 0.002) is corrected for patient age, refractive error, gender, left or right eye, and lens type.
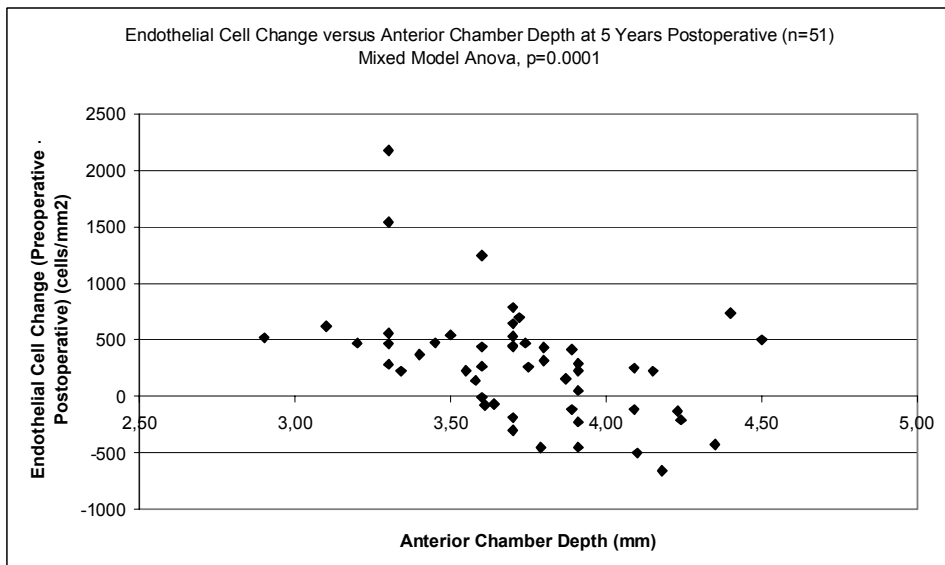
Figure 6. Relationship between anterior chamber depth and endothelial cell loss (preoperative endothelial cell density [ECD] − postoperative ECD) per patient at 5 years postoperatively (n = 51). Mixed model analysis of variance (P = 0.0001) is corrected for patient age, refractive error, gender, left or right eye, and lens type.
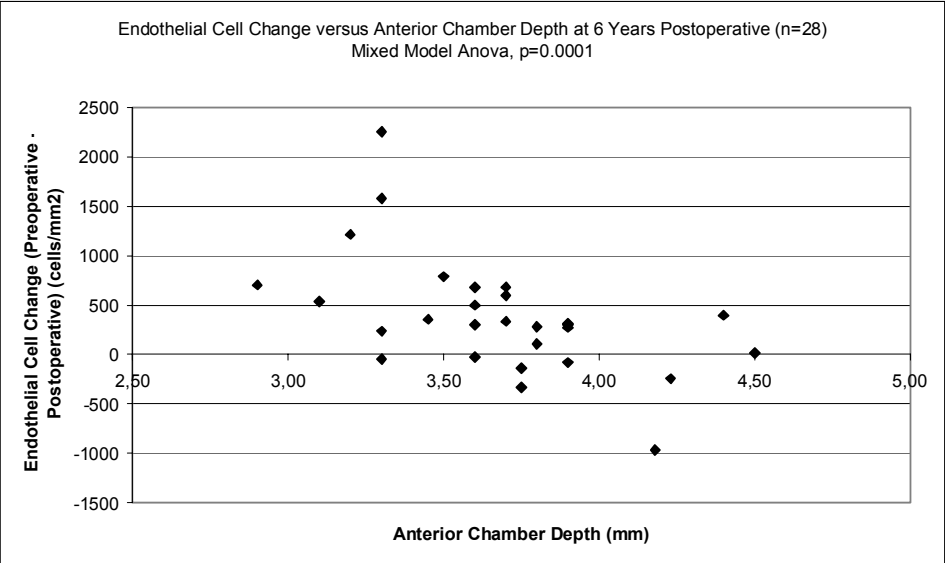
Figure 7. Relationship between anterior chamber depth and endothelial cell loss (preoperative endothelial cell density [ECD] − postoperative ECD) per patient at 6 years postoperatively (n = 28). Mixed model analysis of variance (*P* = 0.0001) is corrected for patient age, refractive error, gender, left or right eye, and lens type.
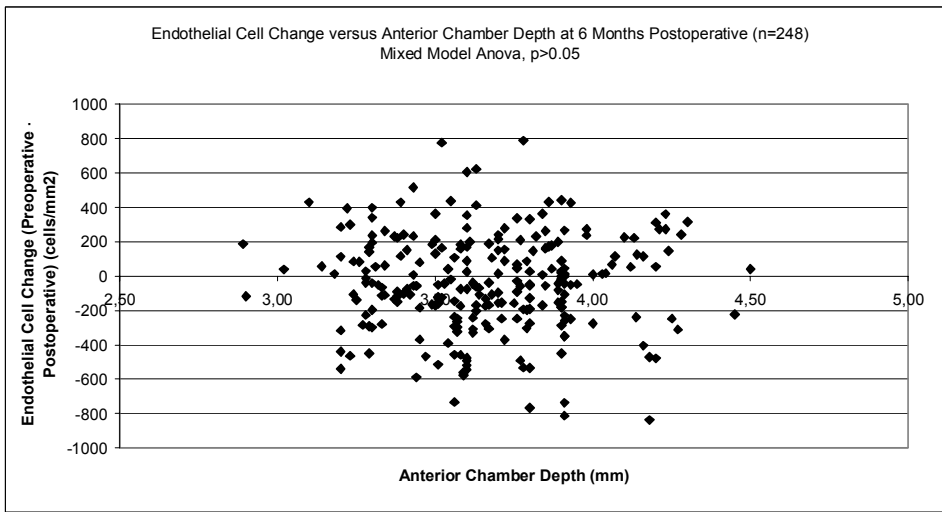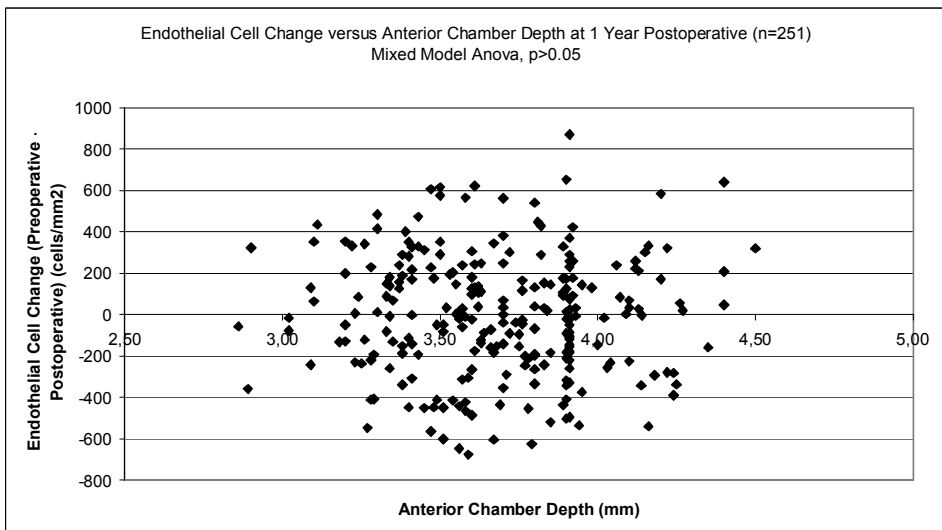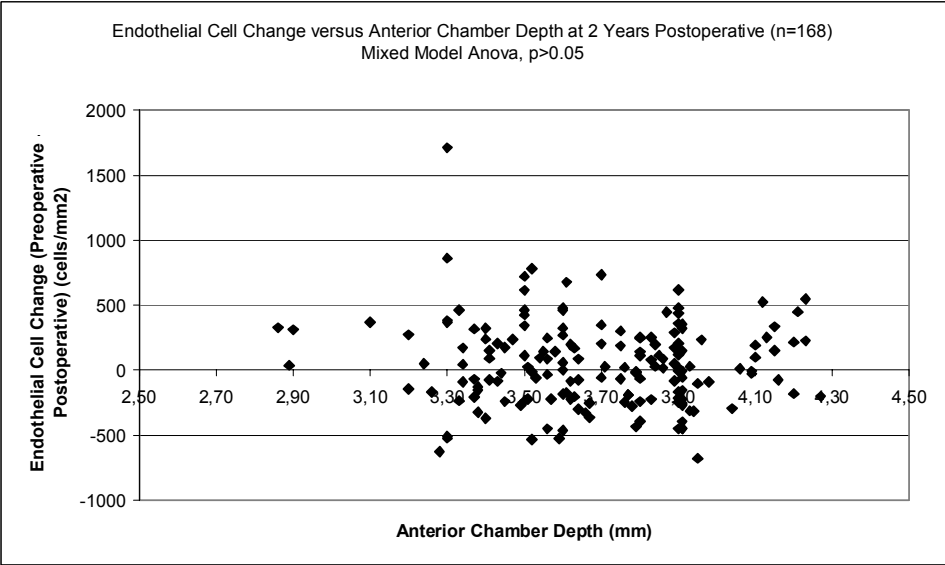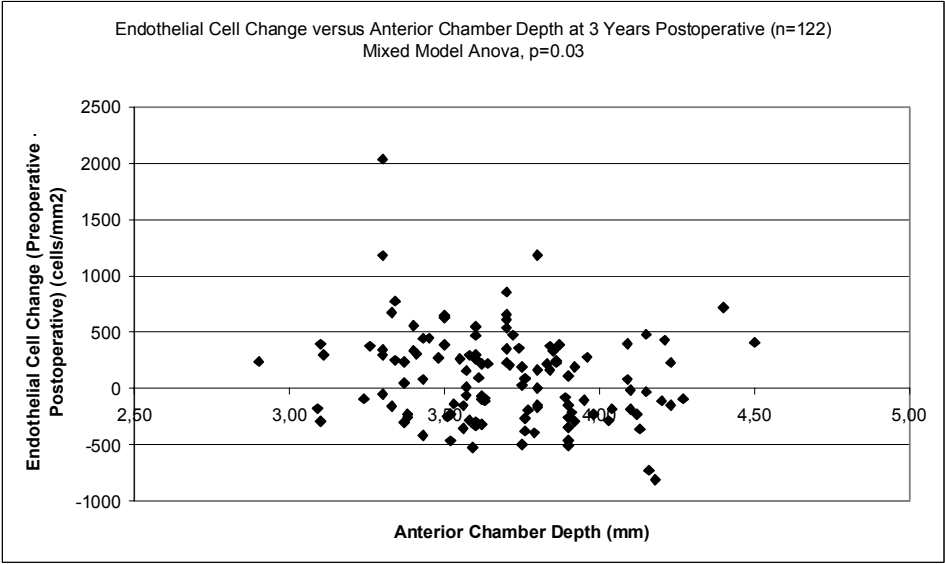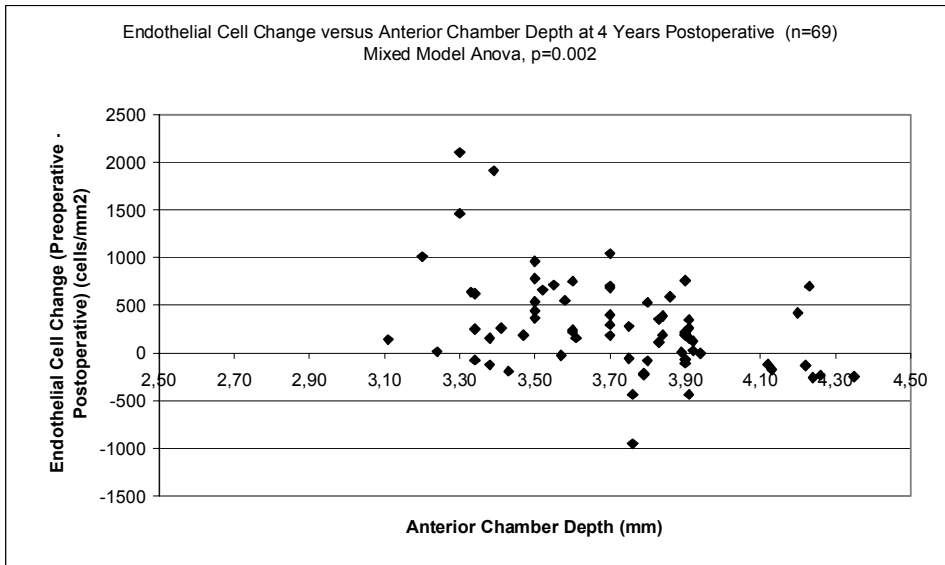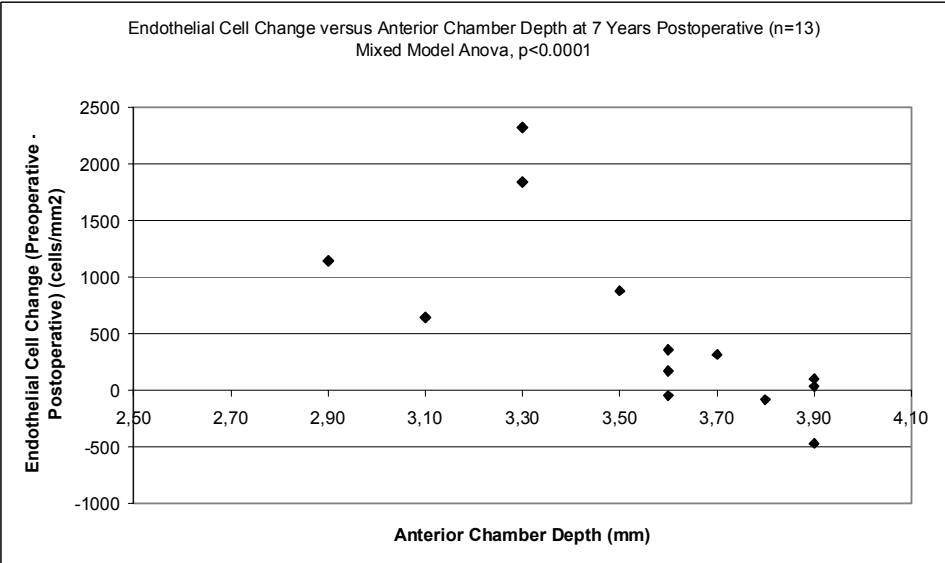

Figure 8. Relationship between anterior chamber depth and endothelial cell loss (preoperative endothelial cell density [ECD] − postoperative ECD) per patient at 7 years postoperatively (n = 13). Mixed model analysis of variance (*P*<0.0001) is corrected for patient age, refractive error, gender, left or right eye, and lens type.

reinforcing previously reported results[14]. Other studies on the Artisan lens do confirm our findings of progressive endothelial cell loss[4, 5]. Continued endothelial cell loss has also been noted in pseudophakic eyes 10 years after CE[21].

Furthermore, we found a significant negative correlation between ACD and loss of endothelium. Menezo *et al* also found a correlation with ACD after 6 months of their 4-year endothelial study and noted significant postoperative endothelial cell loss. As the cell hexagonality remained stable after 2 years, loss of endothelium was attributed to the implantation procedure rather than to the lens itself. The correlation between ACD and cell loss after half a year was considered to be a possible consequence of intraoperative contact[15]. In our study, the negative correlation between endothelial cell loss and ACD only became evident after 3 years and remained significant up to our 7-year follow-up. The factors mentioned previously, as well as corneal wound reorganization, may have blurred a relationship between ACD and decrease in ECD in earlier postoperative years[15,22].

One patient with preoperative ECDs of 2910 (right eye) and 2706 (left eye) had ECDs of 586 (right) and 863 (left) after 7 years with clear corneas. Serial ECD measurements made the first postoperative year (7 times) showed a continual progressive loss; however, the greatest ECD loss occurred between years 1 and 2 (before the switch to IMAGEnet). We could not explain the dramatic decrease in ECD, as the corneas were unremarkable preoperatively, as were the implant procedures. The patient did not rub his eyes and was not known to have allergies. He did undergo uncomplicated strabismus surgery on both eyes within 1 year of Artisan lens implantation, although the procedures took place after the greatest amount of cell loss had already taken place.

We performed endothelial cell counts using the center or dot technique before 2002 and the retracing method thereafter[11]. Thus, the cell measurements of our longer follow-up patients were calculated using 2 different counting methods on the same specular microscope. On regular inspection, the calibration was checked but showed no differences before and after 2002. Although significant ECD loss was only noted after 3 years of follow-up (whereby some patients were operated before we switched to the IMAGEnet program), a similar pattern of loss was found among our hyperopic patients, with whom all follow-up examinations took place before the IMAGEnet system was being used[10]. Nonetheless, it has been demonstrated that the center or dot technique is not as precise as the retracing method, which could question the accuracy of our (preoperative) measurements, although these could have been both underestimated or overestimated[11]. Analysis of cell hexagonality and polymegathism would have strengthened this study, but unfortunately, these data were not available on most eyes operated before 2002.

The study is further limited by the number of patients available for follow-up examinations; at 3 years, data from only 122 of the 318 eyes were available, and at 7 years, from only 13. This partial follow-up was due to the majority of patients having been operated on more recently, whereby the data are not yet available.

Although our study showed significant endothelial cell loss, all of the corneas remained clear. Still, we do find the cell loss noteworthy and offer an approach to the inclusion criteria other than what the manufacturer advises. First, considering the progressive endothelial cell loss we encountered, we recommend lifelong patient follow-up. Patients should be made aware of this before being operated. We further suggest a stricter inclusion criteria for younger patients, proposing ACDs of ≥3.5 mm. This could offset the decrease in ACD with age, which we have found to be 0.12 mm/decade (Cheng YYY, Bhagwandien ACE, Wolfs RCW, Luyten GPM, submitted for publication, 2006). Moreover, it could partially compensate for cell loss after lens implantation. Analogous suggestions were also made by Fechner et al in 1998[23]. Most importantly, we advise that some of the inclusion criteria no longer be looked at individually but as a whole: patient age, ACD, and ECD should be considered jointly. For example, young patients with relatively shallow ACs and ECDs just above 2000 cells/mm^2 should perhaps no longer be considered for implantation of these lenses. Longer follow-up studies of endothelium cell loss in relation to the ACD are necessary before definitive criteria, including patient age, can be reasonably determined. We suggest that surgeons use their clinical judgment when assessing young potential candidates narrowly meeting the inclusion criteria for the Artisan phakic IOL.

Our study showed a significant progressive endothelial cell loss after 3 years and a significant negative correlation between endothelial cell loss and ACD. We suggest caution in operating young patients who narrowly meet the inclusion criteria for ACD and ECDs.

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Part 2

Subjective Results:
The Quality of Life of Myopic Patients

Chapter 5

Vision-Related Quality of Life of Myopic Patients

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PGH Mulder
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GPM Luyten

Chapter 6

Quality of Life of Before and After Refractive Surgery

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R Arkenstijn
MA Landesz
MAH Luger
MC Bartels
G van Rij
GPM Luyten

Part 3

Special Applications of the Artisan Lens

Chapter 7

The Use of the Artisan Phakic Intraocular Lens in the Treatment of Anisometropic Amblyopia

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HM van Minderhout
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High unilateral myopia is difficult to treat in young children and often leads to anisometropic amblyopia[1–5]. Factors such as the depth of the amblyopia and the age of the patient play a key role in the effectiveness of treatment. Success is also frequently hampered by practical problems such as those created by glasses and contact lenses. Thus far, however, patient compliance has been considered the greatest therapeutic impediment[6,7]. In such cases, refractive surgery with the excimer laser or phakic intraocular lens (IOL) implantation can be a solution. There is, however, limited experience in treating myopic children with these procedures[1,2].

As excimer laser corrections are confined to refractive errors of approximately -8.00 to -10.00 diopters (D), effective surgical correction of high myopia in children can only be done with phakic IOLs. Studies of phakic IOLs to correct anisometropic amblyopia in the pediatric population have been reported[3–5]. Concerns about IOL implantation in young patients include cataract formation, pupil alteration, endothelial cell loss, postoperative inflammation, and a possible myopic shift as the patient ages.

Artisan phakic IOL implantation is a reliable and safe procedure in adults[8,9]. Although the IOL is considered experimental in several parts of the world, it has been implanted in patients in The Netherlands since 1991. Thus, when we were confronted with a young anisometropic amblyopic patient with restricted treatment options, we decided to correct his high unilateral myopia using the Artisan phakic IOL. Recently, Chipont and coauthors reported such a case with an 18-month follow-up[5]. Here, we present a patient with 3-year postoperative results.

Case Report

A 4-year-old boy with high unilateral myopia and distinct anisometropic amblyopia in the right eye presented in February 1997. Thirty minutes after 2 drops of cyclopentolate 1%, the child had a cycloplegic refraction of -14.00 +3.00 x115 in the right eye and was emmetropic in the left eye. The cycloplegic best corrected visual acuity (BCVA) in the myopic eye was 0.17 (Amsterdam Picture Chart [APK], translated from the Dutch, Amsterdamse Plaatjeskaart). Stereoscopic vision could not be detected. A spectacle was prescribed with a -10.00 +3.00x115 correction in the right eye and plano in the left eye along with 2 hours a day of left-side occlusion therapy. A refractive undercorrection was deemed necessary to reduce the effects of aniseikonia.

In June 1997, the BCVA in the right eye, measured with a full correction of -14.00 -3.00 x 115, had improved to 0.83 (APK); however, stereovision remained negative

(Lang and Titmus fly tests). Nonetheless, the patient reported that glasses were uncomfortable as they were constantly lopsided; he therefore refused to wear them. This lack of cooperation made it difficult to continue the patch therapy, and the BCVA with full correction had decreased to 0.56 (APK). Thus, a toric contact lens of -11.50 +2.50 x 110 was prescribed for the right eye.

After wearing the lens for 2 months and increasing the daily occlusion therapy to 8 hours, the patient had a poor BCVA at 0.50 (APK); however, the Titmus test was positive. Furthermore, during this period, the boy repeatedly lost his contact lens. Considering that neither glasses nor the contact lens had proved to be worthwhile therapy, refractive surgery was considered. The case was discussed thoroughly in our department and with Jan Worst, MD, the creator of the lens. A decision was made to correct the unilateral refractive error with an Artisan phakic IOL and to continue occlusion therapy. Considering the lens had only been studied in adults, the possible short- and long-term complications reported in the literature were discussed with the child's parents, who were told its use in children was experimental. As they were unhappy with their son's varying progress, they agreed to the operation and signed an informed consent. The aim was slight myopia so that both eyes would eventually have about equal refractive errors. The hope was that further changes in error would occur concurrently in both eyes as the patient grew.

In February 1998, the patient had a -15.00 D Artisan phakic IOL (model 206w; 5.0 mm optic) implanted in the right eye under general anesthesia. The surgical procedure and the IOL power calculation were performed according to standard protocol. The patient received gentamicin ointment 1 day before the procedure. Pilocarpine 4% drops were applied the morning of and 30 minutes before surgery. A bevelled 5.5 mm corneoscleral incision was made at 12 o'clock, and 2 paracenteses were placed at 10 o'clock and 2 o'clock. The anterior chamber was opened and filled with sodium hyaluronate 1% (Healon®) to maintain its depth. After the IOL was implanted with a DO2–72 forceps (Ophtec), it was fixated to the iris with enclavation needles (model OD125, Ophtec). At the end of surgery, a slit iridotomy was performed, the corneoscleral wound was closed with a running suture, and the viscoelastic material was manually irrigated. Gentamicin ointment was applied to the eye.

The early postoperative period was without complications. Occlusion therapy was continued for 8 hours a day. Four months postoperatively, the cycloplegic subjective refraction was -1.50 +1.00 x 135 in the operated eye and -1.00 in the left eye. Snellen BCVA (E chart) was 0.65 and 0.80, respectively. At 29 months, the cycloplegic subjective refraction was -0.75 +0.75 x 155 in the operated eye and -2.00 in the left eye. Stereovision had improved (positive Lang Test of 600"

repeated 4 times; TNO plates I and II). The Snellen BCVA (E chart) was 0.70 and 1.00 in the right eye and left eye, respectively. At 26 months, the refraction remained unchanged but the BCVA was 1.00 in both eyes. Three years postoperatively, the slitlamp showed a healthy crystalline lens with a clear, well-centered phakic IOL. The cycloplegic refraction in the right eye was plano+0.75 x 160 and in left eye, -2.75 +0.25 x 35. The patient now wears spectacles to correct the refractive error. The Snellen BCVA (numerical chart) is 1.2 and 1.0 in the operated eye and unoperated eye, respectively.

Although the patient was initially too young and uncooperative for a preoperative endothelial count, the cell density was 3196 cells/mm^2 (SP-2000-P specular microscope, Topcon) 1 year postoperatively and 3111 cells/mm^2 at 19 months. At the final examination, the endothelium showed normal hexagonal cells (Figure 1); however, the cell density had decreased by 11.9% to 2741 cells/mm^2. A comparison of the cell count with that in the unoperated eye measured on the same day (3302 cells/mm^2) showed a 17% difference. Before this, no endothelial cell counts in the left eye had been performed.
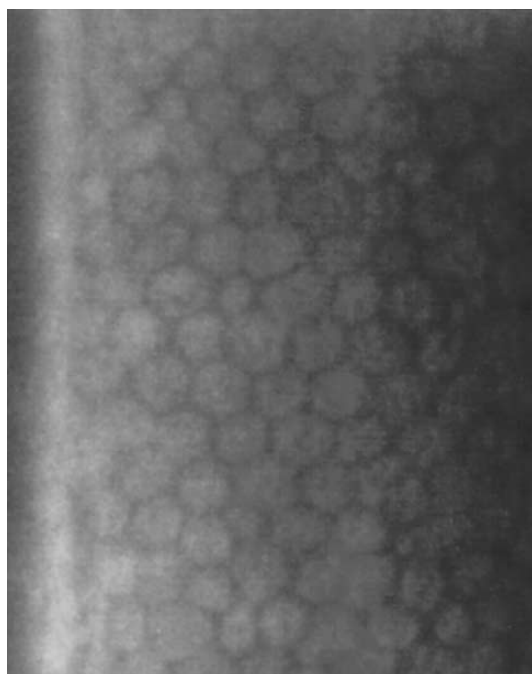
Figure. Endothelium in the operated eye 3 years postoperatively. The cells have maintained a normal hexagonal shape and have a mean cell density of 2704 cells/mm^2 ± 118 (SD).

Discussion

Treating high anisometropic amblyopia is frequently disappointing. Amblyopic treatment is encumbered by several problems[6,7]. Although children are usually capable of compensating for aniseikonia caused by high anisometropia, full spectacle correction is not generally prescribed. Glasses have practical hindrances such as prismatic effects. In addition to our patient's complaint of the glasses being lopsided on his face, there are cosmetic issues and glasses provide far from ideal binocular vision. Contact lenses minimize the magnification differences between the eyes but can be difficult to manage in young children[10]. Therefore, resistance to spectacles and contact lenses may negatively influence the treatment of amblyopia in many cases. However, even after a young patient's refractive error has been surgically corrected, one must always emphasize that patch therapy must be diligently continued.

The European multicenter study of the Artisan phakic IOL in 518 adult eyes established a safety index (postoperative BCVA/preoperative BCVA) of 1.31 and an efficacy index (postoperative uncorrected visual acuity/preoperative BCVA) of 1.03 3 years postoperatively[8]. We found similar results in our study[9]. As the lens is safe and has a good, predictable refractive outcome, we decided to use it to correct the patient's refraction even though it has not been extensively tested in children. The child's refusal to wear the glasses and repeated loss of his contact lens were affecting patch therapy compliance. Thus, we believed that the problems created by glasses and contact lenses outweighed the possible risks created by IOL implantation. By correcting the anisometropia with the Artisan lens, amblyopia treatment was facilitated by encouraging the patient to use the highly myopic eye and increasing occlusion therapy compliance. We believe this allowed the patient to develop stereovision. However, different optotypes were used preoperatively and postoperatively. Experience with the methods of visual acuity measurement and increasing patient cooperation may have distorted the amount of visual improvement.

Our patient was too young to allow valid preoperative endothelial cell measurement; however, comparison between the operated and un-operated eye 3 years after IOL implantation revealed a 17% difference. Earlier postoperative cell counts reveal much higher densities, indicating that rapid cell loss occurred after 19 months. We surmise that the child had begun rubbing his eyes, although we could not definitely establish this. During the multicenter investigation of the Artisan lens in adults, an initial endothelial cell loss of 4.8% was detected, which levelled off to 0.7%[8]. This rate of decline is not significantly different from that found in the general population. In our own series of adult myopic eyes treated with the Artisan phakic IOL, we observed no endothelial cell loss[9]. Basti et al. report no

difference in short-term corneal endothelial cell loss between adult and pediatric cataract patients, although it is questionable whether this comparison is valid among patients with an anterior chamber lens; in these cases, the endothelial layer can be affected when patients rub their eyes[11]. Therefore, endothelial cell loss remains a cause of concern in pediatric patients with an Artisan IOL.

Although intraocular surgery in children is more delicate and prone to inflammatory reactions, there were no adverse reactions or complications in our case. In a similar case of Chipont and coauthors, a low degree of uveitis was detected[5]. It is, nonetheless, possible that the complication rate in this younger population is higher as the clearance between the lens and the corneal endothelium can decrease over time[12]. The patient could also become more myopic with age, in which case additional correction with glasses or contact lenses can be prescribed. In more extreme cases, the lens can be exchanged. In our case, the postoperative refractive outcome was still stable at the patient's last examination at 3 years.

Studies in which anisometropic amblyopia was treated with photorefractive keratectomy yielded promising results in children with myopia[1,2]. Nonetheless, excimer procedures are limited to low and moderate myopia, leaving phakic IOLs as the only feasible surgical option for young patients with high myopia.

BenEzra and coauthors and Lesueur and Arne treated anisometropic amblyopia with phakic posterior chamber IOLs. Although they achieved positive results, posterior chamber IOLs can have serious complications including angle-closure glaucoma, cataract, and chronic inflammation, all of which require fastidious long-term follow-up[3,4]. One advantage of a posterior chamber IOL is the reduced risk of corneal endothelial cell loss, which is especially beneficial in children prone to rubbing their eyes[4]. The angle-supported phakic anterior chamber IOL, another alternative to iris-fixated IOLs, can also lead to complications such as retinal changes and pupil ovalization[13]. Furthermore, eye growth can compromise the stability of the lens, making it an inappropriate choice in developing eyes.

The Artisan lens has not shown early serious complications; however, long-term follow-up results are not available. In our patient, the Artisan phakic IOL was effective in treating anisometropic amblyopia. Although the IOL can provide viable correction of high unilateral myopia in children, its implantation should be considered only if conventional therapy fails.

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Chapter 8

Iris-Fixated Phakic IOLs to Correct Postoperative Anisometropia in Unilateral Cataract Patients with Bilateral High Myopia

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Purpose

To determine the visual outcome and the quality of life of five bilaterally myopic unilateral cataract patients implanted with a phakic intraocular lens (pIOL) in their sound eye.

Methods

Refraction and Snellen visual acuity were measured before and after undergoing both phacoemulsification in one eye and pIOL implantation in the other. Patients (3 presbyopic) completed the Dutch translation of the Refractive Status and Vision Profile (RSVP) for each eye after undergoing both procedures. Follow-up was between 6 and 18 months.

Results

Postoperatively, 4 out of 5 patients were within 1.00 D of emmetropia in the pseudophakic eye and all 5 out of 5 patients were within 1.00 D of emmetropia in the pIOL implanted eye. The safety index of the phakic eyes was 1.40 and the efficacy index was 0.88. There were no significant differences in the quality of life subscale measurements nor in their total scores ($p>0.05$). Patients significantly preferred reading with their phakic eye than with their pseudophakic eye ($p=0.02$).

Conclusion

PIOLs are an option for bilateral myopic patients with unilateral cataract. A larger study needs to be conducted to verify if presbyopic patients prefer reading with their phakic eye.

At present, unilateral cataract patients with myopia may choose to adjust their nearsightedness while undergoing cataract surgery. However, once their eye is treated to (nearly) full refractive correction, highly bilateral myopic patients are rendered substantially anisometropic. Contact lenses are certainly an option, although not all patients adjust to them well. Some patients desire more enduring solutions, so that they may have similar refractive errors in both eyes at all times.

Many such permanent alternatives are currently available for myopes. Not only can they consider the Excimer laser, but also phakic intraocular lenses (IOLs) and clear lens extractions (CLE). As our experience with the Artisan lens has been encouraging in both bilateral and unilateral implantations, we felt that this phakic IOL would be an interesting option for five relatively young patients with unilateral cataract[1-3]. Pure objective postoperative measurements, however, could not allow evaluation of how the patients experience the unique situation of pseudophakia in one eye and a phakic IOL in the other. To gain insight into this, the five patients postoperatively completed the Refractive Status and Visual Profile (RSVP), a vision-related quality of life questionnaire, for each eye[4,5].

In this report, we discuss the objective and subjective results of five bilaterally myopic patients who underwent a cataract extraction and posterior chamber lens implantation in one eye and an Artisan phakic IOL implantation in the other.

Methods

Phacoemulsification and Artisan lens implantation preoperative examinations and procedures were performed according to standard protocol[3]. The following pseudophakic IOLs were used: three AMO SI40 foldable lenses (Allergan Medical Optics, Nieuwegein, the Netherlands), one Acrysof foldable lens (Alcon, Gorinchem, the Netherlands) and one polymethyl methacrylate (PMMA) lens (Flex 652, Domilens, Lyon, France). All operations were performed by G.L. unless otherwise noted.

Objective and subjective refractions were measured with and without the use of cyclopentolate hydrochloride 1.0% eye drops. Both the uncorrected visual acuity (UCVA) and the best spectacle corrected visual acuity (BSCVA) were converted from the Snellen to the logarithmic logMAR notation to calculate the mean and then reverted back to Snellen notation. IOL power calculations were determined using the Van der Heijde formula[1,2].

To assess the subjective aspect of the treatment, patients received two copies of the Dutch consensus translation of the RSVP. Patients were asked to fill out the categories of the two identical questionnaires (concerns, expectations, functioning, driving, symptoms, optic problems, glare, and problems with glasses / contact lenses) simultaneously, so as to be able to compare their eyes. The total score is an average of the eight subscales, which are all weighted equally. The RSVP contains a total of 58 questions[4,5].

Questionnaires were sent out between six and twenty months after Artisan lens implantation. All five patients responded within two weeks. Statistics were performed on the Microsoft Excel Program.

Case Reports

Preoperative and postoperative refractions and BSCVAs are noted in Table 1.

Patient 1

The patient was a 54-year-old male bilateral high myope with a nuclear cataract in his right eye. In August 2000, an Allergan SI40 lens of 13 D (6.0 mm optic) was implanted in this eye after undergoing phacoemulsification. His left eye was fitted with a 6.0 mm -8.5 D Artisan lens two weeks later. At one month postoperative, the refraction was S+0.50 C-1.50 x 22 in the pseudophakic eye, with a corresponding BSCVA of 0.70. The patient required a YAG capsulotomy in October 2000 and was diagnosed the following month with a local rhegmatogenic retinal detachment (RD) in the same eye, created by a tear in an area of lattice degeneration. The RD was reattached by scleral buckling (encircling band and scleral buckle) (M.V.) after which the eye had a refraction of S plan C -2.00 x 10 and a BSCVA of 0.70. One year later, the BSCVA of the right eye could be improved to 1.00 with a glass of S -1.25 C -1.50 x 2. The refraction of left eye remained stable throughout at S –0.75 C –0.25 x 142 with a BSCVA of 1.00.

Patient 2

Patient two was a 51-year-old bilaterally myopic male with a distinct astigmatism in the right eye and a nuclear cataract in his left eye, which created a monocular diplopia. Phacoemulsification was performed and an Allergan SI140 NB lens (6.5 mm optic, 11 D) was implanted in the eye to correct the problem in January 2001. The following week, a toric Artisan lens with S-7.5 x -3.00 D was implanted in the right eye. Nine months later, the patient's UCVA was 1.00 in his right eye and 0.80 in his left. A glass of S +0.75 C-0.50 increased the visual acuity in his left eye by two lines.

Patient	Exam	Pseudophakic Eye Refraction (D)	BSCVA	Exam	Artisan Lens Eye Refraction (D)	BSCVA
1	Preoperative	S -10,25 C -2,75 x 37°	0.40	Preoperative	S -7,50 C -1,50 x 150°	1.00
	12 months	S -1.25 C -1.50 x 179°	1.00	12 months	S-0.75 C-0.25 x 142°	1.25
2	Preoperative	S -7.75 C -1.50 x 150°	0.70	Preoperative	S -6.75 C -2.50 x 11°	1.25
	9 months	S+0.75 C-0.50 x 14°	1.25	9 months	S +0.50 C-0,50 x 111°	1.25
3	Preoperative	S -11.00 C -0.75 D x 70°	0.20	Preoperative	S -9.00 C -1.25 x 90°	0.20
	18 months	S -0.50 C -1.25 x 104°	0.40	18 months	S +1.0 C -1.25 x 96°	0.50
4	Preoperative	S -6.75 C -1.0 x 177°	0.20	Preoperative	S -7.50 C-0.75 x 21°	1.25
	4 months	S plan C -0.75 x 55°	1.60	4 months	S +0.25 C-1.00 x 63°	1.25
5	Preoperative	S -7.50 C -1.25 x 125°	0.63	Preoperative	S -9.25	1.00
	6 months	S -1.0 C -0.50 x 100°	1.00	6 months	S -0.50 C-0.50 x 75°	1.25

Table 1. Preoperative and postoperative refraction and BSCVA

Patient 3

A 54-year-old male high myope had a bilateral myopic retinal degeneration and a cortinuclear cataract in his right eye. After phacoemulsification, his eye was suited with an Acrysof 6.0 mm foldable lens (8 D) in May of 2000 (K.T.). Two weeks hereafter, the refraction in his phakic eye was corrected with an Artisan 6.0 mm lens (-10.5 D). Although his visual acuity remained relatively low due to retinal pathology, his VA had improved by two Snellen lines in his pseudophakic eye and by three lines in his phakic eye when examined eighteen months postoperative.

Patient 4

This 33-year-old colour-blind male myope was diagnosed with a nuclear cataract causing monocular diplopia. As the vision in the eye deteriorated, the patient was treated for his cataract with phacoemulsification and lens implantation (FLEX 652, 6.5 mm optic, 9 D). Two months later, his right eye underwent a phakic lens (Artisan 6.0 mm, -9.5 D) implantation. The last check-up six months postoperative showed no abnormalities and stable refraction in both eyes. His pseudophakic eye could achieve a visual acuity of 1.60 without correction.

Patient 5

A highly myopic female patient 37 years of age was diagnosed with a conjunctival MALT lymphoma in her right eye. As a consequence of radiotherapy, the eye developed keratoconjunctivitis sicca and required punctum plugs on the upper and lower lacrimal ducts two and again three years after the initial diagnosis. During this last examination, a posteriocapsular cataract was also diagnosed in this eye. The patient underwent phacoemulsification and lens implantation (Allergan SI40 NB, 12 D) three months later. Postoperative complaints of aniseikonia with the use of spectacles led to the myopia in her left eye being corrected with the Artisan 6.0 mm lens (-10.0 D) four months hereafter. Six months postoperative, the patient had a stable refraction and a BSCVA of 1.00 or higher in each eye.

Four of the five patients had a postoperative BSCVA of 1.00 or higher in their pseudophakic eye, three of the five patients were within 1.00 D of emmetropia and all five within 2.00 D. All patients were within 1.00 D of emmetropia in their Artisan implanted eye and three within 0.50 D. Three of the five phakic eyes showed a postoperative improvement in their BSCVA and the other two were unchanged at 1.25. The safety index (mean postoperative BSCVA / mean preoperative BSCVA)

was 1.40. The efficacy index (mean postoperative UCVA / mean preoperative BSCVA) was 0.88.

RSVP Questionnaire

There were no significant differences between the eyes in any of the subscales of the RSVP (Table 2). The eyes with the Artisan lens scored on average better in the subscales concerns, functioning, symptoms and glare, while the pseudophakic eyes were, on average, better for driving. There were no differences noted by any of the patients in the subscales expectations, optic problems and problems with glasses/contact lenses.

Two different total scores were calculated, one including all the subscales and one disregarding the subscales "expectations" and "problems with glasses and/or contact lenses", as these two subscales are dependent on the individual patients and not on the individual eyes. The difference between the average scores of the eyes then increased by one point, but remained insignificant (Student's paired t-test, $p>0.05$).

In all but one question, patients experienced no average significant difference between the phakic and pseudophakic eyes. When asked to rate their satisfaction with reading and near vision, 4 of the 5 patients expressed a preference for their phakic eye while one preferred neither (patient 3) ($p=0.02$).

Discussion

When a relatively young highly myopic patient develops a cataract in one eye, it is questionable if he or she will be willing to or even should undergo an operation in their phakic eye. Aversion to yet another operation, not wanting to risk their other eye, being satisfied with their current method of correction or electing for monovision are all reasons for leaving the healthy eye untouched. However, some patients may find their anisometropia troublesome, albeit only having to deal with it until they put on their corrective lenses. Certain patients may not be able to tolerate contact lenses and will have to deal with aniseikonia with the use of spectacles. Yet others may just want to have their refractive error about the same in each eye permanently. Our five patients with unilateral cataract had the myopia of their sound eye corrected with the Artisan lens.

Three of the five pseudophakic eyes were within 1.00 D of emmetropia, and all five within 2.00 D. All patients showed an improvement in visual acuity and all

but one pseudophakic eye had a BSCVA of 1.00 or higher. The remaining patient had improved his visual acuity by two Snellen lines, but it remained low due to the myopic macular degeneration. These results are comparable to large-scale investigations on phacoemulsification[6]. Refractive results of the Artisan implanted eyes were also comparable with more extensive studies[1,2].

RSVP Questionnaire	Average Score (%)	
Subscales	**Pseudophakic Eye**	**Artisan Lens Eye**
Concerns	*23*	*21*
Expectations	*30*	*30*
Functioning	*13*	*8*
Driving	*8*	*15*
Symptoms	*21*	*11*
Optic problems	*7*	*7*
Glare	*16*	*6*
Problems with glasses / contact lenses	*0*	*0*
Total (100)	*15*	*12*
Corrected Total*	*15*	*11*

Table 2.   RSVP subscale and total scores: Higher scores indicate more problems. *The subscales "expectations" and "problems with glasses/contact lenses" are not included in the corrected total score.

RSVP

The Refractive Status and Visual Profile Questionnaire survey led to some interesting results. The patients only experienced one significant difference between their eyes – they preferred reading with their phakic eye. Such a distinction was not made for vision in general (with or without refractive correction). Although this partiality would seem reasonable considering that their preferred eye was their only phakic eye, one must note that two of the four patients who expressed this preference were above the age of fifty. Their partiality for the phakic eye could indicate that one should consider leaving the healthy lenses of presbyopic patients intact and not opt for a clear lens extraction too early, although a much greater number of patients would need to be assessed to be able to conclude this. The one patient of 54 years who felt he read equally well with both eyes (Patient 3) suffered from bilateral macular degeneration and recorded only one difference between the eyes throughout the whole questionnaire: his vision was more often cloudy or foggy in his phakic eye.

As a group, there were no significant differences among the eyes in any of the subscales. While it appeared that, on average, patients had more problems driving with their Artisan eye, this difference lay in one individual, Patient 4, who had a confirmed higher visual acuity in his pseudophakic eye. They also tended to function better with their phakic eyes, however this was due to two patients who had had troublesome pseudophakic eyes (patient 1 and 5, with RD and keratoconjunctivitis sicca respectively). Although the bulk of the difference in the subscale "symptoms" is due to patient 5 (with keratoconjunctivitis sicca in her cataract operated eye), 4 out of 5 patients noted a difference in their "vision being cloudy or foggy". Three experienced more trouble with their pseudophakic eyes and one (Patient 3) with his Artisan implanted eye. Patient 4 did not record any difference.

One shortcoming of our small RSVP survey is that the questions were not also posed preoperatively. This would have allowed a quantitative measurement of the change in vision-related quality of life. In addition, patients should have been asked to complete the questionnaire during identical postoperative periods, instead of between six and eighteen months after Artisan lens implantation. Further variability was also incurred by the periods between the cataract treatment and pIOL implantation, which varied between one week and four months. Moreover, the sample size was limited.

Before selecting the Artisan lens to correct the refractive error for the healthy eye, all possible options available were discussed with the patients. Clear lens extraction (CLE) and implantation of a multifocal lens, which would have rendered both eyes pseudophakic with similar refractions, were considered. However, as

CLEs increase the risk of retinal detachment in myopic eyes, they were rejected[7]. The postoperative RSVP results also indicated that CLEs may not be ideal for younger presbyopes, considering that two of our three patients above the age of fifty favoured reading with their Artisan-implanted eye and did not show this preference for vision in general. Posterior chamber phakic IOLs, on the other hand, do retain accommodation in young patients, however they too may have a higher rate of RD and can also induce pupillary block glaucoma and cataract[8,9]. LASIK could have been performed in our patients with refractive errors less than -10.00 D.

Previous positive experience with the Artisan lens led to its choice[1-3]. Furthermore, preoperative biometry for pseudophakic lens implantation could be performed reliably with the Artisan lens in place if a cataract was to develop. Removal of the iris-fixated lens, phacoemulsification and pseudophakic lens implantation could then also take place in one procedure.

This case series demonstrates the possibility of using the Artisan lens for anisometropia after the treatment of unilateral cataract in myopic patients. The five patients undergoing this treatment significantly preferred reading with their eye implanted with the Artisan pIOL, without displaying the same preference for their vision in general. More patients need to be considered before definitive conclusions can be made.

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Chapter 9

Discussion

The methods of correction of refractive errors have evolved immensely, especially throughout the 20th Century. "Coke Bottle" glasses are no longer the norm for persons requiring refractive correction. Technological improvements in lens development have allowed for thinner glasses, although this has not been able to alleviate the change in image size associated with higher refractive errors. Contact lenses do surmount this problem, and due to improvements in materials, allow for more tolerability and longer wear. Nevertheless, contact lens intolerance due to allergy or over-wear still exists. For these patients, and for those seeking freedom from contact lenses or spectacles, refractive surgery has been able to provide many answers.

This thesis studied many different aspects surrounding refractive surgery and has many clinical consequences associated with it:

The evaluation of the toric Artisan lens displayed excellent visual results with reliable axial alignment of the lens. The observation of consistent incision-induced astigmatism of nearly two thirds of a Diopter led to advice on fine-tuning postoperative astigmatism by systematically correcting for the incision-induced astigmatism. We were also able to demonstrate that our method of using the Javal keratometer to mark the corneal limbus before the operation leads to relatively precise surgical alignment of the lens. A larger series of patients and a study on whether pre-emptively correcting the incision-induced astigmatism leads to more precise astigmatic correction is advised.

Our study of hypermetropic eyes revealed that the Artisan lens for hypermetropia achieves excellent visual results. However, the appearance of posterior synechiae in 15% of the eyes (4 of 26) and eventual removal and phacoemulsification of clear lenses in nearly 8% of the eyes (2 of 26) suggests that these eyes are more prone to postoperative problems than myopic eyes receiving the Artisan lens. These last eyes had convex shaped irides. Special preoperative attention to the anatomy of hyperopic eyes can prevent these complications. Furthermore, the indication of an inverse relationship between anterior chamber depth and endothelial cell loss prompted our seven-year follow-up study on endothelial cell density (ECD) and the Artisan lens. Further analysis is required to see if implementation of our advice does in fact lead to less endothelial cell loss.

The significant relationship between endothelial cell loss and the anterior chamber depth helped to better understand why some eyes suffer a more profound ECD loss. This awareness also allowed us to advise surgeons to assess their patients differently to what the manufacturer advises. Instead of simply checking if the patient meets all the different requirements for lens implantation, we suggested that certain aspects should be evaluated concurrently; young patients just

narrowly meeting the inclusion criteria for ECD and anterior depth should perhaps no longer be considered for the Artisan lens to avoid severe endothelial cell loss or even corneal decompensation in the distant future. Supplementary research is required to identify the mechanism behind this relationship and which relationship of anterior chamber depth, endothelial cell density and age should keep a surgeon from operating.

The Vision-Related Quality of Life (VR-QOL) surveys identified 4 key points:
1. Myopia is negatively correlated with VR-QOL.
2. Patients seeking refractive surgery have a lower VR-QOL than those not seeking refractive surgery, mainly due to their no longer wanting to wear contact lenses or glasses and their not wanting the problems associated with them. This suggests that more comfortable and convenient methods of refractive correction could dissuade some patients from undergoing refractive surgery.
3. After undergoing uncomplicated refractive surgery, VR-QOL increases.
4. Despite Excimer laser surgery and a nearly emmetropic postoperative state, these patients, on average, do not score better on certain VR-QOL surveys than patients who have not permanently corrected their myopia. This implies that there may be some inherent differences between these two patient populations.
Further analysis is required to identify which patients would benefit most, and which patients would benefit least from refractive surgery.

The good visual results of the Artisan lens implanted in a four-year old boy with unilateral high myopia are very encouraging. This can be an option for refractory cases with severe patient compliance issues. Still, many more cases with longer follow-ups extending into adulthood or later are needed before long-term complications (especially regarding corneal endothelial cell loss) can be excluded and refractive surgery can be deemed safe in the pediatric population.

The five-patient case report studying the independent RSVP scores of individual eyes demonstrated that adult patients (presbyopic or nearly presbyopic) show virtually no preference for a myopic eye corrected with a pseudophakic lens after phacoemulsification or corrected with an Artisan lens. However, there remains a preference to read with the phakic eye. Although this study is small, it does demonstrate that reading with a phakic eye is preferred to a pseudophakic eye. This may help to evaluate patients seeking refractive surgery who are considering clear lens extractions. Maintaining some degree of accommodation may be the preferred route if the crystalline lens is clear.

To this day, no refractive surgeon can guarantee 20/20 vision without correction in the healthiest of eyes. Much more research on the known and as yet unknown stumbling blocks of refractive surgery is required before it can be perfected.

More precise lens calculations and algorithms provide better results everyday, as does progress in technology such as smaller incisions, better quality lasers and instruments. In addition, advancements in research, such as the genetic and environmental factors surrounding refractive errors could lead to sound preventive treatments and measures to prevent ametropia. More research regarding Vision-Related Quality of Life can help to guide surgeons in their quest for excellence.

Pioneer Harold Ridley faced much ostracism when his new invention, the intraocular lens, was introduced half a century ago. He recounted some comments he had received throughout the years about his intraocular lens during the Gullstrand Lecture, in Stockholm, Sweden, 1993 (as published in Trivedi *et al*., Sir Nicholas Harold Ridley. He changed the world, so that we might better see it. *Indian J Ophthalmol* 2003;51(3)211-6.)

'Dr. Ridley, Why don't you… GO HOME!'
(Philadelphia)

'Would you have one of THESE THINGS put in your son's eye?'
(Oxford)

'As long as I remain in charge of this department no implant will ever be done'
(European Professor of Ophthalmology)

'This operation should never be done'
(Chicago)

'It offends the first principle of ophthalmic surgery and could cause malignant disease'
(USA)

'Rayners should be prosecuted for supplying intraocular lenses'

Ridley eventually had his invention placed in his own eye and suffered only minor complications.

Needless to say, the world's perspective on the intraocular lens has changed. No doubt the inventors of tomorrow will also be facing such reactions. If these future innovators can persevere and look past the criticism, it will undoubtedly lead to newer and fresher developments in Ophthalmology and change the field of eye care.

Chapter 10

Summary / Samenvatting

Summary

The phakic Artisan lens is an intraocular lens (IOL) that can be implanted in the anterior chamber of the eye to correct nearsightedness, farsightedness and/or astigmatism, without having to remove the natural lens of the eye. This lens can be an ideal option for eyes that are not suitable for other methods of refractive surgery, or for patients who are not comfortable undergoing technically irreversible surgical interventions. This thesis examines the visual results of the Artisan lens implanted in hypermetropic and astigmatic eyes and its effect on the corneal endothelium. Also, it investigates the Vision-Related Quality of Life (VR-QOL) of myopic contact lens wearers and compares this with patients having gone either bilateral Artisan lens implantation or Excimer laser treatments for myopia. Furthermore, unique applications of the Artisan lens are considered.

Chapter 1 is a general introduction of the subjects outlined in this thesis. The essentials of myopia and hypermetropia are summarized. Studies have found that myopia is increasing in alarming rates in Asia. Although inheritance and near work have been recognized as substantial risk factors for ametropia, there are no known truly effective methods to either prevent or undo myopia or hypermetropia. Until recently, one could only correct refractive errors with glasses or contact lenses. Although this usually leads to an increased visual acuity, patients still have to endure the negative aspects of wearing glasses, such as troublesome changes in image size and feelings of self-consciousness. Contact lens wearers risk infections and the development of intolerance. These aspects can affect Vision-Related Quality of Life in some ametropic individuals. Advances in refractive surgery, such as the development of Excimer laser techniques and the Artisan phakic IOL, have allowed patients with either myopia or hypermetropia to decrease their dependence on spectacles or lenses. The development of VR-QOL questionnaires allows us to scrutinize the effects of refractive surgery among these patients.

In **Chapter 2**, we analyze postoperative astigmatism as a factor of incision-induced corneal astigmatism and axial alignment in a series of 54 eyes implanted with the Artisan toric phakic intraocular lens. Also, we calculate both the Safety Index and the Efficacy Index of the lens. All axes are labelled preoperatively on the cornea with a surgical marker with the use of a Javal keratometer. Mean incision-induced corneal astigmatism and mean axial misalignment of the lens are found to be nominal (0.75 ± 0.61 D and $0.37° \pm 5.34°$ respectively). Both the Safety and Efficacy indexes are securely above 1.0, implying good postoperative visual results. We find that the implantation of the toric Artisan lens leads to safe and efficacious results, and that axial misalignment of the lens has minimal effects on astigmatism. However, the consistent minor effect of the incision-induced

astigmatism might warrant a systematic undercorrection of -0.50D to fine tune postoperative cylindrical error.

In **Chapter 3**, we evaluate the results of 26 eyes of 13 patients implanted with the Artisan lens for hypermetropia. The study, with a 22-month follow-up, demonstrates stable and predictable results, with nearly 91% of eyes achieving ±1.00D of intended refractive error. However, 2 patients (4 eyes) develop posterior synaechiae with pigment deposits. One of these patients eventually undergoes bilateral lens removal and clear lens extractions. Furthermore, postoperative analysis of the corneal endothelium reveals large, although statistically insignificant endothelial cell loss, and a negative correlation between anterior chamber depth and the decrease of endothelial cell density.

In **Chapter 4**, we investigate the postoperative decrease in endothelial cell densities (ECD) in 318 myopic eyes that have had Artisan lenses for up to 7 years. Not only do we find a significant loss of cells after three years, we also find a significant negative correlation between the decline in endothelial cell density and the depth of the anterior chamber. This loss shows no correlation with any of the following: patient age, gender, refractive error or the size of the incision.

The Vision-related Quality of Life (VR-QOL) of myopic contact lens wearers not seeking refractive surgery is assessed in **Chapter 5**. This study, with the use of the Dutch translations of the Refractive Vision and Status Profile (RSVP) and the National Eye Institute's Visual-Functioning Questionnaire-25 (NEI-VFQ-25), determines that VR-QOL is adversely affected by myopia. The greater the myopia, the worse one's vision-related QOL. This remains independent of both gender and age. One year after completion of the initial questionnaire, the subjects complete the questionnaires once again, revealing stable results.

In **Chapter 6**, we study the effects of refractive surgery on VR-QOL. We find that nearsighted individuals seeking either bilateral Excimer laser treatments or Artisan pIOL implants express lower VR-QOL scores on both the RSVP and the NEI-VFQ-25 than their myopic counterparts not seeking treatment. This is mostly due to their eagerness to be rid of their contact lenses or glasses. Also, we find that patients undergoing uncomplicated refractive surgery experience a significant increase in their postoperative VR-QOL scores. Lastly, we observe that both Excimer laser and Artisan lens patients score significantly better postoperatively on the RSVP than the myopic contact lens wearers. However, with the use of the NEI-VFQ-25, only Artisan patients have significantly higher VR-QOL scores than contact lens wearers (when correcting for preoperative refractive error). The (nearly) emmetropic patients having undergone Excimer laser treatments do not score significantly better than myopic contact lens wearers, who remain myopic.

The implantation of the Artisan lens in the right eye of a four-year old male patient with severe unilateral myopia is documented in **Chapter 7**. Occlusion therapy had been severely hampered by poor patient compliance with glasses and contact lenses, leading to anisometric amblyopia with a visual acuity varying between 0.50 and 0.83 in the worse eye and an absence of stereovision. Three years after unremarkable surgery, the patient has a best corrected visual acuity of 1.2 in the operated eye (versus 1.0 in the other eye) and demonstrates some stereovision. Still, there is a demonstrable difference in endothelial cell density between both eyes.

In **Chapter 8**, we study both the objective and subjective results of a unique situation where five bilaterally myopic patients (three of which presbyopic) undergo a cataract extraction in one eye and an Artisan lens implantation in the other eye (to correct the resulting anisometropia). Patients show excellent refractive results bilaterally, four out of five being within 1.00 D of emmetropia in the pseudophakic eye and all five being within 1.00 D of emmetropia in the phakic Artisan eye. The patients are also requested to complete two RSVP questionnaires simultaneously, one for each eye. The results of the RSVP demonstrate very similar results for both eyes, however there is a significant preference to read with the eye implanted with the Artisan lens.

Samenvatting

De Artisan lens is een intra-oculaire lens (IOL) die in de voorste oogkamer geïmplanteerd kan worden. De Artisan lens corrigeert bij- en verziendheid en/of astigmatisme, zonder dat de natuurlijke lens van het oog verwijderd hoeft te worden. Deze lens kan een ideale optie zijn voor ogen die niet geschikt zijn voor andere methoden van refractiechirurgie, of voor patiënten die liever geen irreversibele operatie willen ondergaan. Dit proefschrift onderzoekt de visuele resultaten van de Artisan lens in hypermetrope en astigmate ogen en het effect van de lens op het cornea endotheel. Ook wordt de visueel gerelateerde kwaliteit van leven (Vision-Related Quality of Life ofwel VR-QOL) van myope contactlensdragers uitgezocht en vergeleken met de VR-QOL van patiënten die bilaterale Artisan lens implantaties of excimerlaser behandelingen voor myopie ondergaan. Bovendien worden unieke toepassingen van de Artisan lens bekeken.

Hoofdstuk 1 is een algemene introductie tot de onderwerpen die in dit proefschrift worden besproken. De hoofdzaken van myopie en hypermetropie zijn samengevat. Uit verschillende studies blijkt dat de prevalentie van myopie in Azië in zorgbarende aantallen toeneemt. Genetische aanleg en omgevingsfactoren zijn belangrijke risicofactoren voor het ontwikkelen van een refractieafwijking. Desondanks zijn er geen voldoende effectieve mogelijkheden bekend om invloed uit te oefenen op de ontwikkeling of toename van een myopie of hypermetropie. Tot voor kort waren een bril of contactlenzen de enige manier om refractieafwijkingen te corrigeren. Al leiden deze tot een visusverbetering, patiënten moeten alsnog de ongunstige aspecten hiervan verdragen, zoals vervelende veranderingen in beeldgrootte en een negatief zelfbeeld. Contactlensdragers riskeren infecties en het ontwikkelen van contactlensintolerantie. Dit kan bij sommige mensen de VR-QOL negatief beïnvloeden. De opmars van de refractiechirurgie, zoals de ontwikkeling van de excimerlaser en van de Artisan phake IOL, leidt tot minder afhankelijkheid van bril en/of contactlenzen bij patiënten met myopie of hypermetropie. De ontwikkeling van de VR-QOL vragenlijsten laat ons de effecten van refractiechirurgie op de kwaliteit van leven bij deze patiënten onderzoeken.

In **Hoofdstuk 2** onderzoeken wij in een reeks van 54 ogen het postoperatieve astigmatisme veroorzaakt door geïnduceerd astigmatisme door de (wond-) incisie en de axiale positie van de Artisan torische phake intraoculaire lens. Ook berekenen wij de Safety- en Efficacy Index. Preoperatief zijn alle assen met een chirurgische marker op de cornea getekend met behulp van de Javal keratometer. Het gemiddeld "chirurgisch geïnduceerd" corneaal astigmatisme en de gemiddelde axiale afwijking van de lens zijn nominaal (respectievelijk 0.75 ± 0.61 D en $0.37° \pm 5.34°$). Zowel de Safety Index als de Efficacy Index zijn meer dan 1.0, hetgeen een goede postoperatieve visuele resultaten impliceert. Wij

vinden dat de implantatie van de torische Artisan lens tot een veilige en effectieve uitkomst leidt, en dat de axiale afwijking van de lens een zeer gering effect op astigmatisme heeft. Echter het minimale, maar altijd aanwezige effect van astigmatisme geïnduceerd door de incisie zou een systematische ondercorrectie van -0.50 D kunnen rechtvaardigen om postoperatieve cilindrische afwijkingen te kunnen verminderen.

In **Hoofdstuk 3** worden de resultaten de Artisan hypermetrope lens geëvalueerd in 26 ogen van 13 patiënten. Deze studie, met een follow-up van 22 maanden, toont stabiele en voorspelbare resultaten, waarbij bijna 91% van de ogen binnen 1.00 D van de voorgenomen refractieafwijking uitkomen. Toch ontwikkelen 2 patiënten (4 ogen) synechiae posteriores met pigmentdeposities. Bij één van deze patiënten zijn beide Artisan lenzen verwijderd en is er een bilaterale heldere lens extractie (een cataractextractie bij een heldere lens) verricht. Uit deze studie blijkt dat er een groot, echter statistisch niet significant endotheelcelverlies is en dat er bovendien een negatieve correlatie bestaat tussen de voorste oogkamer diepte en de daling van de endotheelcel dichtheid.

In **Hoofdstuk 4** onderzoeken wij de daling van de endotheelcel dichtheid in 318 myope Artisan lens geïmplanteerde ogen tot 7 jaar postoperatief. Wij vinden niet alleen een significant verlies van endotheelcellen na drie jaar maar ook een significante negatieve correlatie tussen de daling in endotheelcel dichtheid en de diepte van de voorste oogkamer. Dit verlies toont geen correlatie met zowel leeftijd als geslacht, refractieafwijking van het oog of incisiegrootte.

In **Hoofdstuk 5** wordt de visueel gerelateerde kwaliteit van leven van bijziende contactlensdragers die geen refractiechirurgie willen ondergaan beoordeeld. Deze studie, waarbij de Nederlandse vertalingen van de Refractive Status and Vision Profile (RSVP) en de Visual Functioning Questionnaire van de National Eye Institute (NEI-VFQ-25) worden gebruikt, laat zien dat de VR-QOL ongunstig door myopie wordt beïnvloed. Hoe groter de myopie, hoe slechter de VR-QOL; dit is onafhankelijk van zowel geslacht als leeftijd. Een jaar na initiële voltooiing van de vragenlijsten, worden de vragenlijsten opnieuw ingevuld. Dit laat onveranderde resultaten zien.

Hoofdstuk 6 beschrijft de gevolgen van refractiechirurgie voor de VR-QOL. Uit deze studie blijkt dat myope individuen die bilateraal excimer laserbehandelingen of Artisan lens implantaties willen ondergaan slechter scoren dan hun bijziende tegenhangers die niet geopereerd willen worden op zowel de RSVP als de NEI-VFQ-25. Dit is met name toe te schrijven aan lage scores vanwege het feit dat ze graag van hun contactlenzen of bril af willen zijn. Na ongecompliceerde refractiechirurgie zien wij een significante toename in de VR-QOL scores. Ten

slotte vinden wij dat zowel excimerlaser als Artisan lens patiënten beduidend beter postoperatief scoren op de RSVP dan de myope contactlensdragers. Echter bij de NEI-VFQ-25 halen slechts de Artisan lens patiënten significant hogere scores dan de contactlensdragers (wanneer er gecorrigeerd wordt voor de preoperatieve refractieafwijking). De (bijna) emmetrope excimerlaserpatiënten hebben geen significant hogere scores op de NEI-VFQ-25 dan de contactlensdragers, die overigens nog steeds myoop zijn.

Hoofdstuk 7 documenteert de implantatie van de Artisan lens in het rechter oog van een vier jaar oud patiëntje met een ernstige unilaterale myopie, resulterend in een anisometropie amblyopie. Door slecht gebruik van de bril en contactlens wordt de occlusietherapie sterk belemmerd, met een wisselende visus tussen 0.50 en 0.83 in het slechtste oog. Tevens is er geen dieptezien. Drie jaar na de ongecompliceerde chirurgie, heeft het patiëntje een visus van 1.2 in het geopereerde oog (tegenover 1.0 in het linkeroog) en er is grof dieptezien aanwezig.

In **Hoofdstuk 8** worden zowel de objectieve als subjectieve resultaten bestudeerd van een unieke situatie waarbij vijf myope patiënten (drie hiervan presbyoop) een cataractextractie ondergaan in één oog en een Artisan lens implantatie in het andere oog (om het resulterende anisometropie te corrigeren). Postoperatief zijn vier van de vijf pseudofake ogen binnen 1.00 D van emmetropie en alle vijf Artisan lenzen geïmplanteerde ogen binnen 1.00 D van emmetropie. De patiënten worden verzocht om twee RSVP-vragenlijsten simultaan in te vullen, één voor elk oog. De RSVP toont zeer gelijkaardige resultaten voor beide ogen, echter met een significante voorkeur om te lezen met het oog met de Artisan lens.

Appendix

Naam: _____

Registratie nummer: _____

Pre-interventie KvL: _____ _____

Post-interventie KvL: _____ _____

    Datum   Score

National Eye Institute
Visual Functioning Questionnaire – 25
Nederlandse Consensus Vertaling
(VFQ-25/NL)

versie 2001

VERSIE OM ZELF IN TE VULLEN (gezichtsscherpte > 0.5)

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Dit is een vragenlijst met uitspraken over problemen die met uw gezichtsvermogen te maken hebben, of over gevoelens die u over uw gezichtsvermogen heeft.
Als u een bril of contactlenzen heeft, ga er dan bij de beantwoording van de vragen van uit dat u deze draagt.

INSTRUCTIES:

1. In het algemeen willen we dat mensen deze vragenlijst zelf proberen in te vullen. Als u vindt dat u hulp nodig heeft, aarzel dan niet om het de projectmedewerkers te vragen, ze helpen u graag.

2. Beantwoord alstublieft alle vragen, tenzij u verzocht wordt vragen over te slaan omdat ze niet van toepassing zijn.

3. Beantwoord de vragen door het juiste cijfer te omcirkelen.

4. Als u niet zeker weet hoe een vraag te beantwoorden, geef dan het best mogelijke antwoord en maak een aantekening in de linker kantlijn.

5. Als u per ongeluk de verkeerde mogelijkheid omcirkeld heeft, dan zet u door deze cirkel een kruis en omcirkelt u het antwoord dat volgens u het juiste is.

6. Vul de vragenlijst in zonder uw antwoorden met uw vrienden of familie te bespreken.

7. De vragen hebben betrekking op uw situatie gedurende de afgelopen maand.

8. Er is een versie met grote letters voor het geval uw gezichtsvermogen tekort schiet om de lijst in te kunnen vullen.

9. Als u nog vragen heeft kunt u terecht bij leden van de staf van het project, zij zullen u graag helpen.

VERKLARING VAN VERTROUWELIJKHEID:

Alle informatie die identificatie mogelijk maakt van enig persoon die deze vragenlijst heeft ingevuld, zal als strikt vertrouwelijk worden beschouwd. Deze informatie zal uitsluitend worden gebruikt voor het doel van dit onderzoek, en zal niet worden onthuld of vrijgegeven voor enig ander doel, zonder voorafgaande toestemming, geopenbaard of gepubliceerd worden, uitgezonderd als vereist bij de wet.

Visual Functioning Questionnaire - 25

DEEL 1 – ALGEMENE GEZONDHEID EN GEZICHTSVERMOGEN

1.   Hoe zou u uw <u>algehele gezondheidstoestand</u> omschrijven:

(omcirkel één cijfer)

Uitstekend 1

Zeer goed 2

Goed 3

Redelijk............................ 4

Slecht...............................5

2.   Zou u op dit moment zeggen dat uw gezichtsvermogen met beide ogen samen (met bril of contactlenzen, als u deze draagt), <u>uitstekend</u>, <u>goed</u>, <u>redelijk</u>, <u>slecht</u>, <u>zeer slecht</u> is, of bent u <u>volledig blind</u>?

(omcirkel één cijfer)

Uitstekend 1

Goed 2

Redelijk............................3

Slecht...............................4

Zeer slecht......................5

Volledig blind 6

3.   Hoe vaak <u>maakt u zich zorgen</u> over uw gezichtsvermogen?

(omcirkel één cijfer)

Nooit………………………………..1

Zelden…………………………….. 2

Soms……………………………… 3

Vaak…………………………….. 4

Altijd………………………………5

4.   Hoeveel <u>pijn of ongemak</u> heeft u <u>in en rond uw ogen</u> gehad (bijvoorbeeld branderigheid, jeuk of pijn)?

(omcirkel één cijfer)

Geen………………………….…..1

Licht……………………………. 2

Matig…………………………. 3

Ernstig…………………………. 4

Heel ernstig……………………. 5

DEEL 2 – MOEITE MET HET UITVOEREN VAN ACTIVITEITEN

De volgende vragen gaan over de moeite die u misschien met sommige activiteiten heeft, met bril op of contactlenzen in, mocht u die voor deze activiteit nodig hebben.

5.   Hoeveel moeite heeft u om <u>normale krantendruk te lezen</u>?

(omcirkel één cijfer)

Geen enkele moeite……………………………………………………1

Een beetje moeite……………………………………………..…… 2

Matige moeite…………………………………………………..… 3

Enorme moeite……………………………………………..…… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen……..…….5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

© R 1996

6. **Hoeveel moeite heeft u met werkzaamheden of hobby's, waarbij u <u>goed dichtbij moet kunnen zien</u>, zoals koken, naaien, dingen in huis repareren, of bij het gebruik van handgereedschap?**

(omcirkel één cijfer)

Geen enkele moeite…………………………………………………..1

Een beetje moeite……………………………………………..…… 2

Matige moeite………………………………………………..…… 3

Enorme moeite………………………………………….…..…… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen……..…...5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

7. **Hoeveel moeite heeft u, vanwege uw gezichtsvermogen, met <u>het vinden van iets op een volle plank</u>?**

(omcirkel één cijfer)

Geen enkele moeite…………………………………………………1

Een beetje moeite……………………………………………..…… 2

Matige moeite……………………………………………..…… 3

Enorme moeite………………………………………………… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen……..…...5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

8. **Hoeveel moeite heeft u met <u>het lezen van straatnaamborden of de namen van winkels</u>?**

(omcirkel één cijfer)

Geen enkele moeite…………………………………………………..1

Een beetje moeite……………………………………………..…… 2

Matige moeite……………………………………………..…… 3

Enorme moeite………………………………………..…..…… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen……..…...5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

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9. **Hoeveel moeite kost het u, vanwege uw gezichtsvermogen, <u>om een afstapje, een trap of een stoeprand af te stappen bij slechte verlichting of 's nachts</u>?**

(omcirkel één cijfer)

Geen enkele moeite………………………………………………………….1

Een beetje moeite………………………………………………….…… 2

Matige moeite………………………………………………………..…… 3

Enorme moeite………………………………………………….…..…… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen……..……5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

10. **Hoeveel moeite heeft u, vanwege uw gezichtsvermogen, <u>om dingen opzij op te merken terwijl u er langs loopt</u>?**

(omcirkel één cijfer)

Geen enkele moeite………………………………………………………….1

Een beetje moeite…………………………………………………..…… 2

Matige moeite…………………………………………………………..…… 3

Enorme moeite………………………………………………….…..…… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen……..……5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

11. **Hoeveel moeite heeft u, vanwege uw gezichtsvermogen, om te <u>zien hoe mensen reageren op wat u zegt</u>?**

(omcirkel één cijfer)

Geen enkele moeite………………………………………………………….1

Een beetje moeite…………………………………………………..…… 2

Matige moeite……………………………………………………..…… 3

Enorme moeite………………………………………………….…..…… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen……..……5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

12. Hoeveel moeite heeft u, vanwege uw gezichtsvermogen, met <u>het uitzoeken en combineren van uw eigen kleding</u>?

(omcirkel één cijfer)

Geen enkele moeite…………………………………………………..1

Een beetje moeite……………………………………………..…… 2

Matige moeite………………………………………………..…… 3

Enorme moeite……………………………………………..…… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen……..…...5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

13. Hoeveel moeite heeft u, vanwege uw gezichtsvermogen, om <u>bij mensen op visite te gaan, op feesten of in restaurants</u>?

(omcirkel één cijfer)

Geen enkele moeite…………………………………………………..1

Een beetje moeite…………………………………………………… 2

Matige moeite………………………………………………..…… 3

Enorme moeite……………………………………………..…… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen……..…...5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

14. Hoeveel moeite heeft u, vanwege uw gezichtsvermogen, met <u>het uitgaan om bioscoopfilms, theater of sportevenementen te zien</u>?

(omcirkel één cijfer)

Geen enkele moeite…………………………………………………..1

Een beetje moeite……………………………………………..…… 2

Matige moeite………………………………………………..…… 3

Enorme moeite……………………………………………..…… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen……..…...5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

15. **Rijdt u <u>momenteel</u> auto, tenminste af en toe?**

(omcirkel één cijfer)

Ja………………………………….…..……...…1
Ga naar vraag 15c

Nee………………………………….…………..……...2

15a. Indien nee, heeft u nooit auto gereden of heeft u het autorijden
opgegeven?

(omcirkel één cijfer)

Ik heb nooit auto gereden……….…...……….....1
Ga naar vraag 17

Ik heb het autorijden opgegeven……………...…...2

15b. ALS U HET AUTORIJDEN HEEFT OPGEGEVEN: Was dat
<u>**voornamelijk vanwege uw gezichtsvermogen**</u>**,** <u>**voornamelijk om een**</u>
<u>**andere reden**</u>**, of** <u>**vanwege zowel uw gezichtsvermogen als om een**</u>
<u>**andere reden**</u>**?**

(omcirkel één cijfer)

Voornamelijk mijn gezichtsvermogen………………………..…..1
Ga naar vraag 17

Voornamelijk om andere redenen...…………………………..…2
Ga naar vraag 17

Zowel mijn gezichtsvermogen als om andere redenen….....…3
Ga naar vraag 17

15c. ALS U MOMENTEEL AUTORIJDT, hoeveel moeite heeft u met
autorijden overdag in een bekende omgeving?

(omcirkel één cijfer)

Geen enkele moeite……………………………………..…1
Een beetje moeite……………………………………….……...2
Matige moeite……………………………………………..…….. 3
Enorme moeite………………………………………..…… 4

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16. **Hoeveel moeite heeft u om <u>'s nachts auto te rijden</u>?**

(omcirkel één cijfer)

Geen enkele moeite……………………………………………………..1

Een beetje moeite…………………………………………………..…… 2

Matige moeite…………………………………………………..…… 3

Enorme moeite……………………………………………………..… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen…….…....5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

16a. **Hoeveel moeite heeft u <u>met het rijden onder moeilijke omstandigheden, zoals bij slecht weer, tijdens het spitsuur, op de snelweg of in stadsverkeer</u>?**

(omcirkel één cijfer)

Geen enkele moeite……………………………………………………….1

Een beetje moeite…………………………………………………..…… 2

Matige moeite…………………………………………………..…… 3

Enorme moeite……………………………………………………..… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen…….…....5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

DEEL 3 – OMGAAN MET PROBLEMEN MET HET ZIEN

De volgende vragen gaan over hoe de dingen die u doet, beïnvloed worden door uw gezichtsvermogen. Omcirkel bij elke vraag het nummer om aan te geven of de uitspraak voor u <u>altijd</u>, <u>meestal</u>, <u>soms</u>, <u>zelden</u> of <u>nooit</u> geldt.

(omcirkel één cijfer op elke regel)

		Altijd	Meestal	Soms	Zelden	Nooit
17.	**<u>Krijgt u minder voor elkaar</u>, vanwege uw gezichtsvermogen, dan u zou willen?**	1	2	3	4	5
18.	**Bent u, vanwege uw gezichts-vermogen, <u>beperkt</u> in hoe lang u kunt werken of andere activiteiten kunt volhouden?**	1	2	3	4	5
19.	**In hoeverre weerhoudt pijn of ongemak <u>in of rond de ogen</u>, bijvoorbeeld branden, jeuken of pijn, u ervan om de dingen te doen die u zou willen doen?**	1	2	3	4	5

Omcirkel na elk van de volgende uitspraken het voor u meest passende antwoord om aan te geven dat de uitspraak voor u <u>helemaal juist</u> is, <u>over het algemeen juist</u> is, <u>over het algemeen onjuist</u> is, of <u>helemaal onjuist</u> is, of dat u <u>het niet zeker weet</u>.

(omcirkel één cijfer op elke regel)

	Helemaal juist	Over het algemeen juist	Weet het niet zeker	Over het algemeen onjuist	Helemaal onjuist
20. Ik blijf vanwege mijn gezichtsvermogen <u>meestal thuis</u>	1	2	3	4	5
21. Ik voel me vaak <u>gefrustreerd</u> vanwege mijn gezichtsvermogen	1	2	3	4	5
22. Ik heb <u>veel minder controle</u> over wat ik doe, vanwege mijn gezichts-vermogen	1	2	3	4	5
23. Vanwege mijn gezichts-vermogen moet ik <u>teveel vertrouwen over wat andere mensen me vertellen</u>	1	2	3	4	5
24. Ik heb <u>veel hulp van anderen nodig</u> vanwege mijn gezichtsvermogen	1	2	3	4	5
25. Ik maak me zorgen dat ik dingen doe, vanwege mijn gezichtsvermogen, <u>die mezelf of anderen in verlegenheid brengen</u>	1	2	3	4	5

Bijlage optionele vragen

SUBSCHAAL: ALGEMENE GEZONDHEID

**A1. Hoe zou u uw <u>gezondheid</u> beoordelen, op een schaal van 0 tot 10, waarbij 0
<u>zo slecht als dood</u> is en 10 de <u>best</u> mogelijke gezondheid?**

(omcirkel één cijfer op elke regel)

0	1	2	3	4	5	6	7	8	9	10

Slechtste   **Beste**

SUBSCHAAL: ALGEMEEN GEZICHTSVERMOGEN

**A2. Hoe zou u nu uw gezichtsvermogen beoordelen (met bril op of contactlenzen
in, als u deze draagt) op een schaal van 0 tot 10 waarbij 0 zo slecht is als
blindheid en 10 het best mogelijke gezichtsvermogen?**

(omcirkel één cijfer op elke regel)

0	1	2	3	4	5	6	7	8	9	10

Slechtste   **Beste**

SUBSCHAAL: DICHTBIJ ZIEN

**A3. Hoeveel moeite heeft u om, met bril op, <u>kleine lettertjes in een telefoonboek,
op een medicijnflesje of in officiële stukken te lezen</u>?**

(omcirkel één cijfer)

Geen enkele moeite…………………………………………...……1

Een beetje moeite…………………………………………...……… 2

Matige moeite…………………………………………………...…… 3

Enorme moeite……………………………………………...……… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen…….....…5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

A4. Hoeveel moeite heeft u, vanwege uw gezichtsvermogen, om te <u>bepalen of rekeningen die u ontvangt kloppen</u>?

(omcirkel één cijfer)

Geen enkele moeite……………………………………………………1

Een beetje moeite…………………………………………………..…… 2

Matige moeite…………………………………………………….....… 3

Enorme moeite…………………………………………………......… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen……..…...5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

A5. Hoeveel moeite heeft u, vanwege uw gezichtsvermogen, met dingen zoals <u>scheren, uw haar in model brengen of make-up op doen</u>?

(omcirkel één cijfer)

Geen enkele moeite……………………………………………………1

Een beetje moeite………………………………………………….…… 2

Matige moeite………………………………………………………..… 3

Enorme moeite……………………………………………………..… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen……..…...5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

SUBSCHAAL: VERAF ZIEN

A6. Hoeveel moeite heeft u, vanwege uw gezichtsvermogen, om <u>bekenden aan de andere kant van de kamer te herkennen</u>?

(omcirkel één cijfer)

Geen enkele moeite……………………………………………………1

Een beetje moeite…………………………………………………..…… 2

Matige moeite…………………………………………………….....… 3

Enorme moeite…………………………………………………......… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen……..…...5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

A7. Hoeveel moeite heeft u, vanwege uw gezichtsvermogen, om <u>actief sport te beoefenen of aan buitenactiviteiten deel te nemen waar u van houdt</u> (zoals golf, bowlen, wandelen of fietsen)?

(omcirkel één cijfer)

Geen enkele moeite…………………………………………………………..1

Een beetje moeite……………………………………………………..…… 2

Matige moeite………………………………………………………..…… 3

Enorme moeite………………………………………………….…..…… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen……..…...5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

A8. Hoeveel moeite heeft u, vanwege uw gezichtsvermogen, met <u>het zien en genieten van programma's op de TV</u>?

(omcirkel één cijfer)

Geen enkele moeite…………………………………………………………1

Een beetje moeite…………………………………………………….…… 2

Matige moeite…………………………………………………………..…… 3

Enorme moeite…………………………………………………….…..…… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen……..…...5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

SUBSCHAAL: SOCIAAL FUNCTIONEREN

A9. Hoeveel moeite heeft u, vanwege uw gezichtsvermogen, met <u>het ontvangen, als gastheer of gastvrouw, van familie en vrienden bij u thuis</u>?

(omcirkel één cijfer)

Geen enkele moeite…………………………………………………………1

Een beetje moeite…………………………………………………….…… 2

Matige moeite………………………………………………………..…… 3

Enorme moeite…………………………………………………….…..…… 4

Hiermee gestopt vanwege het slechte gezichtsvermogen……..…...5

Hiermee gestopt om andere redenen, of op u niet van toepassing. 6

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SUBSCHAAL: AUTORIJDEN

A10. (Deze vraag over het autorijden onder moeilijke omstandigheden is verplaatst en heeft u reeds beantwoord als vraag 16a.)

SUBSCHAAL: ROL BEPERKINGEN

A11. De volgende vragen gaan over dingen die u misschien doet vanwege uw gezichtsvermogen. Omcirkel bij elke vraag het nummer om aan te geven of de uitspraak voor u <u>altijd</u>, <u>meestal</u>, <u>soms</u>, <u>zelden</u> of <u>nooit</u> geldt.

(omcirkel één cijfer)

		Altijd	Meestal	Soms	Zelden	Nooit
a	<u>Krijgt u meer hulp</u> van anderen, vanwege uw gezichtsvermogen?	1	2	3	4	5
b	<u>Bent u beperkt</u>, vanwege uw gezichtsvermogen, in het soort dingen die u kunt doen?	1	2	3	4	5

SUBSCHAAL: WELZIJN (#A12) en AFHANKELIJKHEID (#A13)

De volgende vragen gaan over hoe u met uw gezichtsvermogen omgaat. Omcirkel na elk van de volgende uitspraken het voor u meest passende antwoord om aan te geven dat de uitspraak <u>helemaal juist</u> is, <u>over het algemeen juist</u> is, <u>over het algemeen onjuist</u> is, of <u>helemaal onjuist</u> is, of dat u het <u>niet zeker weet</u>.

<div align="right">(omcirkel één cijfer)</div>

		Helemaal juist	Over het algemeen juist	Weet het niet zeker	Over het algemeen onjuist	Helemaal onjuist
A12	**Ik ben vaak <u>prikkelbaar</u> vanwege mijn gezichtsvermogen**	**1**	**2**	**3**	**4**	**5**
A13	**Ik <u>ga niet buiten mijn huis</u> vanwege mijn gezichtsvermogen**	**1**	**2**	**3**	**4**	**5**

Dit is het einde van de vragenlijst.
Hartelijk dank voor uw hulp.

REFRACTIVE STATUS AND VISION PROFILE

Nederlandse Consensusvertaling

R Saxena, KL de Roon Hertoge, AW Baan, M Larsen, HJ Simonsz, NID te West en GPM Luyten

1. Ziekenhuis / Kliniek: _____

2. Patiëntnummer: _____

3. Naam Patiënt (achter-, voornaam): _____

4. Geboortedatum (dag/maand/jaar): _____

5. Telefoon (thuis): _____ (werk): _____

6. Datum (dag/maand/jaar): _____

7. Behandelend Arts: _____

REFRACTIVE STATUS AND VISION PROFILE

ACHTERGRONDINFORMATIE

Patiëntinformatie

1. Leeftijd   __ __
                          jaar

2. Geslacht:
     Vrouw   ($_1$)
     Man   ($_2$)

Bril- en Contactlensgebruik

3. Ik droeg in de afgelopen maand bij het kijken in de verte:

    a. Alleen een bril   ($_1$)
    b. Voornamelijk een bril, soms contactlenzen
                              ($_2$)
    c. Ongeveer even vaak een bril als contactlenzen
                              ($_3$)
    d. Voornamelijk contactlenzen, soms een bril
                              ($_4$)
    e. Alleen contactlenzen   ($_5$)

4. Droeg u in de afgelopen maand een aparte bril (of bifocale bril) om dichtbij te kunnen zien?
                 (^{ja} $_1$)   (^{nee} $_2$)

5. Indien u in de afgelopen maand contactlenzen droeg, waren dat dan:

    a. Harde zuurstofdoorlaatbare   ($_1$)
    b. Zachte lenzen   ($_2$)
    c. Wegwerplenzen   ($_3$)
    d. Geen lenzen in de afgelopen maand gedragen
                              ($_4$)

6. Indien u in de afgelopen maand contactlenzen droeg, droeg u ze ooit de hele nacht?
                 (^{ja} $_1$)   (^{nee} $_2$)

7. Zo ja (bij vraag 6), hoeveel nachten heeft u ze gewoonlijk ingehouden voordat u ze uitdeed?
                 __ __

Wij zijn geïnteresseerd in uw gezichtsvermogen gedurende de afgelopen maand.

Beantwoordt alstublieft de volgende drie vragen door een getal tussen 0 en 10 op te schrijven, waarbij 0 volledig blind betekent en 10 een perfect gezichtsvermogen:

8. Schat uw gezichtsvermogen **met bril**, gedurende de afgelopen maand:
                             __ __
(geen bril in de afgelopen maand gedragen) ☐

9. Schat uw gezichtsvermogen **met contactlenzen**, gedurende de afgelopen maand:
                             __ __
(geen contactlenzen in de afgelopen maand gedragen) ☐

10. Schat uw gezichtsvermogen **zonder** bril of contactlenzen, gedurende de afgelopen maand:
                             __ __

11. Hoe tevreden was u, gedurende de afgelopen maand, met uw vermogen om te kunnen lezen en om werk, dat dichtbij zien vereist, te kunnen verrichten (met de bril of contactlenzen die u gewoonlijk gebruikt bij het lezen, indien u dat deed) (*slechts één aankruisen*):

Heel ontevreden   ($_1$)
Ontevreden   ($_2$)
Noch tevreden, noch ontevreden   ($_3$)
Tevreden   ($_4$)
Heel tevreden   ($_5$)
Niet van toepassing   ($_6$)

12. Hoe tevreden was u, gedurende de afgelopen maand, met uw huidige gezichtsvermogen <u>met bril</u> (*slechts één aankruisen*):

Heel ontevreden (1)
Ontevreden (2)
Noch tevreden, noch ontevreden (3)
Tevreden (4)
Heel tevreden (5)
Niet van toepassing (geen bril gedragen gedurende de afgelopen maand) (6)

13. Hoe tevreden was u, gedurende de afgelopen maand, met uw huidige gezichtsvermogen <u>met contactlenzen</u> (*slechts één aankruisen*):

Heel ontevreden (1)
Ontevreden (2)
Noch tevreden, noch ontevreden (3)
Tevreden (4)
Heel tevreden (5)
Niet van toepassing (geen contactlenzen gedragen gedurende de afgelopen maand) (6)

14. Hoe tevreden was u, gedurende de afgelopen maand, met uw huidige gezichtsvermogen <u>ZONDER</u> bril of contactlenzen (*slechts één aankruisen*):

Heel ontevreden (1)
Ontevreden (2)
Noch tevreden, noch ontevreden (3)
Tevreden (4)
Heel tevreden (5)

15. Zou u uw gezondheid gedurende de afgelopen maand in het algemeen omschrijven als (*slechts één aankruisen*):

Uitstekend (1)
Heel goed (2)
Goed (3)
Matig (4)
Slecht (5)

16. Hoe bezorgd bent u geweest over uw **gezondheid** gedurende de afgelopen maand (*slechts één aankruisen*):

0 (helemaal niet bezorgd) (1)
1 (2)
2 (3)
3 (4)
4 (5)
5 (6)
6 (7)
7 (8)
8 (9)
9 (10)
10 (heel bezorgd) (11)

REFRACTIVE STATUS AND VISION PROFILE

VRAGENLIJST

Gezichtsvermogen

*Beantwoord de vragen alstublieft voor zover ze op u van toepassing zijn **over de afgelopen maand.***

17. Ik maak me zorgen over mijn gezichtsvermogen (*slechts één aankruisen*):

    Nooit (1)
    Zelden (2)
    Soms (3)
    Vaak (4)
    Altijd (5)

18. Mijn gezichtsvermogen is een zorg in mijn leven (*slechts één aankruisen*):

    Nooit (1)
    Zelden (2)
    Soms (3)
    Vaak (4)
    Altijd (5)

19. Mijn gezichtsvermogen remt mij in mijn doen en laten (*slechts één aankruisen*):

    Nooit (1)
    Zelden (2)
    Soms (3)
    Vaak (4)
    Altijd (5)

20. Ik ben gefrustreerd over mijn gezichtsvermogen (*slechts één aankruisen*):

    Nooit (1)
    Zelden (2)
    Soms (3)
    Vaak (4)
    Altijd (5)

21. Mijn gezichtsvermogen maakt mij minder zelfstandig (*slechts één aankruisen*):

    Nooit (1)
    Zelden (2)
    Soms (3)
    Vaak (4)
    Altijd (5)

22. Vanwege mijn gezichtsvermogen zijn er dingen die ik bang ben om te doen (*slechts één aankruisen*):

    Nooit (1)
    Zelden (2)
    Soms (3)
    Vaak (4)
    Altijd (5)

23. Ik zou een gezichtsvermogen kunnen accepteren dat niet helemaal perfect is als ik geen bril of contactlenzen meer nodig zou hebben (*slechts één aankruisen*):

    Sterk mee oneens (1)
    Mee oneens (2)
    Noch mee eens, noch mee oneens (3)
    Mee eens (4)
    Sterk mee eens (5)
    Geen bril of contactlenzen nodig om het best mogelijke gezichtsvermogen te halen (6)

24. Zolang ik goed genoeg kan zien om auto te rijden zonder bril of contactlenzen, zou ik het niet erg vinden om een gezichtsvermogen te hebben dat niet helemaal perfect is (*slechts één aankruisen*):

    Sterk mee oneens (1)
    Mee oneens (2)
    Noch mee eens, noch mee oneens (3)
    Mee eens (4)
    Sterk mee eens (5)

Wij willen graag weten of uw gezichtsvermogen u enige moeite bezorgde met enkele gewone bezigheden <u>gedurende de afgelopen maand</u>.

De volgende vragen gaan over moeite die u mogelijk had bij een activiteit, met bril, met contactlenzen of geen van beide (noch bril, noch contactlenzen).

Geeft u alstublieft antwoord voor alle drie de vormen van correctie (er is een keuzemogelijkheid "niet van toepassing").

De antwoordkeuzen zijn:

0	Niet van toepassing (heb deze vorm van correctie in de afgelopen maand niet gebruikt)	
1	Geen enkele moeite	
2	Een beetje moeite	
3	Matige moeite	
4	Enorme moeite	
5	Zoveel moeite dat ik deze activiteit niet heb gedaan met deze vorm van correctie	
6	Nooit deze activiteit gedaan om andere redenen (niet in verband met gezichtsvermogen)	

Hoeveel moeite heeft u gehad, gedurende de afgelopen maand, met elk van de volgende activiteiten, gebruikmakend van de onderstaande vormen van correctie?

	Activiteit	Met Bril (omcirkel een cijfer)	Met Contactlenzen (omcirkel een cijfer)	Zonder Correctie (omcirkel een cijfer)
25.	TV of films kijken	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
26.	Buitenspelen of -werken	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
27.	Zorgen voor of spelen met kinderen	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
28.	Uw wekker zien	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
29.	Helder zien als u wakker wordt	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
30.	Een klok aan de muur zien	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
31.	Uw werk doen	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
32.	Aan sport of recreatie doen	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
33.	Zwemmen	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
34.	Uw sociaal leven	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
35.	Lezen en werk dat dichtbij zien vereist	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
36.	`s Nachts autorijden	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
37.	Autorijden als het regent	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
38.	Autorijden als er schitteringen door koplampen van tegenliggers optreden	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6

Wij willen graag weten of u bepaalde problemen ervoer met uw ogen of gezichtsvermogen <u>gedurende de afgelopen maand</u>.

De volgende vragen gaan over elk probleem met bril, met contactlenzen of met geen van beide (noch bril, noch contactlenzen).

Geef alstublieft antwoord voor alle drie de vormen van correctie (er is een keuzemogelijkheid "niet van toepassing").

De antwoordkeuzen zijn:

0	Niet van toepassing (heb deze vorm van correctie in de afgelopen maand niet gebruikt)	
1	Geen enkele last	
2	Een beetje last	
3	Matige last	
4	Enorme last	
5	Zoveel last dat ik deze vorm van correctie niet gebruik	

Hoeveel last heeft u gehad, gedurende de afgelopen maand, van de volgende dingen, bij het gebruiken van de bril, contactlenzen of geen van beide?

Probleem	Met Bril (omcirkel een cijfer)	Met Contactlenzen (omcirkel een cijfer)	Zonder Correctie (omcirkel een cijfer)
39. Het geïrriteerd aanvoelen van uw ogen	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5
40. Tocht (van de verwarming of airconditioning) die in uw ogen blaast	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5
41. Het overgevoelig zijn van uw ogen voor licht	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5
42. Pijn in uw ogen	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5
43. Veranderingen van uw gezichtsvermogen in de loop van de dag	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5
44. Mistig of wazig zien	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5
45. Schitteringen (weerspiegelingen van glimmende oppervlakten, sneeuw)	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5
46. Dingen die er met het ene oog anders uitzien dan met het andere	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5
47. Het zien van kringen rondom lichten	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5
48. Zien in schemerlicht	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5
49. Uw dieptezien	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5
50. Dingen lijken vervormd	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5
51. Het schatten van afstand bij het op- of afstappen van treden (trappen, stoepranden)	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5

De volgende reeks vragen gaat over problemen die u mogelijk had gedurende de afgelopen maand met bril of contactlenzen.

Geef alstublieft antwoord voor elk item (er is een keuzemogelijkheid "niet van toepassing").

De antwoordkeuzen zijn: 0   Niet van toepassing (heb deze vorm van correctie in de afgelopen maand niet gebruikt)

1   Geen enkele last van dit probleem
2   Een beetje last van dit probleem
3   Matige last van dit probleem
4   Enorme last van dit probleem
5   Zoveel last van dit probleem dat ik deze vorm van correctie gedurende de afgelopen maand niet heb gebruikt

Hoeveel last heeft u gehad van de volgende problemen gedurende de afgelopen maand?

(omcirkel een cijfer)

52. Het vies of bekrast worden van uw **bril**   0 1 2 3 4 5
53. Het beslagen of nat worden van uw **bril**   0 1 2 3 4 5
54. Het uit uw oog springen/vallen van **contactlenzen**   0 1 2 3 4 5
55. Het onder uw ooglid vast komen te zitten of in uw oog rondbewegen van **contactlenzen**   0 1 2 3 4 5
56. Het gevoel dat u **contactlenzen** in uw ogen heeft   0 1 2 3 4 5
57. Het niet kunnen dragen van **contactlenzen** zo lang als het nodig is   0 1 2 3 4 5
58. Het kwijtraken van een **contactlens**   0 1 2 3 4 5

EINDE VAN DE VRAGENLIJST

Dank u voor uw tijd.

Heeft u nog vragen of opmerkingen?

_____

_____

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Curriculum Vitae

Ruchi Saxena was born during her parents' holiday in Lucknow, India on December 11th, 1972. At the time, her parents were residing in Delft, the Netherlands, where her older sister, Nupur, was born 2 years previously. At the age of nine months, her family moved to Belgium, and at the age of 5, to Montreal, Quebec, Canada. In 1983, the family moved yet again, this time to Oakville, Ontario, Canada. She graduated in 1992 from Queen Elizabeth Park School, also in Oakville, with a Diploma in French Immersion. In 1996, she graduated from the University of Toronto, Toronto, Ontario, Canada, with an Honours Bachelor of Science, majoring in Human Biology and Zoology. During her stay at the University, she served as President of the New College Residence Council for two years. For her work, she received the Katherine Grace Baker Memorial Award in 1995 and the Gordon Cressy Student Leadership Award in 1996. After following a course in Vertebrate Regeneration and performing microscopic surgery on lizards in her final year, she decided that she wanted to pursue a career in Medicine.

After moving to the Netherlands in 1996 and completing a Dutch language course in 1997, Ruchi began her Medical Studies at the Erasmus University in Rotterdam. In her third year, she followed an elective course on refractive surgery offered by Dr. G.P.M. Luyten at the Department of Ophthalmology, Erasmus MC. This course further stimulated her interest in the field and she went on to publish two articles on refractive surgery, which she had written as her Masters thesis. These studies led to her being awarded the Gerrit Jan Mulder Prize in 2003. During her Medical Clerkship, she continued to work on her research in refractive surgery. This work was in cooperation with Dr. M.A. Landesz and Dr. M.A.H. Luger at Vision Clinics in Delft and with Willem Vreugdenhil from Oculenti Contact Lens Specialists at the Rotterdam Eye Hospital. She received her Medical Diploma in 2004 and is currently completing her specialization in Ophthalmology at Erasmus MC, under Prof. Dr. G. van Rij. The bulk of her research and writing was done during her Medical Clerkship and later, during her specialization.

Unfortunately, Ruchi has inherited the myopia that plagues 11 of the 12 grandchildren on her father's side of the family. Sadly, her eyes are not suitable for refractive surgery and she has to make do with contact lenses. On April 13th 2006, Ruchi married Oliver Gnjec. As you can imagine, she kept her own name.

List of Publications

Saxena R, Minderhout H, Luyten G The Use of the Artisan™ Phakic Intraocular Lens in the Treatment of Anisometropic Amblyopia. J Cataract Refract Surg. 2003 Apr;29(4):835-8.

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Saxena R, Vreugdenhil W, Mulder P,van Rij G, Luyten G. Vision-Related Quality of Life of Myopic Patients. Submitted.

Saxena R, Vreugdenhil W, Alwani M, Arkenstijn R, Landesz M, Luger M, Bartels M, van Rij G, Luyten G. Quality of Life of Before and After Refractive Surgery. Submitted.