UNIVERSIDADE DE LISBOA

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Cataract surgery and Functional Vision: The challenge of a more objective approach in pre-operative evaluation

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Abstract:

Due to the ageing of our population, the need for cataract surgery is increasing. It is generally considered to be a highly successful and cost-effective surgery. The technology of intraocular lenses (IOLs) is advancing as the objectives of the cataract surgery are becoming more embracing. We live in a digital era and patients' lifestyles are different from 15 years ago. The retirement age is more advanced than before meaning more working hours. In addition, patients have more expectations about their vision and frequently desire the spectacle independence after cataract surgery. They do not expect any complication or unsatisfactory result.

Nowadays, in consults eye care providers rely on subjective behavioral data about the patient lifestyle to assess refractive needs, selection of procedure and choice of IOLs. Will Vivior technology provide objective data for surgeons to select the best fit refractive solution according to patients needs and their lifestyle?

Visual Behavior Monitor (VBM) consists of sensors measuring the distance, ambient light, head orientation and motion. It is clipped to prescription or clean spectacles and records the patient's daily activity data for 3-5 days. Data processing is through machine learning algorithm. After downloading the data to the application, we can access our patient measured personal profile. Objective information about the distribution of visual distances helps eye care providers to understand patients' lifestyles and vision needs. Therefore, it is possible to choose the best IOL solution for the patient. With Vivior Monitor patients will have a more realistic expectation of what their personalized vision solution can achieve.

The objective of this work is to have a better understanding of the patients' working distances and improve functional vision after cataract surgery based on a more objective pre-operative approach.

Keywords: cataract surgery, functional vision, intermediate vision, VIVIOR, working distances.

Resumo:

Com o envelhecimento da população, a necessidade da cirurgia da catarata está aumentando. Em geral, é considerada uma cirurgia de elevado sucesso e com ótima relação custo-benefício. A tecnologia de lentes intraoculares (LIOs) está avançando à medida que os objetivos da cirurgia de catarata estão se tornando mais exigentes. Vivemos numa era digital e os estilos de vida dos pacientes são diferentes dos de há 15 anos atrás. A idade da reforma é mais avançada do que antes, o que significa mais horas de trabalho. Além disso, os pacientes têm mais expectativas sobre a sua visão e frequentemente desejam a independência dos óculos após a cirurgia de catarata. Eles não esperam nenhum resultado insatisfatório.

Atualmente, em consultas, os oftalmologistas contam com dados subjetivos sobre o comportamento e o estilo de vida do paciente para avaliar as necessidades refrativas, a seleção do procedimento e a escolha das LIOs. Será que a tecnologia Vivior fornecerá dados objetivos para que os cirurgiões selecionem a solução refrativa mais adequada de acordo com as necessidades dos pacientes e seu estilo de vida?

O Visual Behavior Monitor (VBM) consiste em sensores que medem a distância, luz ambiente, orientação da cabeça e movimento. É colocado nos óculos e regista os dados de atividade diária do paciente por 3-5 dias. Informações objetivas sobre a distribuição de distâncias visuais ajudam os oftalmologistas a compreender o estilo de vida e as necessidades de visão dos pacientes. Portanto, é possível escolher a melhor solução de LIO para o paciente. Com o Vivior Monitor, os pacientes terão uma expectativa mais realista do que sua solução de visão personalizada pode alcançar.

O objetivo deste trabalho é ter uma melhor compreensão das distâncias de trabalho dos pacientes e melhorar a visão funcional após a cirurgia de catarata com base em numa abordagem pré-operatória mais objetiva.

Palavras-chave: Cirurgia catarata, visão funcional, visão intermédia, VIVIOR, distâncias de trabalho

Index:

Cataracts and Cataract Surgery

1.Lens: Accommodation for all distances

The lens is a transparent biconvex structure, which helps to refract and focus the light onto the retina. The lens is composed by fibers, surrounded by a thin capsule, and is supported by zonules on either side.

Accommodation is the mechanism by which the eye changes focus from distant to near images. This is produced by a change in lens shape resulting from the action of the ciliary muscle on the zonular fibers. When the ciliary muscle contracts, the diameter of the muscle ring is reduced thereby relaxing the tension on the zonular fibers creating a more spherical shape lens and a higher refractive power which enable us to see at shorter focal distances. When the ciliary muscle relaxes, the zonular tension increases, the lens flattens, and the dioptric power of the lenses decreases.

The amplitude of accommodation is the amount of change in the eye's refractive power that is produced by accommodation. It diminishes with age and may be affected by some medications and diseases. Younger people generally have 12-16 D of accommodation whereas adults after age of 50 have less than 2 D. (JC et al., 2015)

The lens fibers are generated from the lens epithelium and migrate from the periphery towards the center. Therefore, the nucleus is made up of older fibers and newly formed fibers are in the outermost layers of the lens, the cortex. A cataract is the loss of lens transparency due to opacification of the lens.

Ageing and the loss of accommodation (near and intermediate vision).

Presbyopia is an age-related phenomenon characterized by gradual irreversible loss in accommodation of the eye. It results from a gradual thickening and loss of viscoelasticity of the natural lens causing impairment of near vision. Presbyopia has an estimated prevalence of 80% in Europe and is increasing regularly due to the aging of the population. It is a condition that results in spectacle dependence with common everyday near-vision tasks. Blurred vision and inability to see clear details at the near working distance are the hallmarks of presbyopia. Usually, it starts to become functionally apparent around 40 years and affects individuals for a considerable part of their working life. The odds of developing presbyopia increased by 16% per year from age 40 to 50. If left uncorrected or under-corrected, presbyopia can be an economic and social burden for patients by affecting their work productivity when they require demanding use of near vision to perform work-related tasks. Presbyopia is near universal in older patients presenting for cataract surgery. In cataract patients undergoing surgery, removal of the cataractous lens and implantation with an artificial intraocular lens (IOL) leads to total loss of accommodation, resulting in postoperative presbyopia. Implantation of standard monofocal IOLs corrects only distance vision without near and intermediate vision correction. Uncorrected post-operative presbyopia remains a challenge for patients and ophthalmologists. (Berdahl et al., 2020)

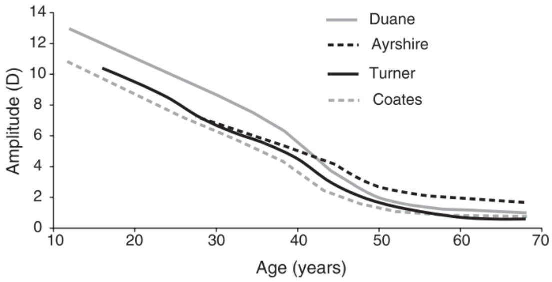


Figure 1: results from a transverse study of the mean monocular subjective amplitude as a function of age.

Cataracts

A cataract is the loss of lens transparency due to opacification of the lens. It is a common condition that, if untreated, can lead to substantial impairment of mental health, quality of life, functioning, and serious falls and fractures, mostly in the elderly population.

Cataractogenesis is a multifactorial process. Each type of cataract has it owns anatomical location, pathology, and risk factors for development. Identifying risk and protective factors provide information about prevention of cataract progression. Cataracts can be classified as:

- Age-related cataracts

- Secondary cataracts: systemic conditions such as metabolic diseases (Diabetes Mellitus) or ocular conditions such as glaucoma, myopia, uveitis.
- Congenital cataracts: lens opacity presents at birth, nucleus is the most affected part.
- Traumatic cataracts: mechanic, chemical or radiation.
- Toxic cataracts: long-term corticosteroid use is strongly associated with posterior subcapsular cataract formation.

The most common type in adults are age-related cataracts, with an average onset between 45-50 years old. Opacity of the lens is a direct result of oxidative stress. The ophthalmologist can evaluate the degree of increased color and opacification by using a slit lamp biomicroscope and by examining the red reflex with the pupil dilated. Age-related cataracts can be further divided into three types, depending on the locations of opacification within the lens. The three types are nuclear, cortical, and posterior subcapsular cataracts. In most patients, more than one type of cataract is found. Two population-based studies found that of the three types, PSC cataracts are associated with the greatest rate of cataract surgery.(Panchapakesan et al., 2003) But in an older population (mean age 79 years) undergoing cataract surgery, nuclear cataracts were most frequently encountered .(Lewis et al., 2004)

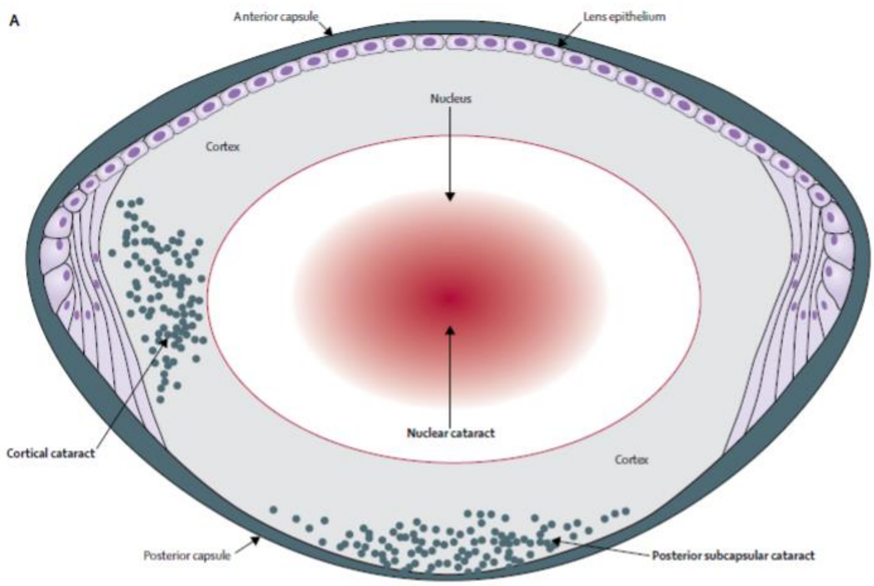


Figure 2: A schematic view of the lens structures and corresponding types of cataracts.

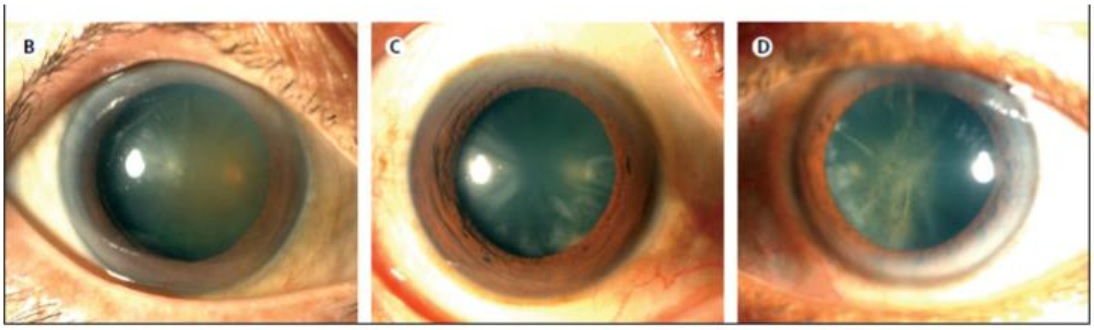


Figure 3: Slit lamp biomicroscopyphotos showing (B) nuclear cataract, (C) wedge-shaped cortical cataract and (D) subcapsular posterior cataract.

Symptoms:

Cataract is a progressive disease. Once visual acuity and function start declining, the natural history is a steady decline without any chance of recovery. The natural history of all types of cataracts is variable, unpredictable, and related in some ways to the type of cataract. Any portion of the lens can become opaque.

Patients often complain of blurred vision and describe glares and haloes from lights. Some patients might only have visual difficulty when performing daily activities such as reading or driving. Nuclear cataracts typically affect distance vision more than near vision. Posterior subcapsular cataracts often reduce near visual acuity more than distance visual acuity.

The progressive nuclear sclerotic changes cause an increase in the lens refractive index. This increase means that the cataractous lens can refract light more than before, and hence the eye becomes more myopic. If this refractive index is not corrected with glasses, the patient will experience deterioration in distance vision and paradoxically some improvement in near vision.

Cataracts Surgery: **Loss of the crystalline and accommodation.**

Treatment is indicated when visual function no longer meets the patient's needs and cataract surgery provides a reasonable quality-of-life improvement. The socioeconomic effect of cataract surgery is substantial. It allows people to increase their economic productivity by up to 1500% of the cost of the surgery during the first postoperative year. If left untreated it can result in productivity losses and severe economic burden. (WHO, 2021)

The standard of care in cataract surgery is a small-incision phacoemulsification with foldable intraocular lens (IOL) implantation. Continuous curvilinear anterior capsulotomy is done to open the capsule, to have a concentric distribution of forces. Injection of BSS to create a liquid wave that separates the lens from the capsule. (It is important to move the lens to ensure that it is separated from the capsular bag). Then the lens is emulsified by an ultrasonic hand piece and is then aspirated. During surgery, an ophthalmic viscoelastic device is injected into the anterior chamber to create some working space and to protect intraocular structures. Their use is essential to protect the corneal endothelium and other intraocular structures from manipulations during surgery. Following cataract removal, an IOL is implanted. Foldable IOL can be inserted into the capsular bag using a special forceps or can be rolled and loaded into a cartridge and then implanted by an IOL injector. Finally, hydration of all incisions is essential, there is no need to suture them.

Femtosecond laser-assisted cataract surgery (FLACS) was first described in 2010. (Liu et al., 2017) The Femtosecond Laser increases the circularity and centration of the capsulorrhexis and reduces the amount of ultrasonic energy required to remove a cataract. (Less trauma to cornea’s endothelium). Femtosecond laser makes clear cornea incisions, anterior capsulotomy, and lens fragmentation. After the laser treatment the surgeon can proceed with phacoemulsification. However, the technology may not yet be cost-effective, and the overall risk profile has not yet been shown to be superior to that of standard phacoemulsification.

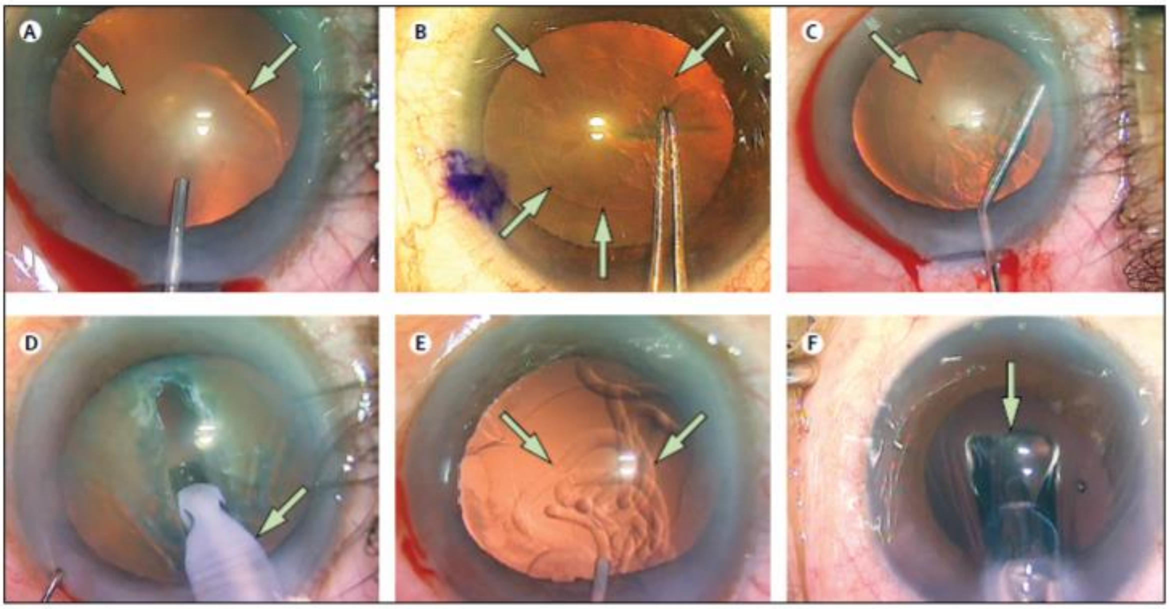


Figure 4: Surgical removal steps in phacoemulsification cataract surgery. (A) OVDs are optically clear (arrows). They are used to maintain the anterior chamber and to protect the corneal endothelium when instruments move inside the eye. (B) Continuous curvilinear capsulorrhexis is done to open the capsule, (C) and the step of hydrodissection used between the capsule and the lens cortex allows the cataractous lens to be freed from the capsular bag. (D) phacoemulsification device is then inserted to emulsify and aspirate the lens materials. (E) After removal of the lens and injection of OVDs, (F) an IOL (foldable) is implanted into the capsular bag.OVD: ophthalmic viscoelastic device; IOL: intraocular lenses.

Complications of Cataract Surgery:

Cataract surgery is a highly successful and cost-effective surgery. Despite the low incidence of complications, the surgeons must be aware because some of them are severe complications. Complications of cataract surgery can occur intra-operatively, in the early or late post-operative period.

Posterior capsule rupture is the most common intraoperative complication, with a prevalence of 0,5–5,2%. Consequences of posterior capsule rupture include retained lens fragments in the anterior chamber or vitreous, cystoid macular oedema, vitreous prolapse or traction, retinal detachment, endophthalmitis, elevated intraocular pressure, intraocular inflammation or hemorrhage, corneal oedema, and intraocular lens dislocation. The occurrence of posterior capsule rupture increases the risk of endophthalmitis and the probability of retinal detachment surgery.(Hong et al., 2015)

Postoperative corneal oedema usually occurs immediately after surgery and generally resolves within 2–4 weeks. Surgical endothelial trauma could damage the corneal endothelial cells irreversibly and lead to bullous keratopathy, a common indication to corneal transplantation. Pre-existing endothelial disease, such as Fuchs' endothelial dystrophy, is a known risk factor associated with persistent corneal oedema after surgery. (Claesson et al., 2009)

Clinical cystoid macular oedema, an inflammatory reaction of fovea, can occur after cataract surgery with peak prevalence at approximately 4-6 weeks.

Endophthalmitis is the most serious sight-threatening post-operative complication. The European Society of Cataract and Refractive Surgeons' multicenter study showed that an intraoperative intracameral injection of cefuroxime (1mg per 0,1 ml) reduced the occurrence of post-operative endophthalmitis. Risk factors include for example: intraoperative complications such as posterior capsule rupture or vitreous loss or immunosuppressive diseases. Treatment of endophthalmitis involves rapid assessment and the use of intensive fortified topical board-spectrum antibiotics and intravitreal antibiotic injections.(Gower et al., 2015)

Posterior capsule opacification (PCO), often referred to as "secondary cataract" is the most common post-operative complication of cataract extraction. In PCO, the posterior capsule undergoes secondary opacification due to the migration, proliferation, and differentiation of lens epithelial cells (LECs). PCO can cause significant visual symptoms (decreased VA, blurred vision, or glare), particularly when it involves the central visual axis. Despite advances in surgical techniques, IOL design and development of therapeutics agents to inhibit PCO this condition continues to impose a significant burden on patients and the health care system. PCO causing visual disturbance is mostly treated with neodymium: YAG (Nd: YAG) laser capsulotomy. Incidences are 11,8% at 1 year, 20,7% at 3 years and 28,4% at 5 years. (Schaumberg et al., 1998)

Intraoperative complications	
Posterior capsule rupture with or without vitreous loss	0·5–5·2%
Intraoperative iris floppy syndrome or iris prolapse	0·5–2·0%
Iris or ciliary body injury	0·6–1·2%
Lens materials dropped into vitreous	0·002–0·2%
Suprachoroidal effusion with or without haemorrhage	0–0·4%
Early postoperative complications	
Transient elevated intraocular pressure	0·3–18·1%
Corneal oedema	0·1–5·4%
Toxic anterior segment syndrome	0·1–2·1%
Intraocular lens decentration or dislocation	0·1–1·7%
Retained lens materials	0·5–1·7%
Wound leak or rupture	0·02–1·1%
Hyphaema	0·02–0·1%
Endophthalmitis	0·006–0·04%
Late postoperative complications	
Posterior capsule opacification	0·3–28·4%
Clinical cystoid macular oedema	1·2–11·0%
Pseudophakic bullous keratopathy	0·3–5·4%
Anterior capsule fibrosis and phimosis	0·47–3·3%
Chronic uveitis	1·1–1·8%
Retinal tear or detachment	0·1–1·3%
Endophthalmitis	0·017–0·05%

Figure 5: Prevalence of complications of cataract surgery

Ocular Biometry:

The knowledge of ocular biometric parameters is essential. It is known that ocular biometric parameters vary with individual characteristics (sex and age) and in different populations (ethnic).

A benefit of cataract surgery is the ability, with the right IOL power, to correct refractive errors. Accurate calculation of IOL power and identification of possible factors that might affect the accurate calculation are crucial to ensure the desired postoperative refractive results.

Important ocular biometric parameters include axial length (AL), average keratometry (Km), anterior chamber depth (ACD), lens thickness (LT). Calculation of IOL power is based on formulas that include average values of biometric parameters. The evaluation of different populations is relevant, as shown in the first 5th generation formula. The Hoffer-5A formula considers the average values of gender and race. Additionally, it is important to evaluate corneal endothelium before cataract surgery because ultrasound can cause damage.

In Portugal, a retrospective study of 3253 eyes of 2928 patients was conducted to describe the average ocular biometric parameters and their associations in a Portuguese population of patients submitted to cataract surgery. The strongest predictor of ocular biometry was sex. Male patients presented with higher AL and ACD, and thinner corneas than female patients. There was no significant correlation between age and AL, ACD or Km. This was the first study trying to characterize the biometric parameters of Portuguese population. The aim of the study was to acquire knowledge to improve the evaluation of the refractive error and the calculation of IOL power in our population. (Ferreira et al., 2017)

In the previous referred study optic biometric Lenstar (Haag-Streit AG) was used. Comparing with ultrasound biometric techniques it revealed more accurate and precise results in the evaluation of ocular biometric parameters. The same machine was used in our VIVIOR patients of Hospital da Luz, to calculate their biometric parameters.

Following cataract surgery and IOL implantation, loss of accommodation or postoperative presbyopia occurs and remains a challenge. With the recent trend towards cataract surgery becoming a refractive procedure, the accuracy of spherical refractive result has increased by using optical biometry combined with new generation intraocular lens (IOL) power calculation formulas.(Koch et al., 2017)

IOLs and their evolution: monofocal, bifocal, trifocal and EDOF.

Calculation of IOL comprise a complex endeavor that includes the combination of preoperatively, intraoperatively, and postoperatively steps. Before undergoing surgery patient’s examination and evaluation of vision loss and factors that could influence the accuracy of IOL calculations is needed. Biometric measurements, calculations of IOL using formulas and patient counseling regarding refractive targeting and the growing array of IOL options are important steps in the selection of the IOL. Intraoperatively factors include surgical precision and positioning of the IOL. Postoperatively it is important to assess the refractive and anatomic outcome and the management of postoperative unwanted residual refractive errors (IOL rotation or exchange or piggyback IOLs), corneal refractive surgery or modification of the power of the IOL in situ.

Nowadays, the most frequently implanted intraocular lenses (IOLs) in cataract surgery are still monofocal lenses, because of their relatively low cost, their excellent outcome for far distance, and the low incidence of photic phenomena (halos and glare). This type of IOL is frequently implanted in eyes with comorbidities such as corneal or macular diseases. Recently, the increasing importance of the near and intermediate distance tasks in modern everyday life has led to a growing interest toward IOLs that may also reduce spectacle independence for intermediate distances without significant side effects, to improve quality-of-life aspects.

Defocus curve is an important concept related with the IOL topic. For example, traditional studies of functional vision with multifocal IOLs involved measurements of a patient's visual acuity at varying distances. However, this can be affected by numerous factors, such as visual quality, reading speed, or neural processing. Additionally, measuring the visual function of multifocal IOLs using this method can be affected by the angular image size, contrast, or lighting conditions. To eliminate some of these sources of error, defocus curves offer a much more controlled means of evaluating visual performance by measuring a patient's visual acuity with varying levels of defocus. Defocus curves are created by presenting a series of positive- and negative-powered lenses in front of a patient's eye and measuring the degree of "defocus" that is induced. Using 0.50-D increments, the defocus curve measures a patient's binocular visual acuity often from +1.00 D to -4.00 D. In doing so, the resulting acuity that is measured can be used to simulate what the patient's visual acuity would be at different distances. To understand this concept, we must remember the most basic formula in optics, the formula for focal length: $f = 1/D$. For example, when an emmetropic patient views a logMAR chart through a plano lens, the image is at infinity representing distance vision. Place a -2.00 D lens in front of the eyes, and this would essentially equate to viewing the chart at 50 cm (20 inches). When looking through a -4.00 D lens, it would be the visual acuity equivalent at 25 cm (10 inches). Thus, the defocus curve can be created in a more controlled means for evaluating visual acuity at various distances. Defocus curves not only allow us to measure the range of focus achieved with various means of presbyopia correction such as multifocal or accommodative IOLs, but they can also be used to assess monofocal IOLs. They allow us to better compare various multifocal technologies to one another. Additionally, they provide an incredible amount of insight into the effects of residual refractive error, corneal astigmatism, spherical aberration, pupil size, and numerous other factors that can affect visual performance of presbyopia-correcting strategies. When ophthalmologists evaluate the best strategy for cataract correction, it is important to understand that defocus curves can vary with real factors such as pupil size or residual corneal astigmatism. (Jeremy Z. Kieval, 2014)

Standard Monofocal lenses are designed to provide the best possible vision at one distance (near, intermediate, or far). Most chosen monofocal IOLs have their set for distance vision and patients use spectacles for near-vision tasks. They provide excellent outcomes for far distance and low incidence of photic phenomena. Monofocal IOLs are not capable of giving good uncorrected intermediate or near visual acuity.

Enhanced Monofocal are newly developed monofocal IOL that provides better spectacle independence for intermediate distance than conventional monofocal IOL, while preserving a similar distance visual acuity and quality. Patients implanted with Enhanced IOLs reported less need for correction for intermediate visual tasks than the conventional monofocal IOL. Spectacle independence for intermediate distance was 80% while preserving a similar distance visual acuity and quality, with a low incidence of unwanted photic phenomena. IOL Enhanced Monofocal may be the best choice for those patients who do not accept the risk of a possible impairment in visual quality, although they want more spectacle independence for intermediate distance. (Mencucci et al., 2020)

Multifocal IOLs are classified as refractive, diffractive, or combined. The refractive models provide proper far and intermediate vision, however sometimes near vision is not sufficient. They are dependent of pupil dynamics very sensitive to their centering, may cause halos and glare, and reduce contrast sensitivity. The diffractive models provide good far and near vision, but the intermediate vison may not be satisfactory in some cases. They are not so dependent of pupil dynamics and more tolerant to their centering, but they usually affect the contrast sensitivity in a greater scale. Although contrast sensitivity in patients with multifocal IOLs is diminished compared with those with Monofocal IOLs, it is usually within the normal range of contrast. Some multifocal may also correct intermediate vision. These IOL are called trifocal IOL they can provide good near, intermediate, and far vision. Trifocal IOLs are an option for patients who require a good intermediate vision.

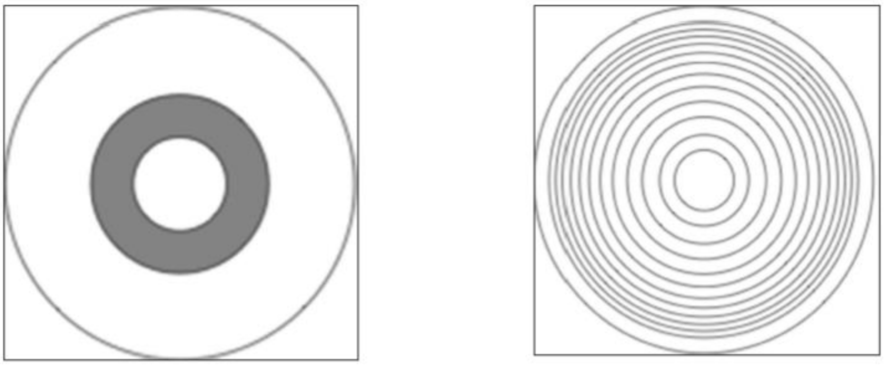


Figure 6: Schematic design of refractive IOL showing the different refractive power annular zones (left). Schematic design of diffractive IOL showing the concentric zones that diffracts light providing focus to different distances.

The main reasons for patient's dissatisfaction following a multifocal IOL implantation are residual ametropia, posterior capsule opacification (PCO), dry eye, IOL decentration, inadequate pupil size and optical high order aberrations. Also, patients frequently complaint about their vision under mesopic conditions. Residual ametropia is one of the most common reasons of patient dissatisfaction as the multifocal IOLs are more sensitive to residual refractive error. It may occur as result of inaccuracies in the biometric analysis, inadequate selection of the IOL power, limitations of the calculation formulas, or errors in the IOL position. Inadequate pupil size affects the visual acuity after IOL implantation because the pupil size determines the multifocal IOLs zones used. IOL decentration affects visual function depending on the degree of decentration, IOL design and the pupil size. (Salerno et al., 2017)

<u>Extended depth-of-focus (EDOF) IOLs</u> have only one corrective zone, but this zone is stretched to allow distance and intermediate vision. Able to provide a full range of continuous, high-quality vision without some of the limitations of multifocal IOLs. Its unique design is intended to deliver well-focused vision over an enhanced range, along with 50% less light loss than a traditional diffractive implant model. The optic design also

corrects for chromatic aberration for added clarity. The defocus curve established in clinical trials thus far shows ample uncorrected intermediate vision, in addition to clear distance and functional near visual acuities. high rate of spectacle independence. This is accompanied by a low incidence of photic phenomena, such as halos and glare. (Matossian, 2015)

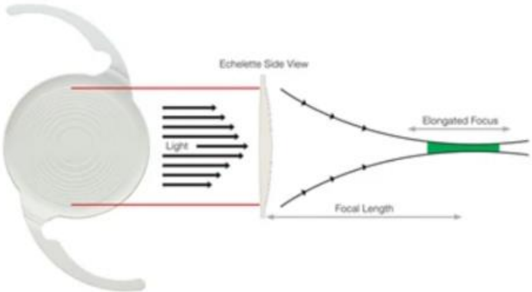


Figure 7: Schematic of EDOF IOL

Both multifocal and EDOF lenses have been shown to increase levels of spectacle independence, however both lens types may be associated with unwanted photic phenomena such as glare and halos. EDOF IOL has performed similarly with monofocal and multifocal IOLs regarding distance visual acuity results, with a trend toward superior uncorrected intermediate visual acuity, while multifocal IOLs have trended toward having superior uncorrected near visual acuity results. (H.Feldman & S.Patel, 2020)

Toric lenses refer to astigmatism correcting IOLs used to decrease post-operative astigmatism. They are universally recommended in cases with preoperative corneal astigmatism of 1D or more. It should be made clear to the patient that spectacles correction will be required for other distances (typically near and intermediate). Realistic expectations on the patient's part make for a successful outcome. With the increased importance of a perfect refractive outcome, management of astigmatism became an integral part of ophthalmic surgery. It is known that correction of astigmatism of more than 0.5 D improves the visual outcomes of cataract surgery, including visual acuity and patient’s satisfaction after surgery. (Ferreira & Ribeiro, 2020) About 29%-40% of patients submitted to cataract surgery have astigmatism of more than 1D, enough to enable visual acuity without correction. (Ferreira et al., 2017)

The presence of astigmatism adds a difficulty in presbyopia-correcting IOLs. PC-IOLs include multifocal IOL and EDOF IOL. The astigmatism must be imperatively corrected in order to maximize efficiency of the PC-IOLs. The careful selection of patient s, the knowledge about IOLs' design and their visual performance added to proper surgical technique and management of possible complications are the key for success implantation of the multifocal IOLs.

Functional Vision in Cataract Surgery: difficulties in characterizing patients working distances.

Nowadays patients are more knowledgeable about their conditions through greater access to information. Value of care is defined as health outcomes that matter to patients relative to the costs to achieve these outcomes. However, there is a lack of transparent and standardized outcome data and a lack of clarity on the definition of value. These factors slow the progress of performance improvement. Visual outcomes are patient-reported, disease-specific, risk-adjusted, and multidimensional to reflect quality of life (QoL). Based on this value definition, there is a need to accelerate the development of outcome-based quality registries to enable medical teams to evaluate, improve, and incentivize their results. (Putera, 2017)

The concept of functional vision is crucial in ophthalmology especially in areas such as cataract surgery. Due to the ageing population, the need for cataract surgery is increasing and more adequate tools for measuring the outcomes considering the patient's perception should be introduced in clinical practice. Cataract surgery is a highly successful and cost-effective intervention. The removal of the opacified crystalline has demonstrated a positive impact on the QoL of patients. However, the implantation of conventional Monofocal IOLs only allows a restoration of distance vision, with minimal postoperative functionality of near and intermediate vision, which are necessary for many common daily tasks. The use of Monofocal IOLs might limit patient functioning and consequently QoL, considering changing lifestyles and increased working years. Therefore, the analysis of a patient's ability to use vision in activities of daily living is necessary, not only the quantitative measure of visual acuity. Indeed, cataract surgery success is typically described in terms of visual acuity improvement (20/20 vision), but patients express their complaints in terms of ability loss (“I can’t work at the computer anymore”). A prospective UK-based study reported a poor correlation between visual function and visual acuity in patients after cataract surgery. (Fung et al., 2016)

The maintenance of functional ability must be the main indicator for cataract surgery and the main objective of the intervention. In Europe patients have been referred for cataract surgery if they have visual acuity of 6/12 or worse in 1 or both eyes. (Day et al., 2016) The National Institute of Health and Care Excellence guidelines for the management of cataracts says that’s visual acuity is a crude measure that fails to detect other vision problems that may justify surgery. Referral for cataract surgery should not be based just on visual acuity and should consider the impact of cataract on patient’s QoL and functioning.(National Institute for Health and Care Excellence [NICE], 2017)

Conventional measures of visual function status must be combined with the use of tools such as the Catquest-9SF questionnaire. The questionnaire analyzes the impact of the level of vision achieved on ADLs. Should be done pre-operative and post-operative. It includes items that are described by most cataract patients to be problematic (eg, walking on uneven surfaces, seeing to engage in hobbies). This tool has shown a robust psychometric performance. (Lundström & Pesudovs, 2009)

There is a need for understanding the relevance of new ADLs associated with social change in our century related to the technology growth. One example is the performance of a great variety of activities with electronic devices, that have become a routine in the last years.

Future research should be focused on defining a more accurate concept of functional vision and optimizing clinical procedures to promote patient’s satisfaction and QoL. This will allow the clinician to provide a more optimized vision care. This is the part where VIVIOR is trying to contribute. VIVIOR developed a device that will allow to have a better understanding about our patients working distances, to provide the best fitted treatment solution for each of them.

(A) Do you experience that your present vision is giving you difficulty in any way in your everyday life?

Yes, very great difficulties	Yes, great difficulties	Yes, some difficulties	No, no difficulties	Cannot decide
☐	☐	☐	☐	☐

(B) Are you satisfied or dissatisfied with your present vision?

Very dissatisfied	Rather dissatisfied	Fairly satisfied	Very satisfied	Cannot decide
☐	☐	☐	☐	☐

(C) Do you have difficulty with the following activities because of your vision? If so, how much? In each row, mark only one cross, in the square you think agrees best with reality.

	Yes, very great difficulties	Yes, great difficulties	Yes, some difficulties	No, no difficulties	Cannot decide
Reading text in the daily paper	☐	☐	☐	☐	☐
Recognise the faces of people you come across	☐	☐	☐	☐	☐
See prices when shopping	☐	☐	☐	☐	☐
Seeing to walk on uneven ground	☐	☐	☐	☐	☐
See to do handwork, woodworking, etc.	☐	☐	☐	☐	☐
Reading text on TV	☐	☐	☐	☐	☐
See to carry on an activity/hobby you are interested in	☐	☐	☐	☐	☐

Many thanks for your help!

Figure 8: Catquest-9SF questionnaire

VIVIOR: What is the best solution for each patient? Is it possible to create an algorithm based on Vivior Monitor information?

Nowadays, in consults eye care providers rely on subjective behavioral data about the patient lifestyle to assess refractive needs, selections of procedure and choice of IOLs. Does the patient rely on near vision? Does the patient frequently drive at night?

Vivior technology provides eye care providers real-time data on patient's lifestyle and recommendation about the choice of vision needs. With Vivior, access to a more objective evaluation of vision needs is possible. Therefore, ophthalmologists can choose the best IOL solution for the patient leading to a more personalized medical care.

Objective biometry data and objective behavioral data will improve patient education about their needs and potential refractive options. For surgeons provides objective data to select the best fit solution according to patient needs and their lifestyles.

Visual Behavior Monitor (VBM):

VBM consists of sensors measuring the distance, ambient light, head orientation and motion. In this study we only discussed distance and ambient light data. VMB is clipped to prescription or clean spectacles and records the patient's daily activity data for 3-5 days. Some of our patients used the VBM for longer periods of time, because of the COVID-19 pandemic and logistic around the second pre-operative consult. The minimum time for accurate results should be 36 hours. The Vivior Monitor does not include a camera or any other sensors which might infringe the privacy of the patient or other people.

Data processing is through machine learning algorithm. After downloading the data to the application, we can access our patient measured personal profile. Objective information about the distribution of visual distances helps eye care providers to understand patients' lifestyles and vision needs to choose the best treatment option.

Working distance distribution is further translated into the refraction distribution. Vivior provide a personal statistic for each day the patient is using the VBM.

For better understanding the VIVIOR application it is important to give some definitions. Near vision corresponds to vision in a range of 0,5 m. Intermediate vision corresponds to a vision range of 0,5 – 1,0 m and far vision to values superior to 1.0 m, as demonstrated in figure 9. In terms of illumination conditions, we have the terms photopic, mesopic and scotopic vision. Photopic vision is the vision under well-lit conditions, is mediated by cone cells, allows color perception, and has a significantly higher visual acuity. Adaptation is much faster under photopic conditions. Scotopic vision is the vision of the eye under low-light levels, produce exclusively through rod cells. Mesopic vision is a combination of photopic and scotopic vision in low but not quite dark lightning situations.

Figure 9: VIVIOR vision statistics of working distances (left) and schema of illumination conditions (right)

After downloading the VBM data to the VIVIOR app we have access to our patients' personal statistics for each day of VBM monitors use. VIVIOR analyzes and gives information about:

1- Distribution of viewing distances (near, intermediate, and far)
2- Distribution vs illumination matrix (photopic, mesopic, scotopic): the size of the circle is directly related to the fraction of time spent under certain distance and illumination.
3- Measurement's information.
4- Vision statistics.
5- Head motion statistics. Head motions statistics give us information about the most used head movements the person uses through out their day (head flexion and lateral bending).

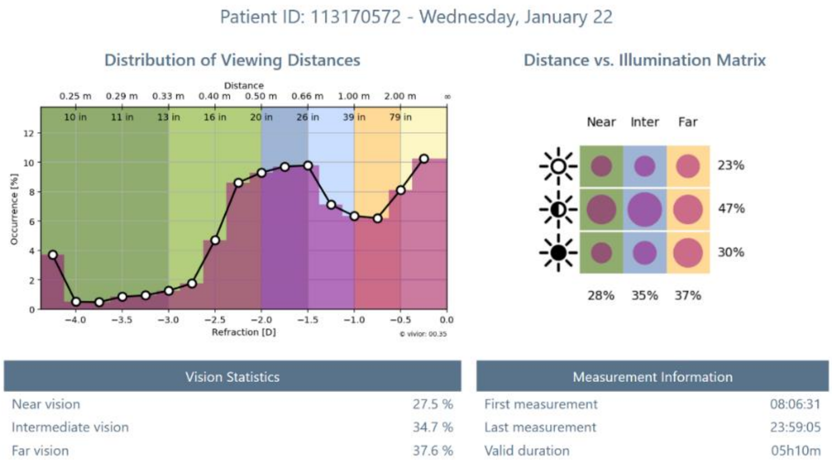


Figure 10: Example of statistics of patient ID 113170572 on the 22nd of January 2020

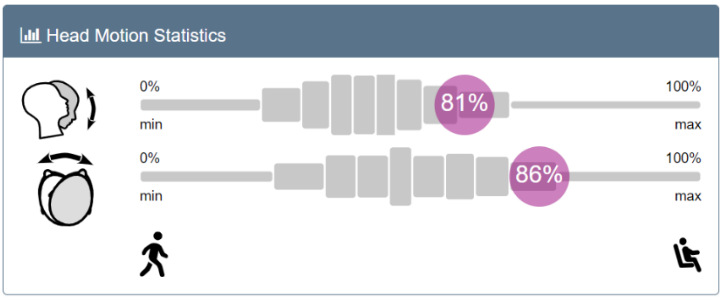


Figure 11: Head motion statistics of patient ID 113170572 on the 22nd of January 2020

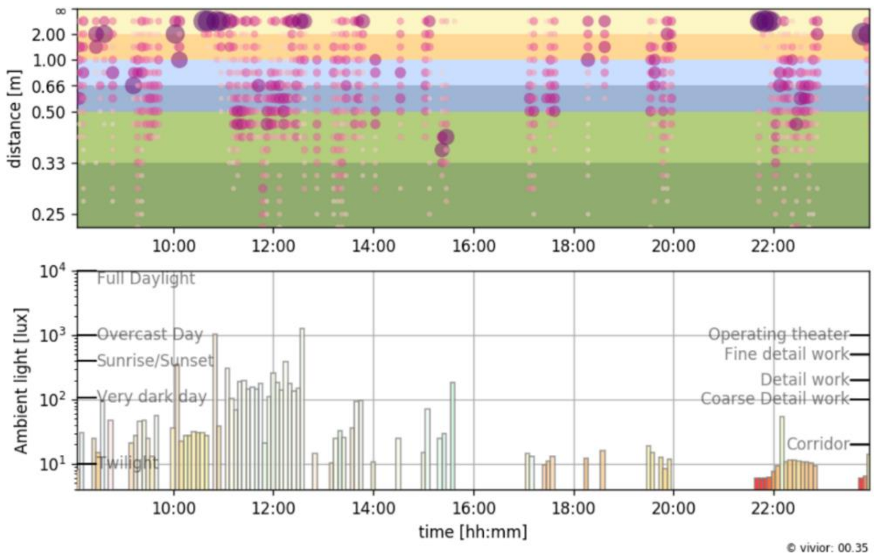


Figure 12- Time plots of distance and ambient light measurements of patient ID 113170572 on the 22nd of January 2020. Larger circles mean more frequent occurrence. Ambient Light is characterized by intensity and color.

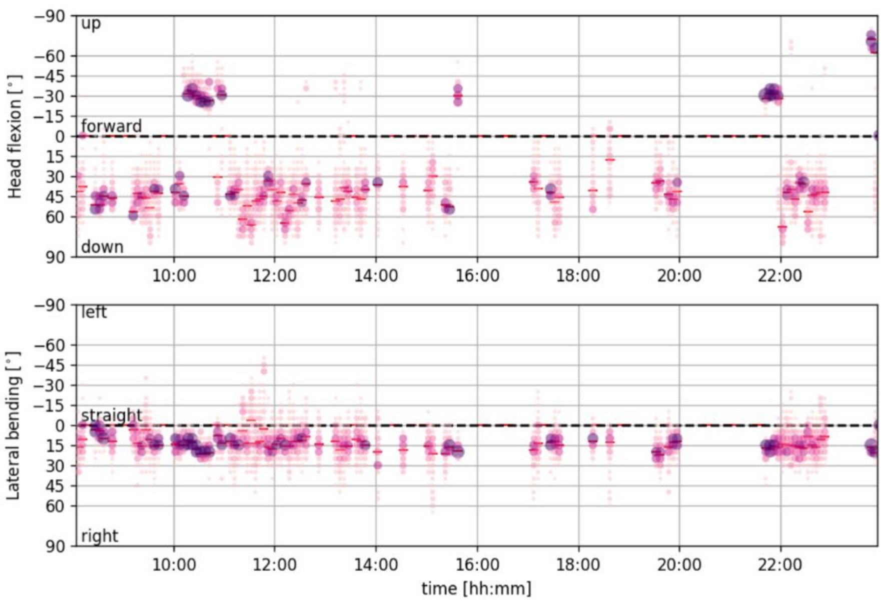


Figure 13- Time plots of head motion of of patient ID 113170572 on the 22nd of January 2020

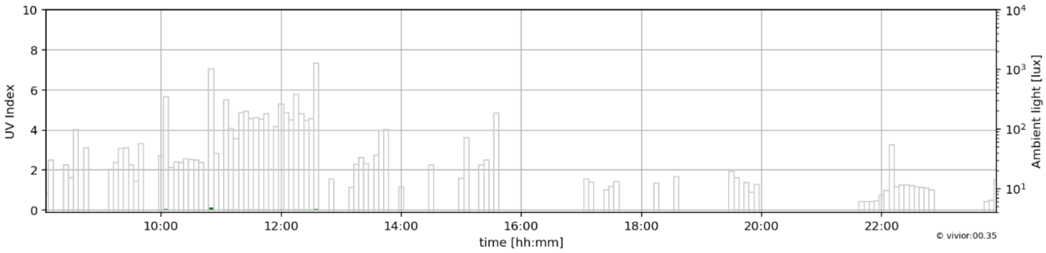


Figure 14- Time plots of UV index and ambient light of patient ID 113170572 on the 22nd of January 2020. The ultraviolet index is an international standard measurement of the strength of sunburn-producing ultraviolet radiation. UV index is calculated according to standard by World Health Organization (WHO). More information can be found at "https://www.who.int/news-room/q-a-detail/ultraviolet-(uv)-index"

VIVIOR app also provides a summary of the days that the patients used the VBM. In this summary we also have the mean statistics of the distribution of viewing distances (near, intermediate, and far), the distribution vs illumination matrix (photopic, mesopic, scotopic), measurement's information and vision statistics. Similar to the VBM day report. In addition, the summary graphics we have access to time spent in harmful UV light and time spent in the blue light. Blue light time is interpreted as digital screen time.

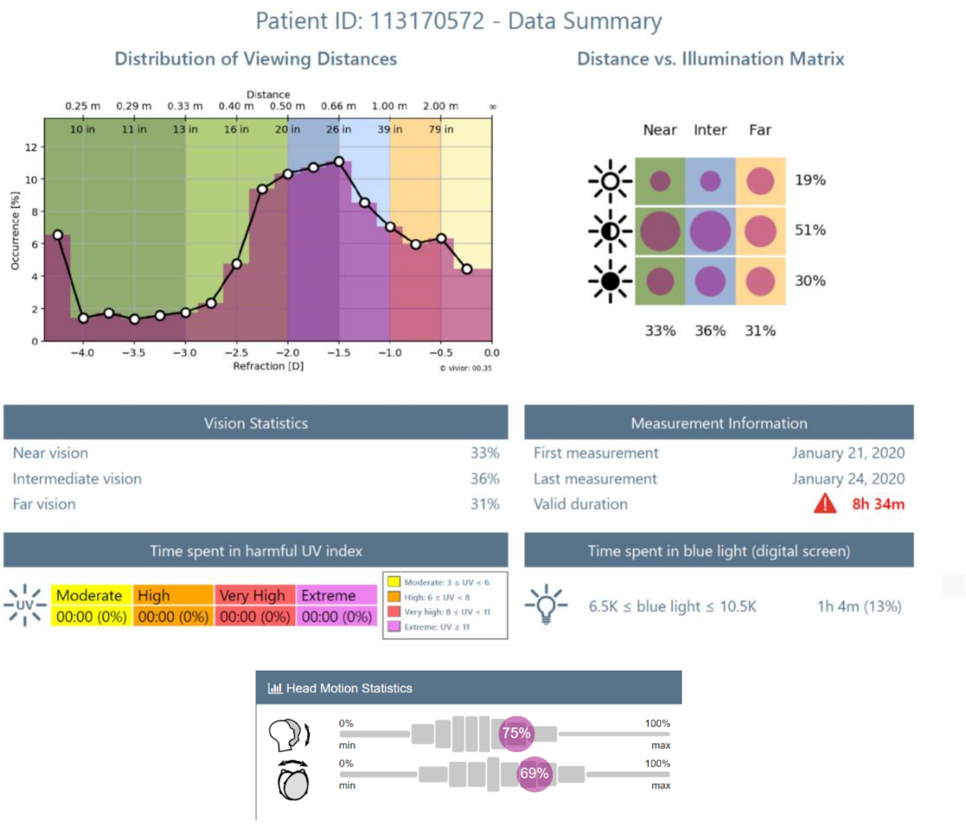


Figure 15- Summary report of patient ID 113170572 between 21st January and 24th January of 2020

The Vivior Monitor objectively measures patient’s behavior and matches it to the performance properties of a range of IOLs to compare Monofocal, bifocal, and various multifocal technologies. Lifestyle Match Index (LMI) matches the patient’s visual behavior with the defocus curve of an IOL quantifying the expected visual comfort, visual acuity and independence from additional visual support (e.g., spectacles) with the selected IOL. The lower LMI number provided corresponds to a generic monofocal IOL, while the additional impact provided corresponds to the IOL selected on the right-hand side.

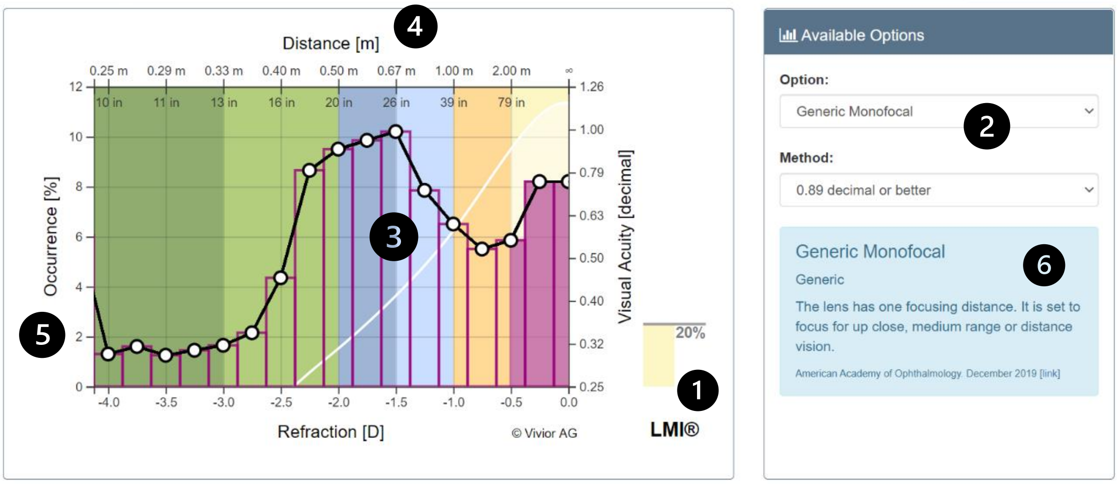


Figure 16- Lifestyle Match Index of VIVIOR for Generic Monofocal IOL

1- The lifestyle Match Index (LMI) quantifies the expected visual comfort of a patient. This percentage corresponds to a Generic Monofocal IOL which is the reference for other IOL.
2- IOL name: in the app we can select the preferred IOL to change the overlay defocus curve. In this case the chosen IOL is Generic Monofocal.
3- IOL visual acuity defocus curve: Available IOLs have different defocus curves that illustrate their potential visual acuity as a function of distance and refraction.
4- Distribution of the patient’s viewing distances according to the Vivior data.
5- Occurrence is the frequency of the patient’s viewing distances in percentage.

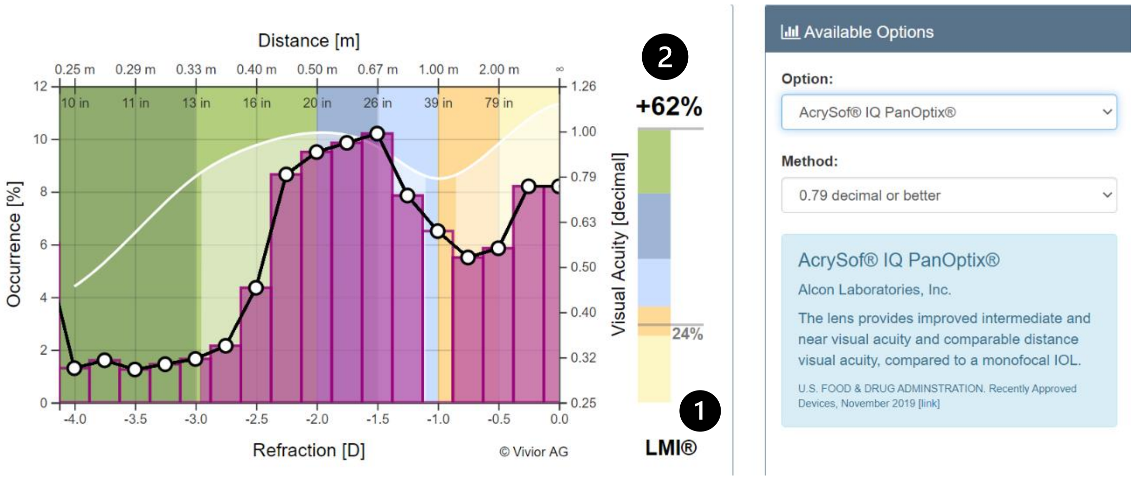


Figure 17- Lifestyle Match Index of VIVIOR for Acrysof PanOtpix IOL

1- Reference LMI corresponds to a Generic Monofocal IOL.
2- Additional LMI impact provided by the trifocal IOL.

Finally, VIVIOR app makes a report that we can deliver to our patients. In this report we have an estimation of the time that the patient will be wearing spectacles with the selected IOL. Useful in helping patients understand their daily vision needs and increase their awareness and understanding of appropriate treatment options. Patients will have more realistic expectations of what their personalized vision solution can achieve.

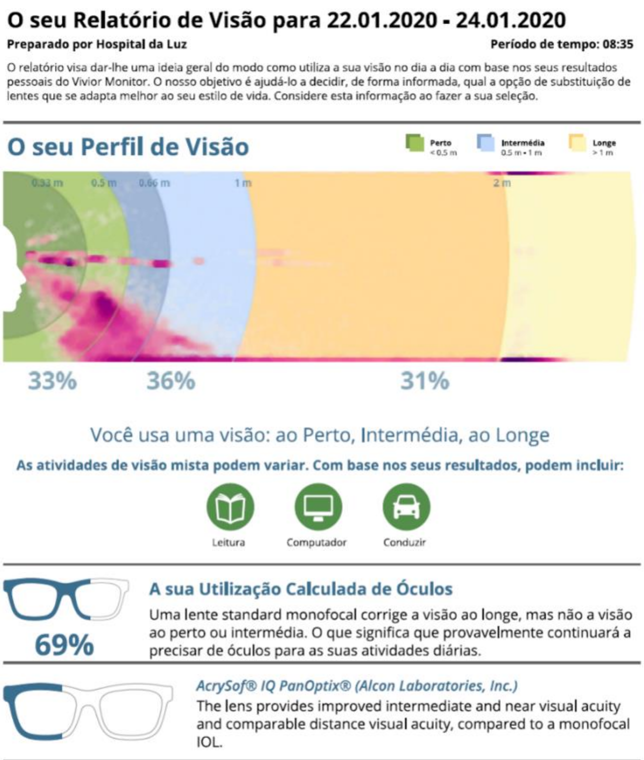


Figure 18: Vision Report by VIVIOR

VIVIOR Hospital da Luz 2020 – 2021: What is the best solution for correcting functional vision?

Objective: To have a better understanding of patients working distances and visual needs in order to improve cataract surgery outcomes related to functional vision. Trying to characterize patients vision pattern using a pre-operative evaluation with VBM to improve quality of life and patient's satisfaction.

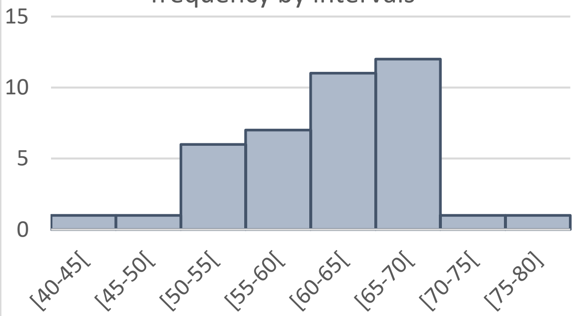
Methods:

Since 8th January 2020 until 29th March 2021 VIVIOR study in Hospital da Luz included a total of 40 patients (N=40). All patients were schedule for bilateral cataract surgery. There were 3 VBM available, each of them was delivered in the first consult and then received in the next week. Each patient received a Vivior box which included: VBM, four adapters and a quick guide, a charger, a cable, and a pair of clear-lens glasses in case the patient does not use glasses. In the upper part of the box, there is an LCD screen and three buttons underneath to play videos on: Introduction of the Monitor and on how to use the Monitor. Each VBM was delivered to each patient in a first consult and returned in the following consult. VBM had to be clipped to prescription or clean spectacles to record patient's daily activity data for at least 3-5 days. In the consult where patients returned the VBM, their data had to be downloaded to a computer. When the Monitor was returned, the data collected was uploaded on the Vivior cloud using VIVIOR application. The Vivior software displays the results in the form of intuitive visuals.

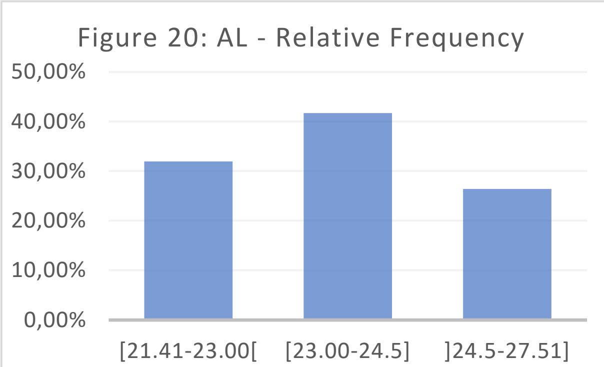
Results:

VIVIOR study in Hospital da Luz included a total of 40 patients. The media age was 60,98 ± 7,21 (43-80) years old, 42,5% were male and 57,5% were female. Age frequency intervals are represented in figure 19.

Figure 19: Patients age - Absolute frequency by intervals



Biometric parameters were measured by study optic biometric Lenstar (Haag-Streit AG). The media Axial Length was 23,85 ± 1,45 (21,41-27,51). Relative frequency of axial length is demonstrated in figure 20.



The following graphic shows the distribution of vision statistics for each patient that used VBM during the VIVIOR study in Hospital da Luz, including the patients who were operated and unoperated patients (N=40). For each patient we have access to their corresponding percentage of near, far and intermediate vision. The yellow zone represents the intermediate vision, the blue zone represents the near vision, and the green zone represents far vision. In general, prevalence of near vision is about 27%, intermediate vision is about 30% whereas far vision is 43%. As we can observe intermediate vision has a significant impact in patients' daily lifestyles.

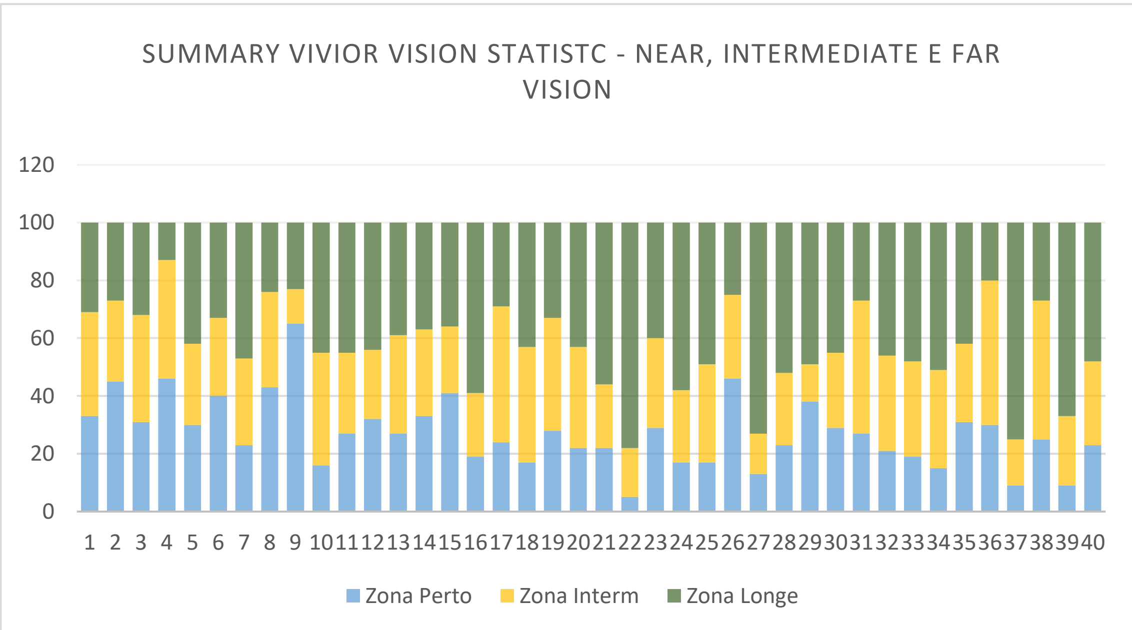
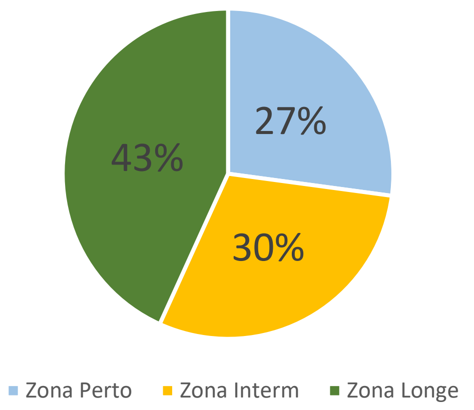


Figure 21: VIVIOR frequency distribution of working distances (near, intermediate and far) by patient.

Figure 22: Prevalence of working distances in VIVIOR patients



The next graphic shows the distribution of frequency of luminosity conditions in each patient. Luminosity conditions are divided in photopic, mesopic and scotopic. Overall, the prevalence of luminosity condition is 33% for photopic conditions, 35% for mesopic conditions and 32% for scotopic conditions.

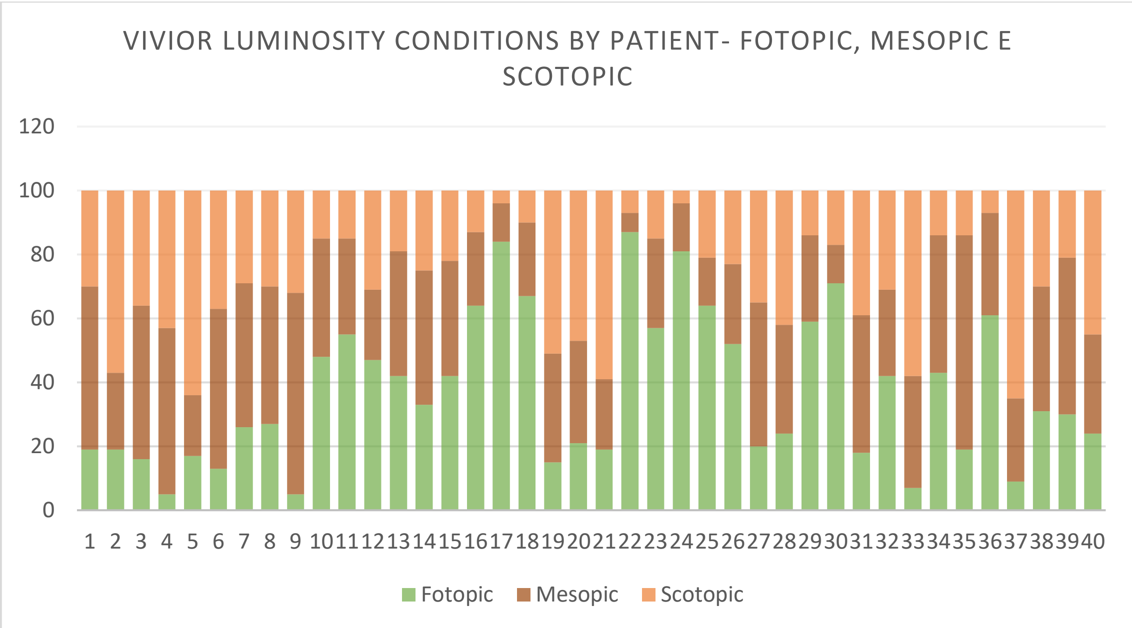
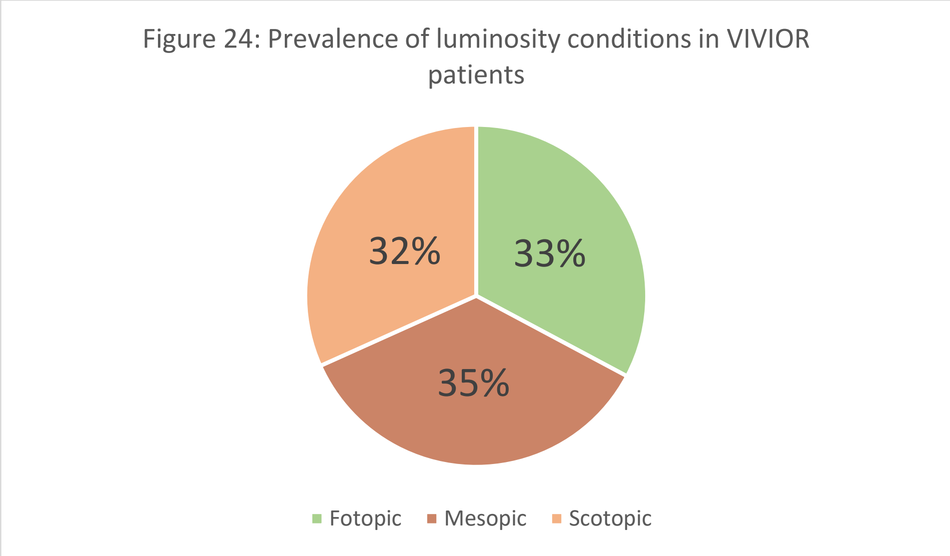
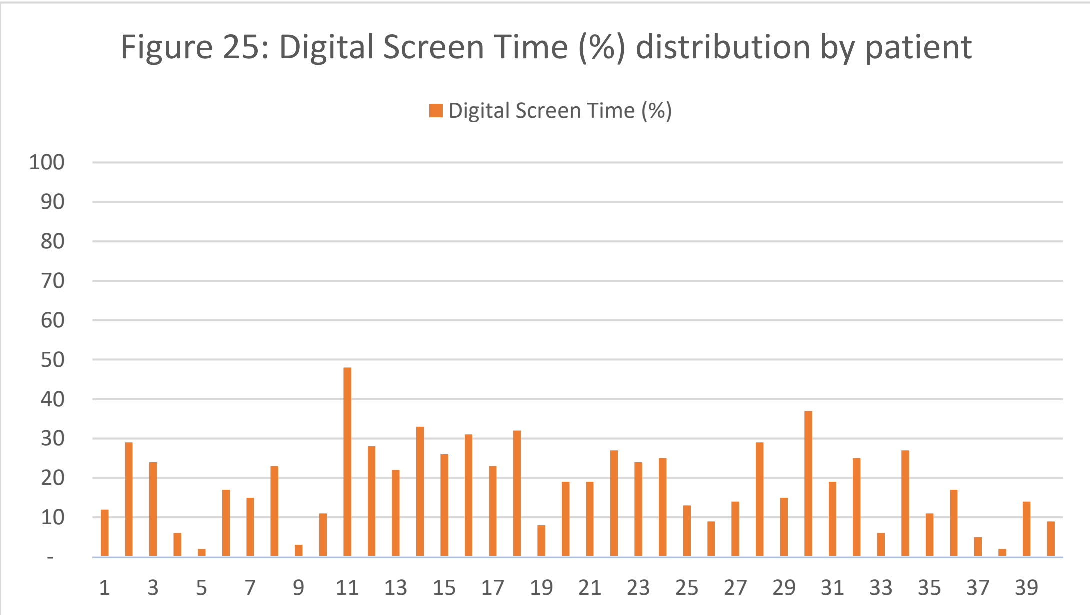


Figure 23: Vivior frequency distribution of luminosity conditions by patient- Fotopic, Mesopic e Scotopic



Vivior monitor also measures the time spent under blue light, typically known as digital screen time. Based on our data, the media of digital screen time was 5 hours and 58 minutes. This value in percentage corresponds to 18,98% of the time that our patients used the VBM. The next graphic shows the percentage of digital screen time of each patient that used VBM.



In the following graphics we can observe the Lifestyle Match Index (LMI) results. LMI allows the correspondence of patients working distance curve with defocus curve of different types of IOLs, quantifying the expected visual comfort, visual acuity, and independence from additional visual support with the selected IOL. The reference value corresponds to a Generic Monofocal IOL. In this graphic we correlate the LMI impact (%) of Generic Monofocal, EDOF, Trifocal, Enhanced Monofocal and the IOL implanted in the patient who went through cataract surgery.

Of this group of 40 patients 17 of them had cataract surgery in both eyes. Making a total of 34 eyes, meaning 34 IOLs were implanted having a pre-surgical evaluation with VIVIOR monitor. Implanted IOLs included: 23 EDOF IOLs and 11 Trifocal IOLs. This subgroup of 17 patients had the data necessary to build the graphic related with different IOLs and LMI impact. Inclusion criteria was having bilateral cataracts, visual acuity superior to 0,5 logMAR, the absence of other ocular pathologies, the use of VBM in pre-evaluation consult, cataract surgery in both eyes, and having the implanted IOL on the list of IOLs in Vivior LMI to have access to the correspondent defocus curve of the implanted IOL.

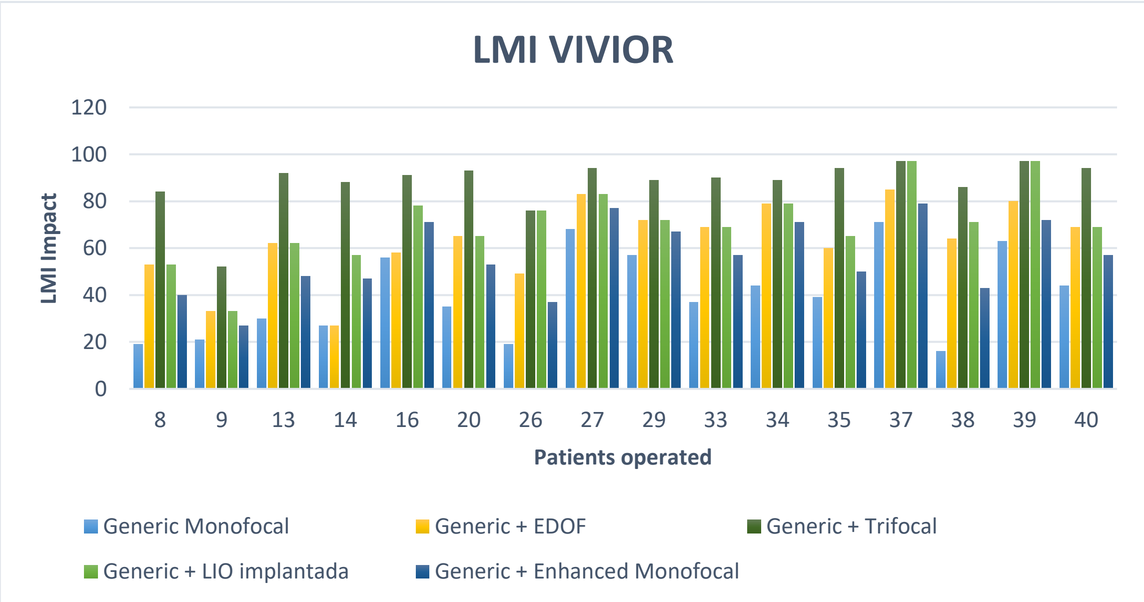
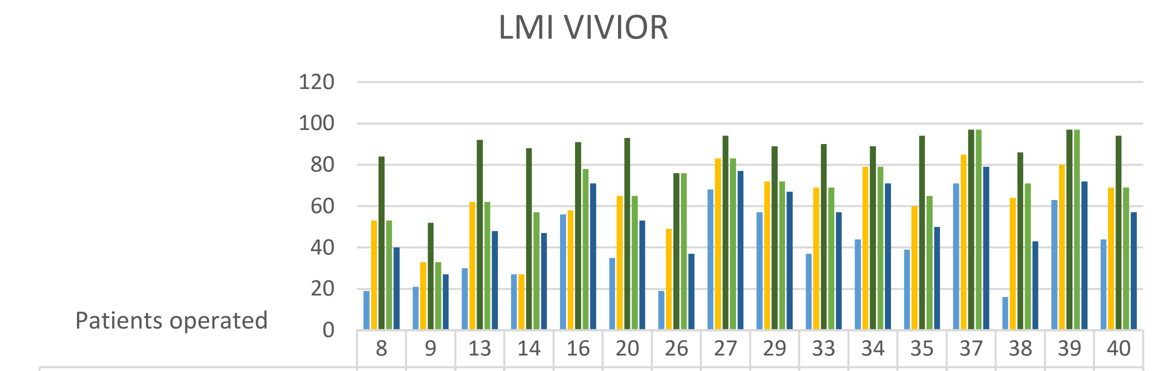


Figure 26: LMI impact distribution of different types of IOL for each case



	8	9	13	14	16	20	26	27	29	33	34	35	37	38	39	40
Generic Monofocal	19	21	30	27	56	35	19	68	57	37	44	39	71	16	63	44
Generic + EDOF	53	33	62	27	58	65	49	83	72	69	79	60	85	64	80	69
Generic + Trifocal	84	52	92	88	91	93	76	94	89	90	89	94	97	86	97	94
Generic + LIO implantada	53	33	62	57	78	65	76	83	72	69	79	65	97	71	97	69
Generic + Enhanced Monofocal	40	27	48	47	71	53	37	77	67	57	71	50	79	43	72	57

Figure 27: Numeric values of LMI impact provided by the different types of IOL for each case.

Discussion:

Working distances distribution: Nowadays with the changing of lifestyle habits, it is important to acquire knowledge about current working distances. There is a clear disparity of working distances in different professions and differences related with gender. With Vivior monitor we had access to the distribution of frequency of near, intermediate, and far vision for each patient. Observing the frequency distribution, we can conclude that intermediate vision is as important as near vision in patients quotidian. In general, prevalence of intermediate vision is about 30%. Meaning that intermediate vision has a significant impact in patients' daily lifestyles. This concept might be a twisting point for ophthalmologists because it is frequent in clinical practice to measure the outcomes of cataract surgery based on the references for near and far vision only. The dimension of intermediate vision is often forgotten and as we can observe it has a great impact in patients' lives. However, in the last years intermediate vision was not well described and characterized. With VBM we have more objective information related with intermediate vision. With Vivior study we hope to obtain more evidence about the importance of intermediate vision and improve cataract surgery outcomes related with it. This topic is highly correlated with the definition of functional vision and its importance in the evaluation of cataract surgery candidates.

Luminosity Conditions: More than 50% of the time patients work under mesopic and scotopic conditions. The percentage of vision work under mesopic and scotopic condition is surprisingly high.

Digital screen time: This information is a very important feature because we live in a digital era. For example, monofocal IOLs are better for patients that use the computer most part of the day because it is associated with less photopic phenomena. Since our patients had different recording VBM timings, the most important value to analyze is the percentage of digital screen time of each patient. As demonstrated in figure 25, our patients spent an important part of their days in front of screens. In average each patient spend 18,25% of their day looking at a screen.

The access to the distribution of working distance, luminosity conditions and digital screen time of each patient is very relevant when choosing the IOL for cataract surgery. It allows the surgeon to choose the most fitted IOL for the patients' vision pattern and expectations.

Lifestyle Match Index (LMI): regarding the most important correlation of Vivior. The objective of comparing the defocus curve of the different types of IOL and the implanted IOL was to ensure the choice of IOL was the best for the patients' vision pattern and expectations. Comparing the LMI impact of the 17 patients, 14 of them have an IOL that does not correspond to the best fitted option in terms of visual comfort and spectacles independence. Between the given options, the IOL related with the highest LMI impact, was the Generic Trifocal. Only 3 patients had an IOL implanted that corresponded to the highest LMI impact. These 3 patients implanted a Trifocal IOL in both eyes. It is also important to take in account the economic flexibility of our patients. Monofocal are the cheapest IOLs in the market whereas Trifocal are more expensive.

With Vivior monitor we have the advantage of combining objective data of patient's visual needs with the subjective information they give us during consults. When choosing the type of IOL ophthalmologist must know patient's preferences, professional activity, hobbies, to understand what the most relevant working distance besides the information of distribution of vision statistics. Therefore, talking with the patient before surgery is essential to try to analyze their daily visual needs and choose the IOL model that best fits their lifestyles. Explaining to patients all factor involved in the outcomes of the surgery and possible complications management is crucial. The choice of the IOL depends on patients' characteristics, visual expectations, and preferences. Involving patients in the process of decision making is fundamental for the success of cataract surgery. With VIVIOR each patient can access to a more graphic and objective information about their vision needs, and therefore, choose the best option for them. As shown in the results, the IOL with highest LMI impact (%) in most cases did not correspond to the IOL implanted during cataract surgery.

Study limitations:

This study had several limitations mainly related with the number of patients. The study had a duration of approximately 1 year. Because of the Covid-19 pandemic the study was interrupted between February and May 2020. When the study restarted, the timing of the second consult to deliver the VBM was longer than a week apart from the first consult. Due to the pandemic the rate of data collection diminished, the surgeries and follow-up consults were delayed. Additionally, 17 patients who used VBM were never operated. Indicating that these patients abdicate surgery, probably related to COVID-19 pandemic. Additionally, in the middle of the study the data base of defocus curves of VIVIOR LMI underwent some alterations, changing the course of the data analyzes.

Conclusion:

Cataract management is an essential step in the healthy ageing of our population. functional vision is becoming more and more relevant for daily activities in the modern society because of increased use of the computer, tablet, and smartphone. Furthermore, it is necessary to a variety of daily tasks such as looking at a car speedometer or walking on an uneven ground. If untreated, can lead to substantial impairment of mental health, quality of life, functioning, and serious falls and fractures.

The technology of presbyopia correction IOLs is advancing as the objectives of cataract surgery are becoming more embracing. Patients have more expectations about their vision and frequently desire the spectacle independence after surgery. In addition, they do not expect any complication or unsatisfactory result. With Vivior patients are more knowledgeable about their conditions through greater access to information. VIVIOR provide us a perspective of investigation on outcomes that should be measured to give the best possible solution for our patients and optimize the results of cataract surgery. With VIVIOR data we have a better assessment of functional vision.

The maintenance of functional ability must be the main indicator and objective for cataract surgery. Future research and efforts should be focused on achieving a better understanding of the relationship between visual function and the ability to perform ADLs in the context of a multidisciplinary approach.

Agradecimentos

Em primeiro lugar, gostaria de deixar o meu agradecimento ao Professor Doutor Carlos Neves por, prontamente, ter aceitado que eu realizasse o meu Trabalho Final de Mestrado no âmbito da Clínica Universitária de Oftalmologia, e à Professora Doutora Filomena Teixeira pela sua orientação, revisão e críticas que muito me ajudaram na realização deste trabalho. Sem a sua partilha de conhecimento e disponibilidade, a conclusão do mesmo não seria possível.

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A jornada é longa, mas ainda agora começou.

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