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PRESBYOPIA CORRECTION WITH MULTIFOCAL INTRAOCULAR LENSES

BACHELOR THESIS

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ABSTRAKTS

Bakalaura darbs ir uzrakstīts angļu valodā uz 47 lapaspusēm. Tas satur 3 zīmējumus, 20 tabulas, 39 literatūras avotus un pielikumu.

Darba mērķis ir salīdzināt divu jaunu intraokulāro lēcu (difraktīvā trifokālā lēca un paplašināta fokusa dziļuma multifokālā lēca) efektivitāti presbiopija korekcijā pēc kataraktas operācijas. Pētījumi tika veikti 3 mēnešu periodā pēc kataraktas operācijas, kad tika novērtēta redzes kvalitāte, mērot redzes asumu un kontrasta redzi fotopiskos gaismas un mezopiskos krēslas apstākļos. Abi introokulāro lēcu veidi nodrošināja lielisku redzes asumu visos skata attālumos un pilnu neatkarību no brillēm. Taču kontrasta jūtība un redzes asums mezopiskos krēslas apstākļos ir labāks multifokālajām lēcām.

Atslēgas vārdi: presbiopija, kataraktas ķirurģija, IOL, redzes asums gaismā un krēslā, kontrasta jūtība.

ABSTRACT

Thesis is written in English on 47 pages, contains 3 figures, 20 tables, 39 references and appendix.

Purpose of this thesis is to evaluate effectiveness of two new *intraocular lenses* for presbyopia correction during cataract surgery: the diffractive trifocal lens and the *Extended Depth of Focus* multifocal lens. In a three-month post-surgical follow-up, outcome visual measures of the two lenses were evaluated: differences in visual acuity and contrast sensitivity were measured in photopic and mesopic conditions. Both lenses have given excellent levels of visual acuity at all distances and a high level of glasses independence. However, contrast sensitivity and mesopic performance measured were better with the multifocal lens.

Key words: presbyopia, cataract surgery, IOLs, photopic and mesopic visual acuity, contrast sensitivity.

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INTRODUCTION

Presbyopia is the most common refractive disorder in advanced age: with the progressive loss of the accommodation reflex, it causes a progressive reduction of *uncorrected near visual acuity* and a progressive increase of the reading distance. Its correction during cataract surgery has the primary objective to resolve both the transparency of the lens and the patient's refractive defects.

The purpose of the trial is to evaluate the effectiveness of two new *intraocular lenses (IOLSs)* for presbyopia correction during cataract surgery: the diffractive trifocal lens *AT LISA tri 839MP* (*Carl Zeiss Mediatec*, Germany) and the *Extended Depth of Focus* multifocal IOL *TECNIS ® Symfony* (*Abbott Medical Optics*, USA). These lenses have two different technologies aiming at the same objectives: to correct *near* and *intermediate visual acuity*; to improve reading speed and contrast sensitivity; to reach high levels of glasses indipendence.

The prospective comparative clinical trial includes 28 patients undergoing bilateral cataract surgery: in 18 patients the diffractive trifocal lens *AT LISA tri 839MP* was implanted; in 10 patients the multifocal lens *TECNIS ® Symfony* was implanted. In a three-month post-surgical follow-up, outcome visual measures of the two lenses were evaluated: the difference in visual acuity, reading performances and contrast sensitivity were measured in photopic and mesopic condition and the patient’s satisfaction was evaluated using a self- evaluation questionnaire.

Both the lenses have given excellent levels of visual acuity at all distances and a high level of glasses independence: 100% of patients reached a 0.0 logMAR (10/10) distance visual acuity (or better) and a 0.1 logMAR intermediate visual acuity (or better); the near visual acuity was better with the trifocal lens (0.18 logMAR) then with the multifocal lens (0.25 logMAR). However, the contrast sensitivity and the mesopic performance measured was better with the multifocal lens.

Moreover, the very positive self-evaluation of the patients reaffirmed the effectiveness of both lenses, and confirmed that the possible presence of glare an d halos, especially at night, does not affect patients’ satisfaction.

This thesis is divided into two sections of three and two chapters respectively: in the first section is introduced and argued about accommodation reflex, presbyopia and relative correction with intraocular lenses during cataract surgery; the second section describes the clinical study of the two intraocular lenses and the evidence are reported and discussed.

1.REVIEW OF LITERATURE

1.1. The lens and the accommodation reflex

1.1.1. Definition and Introduction

The crystalline lens is an intraocular organ. It has the shape of a biconvex lens with a circular contour and an elastic consistency; it is located posteriorly to the iris and anteriorly to the vitreous body and it allows the correct focus of the objects on the retina in function of different observation distances. (Anastasi,Balboni&Motta, 2006)

1.1.2. Morfology of the lens

Table Tab.1.1 shows the morphology of the crystalline lens.

Tab.1.1 Summary table of macroscopic and microscopic characteristics of the crystalline lens

MACROSCOPIC ANATOMY
Biconvex, transparent and flexible structure (this capacity decreases with age). Component of the ocular diopter system thanks to the accommodation reflex allows to focus on the retina objects to different distances of observation. Kept in place by the zonule of Zinn, system of filaments which allow traction through ciliary muscle contraction Thickness of 3,6-4,5 mm, anterior radius of curvature of 10 mm, posterior radius of curvature of 6 mm, fresh weight 65-220 mg (it increases with age) Not vascularized or innervated organ it take nourishment from aqueous humor
MICROSCOPIC ANATONY
Core surrounded by more than 200 concentric layers (as sheet of onion) entirely covered by an elastic capsule Made of transparent proteins with structural function absorbed in an aqueous matrix

1.1.3 Physiology of the crystalline lens

• The crystalline is a natural eye lens; with cornea, humor aqueous and vitreous it forms the ocular diopter (or ocular optical system), the image focusing system on the retina . In this optical system, the lens has the specific task of changing the focal length - changing its radius through the reflex of accommodations - to fit it to the distance of the object to be focused.

• The lens is constituted of transparent proteins, the alpha-crystalline and the beta-crystalline. The proteins are arranged in around 20,000 concentric layers, with an index of refraction that varies from 1,406 (in the middle layers) up to 1,386 (denser in the cortex of the lens).

- A young lens is typically transparent, colorless and elastic; with age, the organ suffers a hardening and dehydration process and significantly loses plasticity. The loss of water also determines opalescence, which is the basis of cataracts and commonly begins from the core and radiates towards the equator.

1.1.4 The accommodation reflex

The mechanism of accommodation is based on the contraction of the ciliary muscle, with consequent decrease of the voltage of the zonular fibers. The lens changes its radius of curvature from 10 to 6 mm, increasing its refractive power.

The accommodative amplitude (A), measured in diopters, is the difference between the refractive power of the eye at rest and that of the eye in the maximum effort accommodative. With age, there is a decrease of accommodative amplitude, as illustrated in Table 1.2.

Tab. 1.2 Table shows accommodation amplitude decreasing with age increasing.

AGE (years)	AMPLITUDE	AGE(years)	AMPLITUDE
10	14.00	45	3.50
15	12.00	50	2.50
20	10.00	55	1.75
25	8.50	60	1.00
30	7.00	65	0.50
35	5.50	70	0.25
40	5.00	75	0.00

The accommodation is regulated by the antagonistic action of the parasympathetic and orthosympathetic autonomic nervous systems. The first is deputed focusing near objects, the second distant objects. The accommodation is a constituent part of a larger reflex, the accomodation- convergence-miosis reflex, activated by the close vision (30 cm) and regulated by the third pair of cranial nerves: in addition to accommodation, convergence allows focusing a point on the fovea of both eyes, miosis instead increases the depth of field.

REFLEX ARC: The reflex is triggered by specific stimuli such as the blurring of the retinal images, the perception of the observed objects,the proximity and the eyeballs convergence in close vision. It originates from the retinal gangliar cells and follows the visual pathways until the visual cortical areas. The sum of the cortical cells responses constitutes a blur sensory signal which is transmitted to multiple brain structures: the parietal-temporal zones of the cortex, the cerebellum and the Edinger-Westphal nuclei that constitute the central cores of the reflex. The efferent pathway - in common with the efferent pathway of the pupillary reflex – consists of parasympathetic fibers

The parasympathetic fibers running from the oculomotor nerve to the short ciliary nerves lead the stimulus to the ciliary muscles that with their contractions determine the relaxation of the zonula of Zinn fibers resulting an increase of curvature and refractive power of the lens and focusing at close distances. (see tab. 1.3)

□Tab. 1.3 Scheme of structures composing the accommodation reflex

RECEPTOR	Retinal gangliar cells;
AFFERENT PATHWAY	Visual pathways, cortical visual areas;
CORE	Nuclei of Edinger-Westphal (III pair of cranial nerves)
EFFERENT PATHWAY	Oculomotor nerve (III), ciliary ganglion, short ciliary nerves
EFFECTOR	Ciliary muscle (contraction → relaxation of zonular fibers → decrease of the radius of curvature of the lens → increase in refractive power.

Rising presbyopia, the accommodative amplitude - maxim between 8 and 12 years old - decreases slowly up to verge on zero after the fifth decade of life.

It follows a table describing the reflex of accommodation

Tab. 1.4 Summary table of reflex of accommodation.

...........……………………………ACCOMODATION……………………………..................
• It is an autonomous reflex to focusing an object on the retina, in function of the distance of observation; • It depends on changing the dioptric power of the lens, regulated by the contraction of the ciliary muscle; • It decreases with age leading to the arise of presbyopia • It decreases with the reduction of ambient brightness (evening or night); • It is stimulated by the blurring of the retinal images, the perception of closeness and the convergence at the near vision.

1.1.5 Mechanisms and theories of accommodation

The reflex of accommodation has been studied for centuries and have been developed, with the progress of the studies, different theories. (Werner, 2000)

To date, the most accepted theory in literature was described by Helmholtz in several studies .(Helmholtz,1909; Glasser, & Kaufman1999)

According to the Helmholtz theory, when the eye - rested – observe to distance, the ciliary muscle is released: being released it keeps in a state of tension the zonular fibers and - through these - the equator of the lens in which they are inserted. When the vision is directed to an object at a closer distance, the ocular strain results in a contraction of the ciliary muscle and a consequent relaxation of zonular fibers, with an elastic return of the lens to larger diameters on the frontal plane. So, the centripetal movement of the ciliary body is directly consecutive to the relaxation of the zonular fibers around the equator of the crystalline lens.(Bacskulin et al., 1995;Strenk el al., 1999)It follows the importance of the elasticity of the lens capsule, which must respond quickly to the sudden change in voltage and must change its curvature radius. (Glasser,& Campbell 1998)

The Helmholtz theory was later completed by Fincham. As suggested by Fincham (1937) there is a relationship between the change of the shape of the lens and the thickness of its capsule, thicker in the anterior surface and at the equator rather than at the poles so that the more thick portions support higher voltages and suffer a lesser curvature.

1.2. Presbyopia

1.2.1. Presbyopia: introduction and definition

Presbyopia is a dynamic visual defect due to the lens progressive loss of accommodation power. The physiological accommodative amplitude reduction is due both to a decrease of the plasticity of the lens, which loses water in its central portion,and to modifications of the ciliary muscle and of the lens diameters. (Azzolini et al.2014)

1.2.2. Epidemiology

In 2005 it was estimated 1.04 billion of shortsighted people (Holden et al.,2008) This number also appears to be intended to reach 1.8 billion in 2050(Agresta et al.,2012).

A Brazilian study conducted in the Fluminenses University of Rio de Janeiro and published in 2013 in Revista Brasileira de Ophthalmologia determined a correlation between presbyopia and body mass index: the cross-study of 1030 patients of different age groups has shown, in fact, that a body mass index of less than 18.5 is correlated to a lower incidence of presbyopia or to a delay in presbyopia onset and progression(Damasceno,&Damasceno2013)

1.2.3. Causes of presbyopia:

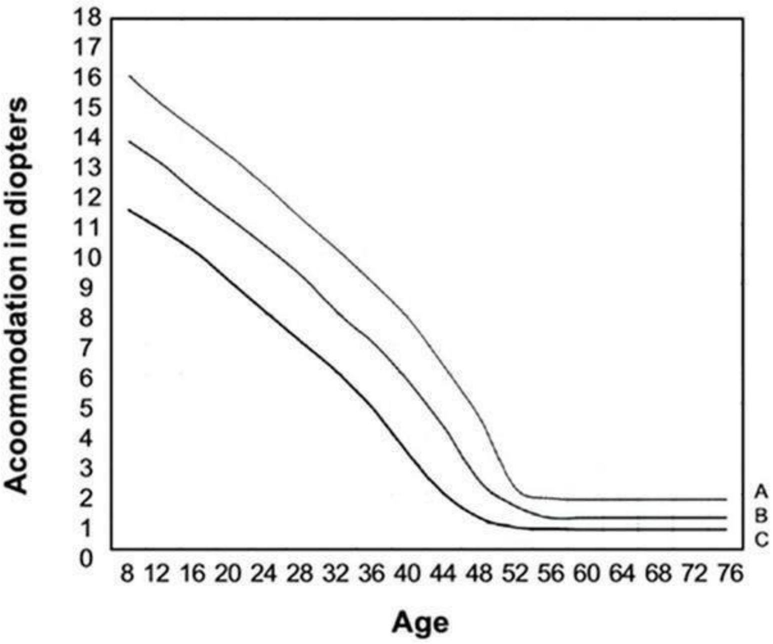
In the changes with age of anatomical structures determining the accommodating reflex, the lens rigidity and its elasticity loss are the age-correlated more significant phenomenon according to several authors.(Smith1883;Heys,Cram&Truscott2004;Weeber)

The progressive rigidity of the lens produces, in fact, the inability to satisfy the required tension variations of the accommodative mechanism, transmitted to the lens through the equatorial insertion of the zonular fibers.(Smith,1883)

According to the Helmholtz theory, the accommodation mechanism derives from the ciliary muscle contraction and the fibers relaxation; the young lenses have the ability to undergo a rapid and efficient elastic recovery of their curvature in all anatomical planes, thus allowing the rapid focus of images on the retina.

The older lenses, instead, coated by an always more less elastic capsule, are unable to the above mechanism.A work conducted by Werner et al.(2000) proposed to study aspects of accommodation and the direct correlation between increasing age and para - physiological mechanisms underlying the progressive reduction of accommodative amplitude. The authors suggest that changes in the accommodative amplitude in function of age are linear and, therefore, predictable on large numbers (see Fig. 1.1)

Fig. 1.1: Accommodative amplitude variation according to age (Duane standard curve: A = low values, (B = normal values, C = high values)



In 2015 a group of researchers from Buenos Aires published a study in which they set out to document a loss of the acquaporin 0-permeability (AQP-0, also known as Major Intrinsic Protein, MIP) with age . (Gerometta&Candia ,2016).According to the authors, during the process of accommodation, there would be a water flow through the lens mediated by these channel proteins also plenty in the cells membranes of the lens. A loss of age-related permeability of aquaporins would be, according to the authors, the base of the lens presbyopic loss of functionality.

1.2.4. Debut and set of symptoms

The symptomatic picture begins with difficulties in low light reading activities, eye fatigue during extended reading, blurred vision at close distances or during changes in viewing distance. (Abati et al.,1996)

The age of onset of clinical presbyopia in an emmetropic subject, is between 42 and 48 years. The age of onset of presbyopia depends on the following factors:

• Refractive condition : - the onset of presbyopia has interactions with spherical refraction defects already present; these, shifting the focus respect to the plane of the retina, interfere with the focus of the images in presbyopic patients . Hyperopia tend to anticipate visual disturbances to the close distances due to the combination of the optical effects of presbyopia and hyperopia. Myopia, resulting in a shift of the focus in the anterior direction respect to the retinal plane, tends to compensate the refractive defect induced by presbyopia. The onset of presbyopia is later in myopic than in emmetropic and earlier in hyperopic rather than in the emmetropic conditions. The astigmatic subjects, however, tend to accommodate bringing the vertical focal on the fovea (the one that provides a clear image of the vertical lines) more relevant to the recognition of the printing. (Faini,2001)

• Working distance: in the stage of incipient presbyopia, the subjects forced to adjacent working distances have an earlier onset of presbyopia;

• Geographical and environmental factors: people of the equatorial regions become prematurely presbyopic; this is attributed to higher temperature and d to a greater exposure to UV radiations,in particular to wavelengths contained between 310 nm and 400 nm.(Faini,2001)

• Nutritional factors: malnutrition underlies many cases of premature presbyopia in underdeveloped countries.(Faini,2001)

• Sex: several studies in the literature agree that female subjects become presbyopic earlier, with an advance of 1-3 years. This aspect is attributed in part to hormonal imbalances associated with menopause. (Abati et al.1,996)

The symptoms of presbyopia is lower in the morning: the ciliary muscle is less fatigued and the more intense lighting, through miosis, increases the depth of field because the increase of the focal length, reduces the level of out-of-focus of the objects observed.

1.2.5. Treatment options

Nowadays, there are several possibilities of correcting presbyopia and restoring vision at proximal observation distances. . (Abati et al.,1996)

The presbyopia’s optical correction with converging lenses occurs after correction of possible pre-existing ametropia: the lenses for the correction of the basic refractive defect are algebrically added to the diopter for correction of presbyopia from about 1.00D in the fourth decade of life up to reach 2.5-3.00 D in the sixth decade.

The conventional optical correction of presbyopia with lenses is not invasive but does not restore or replace the deficient accommodation mechanism ; today recent surgical trends point to eliminate or minimize dependence from optical correction with eyeglasses even for proximal viewing distances. (Nocera,1992)

The presbyopia‘s surgical correction strategies discussed in medical-scientific literature bring to three surgical approaches: 1) the modification of the sclero-ciliary complex, 2) the refractive surgery of cornea or lens; 3) the replacement of the lens with intraocular lens in the same time to the surgical removal of cataracts.(see the next section) (Azzolini et al.,2014)

It follows a brief discussion.

1.2.5.1. Modification of sclero-ciliary complex:

This procedure - effectuated either with laser or scalpel - is subject of several studies and insights. Although the principle may seem controversial, some authors support it is based on the variation of the tension of the zonular fibers: increasing this voltage would potentiate the accommodative capacity. Such zonular tension is applied through scleral implants, as the PresViews scleral implants (Refocus Group), which are inserted between the equator of the lens and the ciliary muscle. (Schachar,2001) It is an invasive technique, encumbered by the following possible peri- and post-operating risks: implant migration or extrusion, scleral perforation, retinal detachment, retinal or choroidal hemorrhage, endophthalmitis. The advantages of the technique are the following: it is an extraocular procedure, surgery does not involve the ocular visual axis, finally the implant is removable therefore the intervention is reversible.

1.2.5.2. Refractive Surgery of cornea / of lens

The corneal surgery represents a newer and no common therapeutic possibilities respect to IOL implant . These procedures include the presby-LASIK (aspherical modification of the cornea with an excimer laser), INTRACOR (creation of a intrastromal cylindrical concentric incision with femtosecond laser) and the implantation of Corneal Inlays. Regards to the lens surgery, it is an experimental developing refractive procedure . They are surgical procedures using femtosecond laser (phaco- photo-modulation) to increase the plasticity and flexibility of the lens and therefore its potential accommodative capacity.

Evidence suggests that the scleral expansion techniques doesn’t restore the accommodation mechanism of the lens and the laser treatments are still developing.

1.2.5.3. Replacing of the lens with IOL (intraocular lens):

The IOLs for the correction of presbyopia are generally divided into multifocal lenses and accommodative lenses. The first use the principle of simultaneous vision, based on the principle that radiation passing through the lens can be differently refracted in function of the incident angle (thus in function of the observation distance): this determines the formation of more coexisting images on the retinal plane , due to the presence of multiple focal points; the eye perceives the image with the best focus (for each viewing distance) and ignores the blurry images of no interest.(Waring,& Berry2013)

The accommodative lenses takes instead advantage of a different mechanism based on antero posterior and postero anterior displacement of artificial lens, generated by the muscles relaxation and contraction(see Ch.1.3).

Today the accommodative lenses are currently less used (despite their developments) while the multifocals and trifocals lenses represent the most effective therapeutic strategy for the correction of presbyopia. Their purpose is the independence from post-operative corrections to multiple observation distances. (Glasser2008) The installation of a corrective IOL during the cataract removal surgery is the subject of this study.The development of the trifocal and multifocal at increased depth of field IOLs allowed to valorize the correction of visual acuity at intermediate distance, as well as at close and remote distance, that appeared penalized with the implant of the less recent monofocal lenses.

Follows, in Ch1.3, more information about the kinds of correction of presbyopia during cataract surgery and the respective types of intraocular lenses currently available.

1.3. IOLs and presbyopia correction during cataract surgery

1.3.1 Introduction and surgical objectives:

Cataract surgery has the primary objective to solve the transparency deficiency of the lens with cataract, but also to solve the patient's refractive problems represented both by presbyopia than by preexisting refractive defects.

This objective can be achieved through artificial lenses that allow an optimal visual acuity at all viewing distances and the complete independence by spectacles.

Today the artificial crystallines guarantee the image’s ssharpness, a satisfactory perception of color, a good contrast sensitivity and an increasingly smaller percentage of unwanted effects such as:

- glare and halos around light sources (especially in the night and in low light conditions, however, they tend to decrease with the time);
- ghost images (ghosting);
- post-operative adaptation relatively long periods (more often with multifocal than with monofocal lenses);
- the need of optical correction with glasses after surgery.

The effectiveness of artificial lenses in focusing at the different observation distances is not reduced with time, allowing to maintain over the years the results achieved.

It will be illustrated developments and characteristics of artificial lenses used for the correction of presbyopia and usefulness of cataract surgery in the correction of refractive defects and in the correction of presbyopia.

1.3.2. intraocular lenses (IOLs):

The intraocular lenses (IOLs) are artificial lenses implanted inside the eye to restore the ability to focus.

Depending on the site of intraocular placement , the IOLs can be distinguished in pseudophakic, phakic and aphakic. The first one are implanted inside the lens capsule, after phacoemulsification and trans-corneal aspiration of intracapsular debris; they may be implanted both during cataract removal both during a refracvtive lensectomy in a subject not with cataract. Phakic lenses can instead be inserted both in the anterior and posterior chamber while aphakic lenses entirely replace the natural crystalline lens (see Tab. 1.5).

Tab1.5 features and indications of the three types of intraocular lenses

	Features	*Indications*
Pseudophakic IOLs	Placed inside the crystalline capsule, simultaneously with the removal of cataracts	Indicated for the correction of presbyopia
Phackic IOLs	Implanted without removing the lens	They allow the correction of severe refractive deficits
Aphakic IOLs	Implanted in aphakic eye	They entirely replace the lens function

The first monofocal lenses allowed (thanks to their unique focusing power) the correction of visual acuity only at one distance (usually remote viewing); thanks to the recent development of multifocal IOLs today it is possible to correct both far and near vision thanks to the coexistence of multiple powers. The purpose of these lenses is to offer a solution to the paraphysiological process of presbyopia, which determines the gradual loss of near vision and the reduction of the reading speed starting from fourth decade of life.

The development of the first intraocular lenses dates back to 1949, when the British physician Sir Harold Ridley implanted the first successful IOL in St. Thomas Hospital in London. The lens was made of polymethylmethacrylate (PMMA) by Imperial Chemical Industries.

In the 70's the further development of optical design and surgical techniques allowed the diffusion.

To date, the World Health Organization estimates that the number of global annual IOL implants exceeds 20 million and that this number is, in all probability, destined to exceed 30 million in 2020.

The development of multifocal artificial lenses has significantly reduced the use of monofocal lenses and, even correcting the refractive deficit to distance guarantees the 'post-surgical' independence from reading glasses too, so that they are today considered a therapeutic solution for the correction of presbyopia . (Carson et al.,2014;Vryghem&Heireman,2013)

1.3.3. IOLs for the correction of presbyopia

The artificial crystalline lenses can be implanted both in the context of the cataract removal that with the purpose of a refractive lensectomy in a subject not with cataract to correct high grade spherical defects in not young or with initial crystalline sclerosis patients: it is a microsurgical technique , performed in topical or local anesthesia, aimed to the lens removal and its replacement with an artificial lens often taken into account in refractive surgery. It may aim to solve presbyopia in cataract absence and, in this case, it is called PRELEX (PREsbiotic Lens Exchange).

In aged people, however, the frequent need of transparency in a cataract lens offers the ideal environment to a surgical implantation of a visus corrective IOL .

The artificial crystalline lenses used in the correction of presbyopia are pseudophakic IOLs designed to provide the best focus at all viewing distances and contemplate different mechanisms.

The possible corrective strategies through IOLs provides the following cases

1. Artificial monofocal criystalline for alternating monovision;

2. Artificial accommodative crystalline;

3. Artificial multifocal crystalline (diffractive and refractive);

4. Artificial trifocals crystalline.

1.3.3.1. Alternating monovision with monofocal intraocular lenses

It is an implantation of a monofocal IOL for remote vision in one eye and of a monofocal IOL for close vision in the contralateral eye. The central nervous system adapts to the new biocular vision focusing one eye or the other one depending on it is required focusing far or close and synthesizing informations from both eyes at intermediate distance. (Azzolini et al.,2014) Often this corrective strategy reduces the use of reading glasses. It is useful that the patient previously evaluates its adaptation ability using temporary contact lenses simulating postoperative visual condition.

1.3.3.2. Accommodative IOLs

It is a IOL inserted into the anterior chamber, interacting with ciliary muscle and ciliary zonules through hinges at both ends; these will mediate its adhesion, allowing the displacements in antero-posterior or postero-anterior direction exploiting the physiological mechanism of accommodation. The loops attaching these lenses are very flexible and the hinges allow the displacement of the optical disc in the sagittal plane and the focusing variation through a mechanism similar to the natural one. The accommodative lenses generally have a 4.5 mm optical edge and a flattened design. The hinges are made with Biosil, a particular silicone carefully tested to ensure an adequate intraocular bending capacity of the lens. (Slade,2009)

They are not dependent on brain’s adaptation mechanisms and prevent the phenomena of glare, ghost image and vision of marks that are very frequent with multifocal lenses. However, despite providing an optimal correction in remote vision, most patients do not reaches the postoperative reading glasses independence.

1.3.3.3 .multifocal lenses: correction of visual acuity in more observation distances

The MIOLs (multifocal IOLs), allow a considerable improvement of near vision, but also of remote and intermediate distance (see Tab.1.6).

The first multifocal IOL was introduced in 1980.

The first MIOLs were only bifocal, exclusively allowing the simultaneous correction of distance vision and close vision; the latest MIOLs, having better optic property, also promoted the intermediate distance to provide the patient a full range of vision. The multifocality of artificial lens increases the depth of field of the eye and the increase of observation distances range allows the eye doesn't perceive a net change of focus at different viewing distances; however, it causes contrast reduction and undesirable phenomena such as halos or glare. (Ye P-P, Li X & Yao K.,2013)

In fact, the concentric rings of different optical zones and the transition zones between them, determine - compared to conventional monofocal lenses - glare and halos with negative consequences on patients vision and so a negative impact on their level of satisfaction, so limiting the installations of standard MIOLs.

This observation is supported by a US study of Sood and Woodward (2011)

In addition, the MIOLs, would not allow to reach a suitable visual acuity at all viewing distances, with a particular reference to intermediate vision. (Vryghem& Heireman,2013)

Tab. 1.6 Comparison between monofocal and multifocal intraocular lenses.

MONOFOCAL IOLs	*STANDARD MULTIFOCAL IOLs*
Single focus power	More focus powers
They allow an optimal correction to a single viewing distance (distance vision)	They allow a good correction to more observation's distances (remote or close) but penalize the intermediate
They require post-operative reading glasses	They reduce or eliminate the need of postoperative correction with glasses
Reduced glare and halos	Determine however reduced sensitivity to contrast and positive dysphotopsie

Today the MIOLs available are of two types: refractive and diffractive (see Tab. 1.7).

In refractive lenses, the optical function results from the refractive zones located concentrically on the optical plane. The main disadvantage of this type of lens is the considerable dependence on the pupil diameter and the loss of energy in the transition zones; the front surface of the lens has some annular areas with different curvature, which exploiting the physical principle of refraction, creates focus points at all viewing distances, especially intermediate.

The diffractive MIOLs, instead, use a diffractive pattern to create an additional focus required for near vision in the first order of diffraction. The anterior curvature of the lens is used to correct the refractive defect for distance; on the posterior face there are instead concentric rings stepped, that exploit the principle of diffraction to create a second point of focus for near vision.

A combined approach, said "Mix and Match", consisting of the installation of a diffractive lens in the dominant eye and a refractive lens in the contralateral eye, allows to reduce the problems of multifocal IOLs and enhances the advantages of both types of lenses, bringing greater degrees of patient's satisfaction in the literature. A Belgian study published by Vryghem and Heireman (2013), performed on 25 patients and 50 diffractive multifocal lenses implanted, showed that the diffractive MIOLs provide good visual acuity in both distance and near vision. According to the authors , however, these would lead to a relatively high percentage of patients depending on optical correction with ophthalmic lenses for intermediate vision.

A further study, evaluating contrast sensitivity and visual acuity after MIOLs refractive and diffractive implants in different groups of patients with unilateral cataracts, showed a marked improvement of visual functions in the groups operated with diffractive rather than refractive lenses (as well as in patients with multifocal IOLs rather than monofocal).

Regarding the contrast sensitivity, it has emerged that these values are lower when compared to those of monofocal lenses. In addition, noted Sood (2011), the multifocal technology with concentric rings on the rear surface of the lens is the base of the reduction of the optical contrast and this explains some of the photic phenomena detected. However, this reduction may be limited or even avoided by minimizing the primary spherical aberration. (Friedrich,2012)

The MIOLs currently available are: multi-zone refractive lenses, rotational asymmetrical refractive lenses, diffractive lenses and hybrid lenses (born from the combination of refractive and diffractive lenses). The last, in particular, have shown an achievement of a good functional vision at all viewing distances and without further optical corrections, although undesirable effects as halos, glare, decrease in contrast sensitivity are not totally excluded.

Tab.1.7 Comparison between intraocular multifocal refractive and diffractive lenses.

REFRACTIVE MIOLs	*DIFFRACTIVE MIOLs*
They allow a good vision at intermediate distances	They allow a good vision at remote and close distances
Remote vision worse than with monofocal,lenses Near vision worse than with diffractive lenses	Intermediate vision worse than with refractive lenses
Highly influenced by pupillary diameter, visual disturbs specially in night driving.	Shortly influenced by pupillary diameter

1.3.3.4 Trifocal IOLs

The multifocal intraocular lenses of old generation offer a remote and close clear vision but don't guarantee an optimal vision at intermediate distance; the MIOLs may also be associated with visual disturbances such as glare and halos around light sources, especially in scotopic vision

A new generation of intraocular trifocal lenses has been recently introduced with the aim both to optimize the intermediate vision (although without interfering with distance and close vision) that to reduce the positive disphotopsie, typically related to the scattering of light due to multifocality. Because of their recent introduction , studies published in the medical literature are still very few.

The peculiarity of these trifocal lenses is based on the presence of a third intermediate focal point that, securing the intermediate distance correction, leads to a lower scattering of light due to the peculiar distribution of the incoming radiation within the lens.

In multifocal ophthalmic lenses the range of powers increases progressively from higher areas toward the lower ones so that by changing the position of the head the subject can pass with his eyes through a focal zone of the lens rather than another, and so it is generated a single point of focusing on the retinal plane for each moment. By contrast, in the case of multifocal intraocular lenses, implanted artificial crystalline lenses are not movable with respect to the center of the pupil: multifocality is achieved by creating within the eye, at the same time, two or more points of focus for the vision at different distances. Therefore, only a part of light incoming is focused for the vision at the desired distance.

In remote vision a part of the light is focused on the retina, another percentage of light rays is simultaneously focused before retinal plane. Similarly, in near vision, a part of the radiation is focused on the retinal plane and a part instead posteriorly . It means that the image on the retina is realized only by a part of the light going through a MIOL: this results - with respect to intraocular monofocal lenses- a reduction in contrast sensitivity and a decay of vision in low light conditions.

Thanks to the presence of three focuses rather than a progression of different focal zones, the aforesaid vision disturbances are significantly minimized in trifocals; also - with respect to the old generation of monofocal or bifocal lenses - the trifocal lenses have the advantage of offering an optimal vision at intermediate distance (60-80 cm) as well as far or near, thus allowing to focus objects at all viewing distances.

More studies demonstrated that intraocular trifocal lenses give at intermediate vision a better visual performance and image quality after cataract surgery. (for these,it refers up) .

To ensure a satisfactory result after cataract surgery, it is very important to do a biometrics before surgery to estimate the exact diopter deficits and properly adjust the power of the IOL; an astigmatism higher than 0.75 / 1:00 D is an indication of toric multifocal IOL implantation. (Friedrich,2012) with the axis of the lens properly aligned with the axis of astigmatism, to avoid the permanence of a residual astigmatism post-implantation.

The first MIOL for the correction of presbyopia during surgery of cataract approved by the FDA has been an Array (Advanced Medical Optics, Santa Ana, CA, USA) in 1997: a multifocal refractive lens with five concentric progressive areas on its front surface . Some early studies showed that the vision for both distance and near was significantly better with Array lens rather than with monofocal (Law,Aggarwal&Kasaby,2014) In 2005, the FDA approved two new multifocal lenses, refractive MIOL Re ZOOM® (Advanced Medical Optics , Inc.) and diffractive MIOL AcrysofReSTOR® (Alcon Laboratories, Inc.). The ReZoom has been shown to provide an optimal correction (and independence from glasses) to 93.4% of eyes for distance, to 92.6% for the intermediate and to 81.4% for near. (www.rezoomiol.com/files/PackageInsert.pdf,April 2013)

Main disadvantages of the aforesaid lens are instead represented by a correction for near less satisfactory than those for distance (patients often require reading glasses) and a greater presence of photic phenomena compared to other MIOL. Regarding the AcrySof® ReSTOR, the correction for near has proved to be better than the ReZoom; However, patients often reported glare and halos. (Vingolo et al.,2007)

In 2009, a further development of MIOL led to multifocal diffractive **Tecnis** (Advanced Medical Optics, Inc., Santa Ana, CA), at increased depth of field. According to different retrospective studies (Hoffman,Fine&Packer,2003) the percentages of postoperative independence from glasses are relatively high (optimal correction in 85% of the eyes at distance in 93.7% at near).

Today, with the introduction of the Advanced Technology IOLs and of the multifocal IOLs - ie intraocular lenses that can correct spherical aberration and astigmatism - simultaneously with the improvement of the surgical technique and responding to the increasing demands of patients to have minimal or even no final refractive error, cataract surgery has become an efficient and safe refractive surgery.

1.3.4 Optical and functional characteristics of the two lenses studied

The two different types of new generation artificial crystalline lens for the correction of presbyopia implanted IOLs are the trifocal AT LISA tri 839MP and the MIOL at increased depth of field (EDOF, Extended Depth of Focus) TECNIS® Symfony. The two types of lens represent two different technologies pointing to the same objective, the enhancement of intermediate distances of observation: the first lens through the addition of a third focal point to previous bifocals, the second one increasing the depth of field to standard multifocal .

Both types of lens aim to the maximum correction of visual acuity al all distances and to the total postoperative independence from glasses.

1.3.4.1 Trifocal AT LISA tri 839MP lens

The AT LISA tri 839MP (Carl Zeiss Meditec, Jena, Germany) IOL is a trifocal intraocular lens pointing to the optimal correction of the intermediate visual acuity, penalized in standard MIOL and obtained by the addition of a third focal point to previous bifocals. The peculiar design is due to the combination of a diffractive bifocal model with a trifocal: in fact, the lens has a central trifocal area with a diameter of 4.34 mm and a bifocal peripheral zone between 4:34 mm and 6.00 mm.

The acronym LISA describes the following features of the lens:

- ***L**ight distributed asymmetrically between distant, intermediate and near focus for improved intermediate vision and greatly reduced halos and glare:*

- ***I****ndipendence from pupil size due to high performance diffractive-refractive microstructure covering the complete 6.0 mm optical diameter:*
- ***S****MP technology for ideal optical imaging quality with reduced light scattering*
- ***A****berration-correcting optimized aspheric optic for better contrast sensitivity,depth of field and sharper vision*.(Alfonso,2007)

The lens is a foldable one-piece of acrylic hydrophilic in aqueous matrix (25%) and with hydrophobic coating surface, with optical diameter of 6 mm and a total diameter of 11 mm,a design with 4 flat haptic devoid of angles and rear beveled edge .

The lens has a power of +3.33 D for near and of +1.66 D for the intermediate, which allows a good intermediate vision even in low light conditions thanks to the asymmetric distribution of the incoming radiation between the three focuses, with 50%, 20% and 30% distribution percentages respectively for far, intermediate and near. The total percentage of transmitted light corresponds to 85,7% of the incoming radiation (Mojzis et al.,2014): This percentage is significant of a low radiation's dispersion due to the absence of sharp angles in the 4 haptic of the lens.

The independence from the pupillary diameter is guaranteed up to a pupillary dilation of 4.5 mm; this ensures a good performance even in lower light conditions (Mojzis et al.,2014).

The peculiar structure of the rear face of the lens is the base of two important characteristics: the squared posterior margin prevents secondary opacification of the posterior capsule; the aspherical optics of the rear surface (the asphericity of lens is – 0:18 mμ) allows an excellent correction of aberrations, particularly spherical aberrations (Law,Aggarwal& Kasaby2014), and so the recovery of the physiological balance between the positive and negative spherical aberrations of cornea and lens, respectively. The correct minimization of spheric aberration correlates with low levels of contrast reduction.

There are powers between 0 and +32 D, progressive steps of +0.50 D (see Tab.1.8).

Tab. 1.8 Summary table of the structural peculiarities of AT LISA tri 839MP lens and concerning advantages.

ADVANTAGES OF AT LISA tri 839MP:	***DUE TO:***
Better correction at the intermediate distance	Asymmetric distribution of light between focuses
Reduction of glare and halos	
Reduced light scattering	Absence of sharp angles between 4 haptic
Independence from pupillary diameter	Coverage of the entire pupil diameter
Prevention of secondary opacification of rear capsule	Squared back margin of lens
Correction of spherical aberration and high Contrast sensitivy	Asphericity of the rear surface of the lens

In a 2012 study P. Mojzis et al. recognize three important advantages of the AT LISA tri:

- in primis the excellent image quality at different viewing distances and a significant independence from glasses after surgery;
- in secundis the lens can be injected with a special injector BLUEMIXS 180 through an incision of a few millimeters, with a greater control of the surgically induced astigmatism and corneal aberrations;
- in tertiis the lens is stable in the crystalline lens capsule and has an excellent optical quality

1.3.4.2 TECNIS® Symfony lens and MIOLs at increased field depth

Both the old generation MIOLs that the accommodative lenses for presbyopia correction involve optical compromises: the MIOLs determine a degree of glare or halos, although the majority of patients fits in a few weeks, and a loss of sensitivity contrast; patients, however, reaches a good distance vision and don’t need reading glasses for most of the visual activity.

The accommodative lenses, however, do not provide sufficient accommodation for a good near visual acuity (the ciliary muscle doesn’t seem to have a sufficient shrinkage capacity for good working of the current accommodative lenses).

Recent multifocal developments tried to determine a solution to contrast sensitivity reduction and to disfotopsie, commonly determined by standard MIOLs. It has been, so , developed multifocal EDOF (Extended Depth of Focus), with increased depth of field, which represent a valid alternative to trifocals in the correction of presbyopia during cataract surgery avoiding the already said disorders.

Increasing depth of field, rather than the addition of a second or third focal point, the MIOLs EDOF are designed to provide a better vision to close / intermediate distances compared to monofocal / accommodative and a better contrast sensitivity, less halos and less glare than standard multifocal. The lens TECNIS® Symfony, produced by Abbott Medical Optics, received the CE mark in 2014 and represents one of the most widespread MIOLs at increased depth of field. It uses two strategies to extend the focusing range, spherical aberration's control and diffractive optics.

- The spherical aberration control is achieved thanks to the addition of a negative spherical aberration induced by the lens to counteract the natural positive spherical aberration of the normal cornea;

- the diffractive strategy uses instead the patented design Echelettes diffractive - structured in the lens rear surface- that increase a single depth of focusing (unlike diffractive multifocal standard which create two distinct focal distances).

The Echelettes correspond to the lens reliefs within each optical ring (height differential): they constitute a new model of diffraction of light which extends the focal distance of the eye, thanks to constructive interference of light emanating from different zones.

Since an increase of the depth of focus correlates with a reduction of image quality, the combined correction of spherical aberration and achromatic technology for chromatic aberration correction are proposed as optical compensation system to restore the high image quality. The achromatic technology, in fact, corrects the eye intrinsic positive chromatic aberration, because of blur and loss of contrast .

The functional advantages of Symfony lens are:

- High quality vision: the lense provides an excellent visual acuity at all distances without optical correction; the contrast sensitivity levels are comparable to monofocal lenses and higher than standard MIOLs that, compared to the monofocal, cause a significant loss of contrast due to the separation of the incoming radiation

- Improvement of functionality: the lens offers a complete range of solutions for a high quality vision, a high tolerance to the cylinder (20/20 correction for astigmatism of 1.5 D) and, thanks to the independence from pupillary diameter, even in low light conditions.

- Long-term sustainability: the lens design, characterized by an edge with a 360 ° proTEC barrier that prevents the migration of epithelial cells of the crystalline lens, reduces the incidence of posterior capsule opacification; also the realization material of the IOL is not associated with glistening” , cause of light scattering and consequent loss of contrast sensitivity.(see Tab.1.9)

Tab1.9Summary table of the structural peculiarities of the lens TECNIS Symfony and respective advantages.

TECNIS® Symfony BENEFITS	*DUE TO:*
Increased depth of field	Diffractive Echelettes strategy
High image quality and low contrast reduction.	Spherical aberration correction
	Chromatic aberration correction
Independence from the pupil diameter	Cover the entire pupil diameter
Prevention of secondary opacification of the rear capsule	Edge barrier 360 ° *ProTEC*

In a comparative study between MIOLs Symfony and standard MIOLs (Tab.1.10), the Symfony determined a correction of an intermediate visual acuity of 20/30, with a low level of independence from the glasses when compared to standard MIOLs; however, the Symfony was associated with lower rates of glare.

Tab1.10Summary table of differences between standard multifocal lenses and increased deep of field multifocal lenses

	MIOLsEDOF	*MIOLs standard*
Halos and glare	-	+
Loss of contrastsensitivity	-	+
Remote Visus	+	+
Intermediate Visus	+	±
Close Visus	±	±

2. RESEARCH

2.1.Clinical study: evaluation of two new intraocular lenses. Patients and study methods

2.1.1. Aim of the study

Presbyopia is the refractive defect most common in the elderly population. The intraocular lenses represent a valid therapeutic option to the correction of refractive defects and their implantation is performed simultaneously with cataract surgery.

The present clinical study is proposed as a prospective comparative trial having the aim to evaluate the efficacy of two new generation's IOLs for the correction of presbyopia: the trifocal lens AT LISA tri 839MP and the multifocal at increased depth of field lens TECNIS® Symfony, both implanted during cataract removal surgery.

The trial is conducted in the Ophthalmology units of the Careggi University Hospital of Florence; from September 2015 to February 2016 were studied 28 patients, 2 males and 26 females with age range between 61 and 80 years, candidates to binocular cataract surgery. During surgery it has been removed the crystalline lens with cataract using phacoemulsification technique and has been implanted an artificial crystalline lens of one of the two aforementioned types. Depending on the implanted IOL, the study population has been divided into two experimental groups: a first group of 18 patients operated with IOL AT LISA tri 839MP (36 eyes), a second group of 10 patients operated with TECNIS® Symfony (20 eyes).

The patients studied were carefully selected and included in the two groups on the basis of strict inclusion and non-inclusion criteria, below discussed.

The study was conducted according to the ethical principles contained in the Helsinki Declaration of 10 June 1996 and the protocols of the International Conference of Harmonization (ICH) regarding Good Clinical Practice.

Objective of the study is to estimate the postoperative results of visual acuity (measured at three different distances-remote, intermediate and near-) and results of contrast sensitivity.

In both groups, the above parameters were studied in two light conditions (photopic and mesopic) and were compared the differences.

Each patient was followed up to the third month after surgery on the second eye and both in pre-operative and in post-operative period with follow-up after one week, one month and three months after surgery to the second eye.

The results obtained in the two experimental groups were compared and statistically significant differences have been discussed.

2.1.2.Selection of the study population

In the trial have been studied patients needing surgical correction of bilateral cataracts and binocular implant of artificial crystalline lens for refractive correction of presbyopia.

Recruited patients were carefully selected as a function of inclusion and non-inclusion criteria corresponding to the following criteria:

- corneal astigmatism <1 D
- cataracts with no risk of peri-operative complications
- lens implant in intracapsular place
- biometrics and cataracts density compatible with the evaluation of the optic biometer IOL Master.

Have been excluded patients with at least one of the following non-inclusion criteria:

- age <18 and> 85
- ocular axial length> 25 mm
- amblyopia history
- ocular fundus abnormalities able to cause a significant loss of vision
- previous surgical intraocular procedures and corneal laser treatments
- concomitant acute and chronic ocular pathologies (trauma, chronic uveitis, corneal opacities,infections)
- treatment with alpha-antagonists (eg.Tamsulodin, cause of Iris Floppy Syndrome)
- diabetes with retinal changes or diabetic retinopathy
- IOP> 24 mmHg or full-blown glaucoma
- pseudo exfoliation syndrome
- keratoconus
- endothelial corneal dystrophies (eg. Fuchs dystrophy)
- severe atrophy of the optic nerve
- choroidal hemorrhage
- pregnant women or nursing mothers.

Selected patients meet all the inclusion criteria and no exclusion criteria and confirmed consent to the inclusion in the trial. Possible trauma of the pupillary margin of the iris and vitreous loss, contingencies not noticed, were considered intra-operative exclusion criteria from the trial.

2.1.3. Study duration and methods

The duration of observation of each patient is around six months; the duration of postoperative follow-up is 12 weeks after the second eye's surgery. For each patient has been used the following procedure: inclusion in the trial visit, surgery on the first eye 2-4 weeks after the inclusion visit, surgery on the second eye 2-6 weeks after the first operation, visit 1 month (30 +/- 5 days) after surgery on the second eye, visit 3 months (90 +/- 15 days) after surgery on the second eye.

During the inclusion visit was evaluated :

- medical and pharmacological history of the patient ;
- general ophthalmologic examination ;
- visual acuity with ETDRS (in logMAR) measured in photopic light condition (85 cd / m^2) at three different observation distances: 4m (distance vision), 80 cm (intermediate vision) and 40 cm (near vision); visual acuity, in monocular and in binocular vision, natural and with correction;
- biometrics with IOL Master to determine the power of the IOL that will be implanted, the depth of the anterior chamber, the axial length of the eye and corneal curvature radius;
- pupilometry in mesopic and photopic condition;
- corneal topography;
- endothelial biomicroscopy;
- OCT

During the visit 1 month after surgery on the second eye it has been evaluated :

- natural and corrected visual acuity , in monocular and binocular vision, at the three distances of observation in photopic light condition ;
- pupilometry in mesopic and photopic light condition;
- control of the IOL position in pharmacological mydriasis condition.

During the visit 3 months after surgery on the second eye it has been finally evaluated:

- monocular and binocular, natural and corrected visual acuity, at the three distances of observation, in mesopic (3cd/m^2)and photopic (85cd/m^2)condition;

- binocular contrast sensivity (in logCS) in mesopic and photopic condition;
- position of the IOL in pharmacological mydriasis

Follows illustration in Tab.2.1.

Tab. 2.1 Schematic illustration of adopted time-table in the investigation, surgery and follow-up process.

	Inclusion	***Surgery***	***Follow-up 1***	***Follow-up 2***
history	**X**			
ophthalmological examination	**X**			
axial lengh	**X**			
anterior chamber depth	**X**			
Informed consent	**X**			
keratometry	**X**			
endothelial count	**X**			
biometrics IOLMaster	**X**			
pupilometry	**X**		**X**	
IOL implant		**X**		
excluding adverse events		**X**	**X**	**X**
Subjective refraction	**X**		**X**	**X**
UDVA [logMAR]	Photop.		Photop.	Photop. + Mesop.
CDVA [logMAR]	Photop.		Photop.	Photop. + Mesop.
UNVA 40cm [logMAR]	Photop.		Photop.	Photop. + Mesop.
DCNVA 40cm [logMAR]	Photop.		Photop.	Photop. + Mesop.
UIVA 80cm [logMAR]	Photop.		Photop.	Photop. + Mesop.
DCIVA 80cm [logMAR]	Photop.		Photop.	Photop. + Mesop.
reading performances			**X**	
Contrast sensitivy				**X**
satisfaction questionnaire				**X**
IOL position control			**X**	**X**

2.1.4. Preoperative investigations

The visual acuity examinations took place after adjusting the environment illuminance with luxmeter ST-1300 Standard, placed parallel to the optotype surface .It has been set to 300 lux and to 10 lux to recreate photopic and mesopic conditions respectively and each mesopic measurement was performed after waiting 5 .ca minutes for dark adaptation.

Was considered a wavelength of 555,02 nm in photopic condition and 507 nm in scotopic condition, values internationally accepted for the maximum visual efficiency of the eyes in the two conditions of light level.

The visus objective measurement was made with auto refractometer Accuref k-900 and the values obtained were eventually subjectively modified until reaching the best correction.

Visual acuity was measured at each control visit: both at the inclusion visit as in all post-operative follow-up; refractive defects of sphere (D), cylinder (D) and axis of the cylinder (°) were measured. The spherical equivalent (SE= Sphere + ½ cylinder), was calculated at all refraction visits.

The above parameters were monitored in the progress of the trial and compared with the preoperative values. For the evaluation of post-surgical stability of refraction, the values reported one month after surgery on the second eye were compared with the values of the next visit after three months.

The visual acuity measurement was made with ETDRS *(Early Treatment Diabetic Retinopathy Study*) and expressed in logMAR (*Minimal Angle of Resolution)*; it has been evaluated in photopic illumination condition at three different observation distances: distance, intermediate and near.

The vision at distance was measured using a backlit ETDRS optotype placed at a distance of 4 meters from the patient; was measured monocular and binocular acuity, natural and with the best correction. The measurement of visual acuity for intermediate and close distances was made using ETDRS cards printed with black letters on a white background, programmed to a distance respectively of 80 and 40 cm from the eye plane of the patient first monocular then binocular, natural and with the best correction.

Three months after surgery on the second eye visual acuity was further measured in mesopic condition and the results obtained were compared with those obtained in photopic conditions.

The instrumental preoperative exams performed for recognition of possible structural and functional abnormalities of the eye structures, possible reason of not inclusion in the trial were the following:

- Biometrics with IOL Master for the exact calculation of the dioptric power of the artificial lens by formula SRK / T o Haigis;
- Corneal mapping with topographer Sirius for a keratometry study;

- Pupillometry to estimate the pupillary diameter in photopic and mesopic condition;
- Endothelial counting of the cornea with biomicroscope Perseus (CSO) to study the corneal endothelium and the qualitative and quantitative regularity of the corneal endothelial layer;
- OCT with DRIOCT Triton-3D Optical Coherence Tomography to study the retinal plane

2.1.5.Surgery

Surgical removal of the opaque lens was made through surgical technique of phacoemulsification followed by implantation of artificial crystalline lens within the intracapsular seat.

2.1.6. Postoperative investigations

Each patient was followed in two subsequent postoperative follow- up: the first one month and the second three month after surgery on the second eye.

Visus natural and corrected, as in the previous pre-operative examination, were measured at three distances (remote, 80cm, 40cm). At the end of each visit were reported refractive values and visual acuity of each patient and it improvements were monitored.

During the visit 3 months after surgery, in addition to photopic visual acuity was measured the mesopic visual acuity and the contrast sensitivity through OPTEC 6500 Vision Tester in which line segments (black-on-white, white-on-black) variously oriented with respect to the vertical axis and progressively less recognizable than the background, with a step 0:15 logCS. are represented. The various recognized contrast levels and eventual missing or erroneous recognitions have been reported in scorecards and subsequently converted to a logarithmic scale, statistically analyzed. The examination was performed to distance in binocular vision.

Although this test provides the eventual best correction, all patients after three months showed a visual acuity of 0.0 logMAR (10/10) or more for distance, so none of them has needed ophthalmic correction during the test sequence.

2.1.7. Analysis and DATA processing

The data detected at the purpose of the study were collected in computer tables and processed with electronic calculation tables (Microsoft Excel, SPSS). Individual values of the quantitative parameters were reported and average, standard deviation and P-value were calculated; the qualitative parameters were instead converted into a percentage.

Data on visual acuity at the three observation distances studied and sensitivity to contrast of each patient were processed.

For an overall assessment of visual acuity and accurate monitoring over time, the following values were compared in each group:

- comparison between the refractive values measured at the three different distances studied, natural and with the best correction;
- comparison between the measured values at the inclusion visit, at the first and at the second post-operative follow-up;
- comparison between the values measured in photopic and mesopic vision.

To study contrast sensitivity levels, the following parameters were compared:

- comparison between different values of CS expressed in 5 increasing levels of cycles/degree;
- comparison between the two different light condition.

Finally, for each analyzed parameter, the averages of the values obtained by the two experimental groups were compared between them: significance levels of each evidence (t-test) were calculated and were considered statistically significant $p < 0.05$ parameters.

2.2. Results

2.2.1. Preoperative values

In this comparative trial were studied 28 patients with presbyopia, average age of 68 years, candidates for cataract binocular surgery. The population of the trial was selected through accurate diagnostic tests, according inclusion and non-inclusion criteria above discussed.

Among the 28 patients undergone surgical removal of the cataract lens, a Group 1 of 18 patients (36 eyes, average age 71) and a Group 2 of 10 patients (20 eyes, average age 65) were implanted, respectively, two different types of new generation IOLs correcting presbyopia: 36 trifocals AT lenses Lisa tri 839 in Group 1, 20 multifocal lenses at increased depth of field TECNIS Symfony in Group 2.

The table Tab. 2.2 shows the average values preoperative of sphere, cylinder, spherical equivalent, UDVA (uncorrected distance visual acuity), CDVA (corrected distance visual acuity), UIVA (uncorrected intermediate visual acuity), UNVA (uncorrected near visual acuity) and of the pupillary diameters of the 28 patients.

Tab 2.2General and refractive average preoperative data of the two groups.

	Group 1	***Group 2***
N° Patients /N° Occhi)	18 / 36	10 / 20
Average age (*anni*)	71	65
Sphere (*D*)	-1.0	-1.25
Cilinder (*D*)	-0.5	-0.75
Spherical equivalent (*D*)	-1.25	-1.50
UDVA/CDVA (*logMAR*)	0.32 / 0.28	0.54 /0.35
UIVA *(logMAR*)	0.4	0.61
UNVA (l*ogMAR*)	0.55	0.56
Diam. Pupill. FOTOP./MESOP. (*mm*)	2.85 / 3.98	2.79 / 3. 96

2.2.2. Visual acuity values

Abstract: The average values reported below are expressed in form of media (dev. Stand.).

The visual acuity values were studied with ETDRS optotypes in all described control visits at the different distance. During the preoperative visit the patients of Group 1 were estimated to have the following visual acuity values: an average visual acuity to 4 m equal to 0.49 (0.28) logMAR in monocular vision and 0.32 (0.19) logMAR in binocular vision; an average visual acuity al 80 cm equal to 0.52 (0.33) logMAR in monocular vision and 0.4 (0.32) logMAR in binocular vision; an average visual acuity at 40 cm equal to 0.61 (0.27) logMAR in monocular vision and 0.55 (0.27) logMAR in binocular vision.

Similarly, in the preoperative visits of the Group 2 patients , the following visual acuity values were estimated: an average visual acuity to 4 m equal to 0.61 (0.34) logMAR in monocular vision.and.0.54 (0.28) logMAR in binocular vision; an average visual acuity at 80 cm equal to 0.63 (0.2) logMAR in monocular vision and 0.61 (0.21) logMAR in binocular vision; an average. visual. acuity at.40 cm equal to.0.69 (0.39) logMAR in monocular vision and 0.56 (0,45) logMAR in binocular vision.

In Group 1, the refractive values measured 1 month after surgery were: an average visual acuity at 4 m (far) equal to 0.02 (0.03) logMAR in monocular vision and -0.01 (0.02) logMAR in binocular vision; an average visual acuity at 80 cm (intermediate) equal to 0.12 (0:07) logMAR in monocular vision and 0.12 (0.08) logMAR in binocular vision; an average visual acuity at 40 cm (near) equal to 0.26 (0.08) logMAR in monocular vision and 0.23 (0.07) logMAR in binocular vision.

In parallel, in Group 2 were measured following values of visual acuity: an average visus at 4 m (far) equal to 0.01 (0.07) logMAR in monocular vision and to -0.01 (0.04) logMAR in binocular vision; an average visual acuity at 80 cm (intermediate) equal to 0.14 (0.13) logMAR in monocular vision and 0.08 (0.04) logMAR in binocular vision; an average visual acuity at 40 cm (near) equal to 0.41 (0.15) logMAR in monocular vision and 0.31 (0.14) logMAR in binocular vision.

Three months after surgery to the second eye, a further measurement of visual acuity was made, first in photopic and secondly, after few minutes of penumbra adaptation , in mesopic vision.

In Group 1, the visual acuity values measured in photopic condition three months after surgery were: an average visual acuity at 4 m of -0.01 (0.05) logMAR in monocular vision and of – 0.02 (0.04) logMAR in binocular vision; an average visual acuity at 80 cm equal to 0.13logMAR (.07) in monocular vision and 0.10 (0.08) logMAR in binocular vision; an average visual acuity at 40 cm equal to 0.23 (0.07) logMAR in monocular vision and 0.18 (0.07) logMAR in binocular vision. In mesopic condition an average visus at 4 m was measured equal to 0.07 (0.07) logMAR in monocular vision and to 0.02 (0.05) logMAR in binocular vision; an average visual acuity at 80 cm equal to 0.3 (0.13) logMAR in monocular vision and 0.25 (0.01) logMAR in binocular vision; an average visual acuity to 40 cm equal to 0.39 (0.01) logMAR in monocular and 0.31 (0.08) logMAR in binocular vision.

In parallel, in the Group 2 were measured following refractive values in photopic lighting conditions: an average visual acuity at 4 m of -0.01 (0.05) logMAR in monocular vision, and of -0.05 (.04) logMAR in binocular vision; an average visual acuity at 80 cm equal to 0.2 (0.12) logMAR in monocular vision and 0.14 (0.11) logMAR in binocular vision; an average visual acuity at 40 cm equal to 0.46 (0.12) in monocular logMAR and 0.36 (0.08) logMAR in binocular vision. Similarly, in mesopic condition an average visus to 4 m was measured at 0.05 (0.13) logMAR in vision monocular and 0,02 (0.08) logMAR in binocular vision; an average visual acuity to 80 cm equal to 0.02(0.12) logMAR in monocular vision and 0.14 (0.12) logMAR in binocular vision; an average visual acuity at 40 cm equal to 0.46 (0.15) logMAR in monocular and 0.36 (0.13) logMAR in binocular vision.

In following tables are reported and compared the average visual acuity values of the two groups of patients measured during different preoperative and postoperative visits and follow-up (Tab.2.3-2.7). The visual acuity values of each of the two groups patients are schematically shown in Appendix, Tab. 1-8.

Tab.2.3 Comparison of visual acuity values and their significance levels of Group 1 between the following visits: preoperative visit (V0), visit at a month (V1) and a visit at three months (V3).

Group 1	V_0	V_{1M}	p_{1M}	V_{3M}	p_{3M}
***UDVA** monocular*	0.49 (0.28)	0.02 (0.03)	< 0.01*	-0.01 (0.05)	0.11
binocular	0.32 (0.19)	-0.01 (0.02)	< 0.01*	-0.02 (0.04)	0.09
***UIVA m**onocular*	0.52 (0.33)	0.12 (0.07)	< 0.01*	0.13 (0.07)	0.026*
binocular	0.4 (0.32)	0.12 (0.08)	< 0.01*	0.1 (0.08)	0.047
***UNVA** monocular*	0.61 (0.27)	0.26 (0.08)	< 0.01*	0.23 (0.07)	0.09
. *binocular*	0.55 (0.27)	0.23 (0.07)	< 0.01*	0.18 (0.07)	0.021*

Tab. 2.4 Comparison of visual acuity values (logMAR) and their significance levels of the Group 2 between the following visits: preoperative visit (V0), visit a month (V1) and a visit to three months (V3).

Group 2	V_0	V_{1M}	P_{1M}	V_{3M}	P_{3M}
***UDVA** monocular*	0.61 (0.34)	0.01 (0.07)	< 0.01*	-0.01 (0.05)	0.13
binocular	0.54 (0.28)	-0.01 (0.04)	< 0.01*	-0.05 (0.04)	0.14
***UIVA** monocular*	0.73 (0.2)	0.14 (0.13)	< 0.01*	0.2 (0.12)	0.3
binocular	0.61 (0.21)	0.08 (0.04)	< 0.01*	0.14 (0.11)	0.67
***UNVA** monocular*	0.69 (0.39)	0.41 (0.15)	< 0.01*	0.46 (0.15)	0.47
binocular	0.56 (0.45)	0.31 (0.14)	< 0.01*	0.36 (0.13)	0.044*

Tab**.** 2.5Comparison of the values of visual acuity (logMAR) and relative significance levels of Group 1 between visits in photopic and mesopic lighting conditions.

Group 1		*photopic*	*mesopic*	***P***
UDVA	*monocular*	-0.01 (0.05)	0.07 (0.07)	**0.012***
	binocular	-0.02 (0.04)	0.02 (0.05)	**< 0.01***
UIVA	*monocular*	0.13 (0.07)	0.3 (0.13)	**< 0.01***
	binocular	0.1 (0.08)	0.25 (0.1)	**< 0.01***
UNVA	*monocular*	0.23 (0.07)	0.39 (0.1)	**< 0.01***
	binocular	0.18 (0.07)	0.31 (0.08)	**< 0.01***

Tab. 2.6 Comparison of the values of visual acuity (logMAR) and relative significance levels of the Group 2 between visits in photopic and mesopic lighting conditions.

Group 2		*photopic*	*mesopic*	***P***
UDVA	*monocular*	-0.01 (0.05)	0.05 (0.13)	**0.033***
	binocular	-0.05 (0.04)	0.0 (0.08)	**0.19**
UIVA	*monocular*	0.2 (0.12)	0.2 (0.12)	**0.012***
	binocular	0.14 (0.11)	0.14 (0.11)	**0.041***
UNVA	*monocular*	0.46 (0.15)	0.46 (0.15)	**0.034***
	binocular	0.36 (0.13)	0.36 (0.13)	**0.023***

Tab. 2.7 Comparison of visual acuity values (logMAR) and their significance levels between group 1 and 2 in the visit after 1 and 3 months from the second eye surgery

	V_{1M}^{1}	V_{1M}^{2}	p_{1M}	V_{3M}^{1}	V_{3M}^{2}	p_{3M}
UDVA *monoculare*	0.02 (0.03)	0.01 (0.07)	**0.5**	-0.01 (0.05)	-0.01 (0.05)	**.07**
mesopic	-	-	-	0.07 (0.07)	0.07 (0.07)	**.035***
binocular	-0.01 (0.02)	-0.01 (0.04)	**0.72**	-0.02 (0.04)	-0.05 (0.04)	**.08**
mesopic	-	-	-	0.02 (0.05)	0.02 (0.05)	**0.012***
UIVA *monocular*	0.12 (0.07)	0.14 (0.13)	**0.22**	0.13 (0.07)	0.2 (0.12)	**0.27**
mesopic	-	-	-	0.3 (0.13)	0.3 (0.13)	**0.017***
binocular	0.12 (0.08)	0.08 (0.04)	**0.077**	0.1 (0.08)	0.14 (0.11)	**0.31**
mesopic	-	-	-	0.25 (0.1)	0.25 (0.1)	**< 0.01***
UNVA *monocular*	0.26 (0.08)	0.41 (0.15)	**0.01***	0.23 (0.07)	0.46 (0.15)	**< 0.01***
mesopic	-	-	-	0.39 (0.1)	0.39 (0.1)	**0.076**
binocular	0.23 (0.07)	0.31 (0.14)	**0.06**	0.18 (0.07)	0.36 (0.13)	**0.019***
mesopic	-	-	-	0.31 (0.08)	0.31 (0.1)	**0.055**

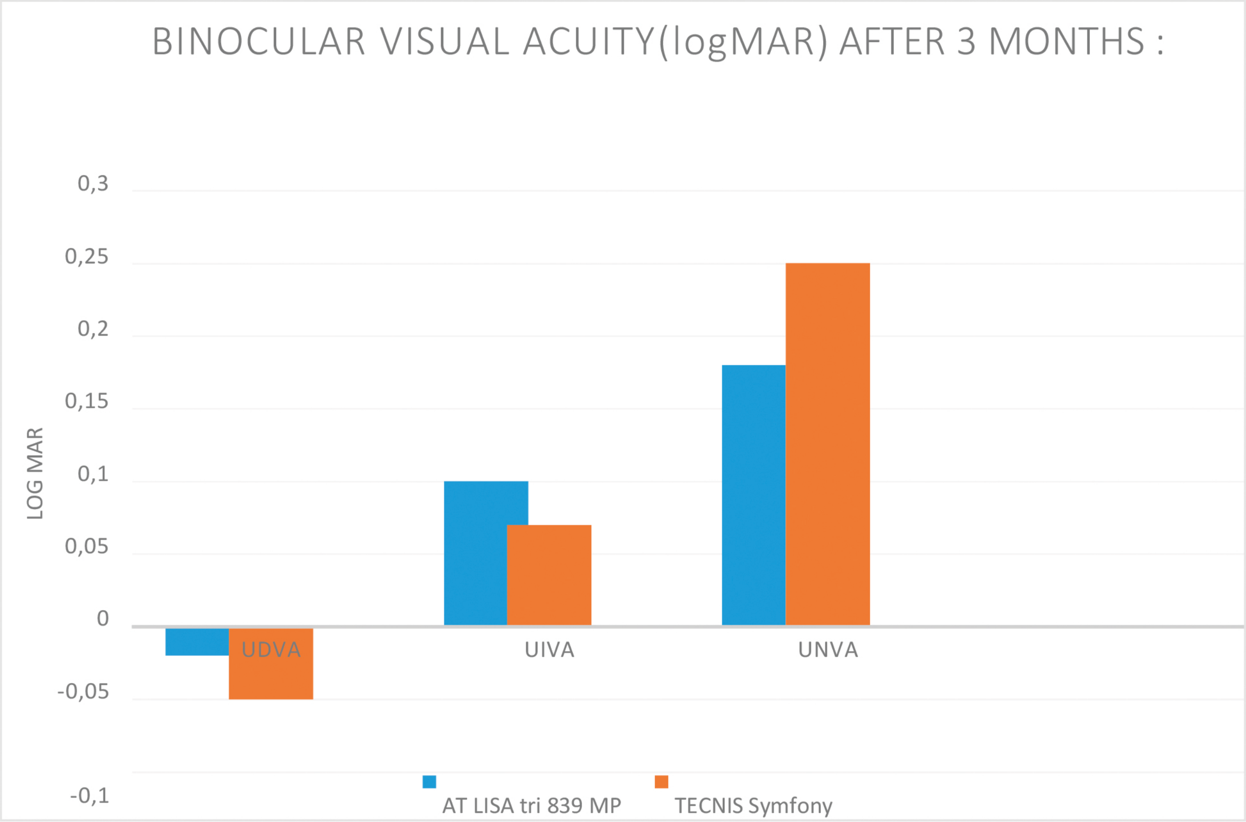


Fig. 2.1 Chart of the photopic binocular visual acuity average values measured 3 months after surgery in the 2 groups at the 3 observation distances studied :far UDVA),intermediate (UIVA)and close(UNVA)

2.2.3. Contrast sensitivity

The CS of each patient was measured during the last follow-up visit at 3 months after surgery on the second eye, using OPTEC 6500 Vision Tester, and after instructing each patient to the correct procedure. The examination was performed both in photopic and mesopic vision, with test distance preset for distance vision.

Since all patients at three months after surgery had a visual acuity of 0.0 logMAR (10/10) or more they didn't use ophthalmic correction during the test sequence.

The instrument showed to each patient 5 decreasing levels (A, B, C, D, E) of degree cycles, in which were proposed nine black stripes on white background with gradually decreasing contrast differences in logCS . The contrast sensitivity values of each patient and the average values, respectively of the Group 1 and Group 2, was measured in photopic light condition and for the five groups of increasing degree/cycles.

In the Group 1 were measured photopic average levels of contrast sensitivity of 1.57, 1.62, 1.68, 1.35 and 0.64 logCS respectively for 1.5, 3, 6, 12 and 18 degree/cycles; similarly in the Group 2 were measured, respectively, average photopic values of 1.76, 1.81, 1.84, 1,39 and 0.86 logCS.

In mesopic lighting condition, however, were measured average values of constrast sensitivity of 1.54, 1.43, 1.24, 0.65 and 0.45 logCS respectively for 1.5, 3, 6, 12 and 18 degree/cycles in the first group, and respective values 1.61, 1.67, 1,58, 1,13 and 0.63 logCS in the second group. The CS values of each patient are schematically shown in Appendix Tab. 9-12.

In table Tab. 2.8 e 2.9 are compared the differences between CS levels, respectively, in Group 1 and 2, between the photopic and mesopic lighting conditions. In the table Tab.2.10 are illustrated the differences between CS values reported in the two groups.

Tab. 2.8. Comparison between the average values of the CS Group 1 for 5 different levels of cycles/degree (A, B, C, D, E).

Group 1	*photopic*	*mesopic*	*p*
A (1.5)	1.57 (0.23)	1.54 (0.25)	0.61
B (3)	1.62 (0.25)	1.43 (0.08)	0.004*
C (6)	1.68 (0.24)	1.24 (0.48)	0.005*
D (12)	1.35 (0.21)	0.65 (0.61)	0.001*
E (18)	0.64 (0.53)	0.45 (0.46)	0.1

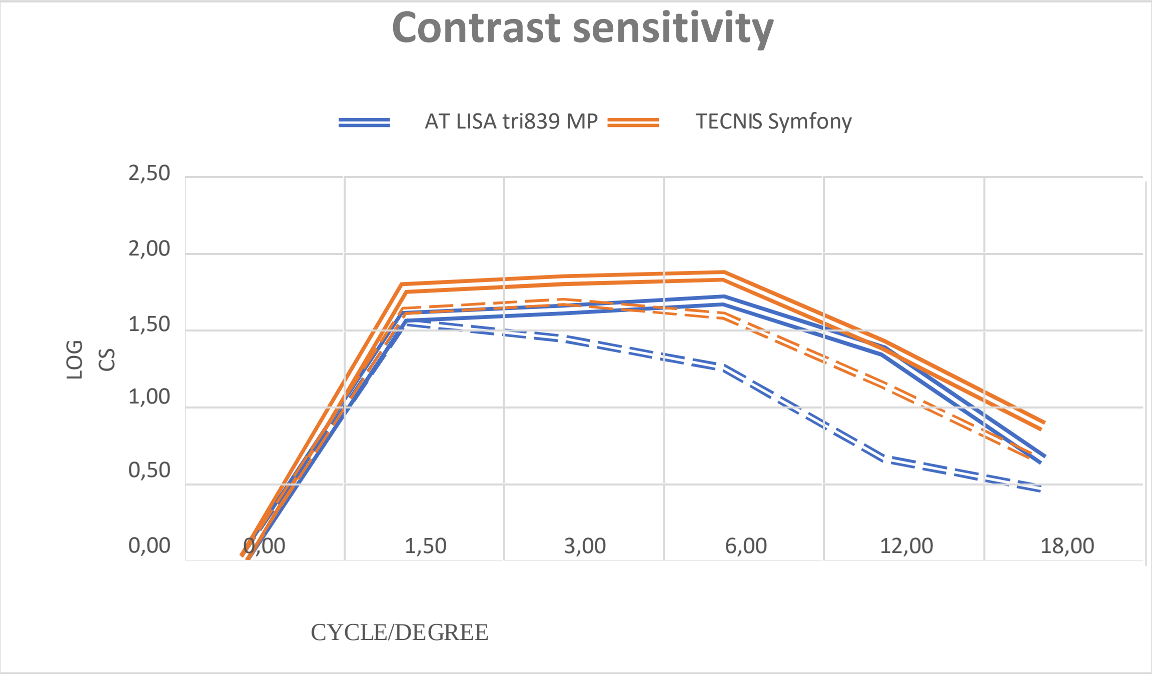
Tab. 2.9. Comparison between the average values of the CS Group 2 for 5 different levels of cycles/degree (A, B, C, D, E).

Group 2	*photopic*	*mesopic*	*p*
A (1.5)	1.76 (0.21)	1.61 (0.21)	0.001*
B (3)	1.81 (0.24)	1.67 (0.12)	0.025*
C (6)	1.84 (0.2)	1.58 (0.3)	0.035*
D (12)	1.39 (0.21)	1.13 (0.56)	0.17
E (18)	0.86 (0.45)	0.63 (0.44)	0.22

Tab. 2.10 Comparison between the average values of CS the two groups, for different levels of cycles/degree (A, B, C, D, E) and in both lighting conditions photopic and mesopic.

		Group 1	*Group 2*	*p*
A (1.5)	*photopic*	1.57 (0.23)	1.76 (0.21)	0.039*
	mesopic	1.54 (0.25)	1.61 (0.21)	0.46
B (3)	*photopic*	1.62 (0.25)	1.81 (0.24)	0.06
	mesopic	1.43 (0.08)	1.67 (0.12)	<0.001*
C (6)	*photopic*	1.68 (0.24)	1.84 (0.2)	0.09
	mesopic	1.24 (0.48)	1.58 (0.3)	0.054
D (12)	*photopic*	1.35 (0.21)	1.39 (0.21)	0.6
	mesopic	0.65 (0.61)	1.13 (0.56)	0.56
E (18)	*photopic*	0.64 (0.53)	0.86 (0.45)	0.27
	mesopic	0.45 (0.46)	0.63 (0.44)	0.32

Fig.2.2 Graph of the contrast sensitivy trend in photopic (solid line) and mesopic (dashed line)conditions



2.2.4. Patients self-evaluation

After the visit at three months after surgery on the second eye, the patients of the two groups were asked about self-evaluation of postoperative results and in both groups were reported positive responses.

The 100% of patients confirmed an optimal distance and intermediate vision. The 67% of the patients of Group 1 reported a total independence from reading glasses, the remaining 33% reported to use them little and partially. In the Group 2, 60% of patients reported total independence from reading glasses and the remaining 40% reported use them in most of the reading activity.

The 100% of patients in both groups reported maximum independence from glasses at distance and at intermediate vision and optimal visus at all observation's distances studied.

2.3. Discussion

Below are discussed the evidence previously reported as the average results of visual acuity and contrast sensitivity.

2.3.1. Improvement in visual acuity

The measurement of visual acuity at different distances of observation and in dual lighting conditions, allowed a comprehensive study of the visual performance with both the lenses studied. The results, very satisfactory, are in agreement with the optical - functional characteristics of the two IOL and with their objectives. As illustrated, the first follow-up shows in both groups, a significant improvement of visual acuity at all viewing distances studied ($p < 0.01$) compared to preoperative visit. At one month after surgery to the second eye are measured, in fact, visual acuity values at 4m of 0.0 logMAR (10/10) in both groups, at 80 cm of 0.1 logMAR in both groups and values at 40 cm of 0.2 and 0.3 logMAR respectively for Groups 1 and 2. The best correction for close distances by trifocals compared to multifocals represents the only statistically significant difference between the values of the two groups at the first follow-up (p 0.01); it is due to the presence of the third optical zone that characterizes the trifocals, with focus point for short distances.

Visual acuity was measured again during the follow-up visit at one month after surgery to the second eye: the results are very satisfactory in both groups and improvements compared to the preoperative visit are statistically significant ($p < 0.05$) in all three observation distances evaluated.

During the visit at three months in both groups we note a further improvement in the average visual acuity at all distances studied but the majority of these further improvements are not significant, so that we can assert that only after one month after surgery of cataract have been achieved optimal levels of vision with both types of IOL. The visual acuity has been measured in dual lighting conditions: the differences of the average values of visual acuity between photopic and mesopic condition were found significant in both groups, especially in Group 1.

A further comparison between the two types of lenses, three months after surgery on the second eye, confirmed a significantly better correction for close distances with trifocals and a minor reduction of visual acuity in mesopic condition with EDOF multifocal. In addition, the distance vision was found to be 10/10, optimal in both groups (0.0 logMAR or more in 100% of patients) and the intermediate vision has so resulted significantly enhanced (0.1 logMAR or less).

2.3.2. The levels of contrast sensitivity

In both groups, it appears that there are fewer levels of CS in mesopic rather than in photopic lighting condition: this reduction of contrast is significant, in both groups, especially for low values of cycles/degree (3-12 in Group 1, 1.5-6 in Group 2). For higher values of cycles/degree (18, E) the differences between the lighting conditions tend to be reduced, in consideration of the physiological decrease of photopic CS for high values of cycles/degree.

In Tab. 2.10 the differences in the levels of CS between the two groups are illustrated: in both groups were found satisfying results of photopic CS: for most of the measurements, these levels are included in the CS physiological range expected by the instrument (threshold values of the normal range: 1.4, 1.6, 1.65,1,034 and 0.78 logCS respectively for 1.5, 3, 6, 12 and 18 cycles/degree).

In Group 2 were measured CS higher levels compared to Group 1. However, most of the differences between the two groups were not statistically significant, to indicate the attainment - with both IOLs – of a CS significantly approaching to that of a phakic eye and higher than that of standard MIOLs.

The trifocal IOLs, despite the presence of three continuous optical zones (which reduces the transmittance of the radiation within the lens in each trasition zone), showed average levels of CS photopic within the expected range. However a reduction of CS is reported in mesopic condition, the reported values remain within the normal range for low values of cycles/degree.

The reason of the IOL Symphony lower contrast reduction in mesopic condition, compared to trifocal, probably resides in contemporary correction of spherical and chromatic aberration that characterizes the lens, already discussed.

In addition to the low value of the intermediate distance, a further compromise of the standard MIOLs is represented by the reduction of contrast sensitivity (especially in low-light condition). However, over time, this tends to progressively improve and - according to some authors (Schmitz et al.,2000) - 6 months after surgery to approximate those of monofocal lenses, not reaching them. The TECNIS Symfony, correcting dual spherical and chromatic aberration, is able to guarantee high levels of CS: TECNIS Sinfony IOLs CS levels are identical to those of a monofocal lens and significantly higher than those of the standard MIOLs (Bormann, 2016)

2.3.3. Satisfaction and self-assessment of patients

After the visit at 3 months after surgery on the second eye, each patient was required a self-assessment of obtained result, his satisfaction of the quality of the vision and his independence by glasses levels reached or the frequency of their use in daily hours.

The results reported with both type of IOLs are considered very satisfactory: 100% of the patients achieved spectacle independence for distance and for intermediate distance. With regard to the reading distance, however, differences between the two groups were identified: 33% of the first group patients reported of sporadically use reading glasses, the 40% of patients of the second group reported use them in most of the reading activity. The above percentages are in agreement with the visual acuity values for the near vision reported in the two groups, higher in the trifocal IOL group.

The positive self-assessment of patients confirms that the possible presence of glare and halos, especially around intense light sources and in the night hours, did not significantly influence patient satisfaction.

2.3.4. Comparison with the evidence in scientific medical literature.

The results obtained in the trial are in agreement with those published in the scientific literature. The average values of photopic monocular and binocular acuity obtained at 1 month visit are similar to those found in a study conduct by Mojzis et al (2014), in the Regional Hospital of Havlickuv Brod,Czech Republic. The average values of monocular and binocular acuity obtained at the 3 month control are similar to those found in a study conduct by Marques and Ferreira (2015).

It was impossible to compare the data obtained in mesopic vision as there are no found in literature works inherent.

CONCLUSIONS

For 28 patients with presbyopia and cataract were implanted two types of IOLs correcting presbyopia: for Group 1 (18 patients) trifocal IOLs and for Group 2 (10 patients) multifocal Extended depth of field IOLs.

1. One month after surgery and Trifocal IOLs implantation for Group 1 patients average binocular visual acuity at 4 m was -0.01 logMAR units; at 80cm intermediate vision 0.12 logMAR units and at near 40 cm distance 0.23 logMAR units.
2. One month after surgery and multifocal Extended depth of field IOLs implantation for Group 2 patients average binocular visual acuity at 4 m was -0.01 logMAR units; at 80 cm intermediate vision 0.08 logMAR units and at 40 cm near distance 0.31logMAR units.

3. Three months after surgery to the second eye for Group 1 patients in photopic conditions binocular average visual acuity at 4 m was – 0.02 logMAR units; at 80 cm distance 0.10logMAR units and at 40 cm distance 0.18logMAR units. For the same patients average mesopic conditions visual acuity was at 4 m distance 0.02logMAR units; at 80 cm distance 0.25logMAR units and at 40 cm 0.31logMAR units.

4. Three months after surgery to the second eye for Group 2 patients in photopic light conditions binocular average visual acuity at 4 m was of -0.05logMAR units; at 80 cm equal 0.14logMAR units and at 40 cm near distance 0.36logMAR units. For the same patients average mesopic conditions binocular vision acuity at 4 m was 0,02logMAR units; at 80 cm equal 0.25logMAR units and at 40 cm distance 0.31logMAR units.

5. In photopic light conditions binocular distance vision acuity for all patients with trifocal IOLs and Multifocal IOLs was equal or better as 0.00 logMAR units for 100% patients, the intermediate visual acuity for all patients reached values of 0.10logMAR units or better.

6. For 40 cm vision trifocal IOLs show statistically significantly better vision acuity 0.18 logMAR units in reference to Extended field multifocal IOLs (0.25 logMAR unit).

7. Three months after surgery was measured contrast sensitivity for 1.5, 3, 6, 12 and 18 cycles/degree in photopic and mesopic conditions. For Group 1 patients with trifocal IOLs in fotopic conditions contrast sensitivity was 1.57, 1.62, 1.68, 1.35 and 0.64 logCS respectively, for Group 2 patients with multifocal IOLs average photopic values was 1.76, 1.81, 1.84, 1,39 and 0.86 logCS. In mesopic conditions Group 1 patients average contrast sensitivity was 1.54, 1.43, 1.24, 0.65 and 0.45 logCS and for Group 2 patients average respective contrast sensitivity values was 1.61,1.67, 1,58, 1,13 and 0.63 logCS.

8. Group 2 multifocal IOLs patients contrast sensitivity in photopic and mesopic conditions show better values as for Group 1 patients with trifocal IOLs. However, most of the differences between the two groups were not statistically significant.

FINAL WORDS

A useful suggestion for subsequent studies is to add to the tests already discussed the reading speed test in both postoperative follow-ups and in the two photopic and scotopic light conditions respecting the penumbra adaptation times aiming to the evaluation of the reading speed, the acuity of reading, and the critical print size

It is advisable to use two different reading board systems such as the MNRead system and the RADNER system more standardized and with a greater restrictions in the sentence structure and to compare the obtained values in both photopic and scotopic light conditions. It would also be well to consider a group of younger patients for a greater collaboration during post-operative testing and with a greater adaptation capacity.

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APPENDIX

Values of visual acuity and contrast sensitivity of individual patients in both groups studied, with relative averages and standard deviations.

Tab. 1 Values of refraction in logMAR preoperative of Group 1 (Trifocal) in photopic light condition;*UDVA*= UncorrectedDistanceVisualAcuity,*UIVA*=UncorrectedIntermediateVisualAcuity,*UNVA*=UncorrectedNear VisualAcuity.

		UDVA			**UIVA**			**UNVA**	
Pazienti	OD	OS	**BIN**	OD	OS	**BIN**	OD	OS	**BIN**
1	0,2	0,2	**0,2**	0,22	0,1	**0**	0,32	0,36	**0,26**
2	0,4	0,48	**0,4**	0,8	0,9	**0,6**	0,8	0,86	**0,8**
3	0,2	0,3	**0,2**	0,2	0,32	**0,2**	0,5	0,4	**0,4**
4	0,98	0,38	**0,3**	0,4	0,3	**0,34**	0,4	0,4	**0,38**
5	0,7	0,74	**0,4**	0,38	0,38	**0,24**	0,3	0,24	**0,2**
6	0,2	0,2	**0,1**	0,2	0,2	**0,1**	0,4	0,52	**0,32**
7	1	0,04	**0,04**	0,9	0,48	**0,4**	1	0,78	**0,8**
8	0,7	0,7	**0,7**	1,2	1,1	**1,1**	0,9	0,9	**0,9**
9	0,56	0,74	**0,3**	0,62	0,74	**0,54**	0,92	0,9	**0,84**
10	0,22	0,2	**0,2**	0,24	0,1	**0**	0,34	0,36	**0,26**
11	0,4	0,5	**0,42**	0,8	0,9	**0,6**	0,8	0,88	**0,8**
12	0,2	0,28	**0,2**	0,2	0,3	**0,2**	0,5	0,38	**0,4**
13	0,98	0,38	**0,32**	0,4	0,3	**0,32**	0,4	0,4	**0,4**
14	0,72	0,74	**0,44**	0,38	0,38	**0,24**	0,3	0,26	**0,24**
15	0,2	0,2	**0,2**	0,2	0,2	**0,2**	0,42	0,52	**0,34**
16	1	0,1	**0,1**	0,9	0,45	**0,4**	1	0,78	**0,8**
17	0,7	0,72	**0,7**	1,1	1,1	**1,1**	0,9	1	**0,9**
18	0,58	0,72	**0,5**	0,62	0,74	**0,56**	0,92	0,9	**0,8**
Media		0,49	**0,32**		0,52	**0,4**		0,61	**0,55**
±σ		0,28	**0,19**		0,33	**0,32**		0,27	**0,27**

Tab.2Values of refraction inlogMAR preoperative of Group2(Multifocal)in photopic light condition;*UDVA* =UncorrectedDistanceVisualAcuity,*UIVA*=UncorrectedIntermediateVisualAcuity,*UNVA*=UncorrectedNear Visual Acuity

		UDVA			**UIVA**			**UNVA**	
Pazienti	OD	OS	**BIN**	OD	OS	**BIN**	OD	OS	**BIN**
1	0,9	0,6	**0,56**	0,86	0,46	**0,5**	0,5	0,46	**0,3**
2	0,1	0,1	**0,1**	0,8	0,74	**0,56**	0,36	0,2	**0,1**
3	1	1	**1**	0,96	0,9	**0,9**	1,2	1,2	**1,1**
4	1	0,66	**0,74**	0,94	0,94	**0,84**	1,12	1,2	**1,1**
5	0,7	0,56	**0,4**	0,56	0,34	**0,34**	0,64	0,26	**0,26**
6	0,9	0,6	**0,56**	0,86	0,46	**0,5**	0,5	0,46	**0,3**
7	0,1	0,1	**0,1**	0,8	0,74	**0,56**	0,36	0,2	**0,1**
8	0.08	0,9	**0,8**	0,76	0,8	**0,8**	1,2	1,2	**1,1**
9	1	0,66	**0,6**	0,8	0,94	**0,8**	1	1	**1**
10	0,72	0,56	**0,52**	0,56	0,36	**0,34**	0,64	0,26	**0,26**
Media		0,61	**0,54**		0,73	**0,61**		0,69	**0,56**
±σ		0,34	**0,28**		0,2	**0,21**		0,39	**0,45**

Tab.3Values of refraction in logMAR 1 month after surgery on the second eye of Group1(Trifocal) in photopic light condition; *UDVA*=UncorrectedDistanceVisualAcuity,*UIVA*=UncorrectedIntermediateVisualAcuity,*UNVA* =UncorrectedNearVisualAcuity.

	UDVA			**UIVA**			**UNVA**		
Pazienti	OD	OS	**BIN**	OD	OS	**BIN**	OD	OS	**BIN**
1	0	0	**0**	0	0,1	**0**	0,2	0,2	**0,2**
2	0	0	**0**	0,2	0,2	**0,2**	0,3	0,3	**0,3**
3	0,06	0,06	**0**	0,2	0,14	**0,2**	0,24	0,1	**0,2**
4	0,08	0	**0**	0,2	0,2	**0,08**	0,26	0,26	**0,24**
5	0,1	0,04	**0,02**	0,12	0,12	**0,1**	0,2	0,3	**0,24**
6	0	0,02	**0**	0,3	0,14	**0,1**	0,3	0,28	**0,2**
7	0	0	**-0,1**	0,1	0,1	**0,04**	0,26	0,1	**0,1**
8	0	0,06	**0**	0,26	0,26	**0,2**	0,38	0,3	**0,3**
9	0	0	**0**	0,18	0,22	**0,2**	0,34	0,36	**0,3**
10	0	0	**0**	0	0,1	**0**	0,2	0,2	**0,2**
11	0	0	**0**	0,2	0,2	**0,2**	0,3	0,3	**0,3**
12	0,06	0,06	**0**	0,2	0,14	**0,2**	0,24	0,1	**0,2**
13	0,06	0	**0**	0,22	0,2	**0,08**	0,24	0,26	**0,24**
14	0,1	0,04	**0,02**	0,12	0,12	**0,1**	0,2	0,3	**0,22**
15	0	0,02	**0**	0,3	0,14	**0,1**	0,3	0,28	**0,2**
16	0	0	**0**	0,1	0,1	**0,04**	0,24	0,1	**0,1**
17	0	0	**0**	0,18	0,22	**0,2**	0,34	0,36	**0,32**
18	0	0,06	**0**	0,26	0,26	**0,2**	0,38	0,3	**0,3**
Media		0,02	**-0,01**		0,12	**0,12**		0,26	**0,23**
±σ		0,03	**0,02**		0,07	**0,08**		0,08	**0,07**

Tab.4Values of refraction inlogMAR 1 month after surgery on the second eye ofGroup2(Multifocal)inphotopic light condition;*UDVA*=UncorrectedDistanceVisualAcuity,*UIVA*=UncorrectedIntermediateVisualAcuity,*UNVA* =UncorrectedNearVisualAcuity.

	UDVA			**UIVA**			**UNVA**		
Pazienti	OD	OS	**BIN**	OD	OS	**BIN**	OD	OS	**BIN**
1	0	-0,06	**-0,05**	0	0,04	**0**	0,14	0,32	**0,16**
2	-0,04	-0,1	**-0,04**	0,16	0,1	**0,08**	0,38	0,38	**0,4**
3	0,04	0	**0**	0,52	0,1	**0,1**	0,78	0,46	**0,52**
4	0	0,1	**0**	0,1	0,12	**0,12**	0,42	0,48	**0,16**
5	0,02	0	**0**	0,12	0,1	**0,1**	0,42	0,32	**0,3**
6	0	-0,06	**-0,05**	0	0,04	**0**	0,14	0,34	**0,16**
7	-0,02	-0,1	**-0,04**	0,16	0,1	**0,08**	0,36	0,38	**0,4**
8	0,04	0,2	**0**	0,5	0,1	**0,1**	0,76	0,46	**0,48**
9	0,1	0,1	**0,1**	0,12	0,12	**0,1**	0,44	0,48	**0,16**
10	0,02	0,02	**0**	0,1	0,1	**0,1**	0,42	0,34	**0,32**
Media		0,01	**-0,01**		0,14	**0,08**		0,41	**0,31**
±σ		0,07	**0,04**		0,13	**0,04**		0,15	**0,14**

Tab.5Values of refraction in logMAR 3 month after surgery on the second eye of Group1(Trifocal)in photopic light condition;*UDVA*=UncorrectedDistanceVisualAcuity,*UIVA*=UncorrectedIntermediateVisualAcuity,*UNVA* =UncorrectedNearVisualAcuity.

	UDVA			**UIVA**			**UNVA**		
Pazienti	OD	OS	**BIN**	OD	OS	**BIN**	OD	OS	**BIN**
1	-0,06	0	**-0,06**	-0,02	0,1	**-0,08**	0,2	0,22	**0,2**
2	0	0,06	**0**	0,26	0,2	**0,2**	0,2	0,3	**0,2**
3	0	0	**0**	0,16	0,1	**0,18**	0,2	0,1	**0,2**
4	0,04	0,04	**0**	0,2	0,18	**0.10**	0,12	0,2	**0,14**
5	0,06	0	**0**	0,1	0,1	**0,1**	0,2	0,26	**0,2**
6	0	0	**0**	0,2	0,1	**0,1**	0,26	0,24	**0,2**
7	0,15	0	**0**	0,1	0,06	**0,06**	0,34	0,12	**0**
8	-0,04	0,02	**-0,04**	0,22	0,16	**0,18**	0,22	0,32	**0,22**
9	-0,06	-0,06	**-0,1**	0,12	0,08	**0,08**	0,36	0,28	**0,26**
10	-0,04	0	**-0,06**	-0,02	0	**-0,08**	0,2	0,2	**0,2**
11	0	0,06	**0**	0,26	0,2	**0,2**	0,2	0,3	**0,2**
12	0	0	**0**	0,14	0,1	**0,16**	0,2	0,1	**0,18**
13	0,04	0,04	**0**	0,2	0,18	**0.10**	0,12	0,2	**0,14**
14	0,06	0	**0**	0,1	0,1	**0,1**	0,2	0,26	**0,2**
15	0	0	**0**	0,2	0,1	**0,1**	0,26	0,24	**0,2**
16	0,15	0	**0**	0,1	0,06	**0,06**	0,34	0,12	**0**
17	-0,06	-0,06	**-0,1**	0,12	0,08	**0,08**	0,36	0,28	**0,24**
18	-0,04	0	**-0,04**	0,22	0,16	**0,18**	0,22	0,3	**0,2**
Media		-0,01	**-0,02**		0,13	**0,1**		0,23	**0,18**
±σ		0,05	**0,04**		0,07	**0,08**		0,07	**0,07**

Tab.6Values of refraction in logMAR 3 months after surgery on the second eye of Group2(Multifocal)in photopic light condition;*UDVA*=UncorrectedDistanceVisualAcuity,*UIVA*=UncorrectedIntermediateVisualAcuity,*UNVA* =UncorrectedNearVisualAcuity.

	UDVA			**UIVA**			**UNVA**		
Pazienti	OD	OS	**BIN**	OD	OS	**BIN**	OD	OS	**BIN**
1	0	0	**0**	0,02	0,04	**0**	0,34	0,34	**0,22**
2	0,02	0	**0**	0,12	0,12	**-0,06**	0,54	0,44	**0,32**
3	-0,04	-0,02	**-0,08**	0,22	0,16	**0,2**	0,54	0,32	**0,34**
4	-0,1	0,08	**-0,06**	0,24	0,08	**0,08**	0,46	0,16	**0,1**
5	-0,1	-0,02	**-0,1**	0,08	0,02	**0,04**	0,44	0,26	**0,26**
6	0	0	**0**	0,02	0,04	**0,02**	0,34	0,34	**0,2**
7	0,02	0,02	**0**	0,12	0,12	**0,12**	0,52	0,44	**0,32**
8	-0,04	-0,02	**-0,08**	0,2	0,16	**0,18**	0,54	0,32	**0,32**
9	-0,12	0,08	**-0,08**	0,24	0,08	**0,08**	0,46	0,18	**0,14**
10	-0,1	-0,02	**-0,1**	0,08	0,02	**0,02**	0,46	0,26	**0,28**
Media	-0,01		**-0,05**	0,12		**0,07**	0,38		**0,25**
±σ	0,05		**0,04**	0,07		**0,08**	0,12		**0,08**

Tab.7 Values of refraction in logMAR 3 months after surgery on the second eye of Group 1(trifocal) in mesopic light condition; *UDVA*= Uncorrected Distance Visual Acuity, *UIVA*=Uncorrected Intermediate Visual Acuity, *UNVA*=Uncorrected Near Visual Acuity.

	UDVA			**UIVA**			**UNVA**		
Pazienti	OD	OS	**BIN**	OD	OS	**BIN**	OD	OS	**BIN**
1	0,06	0,2	**0**	0,2	0,5	**0,2**	0,36	0,66	**0,3**
2	0,04	0,16	**0,12**	0,4	0,4	**0,3**	0,4	0,5	**0,4**
3	0,08	0,18	**0,06**	0,52	0,52	**0,36**	0,52	0,42	**0,36**
4	0,1	0,02	**0,04**	0,38	0,3	**0,34**	0,3	0,32	**0,3**
5	0,06	0,1	**0,06**	0,2	0,26	**0,2**	0,3	0,4	**0,32**
6	0,1	0,14	**0,04**	0,24	0,2	**0,18**	0,3	0,3	**0,28**
7	0,14	0,04	**0**	0,1	0,2	**0,1**	0,44	0,2	**0,14**
8	-0,04	0,06	**-0,04**	0,34	0,34	**0,4**	0,5	0,4	**0,4**
9	-0,06	-0,06	**-0,06**	0,12	0,2	**0,18**	0,36	0,5	**0,34**
10	0,06	0,2	**0**	0,2	0,5	**0,2**	0,36	0,66	**0,32**
11	0,04	0,16	**0,14**	0,4	0,4	**0,3**	0,4	0,42	**0,38**
12	0,06	0,18	**0,06**	0,52	0,52	**0,36**	0,52	0,42	**0,36**
13	0,1	0,02	**0,04**	0,38	0,3	**0,34**	0,3	0,32	**0,28**
14	0,06	0,1	**0,06**	0,2	0,26	**0,2**	0,3	0,4	**0,3**
15	0,08	0,14	**0,04**	0,24	0,2	**0,18**	0,3	0,3	**0,26**
16	0,16	0,04	**0,02**	0,1	0,2	**0,1**	0,4	0,2	**0,14**
17	-0,04	-0,06	**-0,06**	0,12	0,2	**0,18**	0,36	0,5	**0,34**
18	-0,04	0,06	**-0,04**	0,34	0,34	**0,4**	0,5	0,4	**0,4**
Media		0,07	**0,02**		0,3	**0,25**		0,39	**0,31**
±σ		0,07	**0,05**		0,13	**0,1**		0,1	**0,08**

Tab.8Values of refraction in logMAR 3 months after surgery on the second eye of Group 2(Multifocal)in mesopic lightcondition;*UDVA*=UncorrectedDistanceVisualAcuity,*UIVA*=UncorrectedIntermediateVisualAcuity, *UNVA*=UncorrectedNearVisualAcuity

	UDVA			**UIVA**			**UNVA**		
Pazienti	OD	OS	**BIN**	OD	OS	**BIN**	OD	OS	**BIN**
1	0	0	0	0,12	0,1	**0,04**	0,22	0,34	**0,2**
2	0	0	0	0,12	0,1	**0,1**	0,56	0,5	**0,44**
3	-0,04	-0,08	**-0,08**	0,36	0,22	**0,2**	0,68	0,48	**0,52**
4	-0,08	0	**-0,08**	0,42	0,34	**0,34**	0,64	0,54	**0,42**
5	-0,08	-0,08	**-0,1**	0,1	0,08	**0,06**	0,36	0,26	**0,22**
6	0	0	0	0,12	0,1	**0,04**	0,22	0,32	**0,2**
7	0,4	0,2	0	0,14	0,1	**0,08**	0,56	0,5	**0,44**
8	0	0	**-0,02**	0,36	0,2	**0,22**	0,66	0,48	**0,5**
9	0,2	0	0	0,42	0,34	**0,32**	0,64	0,56	**0,44**
10	0,2	0,2	**0,2**	0,1	0,06	**0,06**	0,36	0,28	**0,26**
Media		0,05	0		0,2	**0,14**		0,46	**0,36**
±σ		0,13	**0,08**		0,12	**0,11**		0.15	**0,13**

Tab.9Contrast sensitivity values in logCS of Group 1 (trifocal) returned by the Functional Acuity Contrast Test 3 months after surgery on the second eye in photopic light condition; A, B, C, D, E = increasing values of cycles/degree.

PAZIENTI	**A(1,5)**	**B(3)**	**C(6)**	**D(12)**	**E(18)**
1	1,4	1,46	1,52	1,18	0
2	1,4	1,46	1,65	1,18	0
3	1,4	1,46	1,52	1,48	0
4	1,4	1,46	1,52	1,04	0
5	1,4	1,6	1,52	1,18	0
6	1,4	1,46	1,52	1,36	0
7	1,4	1,6	1,65	1,18	1,08
8	1,85	2,06	2,11	1,63	0
9	1,85	2,06	2,11	1,63	1,08
10	1,4	1,46	1,52	1,18	1,08
11	1,4	1,46	1,65	1,18	1,08
12	1,85	1,46	1,52	1,48	0,9
13	1,4	1,46	1,52	1,63	1,08
14	1,85	1,6	1,52	1,18	1,08
15	1,85	1,46	1,52	1,36	0,9
16	1,4	1,6	1,65	1,18	1,08
17	1,85	2,06	2,11	1,63	1,08
18	1,85	2,06	2,11	1,63	1,08
MEDIA	**1,57**	**1,62**	**1,68**	**1,35**	**0,64**

Tab.10Contrast sensitivity values in logCS of Group 2 (Multifocal) returned by the Functional Acuity Contrast Test 3 months aftersurgery on the second eye in photopic light condition; A, B, C, D, E = increasing values of cycles/degree.

PAZIENTI	**A(1,5)**	**B(3)**	**C(6)**	**D(12)**	**E(18)**
1	2	1,9	1,81	1,34	1,08
2	1,7	1,76	1,81	1,48	1,08
3	1,56	1,6	1,52	1,04	0
4	2	2,2	2,11	1,63	1,08
5	1,56	1,6	1,95	1,48	1,08
6	2	1,9	1,81	1,34	1,08
7	1,7	1,76	1,81	1,48	1,08
8	1,56	1,6	1,52	1,04	0
9	2	2,2	2,11	1,63	1,08
10	1,56	1,6	1,95	1,48	1,08
MEDIA	**1,76**	**1,81**	**1,84**	**1,39**	**0,86**

Tab.11Contrast sensitivity values in logCS of Group 1 (trifocal) returned by the Functional Acuity Contrast Test 3 months after surgery on the second eye in mesopic light condition; A, B, C, D, E = increasing values of cycles/degree.

PAZIENTI	**A(1,5)**	**B(3)**	**C(6)**	**D(12)**	**E(18)**
1	1,4	1,46	1,2	0	0
2	1,26	1,3	1,2	0	0
3	1,4	1,46	1,65	1,34	0,9
4	1,4	1,46	0	0	0
5	1,4	1,3	1,36	0	0
6	1,4	1,3	1,52	0,9	0
7	2	1,46	1,2	0	0
8	1,85	1,46	0	0	0
9	1,85	1,46	1,36	0,9	0,9
10	1,4	1,46	1,2	0	0
11	1,26	1,3	1,2	0	0,9
12	1,4	1,46	1,65	1,34	0,9
13	1,4	1,46	1,65	0,9	0
14	1,4	1,46	1,36	1,34	0,9
15	1,4	1,6	1,52	1,34	0,9
16	1,85	1,46	1,2	1,34	0,9
17	1,85	1,46	1,65	1,34	0,9
18	1,85	1,46	1,36	0,9	0,9
MEDIA	**1,54**	**1,43**	**1,24**	**0,65**	**0,45**

Tab.12Contrast sensitivity values in logCS of Group 2 (Multifocal) returned by the Functional Acuity Contrast Test 3 months aftersurgery on the second eye in mesopic light condition; A, B, C, D, E = increasing values of cycles/degree.

PAZIENTI	**A(1,5)**	**B(3)**	**C(6)**	**D(12)**	**E(18)**
1	1,85	1,76	1,81	1,48	0,9
2	1,4	1,76	1,08	0	0
3	1,56	1,46	1,08	0	0
4	1,85	1,76	1,52	1,34	0,9
5	1,4	1,6	1,52	1,34	0
6	1,85	1,76	1,81	1,48	0,9
7	1,4	1,76	1,81	1,48	0,9
8	1,56	1,46	1,81	1,34	0,9
9	1,85	1,76	1,52	1,34	0,9
10	1,4	1,6	1,81	1,48	0,9
MEDIA	**1,61**	**1,67**	**1,58**	**1,13**	**0,63**

Bachelor thesis “Presbyopia correction with multifocal intraocular lenses” is prepared in Italy.

I certify with my signature, that research has been conducted independently, there have been used only in reference list mentioned sources of information, and electronical copy correspond to printed version.

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Recommend/unrecommended thesis for defensing

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