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Optical and Visual Quality of Two Scleral Lenses

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STATEMENT OF INTEGRITY

I hereby declare having conducted this academic work with integrity. I confirm that I have not used plagiarism or any form of undue use of information or falsification of results along the process leading to its elaboration. I further declare that I have fully acknowledged the Code of Ethical Conduct of the University of Minho.

RESUMO

Atualmente, as lentes esclerais são bastante adaptadas em pacientes que sofrem de doenças da superfície ocular. Estes dispositivos são também indicados em várias doenças ou irregularidades corneais devido à sua capacidade de criarem um reservatório de líquido, que irá compensar a maior parte das irregularidades da superfície.

As inovações tecnológicas têm providenciado uma larga diversidade de desenhos e materiais de lentes esclerais. Contudo, ainda existem poucos estudos que reportem o uso prolongado destas lentes e como a qualidade ótica pode ser influenciada por este uso prolongado. Assim, com este trabalho pretende-se avaliar a resposta da superfície ocular quando uma lente nova e diferente é adaptada bem como entender se é possível readaptar usuários habituais de lentes esclerais a partir dos dados obtidos com a topografia corneal.

Neste estudo, os resultados com uma lente escleral (Senso Mini Sclera, 16.4 mm), usada durante mais de 12 meses, foram comparados com os resultados de uma nova lente de outra marca de lentes esclerais (ICD, 16.5 mm), readaptada e usada durante 1 mês. Dos principais resultados obtidos, observou-se que existiam algumas diferenças na qualidade ótica entre a Senso Mini Sclera e a ICD, no entanto os resultados subjetivos não mostraram diferenças significativas relativamente à visão e ao conforto entre ambas as lentes. Os dados da resposta da superfície ocular mostraram valores significativamente mais baixos de hiperemia bulbar, hiperemia limbar, tingido limbar e tingido corneal após 1 mês de uso da lente ICD, quando comparados aos valores obtidos imediatamente após retirar a Senso Mini Sclera. Os resultados mostraram que os dados de elevação na corda de 6mm, obtidos com um topografo corneal comum, estavam correlacionados com as alturas sagitais das lentes ICD diagnóstico e finais. Os resultados com a lente ICD em duas visitas diferentes (após 3h, na visita de entrega, e após 1 mês) não revelaram diferenças significativas, mostrando que a avaliação a curto prazo é um bom preditor dos resultados a médio prazo. Em conclusão, com este estudo foi verificado que pode ser possível readaptar usuários habituais de lentes esclerais com outra lente escleral, apesar de possuírem características diferentes, mantendo a qualidade ótica e o conforto. As pequenas diferenças entre as duas lentes podem estar relacionadas com o tempo de uso da Senso Mini Sclera, que pode ter um pequeno impacto na degradação da qualidade ótica. Os resultados deste estudo sugerem que as maiores respostas da superfície ocular com a Senso Mini Sclera podem ser devido à degradação que a lente sofre com o tempo ou devido às diferenças nos materiais das lentes.

Palavras-chave: altura sagital, córnea irregular, lente escleral, qualidade ótica.

ABSTRACT

Nowadays, scleral lenses are largely fitted to patients who suffer from ocular surface diseases. These devices are also indicated in several corneal disorders or irregularities due to the capability of create a fluid reservoir, which will compensate most of the surface irregularities.

Technological innovations have provided a large diversity of scleral lenses designs and materials. However, there are still very few studies reporting the long-term use of these lenses and how optical quality could be influenced by this long-term use. This work intents to evaluate the ocular surface response when a new different lens is fitted and to understand if it is possible to refit habitual scleral lenses users, from the data obtained with corneal topography.

In this study, the results with a scleral lens (Senso Mini Sclera, 16.4 mm), used for more than 12 months, were compared to the results of a new lens from another scleral lens (ICD, 16.5 mm), refitted and used during 1 month. From the main outcomes obtained, it was observed that there were a few differences on optical quality between Senso Mini Sclera and ICD, although the subjective results showed no significant differences relatively to vision and comfort between both lenses. The data from ocular surface response showed lower statistically significant values of bulbar hyperemia, limbal hyperemia, limbal staining and corneal staining after 1 month of ICD lens wear when compared to the values immediately after Senso Mini Sclera removal. The results showed that the 6mm chord elevation data, obtained with a common corneal topographer, was correlated with diagnostic and final sagittal depth of ICD lenses. The results with ICD in two different visits (after 3h on the dispensing visit and after 1 month) did not reveal significative differences, showing that the short-term evaluation is a good predictor of the medium-term behavior. In conclusion, with this study we verified that might be possible to refit habitual scleral lens users with another scleral lens, despite the different characteristics, maintaining the optical quality and comfort. The small differences between the two lenses may be correlated with Senso Mini Sclera lifetime, which could have a small impact on optical quality degradation. The results of this study suggest that the highest ocular surface response values with Senso Mini Sclera might be due to the degradation that lens suffered over time or due to the differences on lenses material.

Keywords: irregular cornea, optical quality, sagittal height, scleral lens

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ABBREVIATIONS AND ACRONYMS

BFC_{irreg} Best Fit Circle irregularity

$BFC_{irregSD}$ Best Fit Circle irregularity SD

CCLRU Cornea and Contact Lens Research Unit

CCZ Central Clearance Zone

CL Contact Lens

CXL Corneal Cross-linking

D Diopter

Dk lens permeability

HCDVA High Contrast Visual Acuity with the Best Distance Correction

HCVA High Contrast Visual Acuity with habitual correction

HOA High Order Aberration

HVID Horizontal Iris Visible Diameter

ICD Irregular Corneal Design

ICD Toric ICD lens with toric haptics

ICD+3h 3 hours after ICD lenses use (V2)

ICD+1month.1 month after ICD lenses use (V3)

ICRS Intra Corneal Ring Segment

IOP Intraocular Pressure

IS Inferior Superior Index

LASEK Laser-Assisted Subepithelial Keratomileusis

LASIK Laser-Assisted in Situ Keratomileusis

LCDVA Low Contrast Visual Acuity With the Best Distance Correction

LCVA Low Contrast Visual Acuity

LCZ Limbal Clearance Zone

LDA Light Disturbance Analyser

LDI Light Disturbance Index

LOA Low Order Aberration

LogMAR Logarithm of the Minimum Angle of Resolution

MDF Midday Fogging

OCT Optical Coherence Tomography

OSDI Ocular Surface Disease Index

p Statistical significance

PCCZ Peripheral Corneal Clearance Zone

PK Penetrant Keratoplasty

PMD Pellucid Marginal Degeneration

PMMA polymethylmethacrylate

PRK Photorefractive Keratectomy

PROSE Prosthetic Replacement of the Ocular Surface System

Q Asphericity

RGP Rigid Gas-Permeable

RK Radial Keratotomy

RMS root mean square

s seconds

SAI Surface Asymmetry Index

SD standard deviation

SL Scleral Lens

SLS Scleral Lens Education Society

SLZ Scleral Landing Zone

SRI Surface Regularity Index

TBUT Tear Break up Time

TFSQ Tear Film Surface Quality

TMD Terrien's Marginal Degeneration

V1 First visit

V2 Second visit

V3 Third visit

VA Visual Acuity

VAS Visual Analogue Scale

µm micrometer

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1. LITERATURE REVIEW

1.1 Historic contextualization

The initial conceptualization of neutralizing the refractive power of the cornea was suggested by Leonardo da Vinci in 1508 by putting his head inside a water container showing the role of a contact lens. For that reason, some authors consider him as a contact lens' (CL) precursor.[1] Approximately 400 years later, around 1888, the Müller brothers developed the first scleral lens (SL) and later, Fick create the first SL described in literature.[2]The first scleral "shells" (20mm of diameter) were applied in patients with corneal scarring and Keratoconus , with the goal of to try to compensate corneal aberrations, where it was observed visual improvement in one patient.[2,3] These lenses were created by blown or milled glass which was a barrier to oxygen passage to the cornea, producing edema and hypoxia. They were also difficult to handle due to their diameter and they caused discomfort. Considering all these difficulties, its application was not well tolerated.[4] The clinical practice of glass lenses was established in 1920 by Carl Zeiss, who utilized a trial set of four lenses that permitted to try some fittings with lenses that have a identified specification.[5]

These lenses evolved further with the development of new synthetic materials, namely polymethylmethacrylate (PMMA). However, although PMMA had more advantage than glass for it lower weight, due to its higher durability and a better manufacturing facility, problems related to hypoxia persisted, thought in a minor scale [6]

Some years later, in 1983, Donald Ezekiel of Perth was the first one to describe the fitting of rigid gas-permeable (RGP) SLs, fitting these devices on his patients with ocular conditions that could beneficiate from SLs.[7] The improvement on lens materials, as well as the appearance of oxygen permeable components, allowed to bring new relevance to SLs.[6]

However, the improvement on large diameter SL' materials wasn't enough to allow its commercial availability and expansion.[4] So, the growth of corneal RGP lenses (with smaller diameter) and posteriorly of hydrophilic lenses, potentially decreased the interest in SLs development during the following two decades. [5]

By the end of XX century, the CLs market continued to grow. The appearance of high oxygen permeable materials, the diversity of lenses designs and the improvement on lens diagnostic sets allowed professionals to fit SLs more often.[6] Additionally, the manufacturers' technological development and the search for better visual outcomes increased the SLs popularity.[8] Nowadays, due to all the topics

mentioned above, modern SLs are manufactured in RGP materials like fluorosilicone acrylate, a material with great Dk, which improves the oxygen transmissibility to the cornea.[9]

The first article listed in Pubmed dates of 1945. During the first ten years it was observed a low/null rate of publications till 1959. However, the number of articles stopped to grow in the last two decades of the 20th century. Since 2003, it is visible a crescent number of publications being this growth more evident between 2014 and 2018.Until the data of the search, 2018 is the year with the major number of publications. Availability of buttons to lathe large diameter RGP lenses with high-Dk materials and the increasing manufacturers contributed to the recent popularity of these contact lenses.

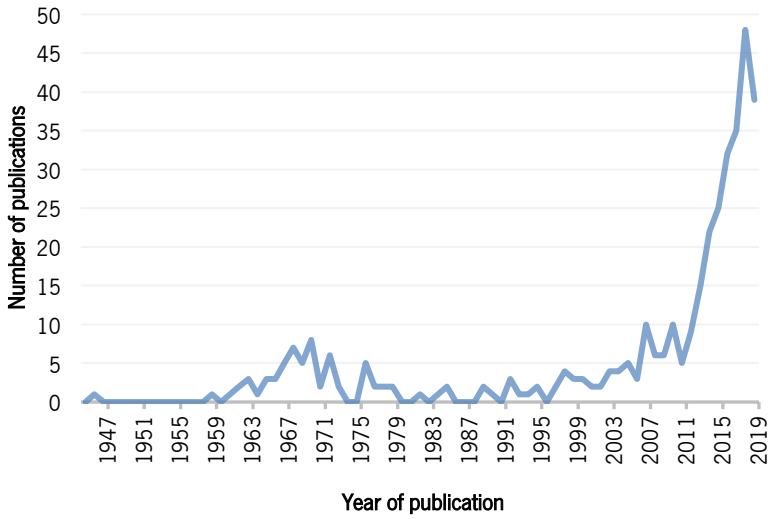

Figure 1.1 Publication rate with "scleral contact lens" keyword without non-related references (www.pubmed.com) by October 2019. Some articles from 2019 are only available in Epub.

1.2 Scleral Shape

1.2.1 Scleral and Conjunctival morphology

A SL is an optic device, made by RGP material that totally lands in the sclera and does not touch the corneal surface or limbus. This lens creates a fluid reservoir between the lens and the cornea that – together with the lens material – neutralizes the corneal irregularities and mask corneal high order aberrations, providing visual improvement. [10]

As SL land exclusively in the conjunctival surface, it is important to take into account the scleral anatomy. The conjunctiva is a thin membrane, of mucosa, vascular and transparent tissue, composed of epithelial cells and collagen. Due to this soft structure, conjunctiva is not sufficiently stable to support the lens by itself.[11] So, being the sclera a more rigid structure than the conjunctiva, it is the scleral tissue underneath the conjunctiva that ultimately supports the lens. The sclera is an opaque and resistant tissue that has an important role to maintain the ocular globe form. Besides, it offers protection to internal structures and supports the extraocular muscles insertions..[12]

1.2.2 Sclera's anatomy

As SL land exclusively beyond the corneal and limbal limits, the scleral anatomy will have an important role on the design of the lens and consequently in the lens fit on-eye. The sclera shows an asymmetric shape with a flatter nasal region. This can cause, in most of the cases, infero-temporal decentering of the lenses. Temporal decentering happens because the lens lands first in the flatter zone/ point with lower sagittal height - nasal - and tends to move on in the opposite direction until stabilization.[13] The inferior decentering occurs due to gravity and eyelid forces.

The scleral asymmetry has been widely studied in the last years. The scleral shape of eyes with regular and irregular corneas was analyzed in a recent study conducted by *Macedo-de-Araújo et al* [11]. The authors observed a progressive increment of scleral sagittal height on 14mm, 15mm and 16mm chord and also an increment of scleral asymmetry as the distance from limbus increases, with higher values of scleral sagittal height in eyes with irregular corneas.

Another study performed by *Consejo et al* [12] analyzed 90 eyes to evaluate and characterize the scleral shape in normal eyes. The authors concluded that the scleral asymmetry increases from the limbus to periphery, and that this increase could be related to muscles insertions. The lower distance between medial and inferior rectus insertions could produce the flattening of the ocular surface (on nasal and inferior zones), while the higher space between superior and lateral rectus insertions could provide

a more steepening form.[13] This distance differences in the rectus muscles insertions is called Spiral of Tillaux.

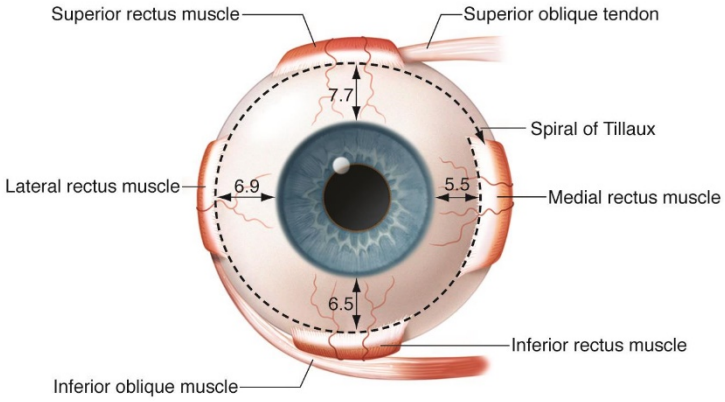

Figure 1.2 Illustrative image of extraocular muscle insertions and Spiral of Tillaux. Source: https://www.aao.org/image/new-mediabeacon-item-7, accessed in January 2019.

Taking into account that, in average, the corneal diameter is 12mm, and accepting Spiral of Tillaux's distances, the maximum diameter that a SL can have, in order to not to reach muscles insertions, is 24mm, expecting minimal or inexistent of lens movement.[5]

In the clinical practice, asymmetry or symmetry of sclera defines the geometry of the lens to be applied. Symmetry is assumed when the difference between the two principal meridians elevations at 15mm chord do not exceed 100µm.[14] The difference between elevations of the two principal meridians can be measured using Optical Coherence Tomography (OCT) or with scleral or corneal topographers. But, to those professionals who don't have this equipment, it is possible to clinically identify an asymmetric sclera. There are two ways:

•By observing a fluorescein pattern.[15] A SL with spherical landing zone on a symmetric sclera will distribute fluorescein equally, over all the meridians, but in an asymmetric sclera, the fluorescein will have the tendency to accumulate itself on the flattest meridian (**Figure 1.4 A)**

•By observing compression on the steeper meridian.[15] A SL, with spherical landing zone, on a symmetric sclera, will land equally in all meridians. However, in an asymmetric sclera, the spherical landing zone might induce localized blanching on the steepest meridian. (**Figure 1.4 B**).

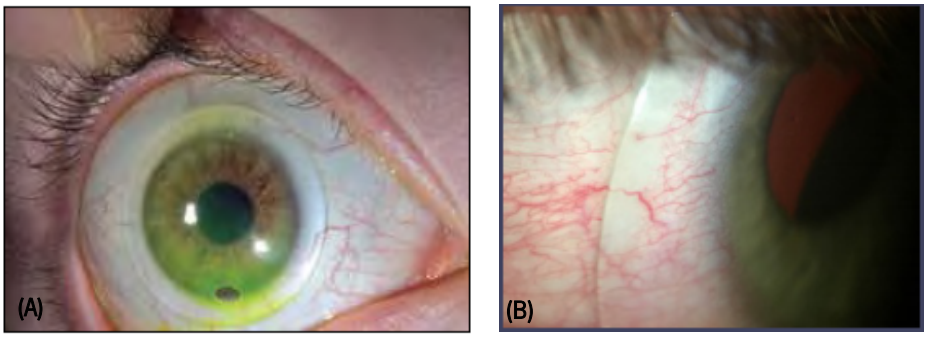

Figure 1.3 (A) Fluorescein pattern in an asymmetric sclera. Source: van der Worp (2015).[5] (B) Example of localized blanching on steepest meridian. Source: Barnett and Fadel (2018).[16]

1.2.3 Corneo-scleral transition and angles

Another structure that deserves special attention is corneo-scleral transition, as it has an important roles in total corneal sagittal height. In 1992, Meier, ocular health professional, defined several transition profiles between cornea and sclera.[17]

- In profile 1 there is a gradual transition between cornea and sclera, where the latter is convex.
- In profile 2, the transition between cornea and sclera is gradual, besides the scleral part is tangential.
- In profile 3 there is an accentuated transition, where the scleral part is convex.
- In profile 4, the transition is accentuated but the sclera is tangential.
- In profile 5 the corneal form is convex whereas sclera's form is concave.

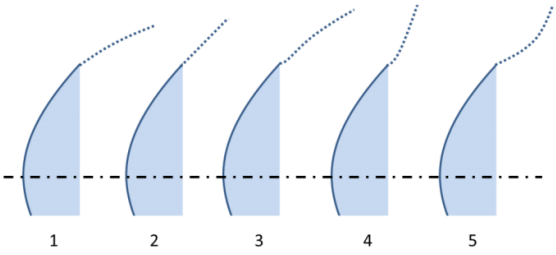

Figure 1.4 Corneo-scleral transition profiles. Source: Meier (1992).[17]

The first profile has the higher sagittal height, while the latest profile has the smaller sagittal height. *Rott-Muff et al* [18] studied the frequency of each profile in the population and the most observed was the second, shadowed by profile 3. The profile 1 was the third most frequently observed, though the prevalence of profile 4 and 5 was very similar (the profile 5 was almost inexistent in the population). More recent studies performed by *Ritzmann et al* [12] concluded that the corneo-scleral transition shows a concave shape in the nasal part and convex and tangential in the temporal part.

A study developed in the Pacific University intended to evaluate the scleral shape (The Scleral Shape Study), evaluating the corneo-scleral angles (between 10mm and 15mm chord), as well as scleral angles (concerning 15mm and 20mm). While limbal angles did not show significant differences in the different quadrants, the scleral angles revealed considerable asymmetries, mainly between the nasal quadrant and the infero-temporal quadrant [5]

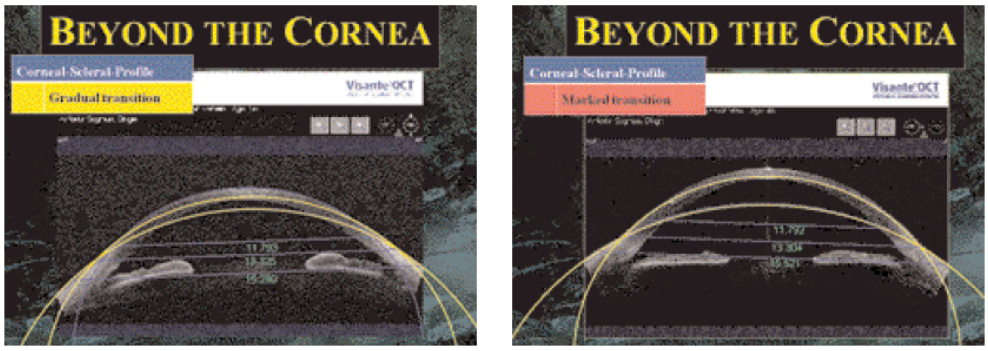

Figure 1.5 Gradual corneo-scleral transition (left) vs accentuated transition (right). Source: van der Worp et al (2010).[19]

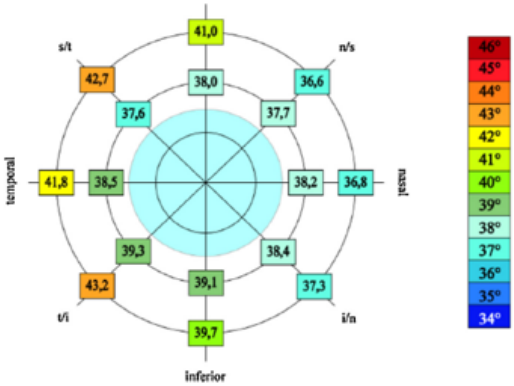

Figure 1.6 Image showing the differences between limbal and scleral angles. Source: van der Worp et al (2014).[20]

1.3 SLs classification

SLs used to be classified according to their diameter: if a lens had a diameter between 12.5mm and 15mm was considered a corneo-scleral lens; if the lens had a diameter between 15-18mm was considered mini-scleral lens and if the lens was bigger than 18mm was considered a full-scleral lens. However, this classification was revised by Scleral Lens Education Society (SLS) and the classification started to be done taking into account the lens bearing points and the horizontal iris visible diameter (HVID). According to this nomenclature, when the lens landing zone was in scleral tissue, and its diameter was 6mm higher than HVID, the lens was designated mini-scleral. If the diameter of the lens exceeded the HVID in more than 6 mm, it was classified as full scleral lens.[4] Also, SLs could be classified with relation to their landing point on the ocular surface. If the lens was fully supported by the cornea it was named corneal lens; a lens who partially landed on cornea and partially landed on sclera it was called corneo-scleral lens. Finally, if the landing was completely on the scleral tissue, regardless lens diameter, the lens was termed scleral lens.[5]

Finally, 2 years ago until now SLS decided to establish a new general classification for SL in order to not to distinguish the nomenclature of SL based on its size or based on HVID. The new nomenclature uniquely defines the term “Scleral Lens” as the lens which vaults the cornea and completely lands on conjunctival tissue, independently of other characteristics.[21]

1.4 Indications and contraindications of SL

Indications

There are many indications to SLs use. Usually, SLs are used when another type of lenses, in particular hydrophilic or corneal RGP lenses, do not promote an appropriated visual acuity (VA) or are not well accepted.[20]

SLs cover all corneal surface and offer ocular surface protection needed in some ocular conditions. Such devices can be used with tree main objectives:

- Visual improvement;
- Ocular surface protection;
- Cosmetic/Sports.

1.4.1 Visual improvement

Relatively to visual improvement, SLs have an important function in several pathologies, particularly on corneal ectasia, that may be primary and secondary (or acquired), and also in ocular trauma.

1.4.1.1 Primary corneal ectasia

Primary corneal ectasia includes conditions characterized by thinning of the cornea as Keratoconus , Keratoglobus, Pellucid Marginal Degeneration (PMD) and Terrien's Marginal Degeneration (TMD), that are non-inflammatory proceeds.[22] According to *van der Worp* [5], corneas that have undergone surgical procedures to control the ectasia, for example, Corneal Cross-linking (CXL) and Intra Corneal Ring Segments (ICRSs) can also be included in this group.

-Keratoconus

Keratoconus is an asymmetric chronic[23] disease which can be unilateral or bilateral and is characterized by a progressive increment of central cornea curvature, where the central part of the cornea assumes a cone form. As consequence of this pathology, the Bowman's layer, the corneal epithelium and the stroma have anatomical anomalies which leads to alterations in corneal thickness and corneal scarring.[23,24] Myopia and irregular astigmatism tend to increase as well as high order aberration (HOA) causing image distortions and halos compromising optical quality and damage the vision, with negative results on patients quality of life.[24] In initial states of Keratoconus, patients can beneficiate from spectacles correction, soft or silicone hydrogel lenses.[25] In more advanced situations, corneal RGP lenses, piggyback

system or hybrid lenses can be needed.[25] However, with the increase of corneal curvature, these devices are not capable of maintaining vision quality and fitting characteristics and it could be necessary to resort to another methods.

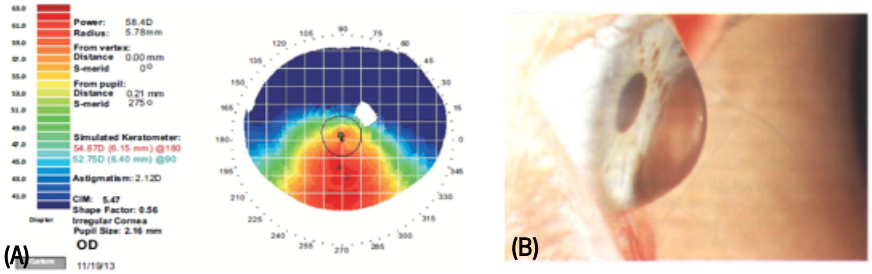

Figure 1.7 (A) Example of Keratoconus topography. Adapted from Barnett and Johns (2017).[1] (B) Profile photo of a Keratoconus case. Adapted from Pullum et al (1999).[26]

-Keratoglobus

In Keratoglobus there is a general decrease in apical thickness. Corneal globular protrusion occurs and it appears that corneal diameter is larger than normal.[27,28] As expected, the decrease of corneal thickness and ocular protrusion leads to high amounts of myopia and irregular astigmatism, which is the major reason of decreased vision. These high refractive errors are not satisfactorily corrected with spectacles because of induced irregular astigmatism and higher order aberrations.[27]

Both Keratoconus and Keratoglobus are non-inflammatory corneal conditions, differing in the local of the thinning: in Keratoconus the main thinning occurs in the infero-central portion of the cornea and in Keratoglobus the main thinning occurs in the periphery of the cornea.[29] Another difference between both is related to the disease progression, as tend to be Keratoconus more progressive than Keratoglobus.[27]

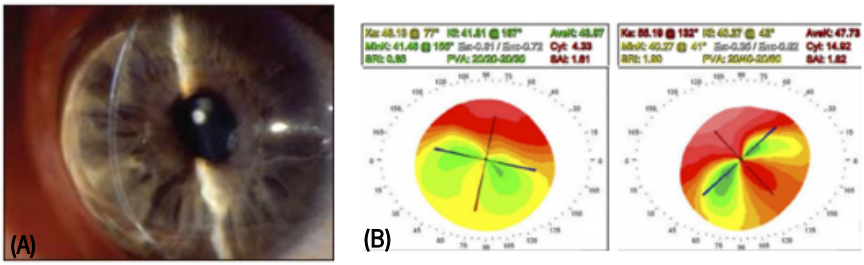

Figure 1.8 (A) Keratoglobus' case, adapted from Caroline and colleagues (2010).[30] (B) Keratoglobus topography, adapted from Mahadevan and colleagues (2013).[28]

-Pellucid Marginal Degeneration

PMD is characterized by an inferior and peripheral decrease of corneal thickness, beginning in the limbus and assuming a form of a crescent band.[1] The corneal topographic pattern normally seems like a "butterfly".[31] Contrarily to Keratoconus , where the maximal protrusion is approximately coincidental with the highest curvature, in PMD the greatest protrusion occurs above to the thinned area that is located near the limbus.[32] PMD patients have a progressive reduction of VA resultant from high amounts of regular and irregular against-rule astigmatism.[33]

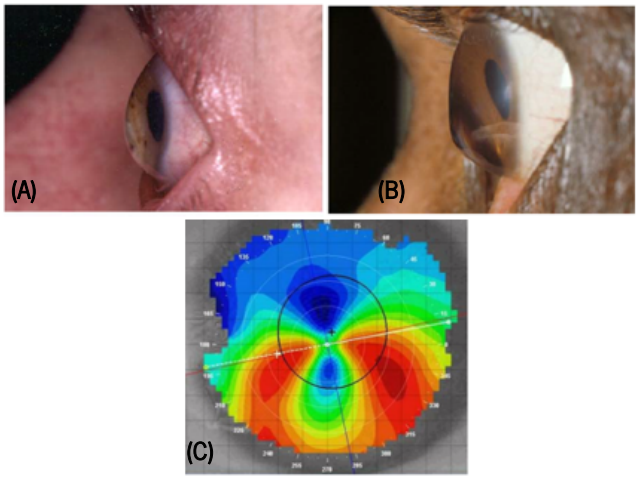

Figure 1.9 (A) Initial state of PMD. (B) Advanced case of PMD. Source: Jinabhai and colleagues.[34] (C) Topographic pattern. Source: http://www.precisionfamilyeyecare.com/pellucid-marginal-degeneration/, accessed in January 2019.

-Terrien's Marginal Degeneration

TMD is a rare condition characterized by a reduction of the peripheral corneal thickness which begins in the supero-nasal quadrant progressing to the central corneal area.[35] The flattening of the peripheral cornea has several negative outcomes particularly against-rule astigmatism resulting in poor VA.[35,36] According to the literature, patients are normally asymptomatic once the disease has a slow progression resulting in several years to develop [35] Neovascularization and yellow-white opacities in stroma with scarring and lipidic infiltrates are common.[35] In advanced stages of the disease, in which VA outcomes are very poor and/or corneal perforation occur, penetrating keratoplasty or lamellar keratoplasty could be the best option for these eyes.[37]

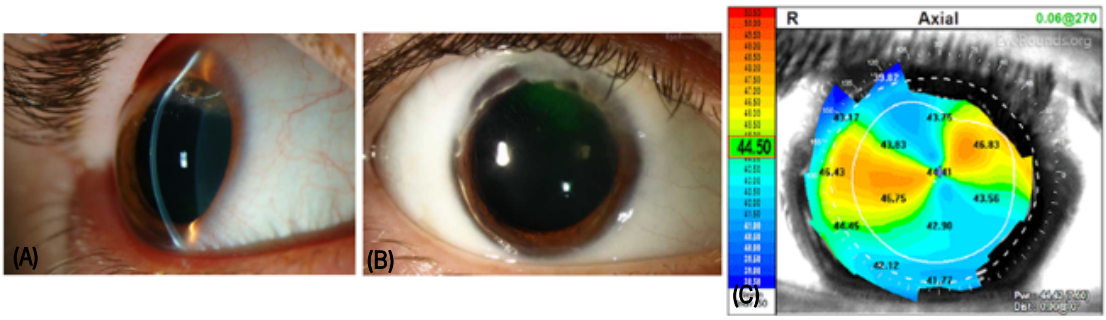

Figure 1.10 (A) Profile photo of TMD. (B) Image showing existent neovascularization in the ectasia. (C) Example of a TMD topographic profile. Source: https://webeye.ophth.uiowa.edu/eyeforum/atlas/pages/terrien.htm, accessed in January 2019.

-Intra Corneal Ring Segments

ICRSs are made of PMMA and are mainly used in primary corneal ectasias (such as Keratoconus) and secondary corneal ectasias (such as after post laser-assisted in situ keratomileusis (LASIK)).[38,39] ICRSs are implanted with the purpose of flatten the corneal curvature, which could led to a decrease in the corneal high order aberrations, and consequently improve VA and avoiding the necessity of corneal transplant.[38,40,41] These devices are an option in patients who have stable Keratoconus who aren't tolerant to CL and which VA is not satisfactory with spectacles correction. [42] A study reported that ICRSs have a lower efficacy when applied in more advanced stages of corneal disorders but successfully results are expected on middle and moderate cases.[43] However, even with ICRS implantation, it might be necessary a CL to achieve a better visual result. As ICRS implantation is a reversible surgery, it could be considered more advantageous than other procedures.[40] A review published by *Giacomin et al* [41] analyzed several indications to ICRSs implantation, mentioning Keratoconus , PMD, Post-LASIK ectasia, corneal transplant, CXL, Photorefractive Keratectomy (PRK), phakic intraocular lens implantation and other combined procedures as the main indications. The authors mentioned some types of ICRSs in the market as Intacs, Keraring, the Ferrara Ring Segment, the Corneal Ring and the MyoRing ICCR.

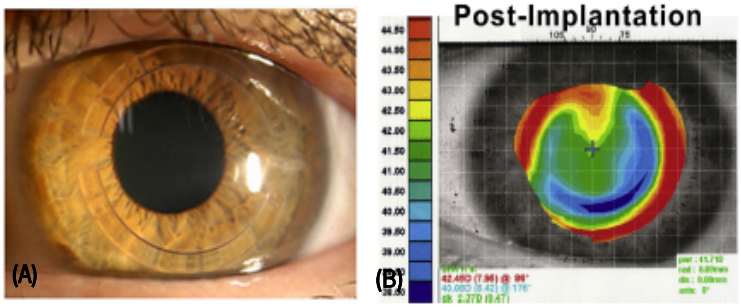

Figure 1.11 (A) ICRSs. Source http://www.eyecairo.net/intacs_kera_rings.html, accessed in January 2019. (B) Post Intra Stromal Rings Implantation topography adapted from Oatts and colleagues.[38]

- Cross-linking

CXL is considered as the less invasive surgical procedure used to halt the progression of corneal ectasia and with the propose of to avoid corneal transplant. It consists in the injection of Riboflavin (vitamin B2) and exposure to ultraviolet A radiation in the corneal stroma, in order to strengthen the corneal structure.[44,45] This treatment is the only that has been proposed to stop the progression of corneal ectasias.[46] In conventional CXL is recommended a minimal corneal thickness of 400μm. However, progressive conditions lately diagnosed could present values lower than 400μm, and for that reason corneas in this stage are not usually indicated to receive the treatment.[47]

CXL is manly used with Keratoconus but it could be also an option for secondary corneal ectasias resulting from LASIK procedures.[48] In their review article, *Randleman et al*[48] analyzed several publications which reported visual improvement and decreased of keratometric values after 2-years of CXL surgery in patients with post-LASIK corneal ectasia.

1.4.1.2 Secondary corneal ectasia

Secondary or acquired corneal ectasia can result from surgical interventions like LASIK, laser-assisted subepithelial keratomileusis (LASEK), PRK and radial keratotomy (RK).[5] These procedures could induce significant aberrations that degrade optic quality. Some of these surgeries are also associated with an increase of dry eye symptoms, making these patients strong candidates to SLs use – as they can beneficiate from fluid reservoir that will maintain the anterior ocular surface moistened. Along with these refractive surgeries, SL can also be indicated for some cases of post penetrant PK, mainly for those cases in which severe corneal irregularities are present.[20] Also, as SL do not touch all the entire corneal surface, these lenses will not mechanically interact/ cause mechanical stress in the suture zones of the transplant. The fluid reservoir typically formed by SLs masks irregularities allowing VA improvement and offering protection to corneal surface. *Severinsky and colleagues*[49] evaluated 36 eyes submitted to PK and observed positive visual results with SLs and suggested that these lenses are the best option in corneal transplant situations.

1.4.2 Ocular Surface Protection

SLs could be an option for ocular surface protection in cases of ocular surface diseases such as severe dry eye. These lenses could be recommended after topic treatment or after surgical intervention.[50] The great advantage of SLs is the creation of the fluid reservoir, which maintains the corneal surface hydrated. In addition, these lenses offer protection to extern agents and mechanical lid's action.

So, SLs can be used in several cases of ocular surface diseases, such as Dry Eye [51–53], Sjögren's [54], Stevens-Johnson [55], as well as exposure keratopathy [56,57], neurotrophic keratopathy [58], and graft versus host disease [59] (a systemic disease that appears as complication of bone marrow transplant).

In cases of epithelial corneal damage, SLs can have an important protective function and eventually act in epithelium regeneration.[60] Limbal cell deficiency, epithelial defects and corneal dystrophias are examples of these conditions.[1]

1.4.3 Other Indications

In addition to corneal irregularities, SLs are capable of protect corneas who suffered from trauma or ocular damage. Some pathologies or accidents can cause some degree of damage for the corneal tissue and, even when totally cured, might leave sequels like scars, opacities and irregularities. Some examples could be viral, fungi or bacterial keratitis cases, Herpes Simplex, or accidents resulting in corneal perforation.[1,5]

Almost all described indications are based on pathological or abnormal situations. However, these devices can be fitted in patients without corneal irregularities or pathology (regular corneas). SLs have advantages (when compared to typical hydrophilic lenses) by their own capacity to maintain ocular surface humidified all the time, and not causing the common discomfort symptoms related to hydrophilic lens dehydration process. Moreover, with simple act of blinking, the hydrophilic lens tends to move, causing fluctuations in VA, mainly in patients with high astigmatism. These patients could benefit from the stability promoted by SLs.[61] So, patients with high refractive errors, like high myopia, high hyperopia and high astigmatism, could be candidates to SLs wear as well, mainly when other kind of visual correction options fail.[62]

SLs can be also used for cosmetic purposes such as lenses that are hand-painted for esthetical purposes, SL with artificial iris for cases of aniridia or irregular pupils, for instance.[20,63] CL wear is a common option for people who practice some kind of sports. Hydrophilic CL tend to lose proprieties with use, and for example, dehydration occurs. Additionally, patients with significant astigmatism could

experience lens rotation, which will impact the visual quality and therefore the sport performance.[62] When SLs and corneal RGP lenses are compared, it happens that the last one become dirty once a particle of dirt is lodged between cornea and lens.[62] Also, corneal RGP lenses are less stable on-eye (when compared to SLs). Similarly, to other CLs, SLs also offer UV protection.

Contraindications

It is important to know that, besides its excellent optical performance and comfort in many ocular conditions, SLs should be fitted with caution in some cases

The contraindications to SLs are underreported in the literature. According to *Fadel and Kramer* [64] patients who have corneal endothelial abnormalities and glaucoma are contraindicated to SLs wear. Corneal endothelial abnormalities include low endothelial cell density (which can be correlated to age, diabetes, dry eye, contact lens wear and ophthalmic procedures like kerotoplasty) and Fuchs endothelial corneal dystrophy. However, a patient with Fuchs dystrophy who was submitted to corneal transplant could be already fitted.

Contraindications to SLs wear are extended to patients with keratoblepharon and conjunctivalized corneas. In glaucomatous patients, the fitting might be affected by drainage devices and blebs developed after surgery. Other contraindications are related to patients with lack of compliance, including patients that do not remove SL overnight (which will be led to hypoxic problems) and patients who are not capable of maintaining lenses adequately clean or patients that are not able to insert and/ or remove the SL safely.

1.5 Scleral lens complications

Several complications related to SL wear have been described. In 1995 *Tan et al* [65] reported, in a retrospective analysis, the main complications observed during PMMA SLs wear, indicating hypoxia and corneal edema as the major complication, followed by neovascularization. Some of these patients were re-fitted with RGP SLs and it was reported a significant decrease of hypoxia-related complications.[66] However, as previously mentioned, the material of SLs underwent several improvements through the last years and nowadays there are materials with good characteristics.

RGP materials have several relevant properties, but in SLs field some of these properties have an important role on fitting procedure and on long term wear. Current SLs materials have high Dk values equal or superior to 100 Fatt units to minimize corneal hypoxia and to decrease complications related to SLs wear. Wettability is another propriety that has a great impact on subjective comfort and quality of vision. It is defined by the contact angle that corresponds to the angle formed by the tear and the lens surface in which lower contact angles allow a better spreading of the tear on the lens surface.[67]

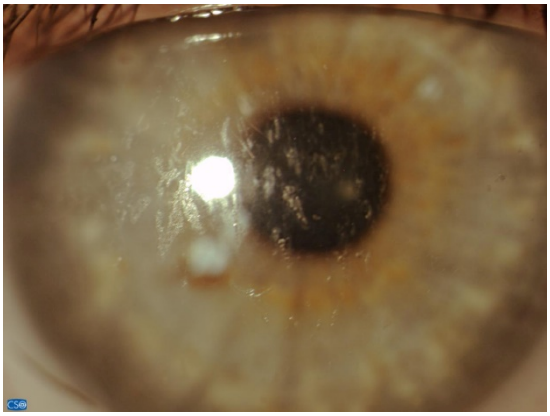

Figure 1.12 Example of wettability issues on lens anterior surface reported by patients as "cloudy vision". This picture was obtained in one of the patients of the study during V3.

Although SLs have satisfactory results in comfort and optical quality, being a good option to some patients, there are a few advents that might not be related to SLs material. Conjunctival staining, conjunctival prolapse, infections and inflammations or corneal edema can appear with SLs wear and should be handled carefully.

1.5.1 Hypoxia

Cornea is the main responsible for eye refractive power, so it is important to maintain it health and integrity. It is an avascular tissue that gets oxygen from tear film and atmosphere and when cornea is deprived of normal oxygen levels hypoxia occurs.

Hypoxia can led to several complications such as neovascularization, decrease of corneal transparency, and changes in the metabolism of corneal cells.[68] It is known that during night, when lids are closed, cornea doesn't received the normal quantity of oxygen, which will cause a physiologic corneal edema around 4% that does not compromise corneal tissue.[69] *Barnett and Johns* [1] define that hypoxia can happen due to ocular causes and due to SL wear, among others. As example of ocular causes, the authors identified high intraocular pressure (IOP), endothelial disorder, low endothelial cell number and some medications. Relatively to SL, the authors delineate the importance of limbal clearance, high Dk materials and lens thickness.

When a SL is fitted, there are two barriers to the oxygen transmission – the lens thickness and the thickness of the fluid reservoir between the lens and the cornea. If those thicknesses (lens and fluid reservoir) are high and/or if there is a low Dk value, it can lead to a hypoxic stress that can cause an edema response of the cornea, and therefore compromise ocular health. To avoid this kind of complication, it is important to consider the lens thickness, the fluid reservoir thickness and the oxygen permeability of the SL material.

Table 1.1 Resume of estimated values of oxygen permeability of the lens, thickness of the lens and post-lens teral film thickness to prevent hypoxic problems during scleral lens wear.

Author	Lens oxygen permeability	Post lens tear film thickness	Lens central thickness
Michaud et al[68]	150-170 Fatt units (highest Dk available)	200 µm	250 µm
Compañ et al[69]	125 Fatt units	150 µm	200 µm

Table 1.1 shows two studies which were conducted to understand which combination of these 3 factors is more appropriated in order to minimize corneal edema associated with SLs wear. According to *van der Worp and Bhattacharya et al* [5,70], the best way to improve the corneal oxygen availability during SLs wear is to decrease the post lens tear film thickness (by decreasing lens sagittal height), decrease the lens thickness (if possible) and/ or change for a material with a higher DK value.

For *Pucker and Laurent* [71] the vault of fluid reservoir can have more influence on oxygen passage than the thickness and lens material. The tears transmissibility is around 80 barrer/cm, a value that is lower than some modern SLs materials. So, the authors suggested that lens might be fit with the minimal possible vaulting of the cornea without corneal and limbal touch.

Other studies evaluate the corneal edema induced by current SLs. *Tan et al* [72] concluded that a short-term wear of modern SLs induced a corneal edema lower than physiological edema produced by lids closing. The same was found by *Vincent and colleagues* [73],although this authors quantified the level of corneal edema directly after 8 hours of SLs use and founded a value of 1.70%. And lastly, according to *Jaynes et al* [74] it is suggested that clinicians should be prudent when recommend SLs, advising the highest possible Dk and making a fit with adequate clearance in order to avoid hypoxia. The great majority of these studies are theoretical or were done in a healthy cornea population and over an 8-h period of lens wear – and we still don't know what could be the long-term consequences of a cornea being exposed to a subclinical hypoxia like this. Therefore, studies evaluating these hypoxic stresses in unhealthy corneas and over a longer period of time are needed.

1.5.2 Conjunctival prolapse, conjunctival hooding or conjunctival chalasis

With age, there are alterations in the conjunctiva morphology. It is common to see loss of transparency, conjunctival thinning and tortuosities.[75] However, CL wear can accelerate some of these modifications in the conjunctival tissue. One is the conjunctival prolapse - that is an excess of conjunctival tissue. It can be induced by SLs wear and it appears in a small group of wearers. Besides, it is considered benign in the short-term use of SLs, the long-term consequences are undetermined.[75,76]

Conjunctival prolapse occurs when redundant conjunctival tissue migrates underneath the lens, close to the limbus.[75] This phenomenon is caused by lens negative pressure which can lead to redundant conjunctival tissue, allowing the conjunctival tissue to migrate to peripheral cornea (to lens transition zone). It rarely affects the optical zone[77]. Conjunctival prolapse may be influenced by the relation between anterior ocular surface shape and the geometry of the SL landing zone, as well as the thickness of the tear film reservoir underneath the lens. To relieve the problem, it is advised to fit SLs with asymmetric designs and, when possible, to reduce the sagittal depth of the lens (in both corneal and limbal area), without promoting corneal touch.[5,76]

Also *Barnett and Johns* [1] recommend to change lens parameters, to act in central and limbal clearance, and to adjust the lens alignment with sclera.

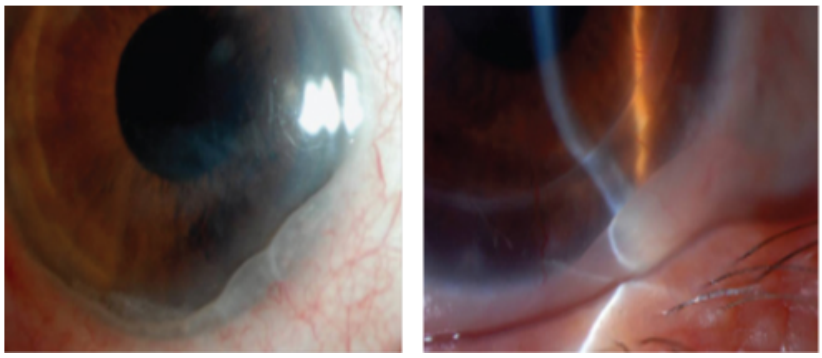

Figure 1.13 Examples of Conjunctival Prolapse. Source: https://www.clspectrum.com/issues/2012/april-2012/contact-lens-case-reports, accessed in February 2019.

1.5.3 Midday fogging (MDF)

MDF is a common problem in SLs wear that affects 25-33% of SLs wearers, according to some studies. It is characterized by an accumulation of matter/ particles in the liquid reservoir between the SL and the cornea, or in the front surface of the lens. [78,79] According to *Caroline and André* [79] *"To date no one appears to know the exact nature of the opaque substance. Our working hypothesis is that it is perhaps an accumulation of mucin-rich tears related to excessive pressure of the haptic on the mucin-rich goblet cells of the bulbar conjunctiva and/or excessive interaction of the lens edge on the palpebral conjunctiva. When this is combined with a greater-than-normal vaulting (in excess of 400 microns), the volume of the fluid interface is great enough to dramatically affect the patient's visual acuity."* Other authors suggest that this is a multifactorial condition.[80]

MDF is more predominant in patients who have atopic diseases, ocular surface diseases, postsurgical eyes and Dry Eye.[5] It is reported to be a bilateral condition, typically worse in one eye.[5] It can appear after lens application, minutes after lens application, or progressively with lens wear. Frequently it causes blur vision and consequently affects comfort and vision.[1,5,81]

According to the literature[1,5] there are three etiologies of fogging: mucus debris, fogging allied with atopic disease and meibomian debris. These three types can happen collectively but each type of MDF should be handle in its own way.

In order to decrease the associated symptoms, some patients have to remove and clean the SL and then fill up with clean solution several times a day.[81] *Pucker and Laurent* [71] believe that lenses cleaning can relieve the bad wetting and improve vision. Fill the lens with drops of non-preserved artificial tear instead of non-preserved saline could be beneficial for some patients.[80] In another patients, sometimes it

is necessary change lens parameters or maintenance products to reduce fogging.[79] *Walker and colleagues* [81] believe that a thinner post-lens fluid reservoir can reduce the MDF incidence because it helps to decrease reservoir debris.

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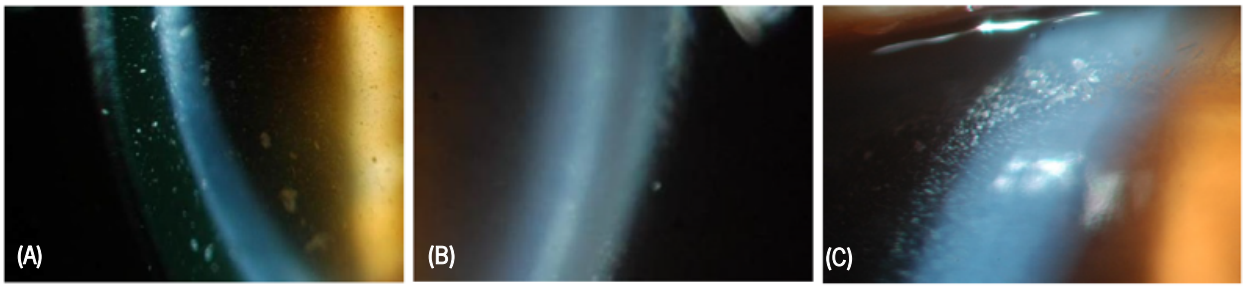

Figure 1.14 Types of MDF. (A) Mucus debris, (B) MDF in atopic disease, (C) Meibomian debris. Source: Barnett and Johns.[1]

1.5.4 Air Bubbles

There are few reports on the literature about this difficulty, however it's a common situation during SLs application, namely of unexperienced wearers. Air bubbles appear behind the lens and can cause discomfort and visual problems. It occurs due to handling problems or inadequate lens parameters. According to *van der Worp* [5] if the air bubble appears regularly, there is a big possibility to be caused by issues with the lens fitting. Some examples that could result in post-lens air bubbles are excessive lens movement or edge lift in more than one region.[1] However, if the air bubbles only occur from time to time, it may be due to the technique used by patient to apply the lens. Both authors agree that small bubbles with movement are acceptable if they do not affect the pupil area, while big static bubbles can't be tolerated – these can cause corneal dissecation and corneal staining.

1.5.5 Discomfort

In general, SL are comfortable for the wearer. However, some patients report to feel discomfort during SLs wear. The discomfort can be caused, for example, by air bubbles entrapped underneath the lens. In these cases, it is necessary to remove and to re-insert the lens in order to eliminate air bubbles. Another cause can be the fit parameters. *Barnett and Johns* [1] defined that the main reason for SLs-related discomfort is an inadequate alignment of the landing zone of the lens with the scleral surface. The lens can be too tight or have too much edge lift ant these will cause discomfort. It is also important to pay attention to corneal and limbal clearance in order to avoid contact between the lens and these structures that can lead to discomfort and ocular complications. Also *van der Worp* [5] mentioned discomfort

associated with SLs that might be related to toxic responses due to preservatives contained in solutions (which can be solved with non-preservative solutions) or debris in the liquid reservoir.

1.5.6 Inflammation and infection related complications

There are few cases in literature related to infection and inflammation complications during SLs wear. A recent case report related a case of Acanthamoeba keratitis in a patient using SLs.[82] According to the authors, it is not necessary that the patient have corneal erosion to Acanthamoeba can penetrate. Just an epithelial fail is needed in order to the organism penetrate. Another article[83] reports a case of a 45-year-old man with graft versus host disease and Dry Eye using Boston Scleral Lenses who was diagnosed with Acanthamoeba keratitis and *Fernandes and Sharm* [84] described a microsporidial and polymicrobial keratitis in a patient with Sjogren's syndrome.

A review published in 2016[81] revealed that the small number of SLs worldwide wearers and the low rates of prescriptions for extended wear could be possible explanations of the decrease risk of SLs-related infections. However, other authors also warn that the SLs-related complications could be underreported in the literature. SLs cleaning and disinfection must be rigorous, which can contribute to a lower risk of complications. The same article only mentioned two published works related to inflammatory events.

1.5.7 Conjunctival staining

As mentioned above, SL does not touch the corneal surface, so the corneal tissue has a small involvement with SL wear. As SL land on the conjunctival tissue, it is common to observe conjunctival staining after lens removal which can be due to a steeper landing zone or due to the pressure exerted by some portion of the SL (in cases of spherical landing zone fitted on an asymmetrical sclera).[5] Because of that, it is possible to reduce conjunctival staining by modifying the geometry of SL landing zone (flattening the surface, changing to toric or quadrant-specific lens designs). If no change is made, conjunctival staining tends to increase with SLs wear.[1]

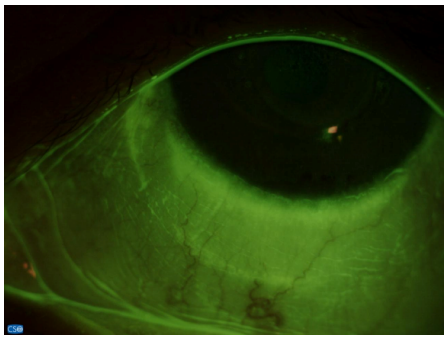

Figure 1.15 Image showing conjunctival and limbal staining. This picture was obtained in one of the patients of the study during V1.

1.6 General aspects of SLs

The SL design is specific of each manufacturer but hold some common characteristics. In general, SL can be divided into 3 to 4 different zones – the optic zone, mid-peripheral zone, intermediate zone and landing zone. In some manufacturers, each one of these zones can be adjusted independently but in other fabricants the adjustments in each zone can condition the fitting of the other zones.

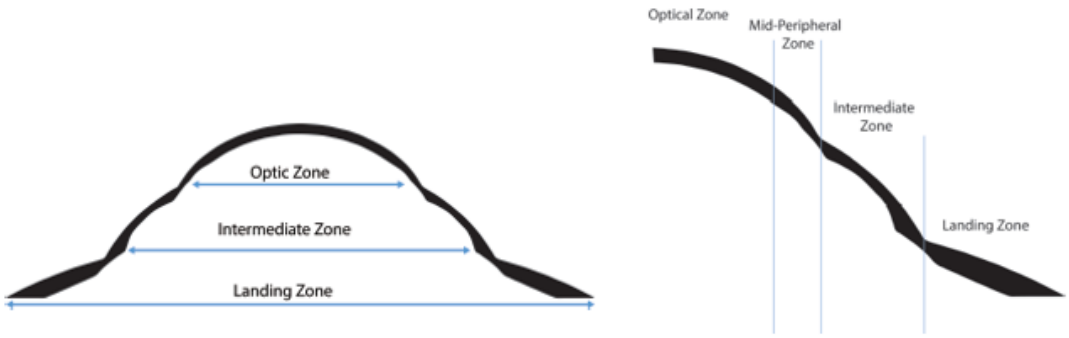

Figure 1.16 Examples of SLs with three and four zones. Adapted from Barnett and Johns.[1]

The optic zone is the central part of the lens. This zone is characterized by dioptric power or radius power, that defines the curvature from the optic zone, or in sagittal depth.[1] All these parameters can be adjusted in order to provide an adequate vault that allows a correct oxygen passage. The front surface of the optic zone allows to correct residual astigmatism- which could come from HOA or could be an internal astigmatism- by adding the respective amounts of sphero-cylindric refraction.[6] According to the manufacturer, this zone can have different nomenclatures as clearance zone, clearance curve, central clearance zone, anterior clearance zone, apical clearance zone, corneal vault zone, corneal zone, base curve, base curve radius zone and other terms.[1]

Relatively to central clearance zone fitting philosophy, several articles were analyzed, and different lenses were used. Analyzing **Table 1.2**, in some articles the fluid reservoir was quantified comparing it with corneal thickness but, according to *van der Worp* [5], as the corneal thickness in ectasic corneas is variable, it is more reliable to compare the fluid reservoir with the lens thickness, if this is known for the given optical power. Depending on the used lens in each article, the values of tear reservoir thickness range from 100µm to 400µm with lens thicknesses between 290µm and 500µm. It is observed that regardless of lens thickness, the fluid reservoir could have different values, i.e. for a lens thickness of

500µm, some authors consider 250µm to be an adequate vault while other assume values ranged between 100µm and 400µm. The same is observed to lenses with thickness of 300µm, which tear clearance could be 250µm or 400µm. Despite these values were mentioned in some publications, eyecare practitioners should be aware of high amounts of spherical over-refraction, once the lens thickness is dependent on lens power.

Table 1.2 Fluid reservoir thickness according to lens thickness and diameter for several scleral lenses used in some clinical studies.

Author	Fluid reservoir thickness (µm)	Measure method	Lens (manufacturer)	Lens thickness (µm)	Lens diameter (mm)
Schornack et al (2008)[59]	100 to 400 comparing it with the thickness of the cornea	N.M	Jupiter (Medlens Innovations or Essilor Contact Lens)	N.M	18.2
Schornack and Patel(2010)[85]	150 to 400	SLB		N.M	
Schornack and Patel (2010)[86]	from 1/4 to 1/2 of the corneal thickness	SLB		N.M	
Schornack et al (2014)[87]	1/3 to 2/3 of the corneal thickness	N.M		N.M.	
Kauffman et al (2014)[88]	250 to 400	OCT	Jupiter (Visionary Optics)	500	
Asena and Altınörs (2016)[31]	N.M.	SLB	Misa (Microlens)	N.M.	16.5 and 17
Yildiz et al (2018)[89]	1/2 of the corneal thickness).	N.M		N.M.	N.M
Consejo et al.(2019)[90]	N.M.	OCT		300	16.5
Consejo et al.(2018)[91]	N.M	OCT		300	16.5
Dalton and Sorbara (2011)[92]	N.M	SLB	MSD (Blanchard)	N.M	15.8
Kauffman et al (2014)[88]	250 to 400	OCT		300	15.8
Bray et al (2017)[93]	N.M.	OCT		N.M.	15.8
Alipour et al (2016)[94]	N.M.	SLB		N.M.	15.8
Visser et al (2006)[95]	250	SLB	(Procornea)	500 (-3.00D)	18.0 to 25.0
Macedo-de-Araújo et al (2019)[11]	100 to 200	SLB		N.M.	16.4
Macedo-de-Araújo et al (2019)[96]	100 to 200	SLB		N.M.	15.2 to 16.4
Vincent et al (2014)[97]	400	OCT	ICD (Paragon Vision Sciences)	300	16.5
Piñero Llorens (2015)[98]	300 to 400	OCT		N.M	16.5
Carracedo et al (2016)[99]	300 to 400	SLB		300 (-3.00 D)	16.5
Vincent et al (2016)[73]	300 to 400	SLB		300	16.5
Vincent et al (2016)[100]	300 to 400	SLB		300	16.5
Vincent et al (2018)[101]	200 to 400	SLB		300	16.5
Suarez et al (2018)[102]	1/3 to 1/2 of the corneal thickness	SLB	ICD (Laboratory Contact Service)	290 (-3.00 D)	16.5
Vincent et al (2019)[103]	200 to 400	SLB	ICD (Paragon Vision Sciences)	300	16.5
Serramito et al. (2019)[104]	300 to 400	SLB		300	16.5
Serramito et al. (2019)[105]	300 to 400	SLB		300 (-3.00 D)	16.5

N.M.-Not Mentioned, SLB- Slit Lamp Beam

Only 14 articles have reference to lens thickness and just 4 specify the lens power for the given thickness. In general, there is a lack of information on lens thickness and this is more significant to specify lens power associated to the referred thickness.

The intermediate zone connects the central zone with landing zone. Normally this transition covers the limbal area and conjugate an adequate vault with a good alignment of landing zone.[6] This zone can be called as limbal curve, limbal clearance curve, limbal zone, limbal clearance zone, transitional zone, limbal vault zone, peripheral curve or limbal lift zone.[1] Limbus has an important role in the renewal and proliferation of corneal stem cells, so it is important to provide an adequate limbal clearance to prevent problems such as debris entrance, and to permit a better lens centration. An excessive limbal clearance could lead to hypoxic stress and cause several corneal complications such as epithelial break down, limbal edema, neovascularization and keratitis.[16] A small limbal clearance will potentially cause mechanical stress. When problems of MDF or lipids and mucin accumulations are present, to reduce the limbal clearance could be helpful to decrease them [16]

The landing zone is the only zone of the lens that is in contact with the ocular surface. It can also be named as scleral zone or haptic zone.[6] It is very important to maintain a good alignment between the landing zone of the lens and the scleral shape. As the scleral shape is asymmetrical in nature, it is often required to fit SL with toric landing zones. In fact, this zone can be designed with curves or tangential angles depending on the manufacturer and professionals can modified this area by altering the landing angles or modifying the curvature radio of the landing zone.[5] When the lens is not aligned with the ocular surface, it can cause conjunctival blanching or edge lift. When conjunctival blanching is noted in all conjunctival meridians, it means that landing zone is too steep and could be adjusted. Then, if occurs in one or two located regions, the professional should re-fit the SL with a toric or quadrant specific landing zone.

In **Table 1.3** it is possible to see some scleral lenses available in the market. Nowadays there are a range of SL that allow professionals to make alterations in every way. However, even with all the available variability of SL, today there are some devices that are completely customized and individually designed for each corneal disorder.

Prosthetic Replacement of the Ocular Surface System (PROSE).is available as a non-fenestrated scleral device, made of RGP material with a DK of 85 or 127 [ISO/Fatt], approved in 1994 by FDA and manufactured by BostonSight.[106] BostonSight uses exclusive computer designs and programs (CAD/CAM technology) which allow an exactly alignment between the device and corneal and conjunctival curvature.[107,108]

Also EyePrint Prosthetics is a scleral device based on impression techniques which fully obtain a mold of corneal and conjunctival surface curvature that is posteriorly 3D scanned. EyePrint Prosthetics are made of Contamac Optimum Extra, available DK of 100, with a Hydra-PEG technology in order to improve subjective comfort and lens wettability. Multifocal design and optical prisms are also available.[109]

Table 1.3 Available parameters of some scleral lenses.

	ICD	Jupiter	MISA	MSD	ZENLENS	AVT	Senso Mini Sclera
Lens material	HDS 100*	Optimum GP , Boston XO and Boston XO_2 [86]	Optimum Extreme, Tyro 97 and Boston XO_2*	Boston XO[88]	Boston XO and Boston XO_2[110]	Paragon HDS 100, Tyro 97 and Optimum Extra[111]	Boston XO[96]
Dk (Barrer)	100*	50 to 200*	125[91]	100[88]	100 and 141[110]	97 and 100[111]	100[112]
Lens thickness (µm)	300*	300*	300 to mini Misa 500 to full Misa (-3.00 D*)	300[88]	W.I	350[111]	250 to -3.00 D[113]
Available diameters (mm)	16.5*	13.5 to 22*	16.5 to 17.5 in 0.5 steps for mini Misa and, 18.5 to 23.0 in 1.5 steps for full Misa**	15.8 and 18.0[114]	16.0 and 17.0[110]	15.0 to 20.0[111]	14.8 to 18.0 in 0.40 steps[113],*
Spherical correction	-40.00 D to +30.00 D in 0.25 D steps*	-75.00 D to +50.00 D in 0.25 D steps [115]	-20.00 D to +20.00 D in 0.25 D steps. Powers higher than +/- 20.00 D in consultation with Microlens*	N.A	-20.00 D to +20.00 D in 0.25 D steps[110]	-30.0 D to +30.0 D[111]	-25.00 D to +20.00 D in 0.25D steps[113]
Cylindrical correction	0.00 D to -10.00 D in 0.25D steps*	-0.25 D to -15.00 D in 0.25 D steps [115]	-0.75 D to -4.75 D in 0.50 D steps*	W.I.	-0.25 D to -6.00 D in 0.25 D steps *	-10.00 D to +10.00 D[111]	-0.50 D to -3.00 D in 0.25 D steps[113]
Axis	0° to 180° in 1° steps*	0° to 180° in 1° steps*	0° to 180° in 1° steps *	W.I.	0° to 180° in 1° steps*	0° to 180° in 1° steps[111]	0° to 180° in 1° steps[113]
Multifocal Design	N.A	Add Power from +1.00 D to +3.50 D in +0.50 D steps [115]	W.I.	W.I.	Zen Multifocal, Add power from +1.00 D to +3.50 D in 0.25 D steps[116]	Add power from +0.50 D to +3.50 D in 0.25 Dsteps[111]	Add power from +1.00 D to +2.50 D in 0.50 D steps[1]
Base curve	38D to 56D*	Any in 0.10mm steps [115]	W.I.	W.I.	W.I.	Any[111]	7.00 to 9.40 in 0.20mm steps[113]
Sagittal height	3900 µm to 4900 µm in 100 µm steps, 5100 µm, 5300 µm and 5600 µm*	Any*	2500 µm to 5000 µm in 125 µm steps*	3600 µm to 5800 µm in 100 µm steps[94]	3200 µm to 6700 µm in 10µm steps[110]		0.25 to 7.25 in 0.25 steps0
Peripheral corneal zone modifications	-15 to +15 in 1° steeps*	N.A	N.A	Decreased (D), Standard (S), Increased (I), and Double Increased (II)[114]	N.A	N.A	N.A
Limbal zone modifications	-15 to +15 in 1° steeps*	N.A	N.A	Decreased (D), Standard (S), Increased (I), and Double Increased (II)[114]	N.A	N.A	N.A
Landing zone modifications	-15 to +15 in 1° steeps*	N.A	13.0mm Normal, 14.0mm Wide, 15.0mm Extra Wide*	For 15.8mm: Standard, 1 Flat and 2 Flat. For 18.0mm: Standard and 1 Flatt design[114]	Advanced Peripheral System (APS): -10 Steep to -1 Steep, Standard,-10 Flat to -1 Flat in 30 µm steps[110]	2 steep angle-low, 1 steep angle-medium, High- standard, 1 flat angle- extra high, 2 flat angle-extra extra high[117]	-8 to +8 in steps of 1[118]
Scleral toricity	0 to +15 in 1° steps	Toric haptic up to 800 µm in 50 µm steps*	For 20.0mm: 500 µm to 1500 µm in steps of 250mm. For 21.5mm:500 µm to 1000mm, in steps of 250mm.For 23.0mm: 500 µm *	W.I.	Toric APS[110]	W.I.	1 to 6 in steps of 1[118]
Available Designs	Aspheric Design*	Jupiter Standard Design, Jupiter Advanced Keratoconic Design and Jupiter Reverse Geometry Design[115]	W.I.	W.I.	Oblate and Prolate Design[110]	W.I.	W.I.
Other information		Notching and Precision Lift, quadrant-specific or multi-meridian designs [119]	Elongation Curve[120]	W.I.	Micro Vault, Custom Center Thickness, Flexure Controlling Profile and SmartCurve™ technology[110]	Sag Sight Technology and Notching[111]	W.I.

*Data from manufacturer
N.A.-Not Available
W.I- without information

2. HYPOTHESIS AND OBJECTIVES OF THE STUDY

2.1 Problem formulation

Although SL market underwent a huge increment in the last years, there are still few long-term prospective results addressing several SL fitting aspects and the on-eye behavior of these lenses. It is reasonable to say that the anterior surface of a SL will suffer some degree of degradation overtime which could impact the visual outcomes and the overall comfort reported by patients wearing SL for longer periods of time. Many manufacturers recommend not to exceed 1 year of lens use without lens exchange in order to avoid these problems related to visual deterioration and discomfort. In addition, patients with corneal ectasia – that is a progressive disease – will probably need to have their lenses exchanged more frequently in order to prevent apical touch between the SL and cornea. However, not all the SL designs are available in all the countries, so it is important to know if it is possible to maintain the fitting characteristics, visual outcomes, comfort and performance when a patient is re-fitted with a different lens design. The present study aims to quantify the potential visual improvements related to the re-fitting of SL wearers with a brand-new lens from another manufacturer, and to compare the outcomes between the two lens designs. This will allow to inform practitioners who need to re-fit their patients with different SL designs, in order to anticipate some possible complications. Secondary goals are to quantify the changes in corneal topography induced by SL wear and to understand and compare the impact of both SL designs in the tear film dynamics. Also, other goal was to quantify if it is possible to predict the best diagnostic SL vaulting for each eye based in the ocular sagittal height derived from a regular corneal topographer.

2.2 Hypothesis

The hypotheses of this thesis are:

H0: There are no significant differences between optical quality and visual performance with the two SLs.

H1: There are significant differences between optical quality and visual performance with the two SLs.

H0: There are no significant differences on Ocular Surface Response with the two SLs.

H1: There are significant differences on Ocular Surface Response with the two SLs.

H0: Lens sagittal depth is not correlated with corneal sagittal depth derived from topography.

H1: Lens sagittal depth is correlated with corneal sagittal depth derived from topography.

2.3 Objectives

The main goals of this thesis are:

1.To determine the possibility to successfully refit habitual SL wearers with a different lens design, using ocular sagittal height parameters derived from corneal topography data;

2.To compare the optical quality and ocular surface response between the two lenses.

Secondary goals:

a)To analyze the topographic differences between measurements performed 5 minutes after SL removal or after 3 days of scleral lens wear discontinuation in order to evaluate the necessity to make an interruption in SL wear to perform a new fitting;

b)To evaluate the TFSQ (Tear Film Surface Quality) at different wearing times and compare them with the two lenses.

3. MATERIAL AND METHODS

3.1 Study design

This study was an experimental and prospective case series once the subjects were refitted with SLs and there was a follow up over time in order to evaluate the new fitting.

The research was conducted in the Clinical and Experimental Optometry Research Lab (CEORLab) at the University of Minho (Braga, Portugal). All the devices used in this study were available at CEORLab. The protocol of the study was reviewed and approved by the Subcomité de Ética para as Ciências da Vida e da Saúde / Ethics Subcommittee for Health and Life Sciences (SECVS) of the University of Minho. Following the guidelines of the Declaration of Helsinki, all subjects signed a Consent Form where the objectives, procedures and risks were fully explained to patients and they were allowed to make as many questions as they needed before deciding to participate on the study.

3.2 Participants and Sample Size

Sixteen (16) patients (28 eyes) with corneal ectasias (primary and secondary) or keratoplasty were random selected from another study entitled "Clinical performance and biological interactions in scleral contact lens wear"[121] to participate in this study. All patients were wearing Senso Mini Sclera lenses for more than 12 months.

From the 16 recruited subjects, 12 of them completed the study protocol: one patient lost to follow-up, two patients didn't complete all the visits because of visual problems with the new scleral lens and one patient had incompatibility of schedules. 21 eyes were considered for the Statistical Analysis once 3 participants just use SL in one eye.

3.3 Experimental Procedure

3.3.1 Scleral Lenses Used

The scleral lens used in this project was Irregular Corneal Design (ICD) 16.5mm (Lenticon, Madrid, Spain). ICD lenses are manufactured in HDS 100 material (Paflufocon D), with a Dk of 100 (ISO FATT), central thickness of 300µm for diagnostic lenses and water content lower than 1%. ICD has an optic zone of 10mm with a contact angle of 42° and a refractive index of 1.442.

ICD lens is divided in four specific zones. The main zone is Central Clearance Zone (CCZ) followed by Peripherical Corneal Clearance Zone (PCCZ). The third zone is Limbal Clearance Zone (LCZ) and the last one is Scleral Landing Zone (SLZ). **Figure 3.1** shows the schematic design of these zones.

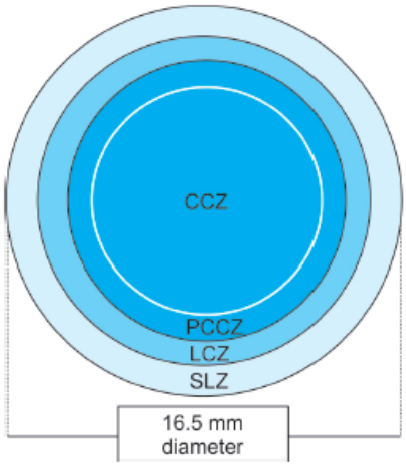

Figure 3.1 Schematic design of ICD. Source: Piñero Llorens[96] .

Sagittal depths of ICD 16.5 ranged from 3900µm to 4900µm in 100µm steps, 5100µm, 5300µm and 5600µm. PCCZ can be adjusted in 1° steeps from -15 to +15 as well as LCZ and SLZ. The necessary adjustments in PCCZ, LCZ and SLZ will change vault thickness: each step in PCCZ modifies 30µm in corneal clearance and 1° in LCZ and SLZ modifies 25µm in vault depth. Spherical power is available from -40.00D to +30.00 and cylinders from -10.00D to 0.00D both in 0.25D steps, with axis ranging from 0° to 180° in 1°steps. The power profile of ICD is displayed on **Figure 3.2** where it is possible to see the variation on lens potency as long as the distance from the optical centrum increases.

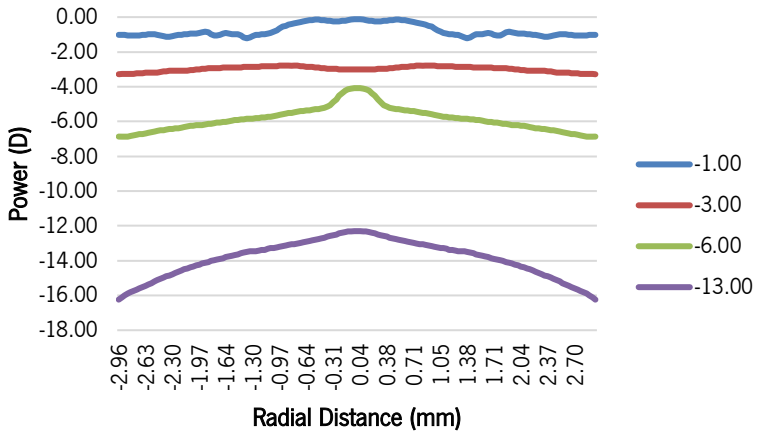

Figure 3.2 Power profiles of ICD lenses of different distance optical power.

ICD is also available with a toric design (ICD Toric) in which the lenses have two different sagittal depths in two orthogonal principal meridians. Each lens has two marks allowing to identify the scleral stabilization axis, i.e. the scleral flattest meridian. These lenses are recommended in three situations: when the sclera is toric, when there is an intern astigmatism in which a satisfactory visual acuity is not achieved with spherical equivalent and when ICD is flexing and is creating a residual astigmatism. With ICD Toric is possible to change LCZ Steep (the band that has scleral toricity) in 1° steps ranged from 0 to +15 and each step modify corneal clearance in 30 µm.

The ICD diagnostic set used in this work included 26 scleral lenses: 14 ICD lenses with diameter of 16.5mm (11 lenses ranged from 3900µm to 4900µm in 100µm steps and 3 lenses with 5100µm, 5300µm and 5600µm); 6 ICD lenses with diameter of 14.5mm (sagittal depths of 3400µm, 3700µm and 4000µm) and 6 ICD Toric lenses (LCZ Steep of +5.00) with diameter of 16.5mm with sagittal depths of 4200µm, 4500µm and 4800µm. From the 26 SLs, those with diameter of 14.5mm were not used in the diagnostic procedure.

The initial diagnostic lens was selected according to manufacturer fitting guide and based on patient corneal sagittal depth at 10mm chord in the steepest meridian (measured with corneal topographer). To this value of corneal sagittal height at 10mm, it was needed to add a sagittal correction factor (as recommended by manufacturer) of 2000µm (considering the diameter of the scleral lens to be fitted) and also to add the desired amount of initial corneal clearance (300µm, for instance). The sum of these three components showed the desired sagittal height of the diagnostic SL. Before diagnostic lens application, the lens was filled with non-preservative saline (Saline, Avizor) and sodium fluorescein to

allow the visualization of post lens tear film reservoir in order to quantify corneal clearance and to identify zones of corneal touch.

The habitual SL used by the subjects enrolled in this study was Senso Mini Sclera. This lens has a diameter of 16.4mm and is manufactured by Procornea, Netherlands. Technical information about Senso Mini Sclera is showed in **Table 3.1** and power profile of this lens is displayed on **Figure 3.3.**

Table 3.1 Characteristics of Senso Mini Sclera lens.

Parameter	
Material	Boston XO (Hexafocon A)
Dk (ISO/Fatt) (Barrer)	100
Central thickness (-3.00D)	250µm
Optic Zone Diameter	9.6mm
Diameter	From 14.80 to 18.00mm in 0.40 mm steps
Back Optic Radius	8.20 mm (from 7.00 to 9.40 mm in 0.20 steps)
Power	Sphere: 25.00 D to +20.00 D in steps of 0.25 D; Front cyl -0.50D to -3.00D in steps of 0.25D; Axis 0 to 180 degrees in steps of 1 degree
Refractive Index	1.415
Contact Angle	49°
Sagittal height	From 0.25 to 7.25 in 0.25 steps
Peri-Factor/Sclera Opening	From -8 to +8 in steps of 1
Toricity (difference in peri-factor)	From 1 to 8 in steps of 1

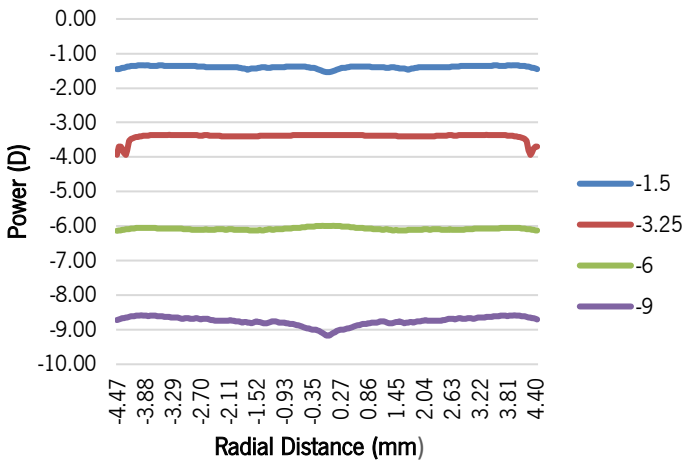

Figure 3.3 Power profiles of Senso Mini Sclera lenses

3.3.2 Clinical Examination Routine

Three visits were scheduled according to the subject's availability. **Figure 3.4** shows a representative diagram of the visits.

The first visit was divided in two parts which were defined as Baseline (an initial part where data without SL were obtained and where diagnostic ICD was tried) and Visit 1(V1) (a second part where data with Senso Mini Sclera was recorded). In Baseline appointment, all patients assigned consent form, where the main goals of the study, the appointments, the measurements and potential risks were explained. For this appointment, patients were advised to not wear their SL for 3 days before the session. Firstly, a slit lamp biomicroscopy evaluation with instillation of fluorescein was performed in order to analyze the anterior segment and then a subjective refraction was determined, as well as high contrast visual acuity (HCVA), low contrast visual acuity (LCVA) and light distortion analysis (LDA), both measured with subjective refraction. After this, a corneal topography followed by tear film analysis and aberrometry were performed. All these measurements will be explained in detail in the next sections.

After these Baseline evaluations, the first diagnostic lenses were chosen and fitted. In V1, the diagnostic lens was chosen taking into account corneal topography measurement, as described previously. The diagnostic SL fit was evaluated with slit lamp observation, with special attention to corneal clearance, limbal clearance and landing zone alignment. If the fit was unsatisfactory, another diagnostic lens was inserted. Firstly, SLZ was assessed with diffuse illumination and local or general blanching was verified. The fluorescein pattern was accessed with focal direct illumination to observe limbal clearance and patients were advised to look up, down, temporarily and nasally in order to ensure a fully vaulted corneal and limbal area. With optical section, limbal vault was verified again when patients looked down, up and to both sides. For all trials was tried to obtain an initial corneal clearance between 300 to 400μm. Once all these parameters were achieved, patients stayed with the diagnostic lenses during 1h30 and the fitting was verified again followed by an over-refraction and measure of HCVA and LCVA. Completed all the needed measures, patients were instructed to remove diagnostic lenses and a new slit lamp biomicroscopy with instillation of fluorescein was done. At the end of this first evaluation appointment, patients inserted their usual SL and HCVA, LCVA, LDA, aberrometry, and tear film analysis were measured after some minutes of lens stabilization. At the end, all participants completed two questionnaires to evaluate the ocular symptoms with Senso Mini Sclera lenses: the ocular surface disease index questionnaire (OSDI) and another questionnaire developed at CEORLab with a Visual Analogue Scale (VAS).

In the second visit (V2), patients attended with their usual SL at daily usual time without any interruption in the use. After lenses removal, corneal topography and tear film analysis with Medmont were made following by an ocular surface evaluation. Then, the new SL (ICD) was applied and evaluated. The lenses were filled with fluorescein in order to help the practitioner to evaluate the fitting. A slit lamp biomicroscopy was performed and the lens fitting – corneal and limbal clearance and landing zone – was evaluated. Subjects were asked to wear the lenses for 3 hours (ICD+3H) and then come to another evaluation. After the 3 hours, the fitting of the lenses was re-evaluated with slit lamp (clearance and landing zone). Then, over refraction, HCVA, LCVA, aberrometry, topography, tear film analysis and LDA were evaluated with the lens on-eye. After that, scleral lens was removed and a complete slit lamp evaluation with instillation of fluorescein was done. For those patients who didn't achieve good visual results or a satisfactory fitting, a second lens was reorder and a new visit was scheduled to obtain the same measurements with the new lenses.

The last visit (V3) was done 1 month after ICD lenses use (ICD+1month). Subjects were advised to put the lenses at normal daily hour and the visit was scheduled in an hour where it was possible to evaluate the fitting with 6 to 8 hours of use. Lens fitting was assessed as well as presence of any ocular problem relatively to lenses wear. Final HCVA and LCVA, aberrometry, LDA and tear film analysis were measured with ICD lenses. After that, lenses were removed and limbal and conjunctival hyperemia as well as corneal, limbal and conjunctival staining were quantified with slit lamp evaluation.

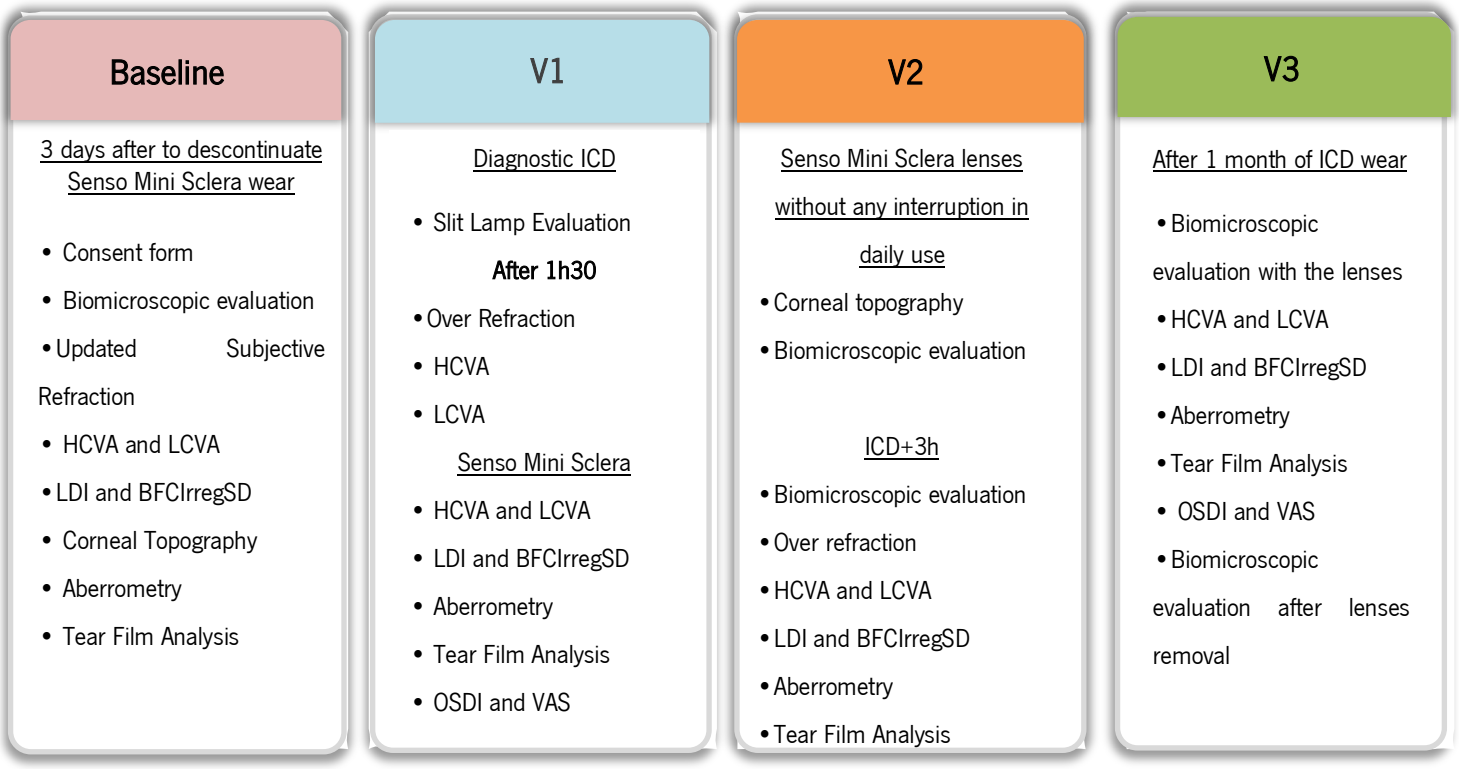

Figure 3.4 Resume diagram of the necessary visits to this study.

3.3.3 Visual Acuity

HCVA (100% - CAT No 2110) and LCVA (10% - CAT No 2153) were measured with the Logarithmic Visual Acuity Chart ETDRS (Precision Vision. IL) at 4 meters (Cabinet Illuminator No 2425). This chart has 14 lines with 5 letters each and quantify visual acuity from 1.00 LogMAR units to -0.30 LogMAR units, which is equivalent to 0.10 and 2.00 respectively in decimal scale. Each correct letter means -0.02 and each wrong letter means +0.02 in LogMAR scale.

VA was obtained monocularly and binocularly in the mentioned conditions.

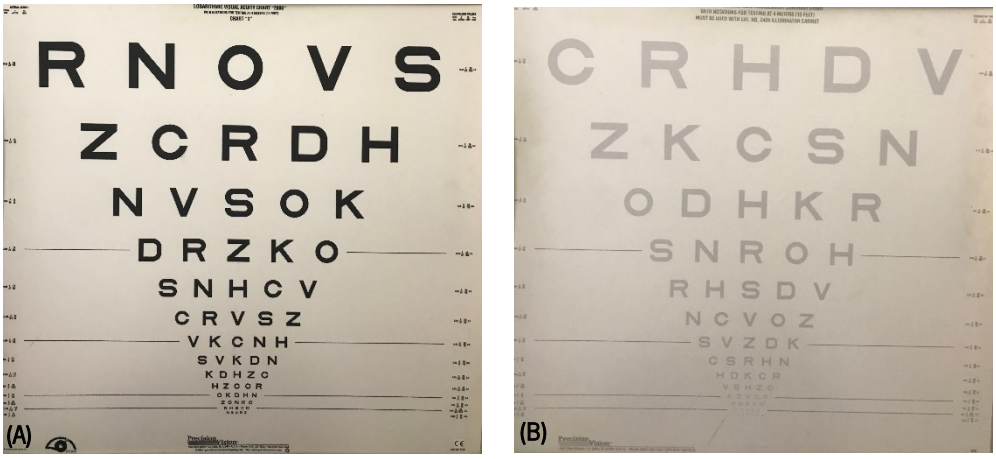

Figure 3.5 ETDRS chart for high (A) and low (B) contrast visual acuity measurement.

3.3.4 Biomicroscopy

Slit lamp examination was performed before and after SL wear. Cornea and Contact Lens Research Unit (CCLRU) grading scale was used to evaluate limbal and bulbar redness, corneal and conjunctival staining. CCLRU scale has 4 grades: Grade 1, Grade 2, Grade 3 and Grade 4. For bulbar and limbal redness, Grade 1 means a very slight redness, Grade 2 indicates a slight redness, Grade 3 shows moderate redness and Grade 4 designates severe redness. The corneal staining is classified relatively to type, depth and extent. Corneal staining type can be micropunctate (1), macropunctate (2), coalescent macropunctate (3) and patch (4). The classification grades for extent are 1-15% (1), 16-30% (2), 31-45% (3) and >45% (4), and for corneal staining depth CCLRU scale defines Grade 1 when it is in superficial epithelium, Grade 2 if goes to the deep epithelium and delayed stromal glow, Grade 3 if the

staining is immediate localized in stromal glow or Grade 4 if archives immediate diffuse stromal glow. For conjunctival staining, Grade 1 means a very slight staining, Grade 2 indicates a slight staining, Grade 3 shows moderate staining and Grade 4 designates severe staining. The evaluation was recorded in steps of 0.5 and the grades of each evaluated area were summed. Limbal staining was evaluated making an extrapolation of the conjunctival staining to the limbal area.

To evaluate corneal, conjunctival and limbal staining, Fluorescein Fluostrips (Contacare Ophthalmics and Diagnostics) were used with single doses of saline solution (Avizor) that were applied in the superior fornix of conjunctiva.

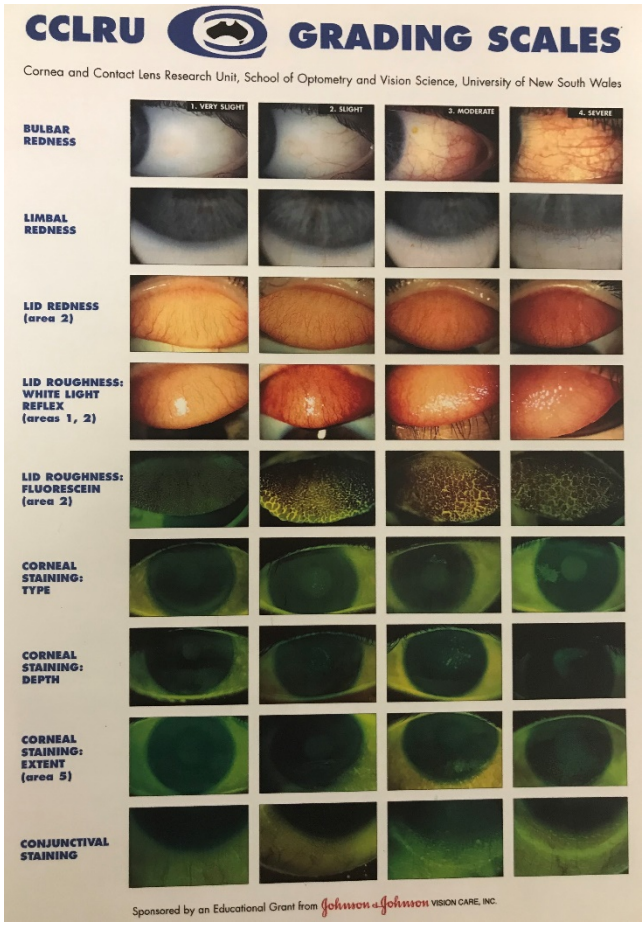

Figure 3.6 CCLRU scale used in biomicroscopic evaluation.

Biomicrocopy was also used to assess SL fitting. Optic section was done to estimate and to observe central, peripheral and limbal vault to make sure that corneal or limbal touch does not occur. Vault estimation was made using lens thickness as reference. Whit this illumination was also possible to

find the position of ICD Toric marks allowing to identify the lens stabilization axis. After this, the alignment between sclera and haptic zone was evaluated with diffuse illumination and any signs of blanching or edge lift were verified.

3.3.5 Corneal Topography and Tear Film Analysis

Tear Film Analysis and Corneal Topography were obtained with corneal topographer (Medmont E300, Australia). In each visit one measure for Tear Film Analysis and three Corneal Topographies were accessed in each eye

The tear film dynamics assessment with Medmont is based on the reflection of Placido rings on the ocular surface or on the lens anterior surface. Once the patient is aligned with the target and the mires are focused, the professional instructed him to blink twice. While the topographer is capturing the exam, the examiner controls the joystick to confirm the maximum centering and alignment. The blinks are detected automatically, and topographer starts capturing the exam every 0.25s. The capture stops when a new blink is sensed or when the 15 seconds of exam duration are reached. In each tear film dynamics measure, average Tear Film Surface Quality (TFSQ), average area of TFSQ (%), and auto Tear Break Up Time (TBUT) were taken for all subjects. TFSQ analyses the distortion of the ring pattern in which values of 0.30 or higher means that the distortion is visible.[122] The TFSQ can also be represented in percentage of area. This parameter analyses the percentage of area of the central 7 mm zone where TFSQ reaches a limit value of 0.30 and breaks.[122] Automatic TBUT is measured in seconds and represents the time at which the average area of TFSQ (%) is at least 5.0% in two consecutive photokeratoscopic images.[122]

Three repeated corneal topographic measures were done in each eye at all the follow-up visits. For the purpose of this study, a sagittal depth at 10mm chord in steepest meridian was needed, however it was not possible for all the patients. Thereby, 6mm chord was considered for the statistical analysis once it was the chord where it was possible to obtain sagittal height values for all the eyes. Simulated Keratometry (Sim K), Surface Asymmetry Index (SAI), Surface Regularity Index (SRI), Asphericity (Q) value and Inferior-Superior (IS) index were also obtain from corneal topography.

Simulated Keratometry gives information about location and dioptric power of steepest and flattest corneal meridians, not being necessary to resort to a separated keratometry provided by keratometer measurements.[123,124] In Medmont topographer Sim K is expressed as Flat K and Steep K and the difference between these two values represents the corneal astigmatism value.

SAI is an index that indicates a mean value of corneal power differences between the points at 180° on 128 meridians that are equidistant. This index detects alterations in corneal asymmetry as irregular astigmatism or off-center Keratoconus apices, but the values don't increase with regular astigmatism or centrally located cones. SAI value is closer to zero in a radially perfect surface, the values for normal corneas ranged from 0.10 to 0.42, becoming higher with the increase of corneal asymmetry.[123–125]

SRI describes the regularity in a central area of 4.5mm which includes the 10 central rings of Placido Disc.[124] SRI is determined through an average summation of local changes in corneal power along 256 equidistant semi meridians and it can be used in order to predict the optical results based on corneal topography.[125] The SRI value is zero for a perfectly regular corneal surface, for normal corneas is lower than 0.56 and increases with irregular astigmatism increasing. [123,124]

Q is an index that indicates the changes in corneal curvature from center to periphery. If there is no change of corneal curvature the cornea is spheric and Q value is zero. In normal corneas, that have a prolate ellipse shape, Q values are moderately negative (usually between 0.2 and 0.6). Such corneal profile has a steeper center and a flatter periphery and this difference becomes larger in pathological corneas like Keratoconus .[124]

IS values provides information about corneal curvature in 3mm chord in intervals of 30° giving the power difference between 5 points situated in inferior hemisphere and 5 points localized in superior quadrant. With values ranged from 1.4D to 1.8D it is possible to suspect of Keratoconus , while values higher than 1.8D indicates a clinical Keratoconus .[124]

3.3.6 Aberrometry

Aberrometry measurements provide information about the quality of retinal image and make an objective quantification of the optical proprieties.[126]

IRx3 Hartmann-Shack aberrometer (ImaginEyes, France) was used to obtain the low order aberration (LOA) and HOA coefficients. The average of three repeated measures in each eye was considered for analysis. The Zernike coefficients up to 6th order and the root mean square (RMS) of HOA up to 6th order were analyzed. For the present study were considered values of HOA RMS from 3rd to 6th order, Spherical-like RMS with Z_4^0 and Z_6^0 and Coma-like RMS including Z_3^{-1}, Z_3^1, Z_5^{-1} and Z_5^1.

Aberrometry was measured in three instants: Baseline measurement – performed after a 3 days washout period, measurements with habitual lenses (Senso Mini Sclera) and with ICD lenses after 1

month of wear. In each measure, subjects were instructed to blink and then to fix the E letter inside the aberrometer, maintaining the eye open for good quality of capture image.

For the 3 situations, 3 measures were taken for each eye (although in 3 eyes with intra corneal segments was not possible to obtain aberrometry values). All the measurements from aberrometry were extracted to a 4mm pupil.

3.3.7 Light Disturbance Analyzer

Halometry was determined with Light Disturbance Analyzer (LDA, CEORLab, University of Minho, Braga, Portugal), a system that has a high intensity central light (LED) surrounded by 240 smaller LEDs with lower intensity, distributed in 24 semimeridians, with a separation of 15°.[127] The central LED creates the glare condition and the smaller LEDs define the limit of visual field in different angles. [128] With LDA is possible to quantify the size and shape of the light distortion caused by the central LED.

The subjects were instructed to look to the central stimulus and to press the mouse button anytime they see the peripheral lower intensity lights. These measurements were taken with a distance of 2 meters between the subject and the display.

After all the procedure, the following metrics were recorded:

-Light Distortion Index (LDI, %): is the size of the light distortion, in percentage (%). quantifies the percentage of whole tested area which isn't perceived due to the damage caused by light distortion. When higher values of LDI are achieved, it means the subject has a small capacity to differentiate small stimuli that surround the central light;[128]

-Best Fit Circle irregularity (BFC_{Irreg}): It is expressed in mm and represents the sum of deviations between the distortion area and the outer perimeter of the best adjusted circle along the semi meridians; [128]

-Best Fit Circle irregularity SD ($BFC_{IrregSD}$): higher values of this metric represent a higher irregular distortion and it is calculated with the sum of the differences squared divided by the total number of evaluated semi meridians. Also expressed in mm; [128]

-Best fit circle center coordinates (XCoord and YCoord): it is defined by x e y coordinates from the center of the central LED in mm.[128]

3.3.8 Ocular Surface Disease Index (OSDI)

OSDI Questionnaire was completed by all subjects in order to evaluate the severity of dry eye symptoms with previous lens and one month after ICD lens wear. The questionnaire relative to Senso Mini Sclera lens was completed in the first visit and the questionnaire relatively to ICD lens was done in the last visit.

OSDI has 12 questions relatively to ocular signs and associated limitations during the previous week. Each question is graded on a scale ranged from 0 to 4 where 0 means there is no symptoms; 1, almost never; 2 sometimes; 3, frequently and 4, always.

The total score of OSDI questionnaire was calculated with the formula OSDI= [sum of scores of all answered questions) x 100] / [(number of questions answered) x 4)]. OSDI values allow to quantify subjects with normal, mild, moderate or severe dry eye disease.

3.3.9 Subjective Questionnaire

This is a visual analogue scale (VAS) questionnaire and was developed at CEORlab (Universidade do Minho). It has a 10cm vertical line where patients putted an arrow in the point of the line that quantified their symptoms.

Subjects filled the questionnaire twice: relatively to Senso Mini Sclera wear and after one month of ICD wear. The first questionnaire intended to quantify ease of handling with SLs, comfort after lens application, comfort after 4 and 8 hours of use, grade of dryness and quality of vision during the day and after 8h of lenses wear. It allowed to quantify all these parameters between 0 and 10. The questionnaire filled after 1 month of ICD wear had exactly the same questions (allowing to compare with the other SL) and also had 5 forced-choice questions in which the subjects were forced to designate which the two lenses they opted relatively to dryness, comfort, vision quality and their average preference.

3.4 Statistical Analysis

Statistical analysis was performed with SPSS Statistic software version 25.0 (SPSS Inc, Chicago, IL). The descriptive data were presented in terms of mean ± standard deviation (SD). The normality of all variables was evaluated using the Shapiro-Wilk test, since the sample was less than 30. In the normality test, if the parameter of statistical significance (p) was less than 0.05, the null hypothesis was rejected, meaning that there were differences in the distribution of the sample compared to a sample with normal distribution. If the alternative hypothesis was accepted, means that there were no differences to the normal distribution and the variable in question had a normal distribution.

Pairwise comparisons were done to compare the different outcomes through the different visits: Paired Samples T-Test was used if the variable presented a normal distribution and Wilcoxon was used if the variable did not present a normal distribution.

The correlations were achieved by Pearson test if the sample had a normal distribution; otherwise the Spearman correlation was used. The correlations were considered strong if >0.80, moderately strong if between 0.5 and 0.8, fair if between 0.3 and 0.5 and poor if <0.30.[129]

The level of significance of the study was set at α=0.05.

4. RESULTS

Table 4.1 shows the demographic characteristics of the sample, obtained in Baseline visit. The values of M, J0 e J45 were derived from a complete refraction. In 1 eye was not possible to find a complete refraction in order to improve VA. Both visual acuity and LDA outcomes were evaluated with the best spectacle correction of the subjects.

Table 4.1 Demographic data of the sample.

N	21
Gender	7 females (58%) 5 males (42%)
Age (years)	42.95±7.93 (range: 29 to 62)
M (D)	-5.95±4.95
J0 (D)	-0.20±1.59
J45 (D)	0.24±2.03
Monocular HCDVA	0.43±0.47
Binocular HCDVA	0.17±0.16
Monocular LCDVA	1.07±1.41
Binocular LCDVA	0.41±0.19
Monocular LDI (%)	49.62±25.19
Binocular LDI (%)	32.32±24.09
Monocular $BFC_{IrregSD}$	8.57±5.12
Binocular $BFC_{IrregSD}$	6.07±3.18
Corneal condition	11 eyes with Keratoconus (52.4%) 4 eyes with Keratoconus and ICRSs (19%) 3 eyes post-PK (14.3%) 3 eyes post-LASIK ectasia 14.3%)
Time of wear of Senso Mini Sclera in Baseline visit (months)	27.9±7.4 (range: 22 to 44)

4.1 Fitting Characteristics

4.1.1 Sagittal depth

With corneal topographer was possible to obtain corneal sagittal depth for all the patients and the 6mm chord was considered.

There were statistically significant differences (p=0.020, Paired Samples T-Test) between Baseline sagittal depth at 6mm chord (measured after 3 days of SL discontinuation: 651±6 μm) and sagittal depth at 6mm chord measured immediately after lens removal at V2 (639±11μm).

4.1.2 Diagnostic lenses and ordered lenses

With the diagnostic fitting set, the possible modifications were on CCZ and on scleral toricity. For the 21 analyzed eyes, a mean of 2.19±0.62 diagnostic lenses were used. In 2 eyes a good initial fit was achieved with the first diagnostic lens but for the other 19 eyes additional diagnostic lenses were needed. 62% of the alterations on diagnostic lenses were made due to an inadequate vault, being 14% intended to increase the sagittal depth and 48% to decrease the vaulting between the lens and the cornea. Additionally, 67% of the needed modifications were as a result of an asymmetric sclera that demands a non-rotationally symmetric periphery in order to avoid localized blanching and to improve comfort.

A total of 1.81±0.73 ordered lenses were required for each patient and the principal reasons of the reorders are described in **Table 4.2**.

Table 4.2 Main reasons to the needed reorders.

Causes of alteration	N	Percentage (%)
Inadequate landing zone toricity	4	17
Inadequate refraction	5	21
Inadequate landing zone toricity and refraction	4	17
Inadequate sagittal depth and refraction	3	13
Inadequate periphery, inadequate sagittal depth and inadequate refraction	2	8
Without alteration	6	25

4.2 Optical quality

4.2.1 Visual Acuity (VA)

The HCVA and LCVA were measured under monocular and binocular conditions with Senso Mini Sclera and with ICD (after 3 hours and after 1 month). Mean binocular VA had higher values than monocular VA for all visits. VA was obtained on LogMAR scale and the values of each condition are presented on **Table 4.3**. and on **Table 4.4**.

There were statistically significant differences on monocular conditions between Senso Mini Sclera and ICD+3h (p=0.011, Paired Samples T-Test), with an improvement of 3.5 letters, and between Senso Mini Sclera and ICD+1month (p=0.023, Paired Samples T-Test), with an improvement of 3 letters. Conversely, there were no statistically significant differences between ICD+3h and ICD+1month (p=0.143, Paired Samples T-Test). On binocular conditions, there were no significant differences between Senso Mini Sclera and ICD neither between the two visits with ICD lens (p>0.05, Paired Samples T-Test).

Table 4.3 Monocular and binocular HCVA on LogMAR scale (Mean ± SD) measured with Senso Mini Sclera and with ICD.

	Monocular	**Binocular**
Senso Mini Sclera	0.14±0.44	0.06±0.10
ICD+3h	0.07±0.34	0.01±0.09
ICD +1month	0.08±0.36	0.01±0.08
	p value	
Senso Mini Sclera vs ICD+3h	***0.011+***	*0.183+*
Senso Mini Scleravs ICD+1month	***0.023+***	*0.081+*
ICD+3h vs ICD+1month	*0.143+**	*0.542+*

Statistically significant differences between the groups are presented in bold;
(+) Paired Samples T-Test
(*) Wilcoxon

Table 4.4 shows the differences on LCVA measured for both conditions and both lenses. It can be observed a significant improvement with ICD+3h comparing to Senso Mini Sclera on both monocular (p=0.001, Wilcoxon) and binocular (p=0.030, Paired Samples T-Test) conditions. On monocular conditions, it was observed that LCVA improved 1 line, however on binocular conditions the improvement was 4 letters.

Comparing LCVA between Senso Mini Sclera and ICD+1month, it can be observed a statistically significant difference on monocular values (p=0.001, Pared Samples T-Test) contrarily to the differences on binocular conditions (p=0.375, Paired Samples T-Test). There were no statistically significant differences between visits with ICD.

Table 4.4 Monocular and binocular LCVA in LogMAR scale (Mean±SD) measured with Senso Mini Sclera and with ICD.

	Monocular	**Binocular**
Senso Mini Sclera	0.44±0.14	0.31±0.11
ICD+3h	0.34±0.14	0.23±0.11
ICD +1month	0.36±0.11	0.28±0.10
	p value	
Senso Mini Sclera vs ICD+3h	***0.001****	***0.030+***
Senso Mini Sclera vs ICD+1month	***0.001+***	*0.375+*
ICD+3h vs ICD+1month	*0.225**	*0.378+*

Statistically significant differences between the groups are presented in bold;
(+) Paired Sample T-Test;
(*) Wilcoxon

4.2.2 Aberrometry

In some patients was not possible to obtain data due to the ICRSs. Aberrations were analyzed from 3th to 6th order and the values of HOA RMS, spherical RMS and coma RMS are presented on **Table 4.5**, on **Table 4.6** and on **Table 4.7** respectively.

Comparing the first two visits (3 days without Senso Mini Sclera vs after to remove Senso Mini Sclera), it was observed a decrease of HOA RMS, spherical RMS and coma RMS when the measure was performed immediately after to remove the lens. However, these differences were not statistically different (p>0.05, Paired Samples T-Test and Wilcoxon).

The values of HOA RMS between Senso Mini Sclera and ICD+3h as well as between Senso Mini Sclera and ICD+1month were not statistically significant (p>0.05, Wilcoxon and Paired Samples T-Test).

There were small differences in spherical HOA RMS between Senso Mini Sclera and ICD and comparing the measures it was observed a non-statistically significant difference between them (p>0.05, Paired Samples T-Test and Wilcoxon).

Table 4.5 HOA RMS values (Mean±SD) on different visits.

	HOA RMS (µm)	*p value*
3 days without Senso Mini Sclera	0.729±0.203	*>0.05**
After lens removal	0.651±0.158	
Senso Mini Sclera	0.337±0.221	
ICD+3h	0.406±0.259	*>0.05+*
ICD +1month	0.403±0.196	

(+) Paired Sample T-Test
(*) Wilcoxon

Table 4.6 Spherical RMS values (Mean±SD) on different visits.

	Spherical RMS (µm)	*p value*
3 days without Senso Mini Sclera	0.133±0.107	*>0.05**
After lens removal	0.089±0.075	
Senso Mini Sclera	0.090±0.053	
ICD+3h	0.113±0.89	*>0.05+**
ICD +1month	0.085±0.066	

(+) Paired Samples T-Test
(*) Wilcoxon

Table 4.7 Coma RMS values (Mean±SD) on different visits.

	Coma RMS (μm)	*p value*
3 days without Senso Mini Sclera	0.550±0.227	*>0.05+*
After lens removal	0.434±0.177	
Senso Mini Sclera	0.289±0.222	
ICD+3h	0.309±0.220	*>0.05+*
ICD +1month	0.309±0.194	

(+) Paired Samples T-Test
(*) Wilcoxon

4.2.3 Light Disturbance Analyser (LDA)

The values of LDI are presented on **Table 4.8**. Although LDI was lower with Senso Mini Sclera lens, there were no statistically significant differences between lenses. Both measurements performed with ICD (ICD+3h and ICD+1month) were very similar (p>0.05, Wilcoxon).

Table 4.8 LDI values (Mean ±SD) with Senso Mini Sclera, with ICD+3h and with ICD+1month.

	Monocular (%)	Binocular (%)
Senso Mini Sclera	17.87±8.31	11.24±5.98
ICD+3h	19.06±12.03	11.97±6.92
ICD +1month	19.73±10.27	12.29±6.54
	p value	
Senso Mini Sclera vs ICD+3h	*0.741**	*0.722**
Senso Mini Sclera vs ICD+1month	*0.411+*	*0.790**
ICD+3h vs ICD+1month	*0.728**	*0.889**

(+) Paired Samples T-Test
(*) Wilcoxon

The values of $BFC_{IrregSD}$ are presented on **Table 4.9.**

The values of $BFC_{IrregSD}$ revealed higher results for monocular conditions which means that the irregularity of the light distortion was higher when each eye was separately evaluated. Comparing the monocular results between both lenses, measurements with Senso Mini Sclera revealed higher irregularity of the light distortion than measurements performed with ICD, although without statistically significant differences. There were no differences between ICD+3h and ICD+1month (p>0.05, Wilcoxon).

Table 4.9 $BFC_{IRREGSD}$ values (Mean ±SD) with Senso Mini Sclera, with ICD+3h and with ICD+1month.

	Monocular (mm)	**Binocular (mm)**
Senso Mini Sclera	4.12±1.48	2.61±0.96
ICD+3h	4.07±1.39	2.88±1.10
ICD +1month	3.99±2.11	3.10±1.28
	p value	
Senso Mini Sclera vs ICD+3h	*0.741**	*0.505**
Senso Mini Sclera vs ICD+1month	*0.768**	*0.169**
ICD+3h vs ICD+1month	*0.728**	*0.441**

(+) Paired Samples T-Test
(*) Wilcoxon

Relatively to binocular conditions, it was observed an increase of $BFC_{IrregSD}$ value with ICD lens when compared to Senso Mini Sclera but without statistically significant differences (p>0.05, Wilcoxon). Measurements performed with ICD lens on different wearing times, showed a slight increase on the irregularity of light distortion after 1 month of ICD lens wear, however without statistically significant differences (p>0.05, Wilcoxon).

4.3 Topography

Topographic measures were performed in four moments: in the Baseline visit after 3 days without Senso Mini Sclera; in the second visit immediately after to remove Senso Mini Sclera and immediately after to remove ICD after 3 hours of use; and in the last visit after to remove ICD.

Table 4.10 shows the mean values of topographic parameters. For Senso Mini Sclera, the values of Baseline visit were compared to the values of V2, and for ICD lens the values of V2 were compared to the values of V3. Between all the comparisons it was observed just one statistically significant difference in Steep K values between Baseline visit and immediately after to remove Senso Mini Sclera on V2 (p=0.001, Wilcoxon). Relatively to Q, apparently it seemed that it tended to be lower immediately after lens removal but without significant differences (p>0.05, Pared Samples T-Test). The results comparing different wearing times of ICD were not consistent. Also, the variations on irregularity indices were not statistically significant after both lens removal.

Table 4.10 Analyzed topographic parameters (Mean±SD).

	Baseline	V2-after to remove Senso Mini Sclera	V2-after to remove ICD	V3-after to remove ICD	*p value*
Flat K (mm)	7.54±0.86	7.58±0.85	7.61±0.86	7.52±0.91	>0.05+
Steep K (mm)	6.77± 0.55	6.91 ±0.56	6.89±0.55	6.85±0.63	Baseline vs V2 **<0.002**
Flat Q	-0.50 ± 1.05	-0.46±1.02	-0.14±1.40	-0.59±0.77	>0.05+
Steep Q	-0.54± 0.70	-0.24±1.22	-0.50±0.85	-0.25±1.19	>0.05*
IS index	3.31±1.62	3.44±1.88	3.58±1.72	3.55±1.55	>0.05+
SAI	4.81±2.08	5.15±3.29	5.14±3.16	5.44±3.16	>0.05*
SRI	1.59±0.46	1.53±0.37	1.58±0.41	1.57±0.58	>0.05*

Statistically significant differences between the groups are presented in bold;
(+) Paired Samples T-Test
(*) Wilcoxon

4.4 Tear Film Surface Quality (TFSQ)

Figure 4.1 shows the values of Avg TFSQ for all the conditions analyzed. The measurement performed with Senso Mini Sclera showed a better behavior (better tear film surface quality) than Baseline measurement (p=0.011, Wilcoxon) and also than measurements with ICD+3H (p=0.025, Pared Samples T-Test) and ICD+1month (p=0.002, Wilcoxon). Although a worsening in Avg TFSQ was observed between ICD+1month and ICD+3h, the difference was not statistically significant (p=0.099, Wilcoxon).

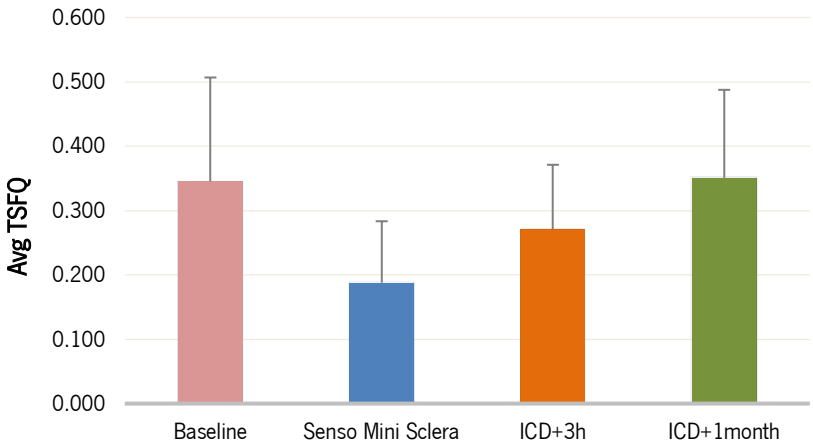

Figure 4.1 Average TFSQ (Mean±SD) values in Baseline visit, with Senso Mini Sclera, with ICD+3h and with ICD+1month.

Figure 4.2 shows the average TFSQ area (%) at each one of the visits. A statistically significant reduction in Avg TFSQ area was observed with Senso Mini Sclera (15.58±15.45) when compared to Baseline visit (p=0.027, Wilcoxon), meaning that with Senso Mini Sclera the tear film was more stable. Comparing both lenses, it was showed that ICD lens leaded to a largest area with disrupted tear film than Senso Mini Sclera (p<0.005, Wilcoxon). Although there were no statistically significant differences between Baseline measures and ICD measures (p>0.050, Pared Samples T-Test), there was a statistically significant increase in the percentage of area with tear film disrupted between ICD+3h and ICD+1month (p=0.042, Paired Samples T-Test).

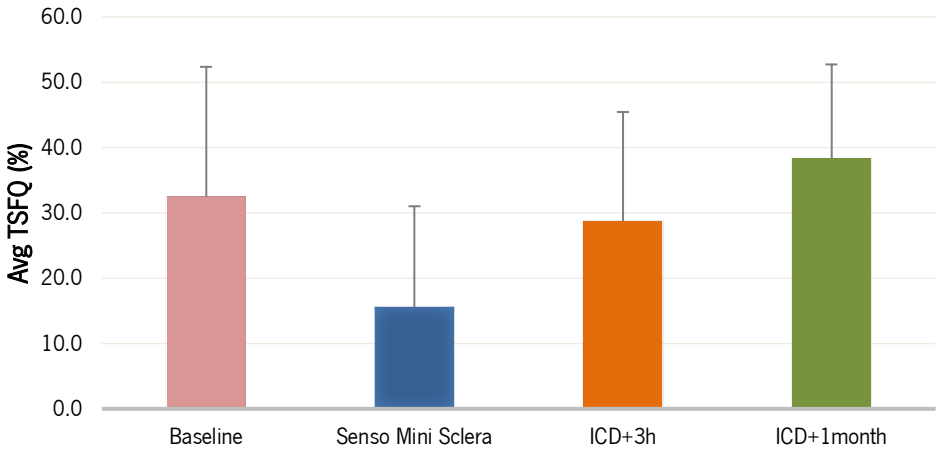

Figure 4.2 Values of Avg TFSQ (Mean±SD) expressed in area in Baseline visit, with Senso Mini Sclera, with ICD+3h and with ICD+1month.

Figure 4.3 shows the values of automatic BUT (TBUT) measured with Medmont for different conditions. The measurement performed with Senso Mini Sclera revealed the highest TBUT (meaning more stable tear film), which was better than those measured at Baseline visit (p=0.003, Wilcoxon) and with ICD+3h (p=0.001, Wilcoxon) and with ICD+1month (p=0.013, Wilcoxon). There were statistically significant differences between Baseline and ICD+3h (p=0.026, Wilcoxon), but not between Baseline and ICD+1month. There was a slight increase on TBUT values between the two visits with ICD lens, meaning an improvement on tear film stability with ICD wearing time, however without statistically significant differences between them (p=0.072, Wilcoxon).

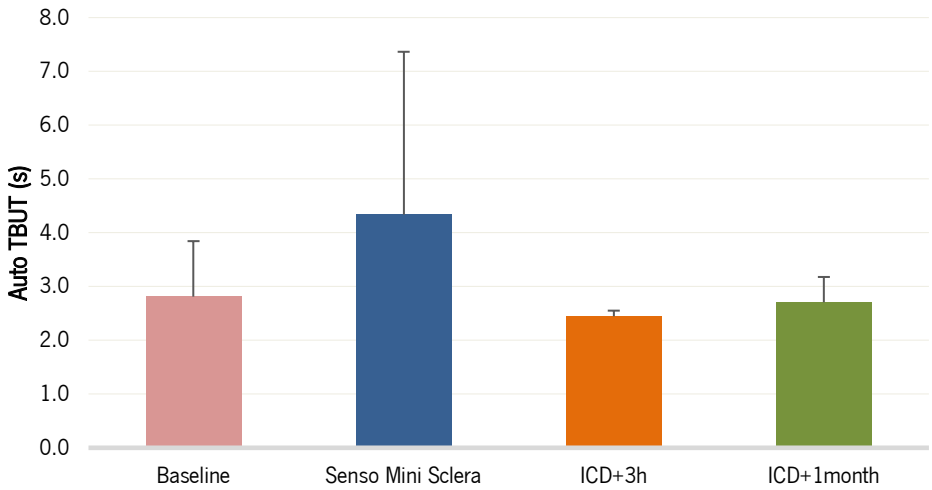

Figure 4.3 Values of auto TBUT (Mean±SD) in Baseline visit, with Senso Mini Sclera, with ICD+3h and with ICD+1month.

4.5 Ocular surface response

Table 4.11 shows the mean values of slit lamp examination after remove ICD lens on three of the four visits. V1 represents the measurements performed after diagnostic lens removal, V2 represents the measurements performed after lens removal at lens dispensing visit, and V3 represents the measurements performed after lens removal after 1 month of ICD lens wear. The represented p values for each parameter indicate the significance between V1 and V2; V1 and V3; V2 and V3 respectively.

Observing the results relatively to bulbar hyperemia, there were statistically significant differences ($p=0.008$, Pared Samples T-Test) between V1 and V2, with a higher hyperemia value on V2. There were no statistically significant differences between V1-V3 and V2-V3 ($p>0.05$, Pared Samples T-.test).

Statistically significant differences were found on limbal hyperemia between V1 and V2 and between V2 and V3 ($p<0.02$, Pared Samples T-test), with the results showing a lower value on V1 and a higher value on V2. The differences between V1 and V3 were not statistically significant ($p=0.086$, Pared Samples T-Test).

For conjunctival staining, statistically significant differences were observed between V1 and V2 and between V1 and V3 ($p<0.02$, Wilcoxon) with a higher value on V1 and a lower value on V3. Between the last two visits, the results did not show significant differences ($p>0.05$, Wilcoxon).

Comparing the limbal staining on the three visits, there were statistically significant differences only between V1and V2 ($p<0.02$, Pared Samples T-test) with V2 showing a higher value and V1 showing a lower value. There was a reduction on limbal staining from V2 to V3 although without statistical significance ($p>0.05$, Pared Samples T-Test). There were differences on corneal staining between V1 and V2 and between V1 and V3 ($p<0.02$, Wilcoxon) but not between V2 and V3 ($p=0.076$, Pared Samples T-Test). The lower value of corneal staining was obtained on V1 (0.06 ± 0.19) and the higher value was observed on V2 (0.72 ± 0.61).

Table 4.11 Values (Mean±SD) of bulbar hyperemia, limbal hyperemia, bulbar staining, limbal staining and corneal staining after ICD removal for different visits.

	V1	V2	V3	*p value*
Bulbar hyperemia	2.11±0.60	2.49±0.59	2.30±0.58	***0.008+***
				0.150+
				0.097+
Limbal hyperemia	1.98±0.78	2.70±0.65	2.24±0.80	***0.001+***
				0.086+
				0.010+
Bulbar staining	1.54±0.82	0.79±0.94	0.71±0.89	***0.001****
				0.000*
				*0.589**
Limbal staining	0.76±0.62	1.32±1.06	1.04±1.03	***0.009+***
				0.090+
				0.053+
Corneal staining	0.06±0.19	0.72±0.61	0.51±0.36	***0.001****
				0.002*
				0.076+

Statistically significant differences between the visits are presented in bold;
(+) Paired Sample T-test
(*) Wilcoxon

The results regarding slit lamp evaluation after Senso Mini Sclera removal are represented in **Table 4.12**. Two evaluations were made relatively to this lens: 3 days after lens removal (registered on V0) and immediately after Senso Mini Sclera removal (recorded on V2). There were statistically significant differences between V0 and V2 on almost all the parameters, with higher values when the evaluation was performed immediately after lens removal. Bulbar staining was the only parameter that underwent a decrease between V0 and V2, but without statistically significant differences.

Table 4.12 Values (Mean±SD) of bulbar hyperemia, limbal hyperemia, bulbar staining, limbal staining and corneal staining after Senso Mini Sclera removal on different visits.

	V0	V2	*p value*
Bulbar hyperemia	1.76±0.55	2.40±0.58	***<0.001+***
Limbal hyperemia	1.73±0.73	2.61±0.83	***<0.001+***
Bulbar staining	1.56±0.67	1.30±1.10	*0.317+*
Limbal staining	0.73±0.54	2.14±1.01	***<0.001****
Corneal staining	0.07±0.15	0.78±0.63	***<0.001****

Statistically significant differences between visits are presented in bold;
(+) Paired Samples T-Test
(*) Wilcoxon

Table 4.13 shows the values of slit lamp examination recorded on V2 after Senso Mini Sclera removal and recorded on V3 after ICD removal. For all the parameters, ICD showed a lower value. There were no statistically significant differences between the two lenses on bulbar hyperemia and corneal staining. However, on limbal hyperemia, limbal staining and bulbar staining there were statistically significant differences between the two lenses.

Table 4.13 Values (Mean±SD) of bulbar hyperemia, limbal hyperemia, bulbar staining, limbal staining and corneal staining after Senso Mini Sclera and ICD removal on different visits.

	Senso Mini Sclera	ICD	*p value*
Bulbar hyperemia	2.40±0.58	2.30±0.58	*0.234+*
Limbal hyperemia	2.61±0.83	2.24±0.80	***0.006+***
Bulbar staining	1.30±1.10	0.71±0.89	***0.005+***
Limbal staining	2.14±1.01	1.04±1.03	***0.003+***
Corneal staining	0.78±0.63	0.51±0.36	*0.056+*

Statistically significant differences between the visits are presented in bold;
(+) Paired Samples T-Test
(*) Wilcoxon

4.6 Subjective Response

4.6.1 Ocular Surface Disease Index (OSDI)

OSDI questionnaire was performed in the first visit and in the last visit in order to compare the severity of dry eye symptoms with Senso Mini Sclera and with ICD. The mean values of Senso Mini Sclera and ICD were 35.59±19.28 and 31.63±16.76 respectively. It was observed a decreased of dryness with ICD, however this difference was not statistically significant ($p>0.05$, Pared Samples T-test), suggesting that there were no subjective differences on dryness between the two lenses. Also, OSDI scores ranged from 0.00 to 70.93 with Senso Mini Sclera, being lower with ICD with a minimum value of 0.00 and a maximum value of 60.42.

4.6.2 VAS questionnaire

VAS questionnaire was applied on the first visit and on the last visit. **Table 4.14** shows the mean values of each question with VAS questionnaire. There were no statistically significant differences between Senso Mini Sclera and ICD lenses for all the analyzed parameters. Regarding handling, the results suggested that the difficulty/ easiness of handling was the same for both lenses, with the scores being higher with ICD lens. The comfort post-insertion was slightly higher with Senso Mini Sclera but the comfort after 4h and 8h of lenses wear was superior with ICD. It was observed a lower dryness during daily wear with ICD lens but after 8h of use it seemed that Senso Mini Sclera was associated to an inferior degree of dryness. Subjects considered that the visual quality with Senso Mini Sclera was better during the day and after 8h of lens wear.

Table 4.14 Values of VAS questionnaire (Mean±SD) with Senso Mini Sclera and ICD.

Question	Senso Mini Sclera	ICD	*p value*
Ease of handling	8.2±1.8	9.0±0.9	*0.124+*
Comfort post-insertion	8.6±1.1	8.3±1.2	*0.393+*
Comfort after 4h of use	8.3±0.9	8.4±1.1	*0.604+*
Comfort after 8h of use	7.2±1.8	7.6±1.5	*0.131+*
Grade of dryness during daily wear	7.1±2.7	7.4±1.9	*0.930+*
Grade of dryness after 8h of use	6.0±3.1	5.5±2.8	*0.872+*
Vision during daily wear	8.1±1.2	7.5±2.1	*0.909+*
Vision after 8h of use	7.0±2.3	6.8±2.1	*0.844+*

(+) Pared Samples T-Test
(*) Wilcoxon

The results of the 5 forced questions between both lenses are represented in **Figure 4.4.**

Relatively to the first question, 50% of the subjects chose ICD as the lens that caused more dryness while another 50% had chosen Senso Mini Sclera. ICD was chosen by 58% of the patients in terms of comfort and by 75% of the subjects in terms of vision. Relatively to preference, ICD obtained a score of 58% while 42% of the subjects continuing to choose Senso Mini Sclera.

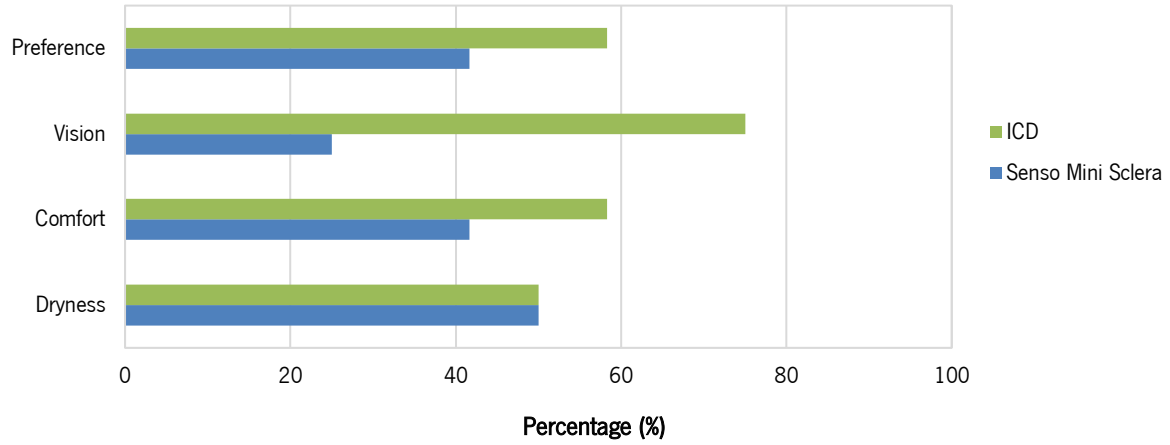

Figure 4.4 Percentage of choice between ICD and Senso Mini Sclera.

4.7 Visual Acuity and Light Disturbance Index

Figure 4.5 shows the correlations between VA and LDA (measurements performed with Senso Mini Sclera). Both HCVA (r=0.664, p=0.001 Spearman correlation) and LCVA (r=0.570, p=0.007) showed a positive moderate strong correlation with LDI values. However, there was a poor correlation between $BFC_{IrregSD}$ and HCVA (r=0.267, p=0.243, Spearman correlation) and LCVA (r=0.298, p=0.190, Spearman correlation) where it was observed a weak adjustment of the points to the line for both variables.

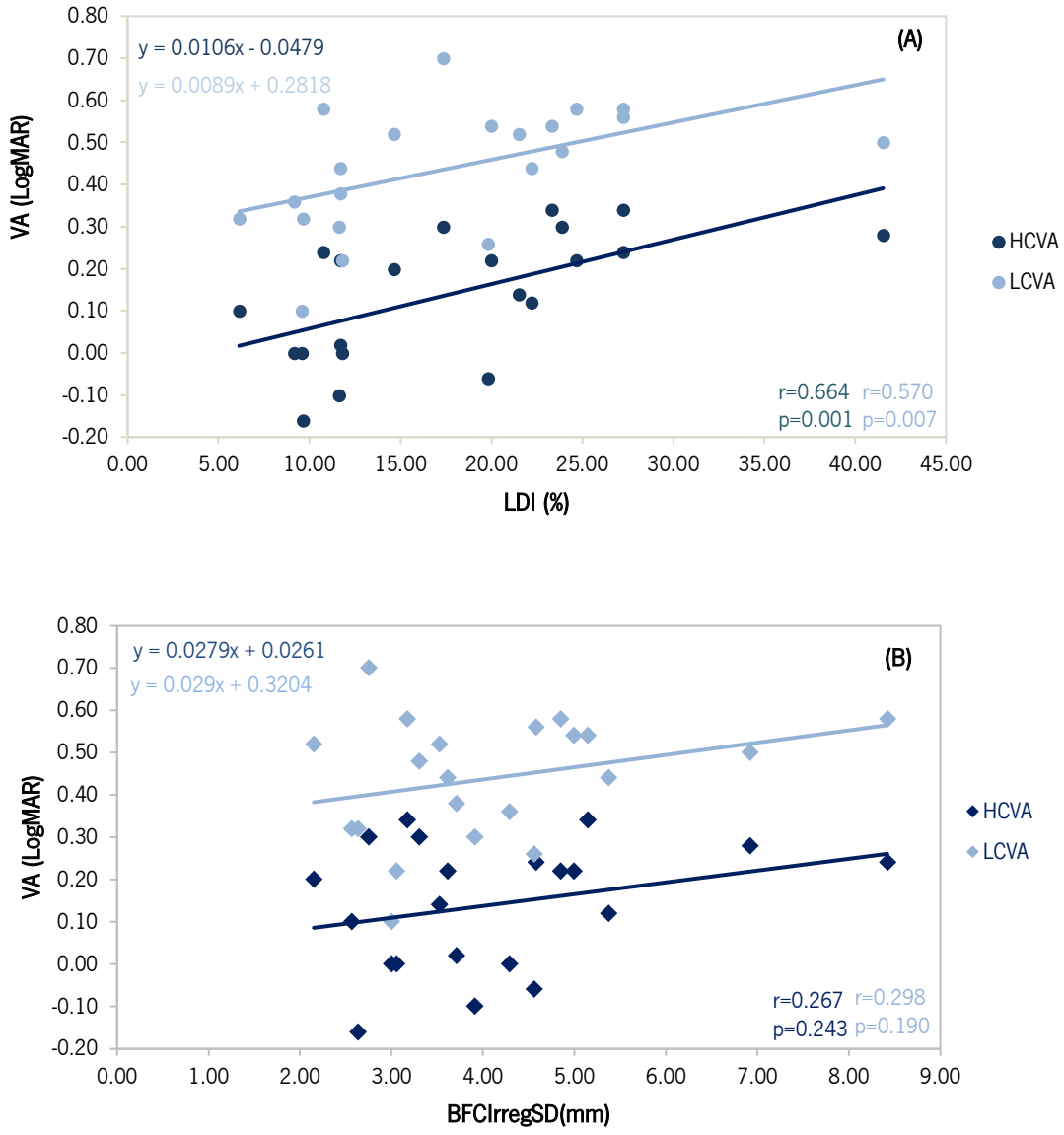

Figure 4.5 Correlation between VA and LDI (graph A) and between $BFC_{IrregSD}$ and VA (graph B) to Senso Mini Sclera .

According to the results presented in graph A from **Figure 4.6**, there was a fairly and statistically significant correlation (r=0.517, p=0.016, Pearson correlation) between LDI values and HCVA with ICD lens. The same was observed to LDI and LCVA with the results showing once again a positively strong correlation between the two variables (r=0.545, p=0.011, Pearson correlation).

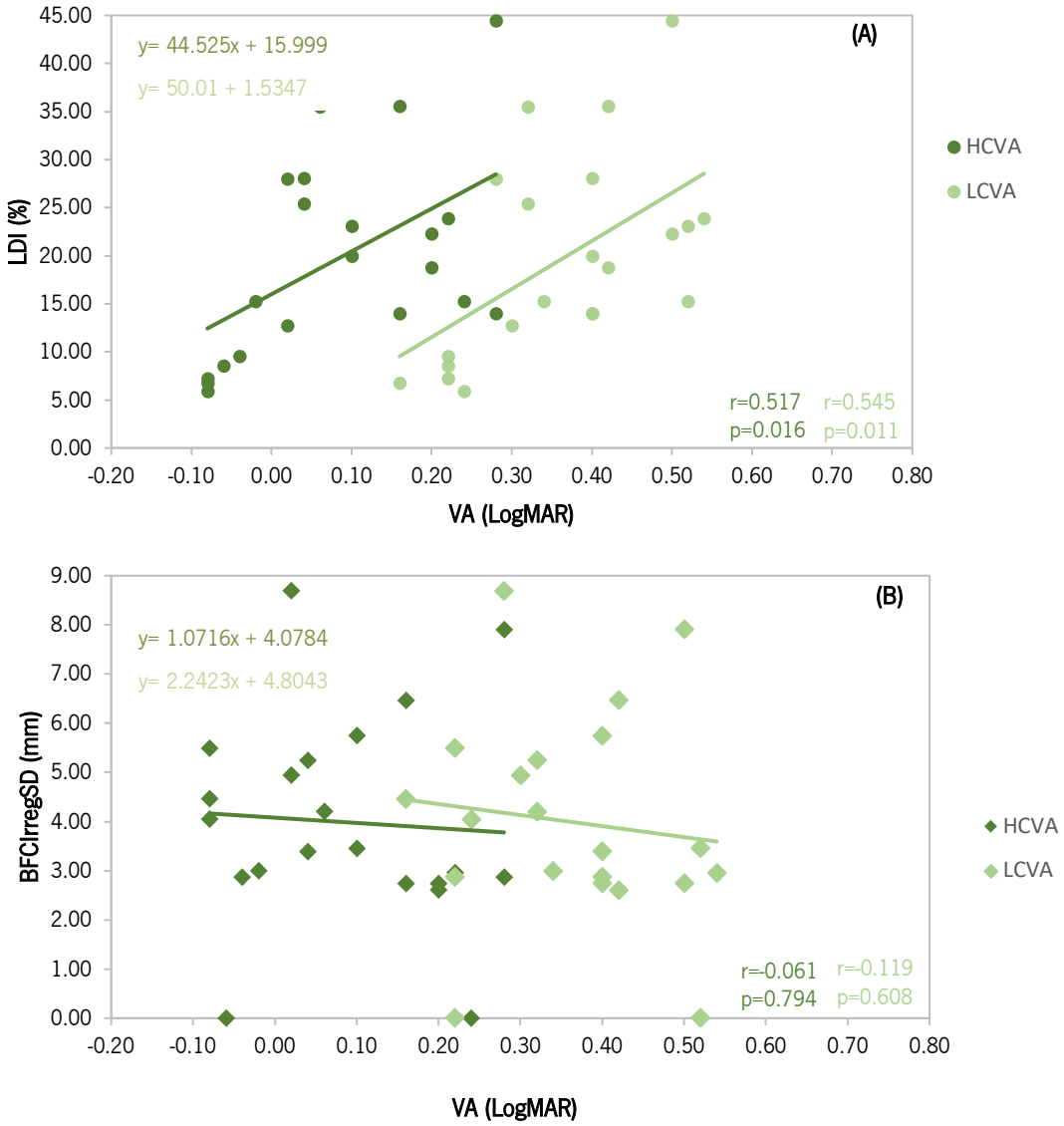

Figure 4.6 Correlation between VA and LDI (graph A) and between VA and $BFC_{IrregSD}$ (graph B) to ICD.

Analyzing the results represented on graph B from **Figure 4.6**, there was a poor and non-significant correlation between $BFC_{IrregSD}$ and HCVA (r=0.061, p=0.794, Pearson correlation) with the results showing the same non-significant relation for $BFC_{IrregSD}$ and LCVA (r=0.119, p=0.608, Pearson correlation). Besides, comparing the linear regression between $BFC_{IrregSD}$ and VA for both lenses, it was observed a positive correlation to Senso Mini Sclera lens contrarily to what happens with ICD lens.

4.8 Visual Acuity and HOA RMS

Figure 4.7 represents the graphical correlations between HOA RMS values and visual acuity to Senso Mini Sclera (A) and ICD (B).

It was observed a fairly statistically significant correlation between the two variables to both HCVA (r=0.457, p=0.043, Spearman correlation) and LCVA (r=0.494, p=0.027, Spearman correlation) with Senso Mini Sclera lens. Comparing the results from graph B, ICD lens showed a moderately strong statistically significant correlation between HOA RMS and HCVA (r=0.635, p=0.003, Spearman) and the same was observed to LCVA (r=0.603, p=0.005, Spearman correlation).

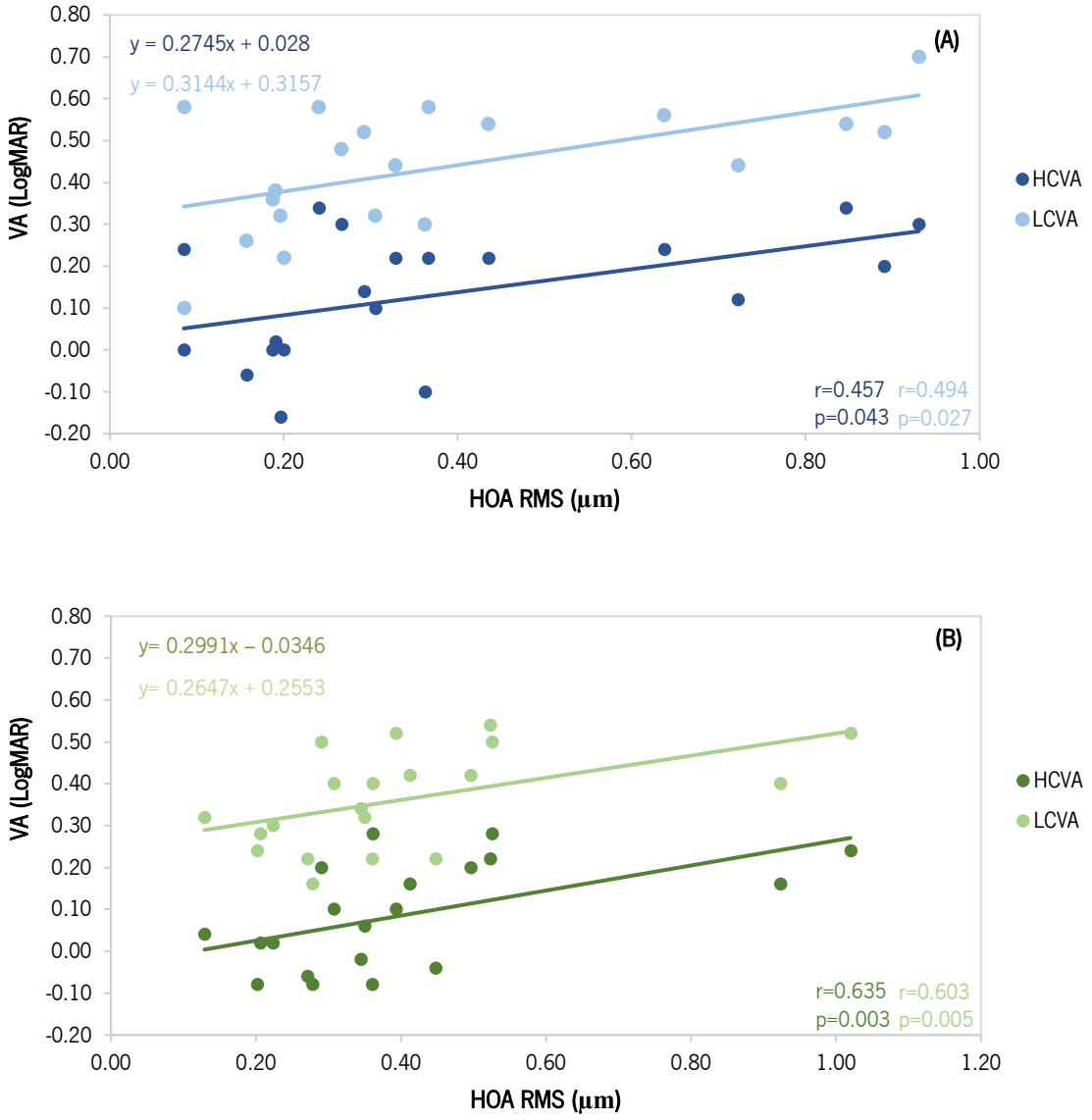

Figure 4.7 Correlations between HOA RMS and visual acuity to Senso Mini Sclera (graph A) and ICD (graph B).

4.9 Light Disturbance Analyzer and Aberrometry

Figure 4.8 shows the correlations between spherical RMS (A) and HOA RMS (B) with LDI. There was no statistically significant correlation between LDI and spherical RMS to both lenses. When LDI was correlated to HOA RMS (graph B), the results showed a moderately strong significant correlation ($r>0.300$, $p<0.050$, Spearman correlation) between the variables to Senso Mini Sclera, however the same was not observed to ICD lens ($r=0.214$, $p=0.366$, Spearman correlation).

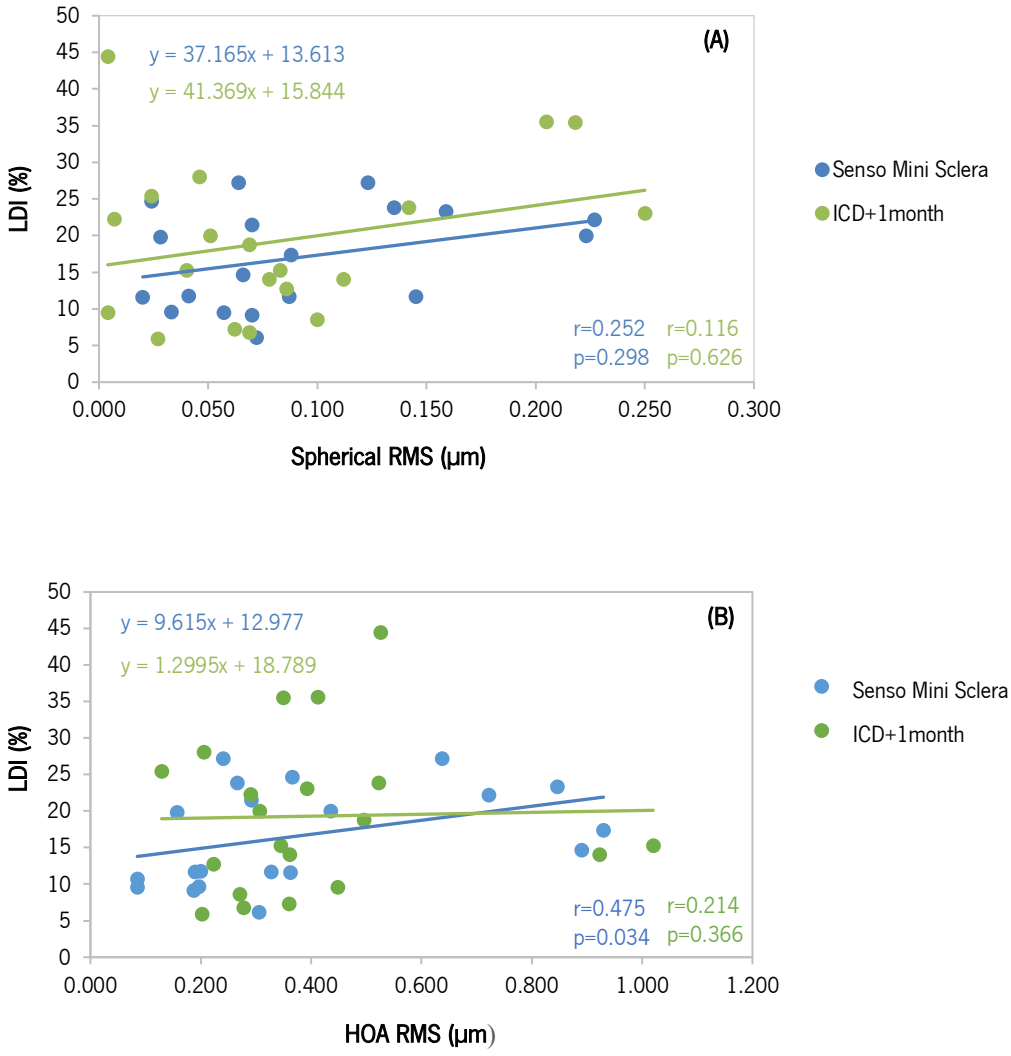

Figure 4.8 Correlation between LDI and Spherical RMS (graph A) and between LDI and HOA RMS (graph B).

Figure 4.9 shows the correlations between coma RMS (A) and HOA RMS (B) with $BFC_{IrregSD}$. It was observed that none of the results showed significant correlations between the variables, however the two correlations were higher for ICD lens.

Contrarily to all correlations from **Figure 4.7** where it was observed a positive correlation, in **Figure 4.9** there was a negative relationship between $BFC_{IrregSD}$ and HOA RMS and coma RMS for ICD lens, which means that when HOA RMS and coma RMS increased, $BFC_{IrregSD}$ tended to decrease.

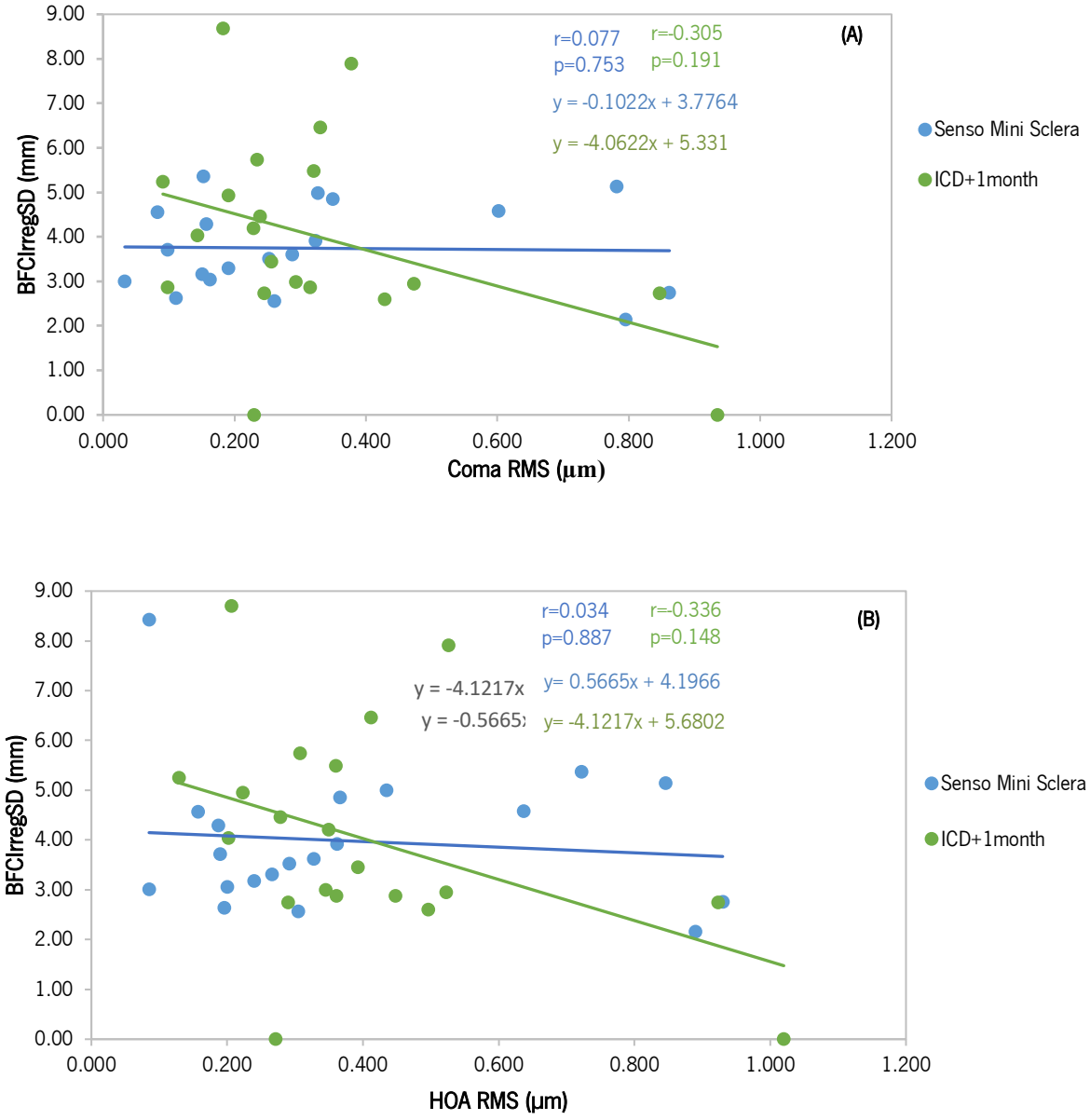

Figure 4.9 Correlation of BFCIrregSD with Coma HOA (graph A) and Total HOA RMS (graph B)

4.10 ICD sagittal depth and sagittal height on 6 mm chord

The selection of the first diagnostic lens was based on topographic measurements from 6mm chord. **Figure 4.10** shows the relation between sagittal height on the mentioned chord and sagittal depth of diagnostic lens and final lens. The mean sagittal depth of the final lenses was 4138±155 (range: 3900 to 4400). Observing the linear regression, there was a fairly statistically significant correlation between diagnostic lens sagittal depth and sagittal height of the ocular surface (r=0.480, p=0.028, Spearman correlation). When sagittal depth of the final lens was correlated to sagittal height on 6mm chord, the results showed a moderately strong statistically significant correlation between the two analyzed variables (r=0.735, p<0.001, Spearman correlation).

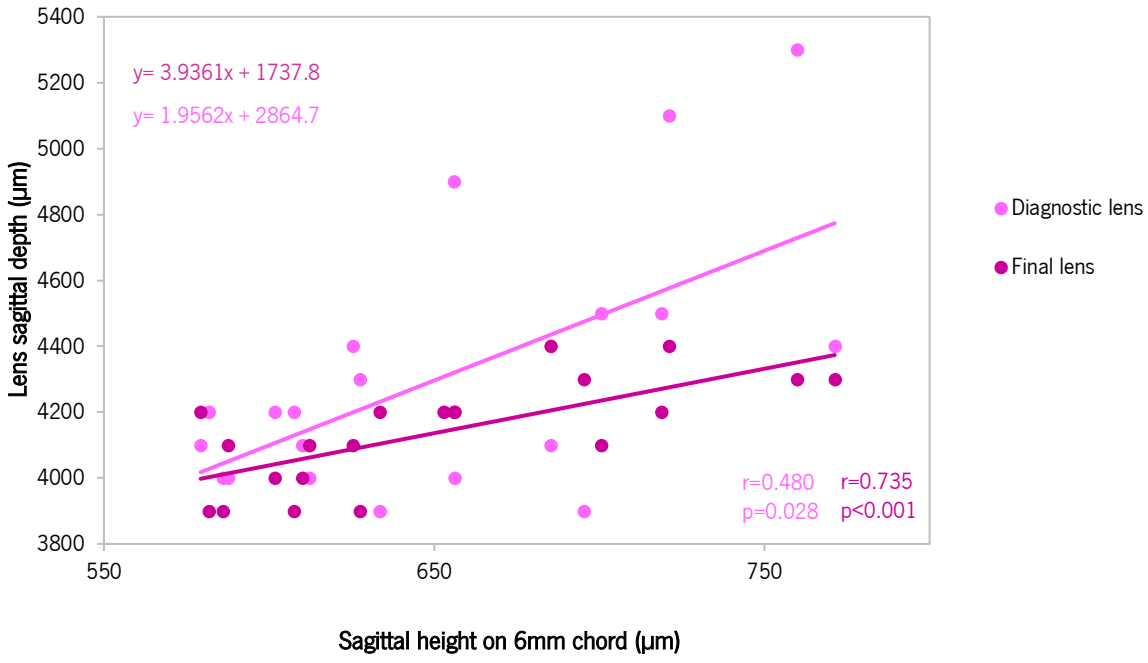

Figure 4.10 Correlation between sagittal depth of the diagnostic lens and final lens with sagittal height on 6mm chord.

4.11 OSDI scores and TFSQ parameters

Correlations between OSDI scores and TFSQ parameters are presented on **Figure 4.11**. For both lenses, there was no significant correlation between subjective OSDI parameters and objective TFSQ parameters. However, analyzing the graphs of all the related variables, the correlations always showed higher values with Senso Mini Sclera lens than with ICD lens.

Avg TFSQ showed a strong but non significant correlation with OSDI scores to Senso Mini Sclera (r=0.519, p=0.102, Spearman correlation) and the correlation became lower when OSDI scores and TFSQ were compared to ICD lens (r=0.058, p=0.866, Pearson correlation). For Avg TFSQ area and OSDI scores, there was a positive non-significant correlation between the variables to Senso Mini Sclera (r=-0.360, p=0.277, Spearman correlation), however it was observed that the same correlation to ICD lens showed negative and non-significant values (r=-0.238, p=0.482, Pearson correlation). Relatively to OSDI scores and TBUT, it was observed a negative and non significant correlation between the variables to both lenses (Spearman correlation).

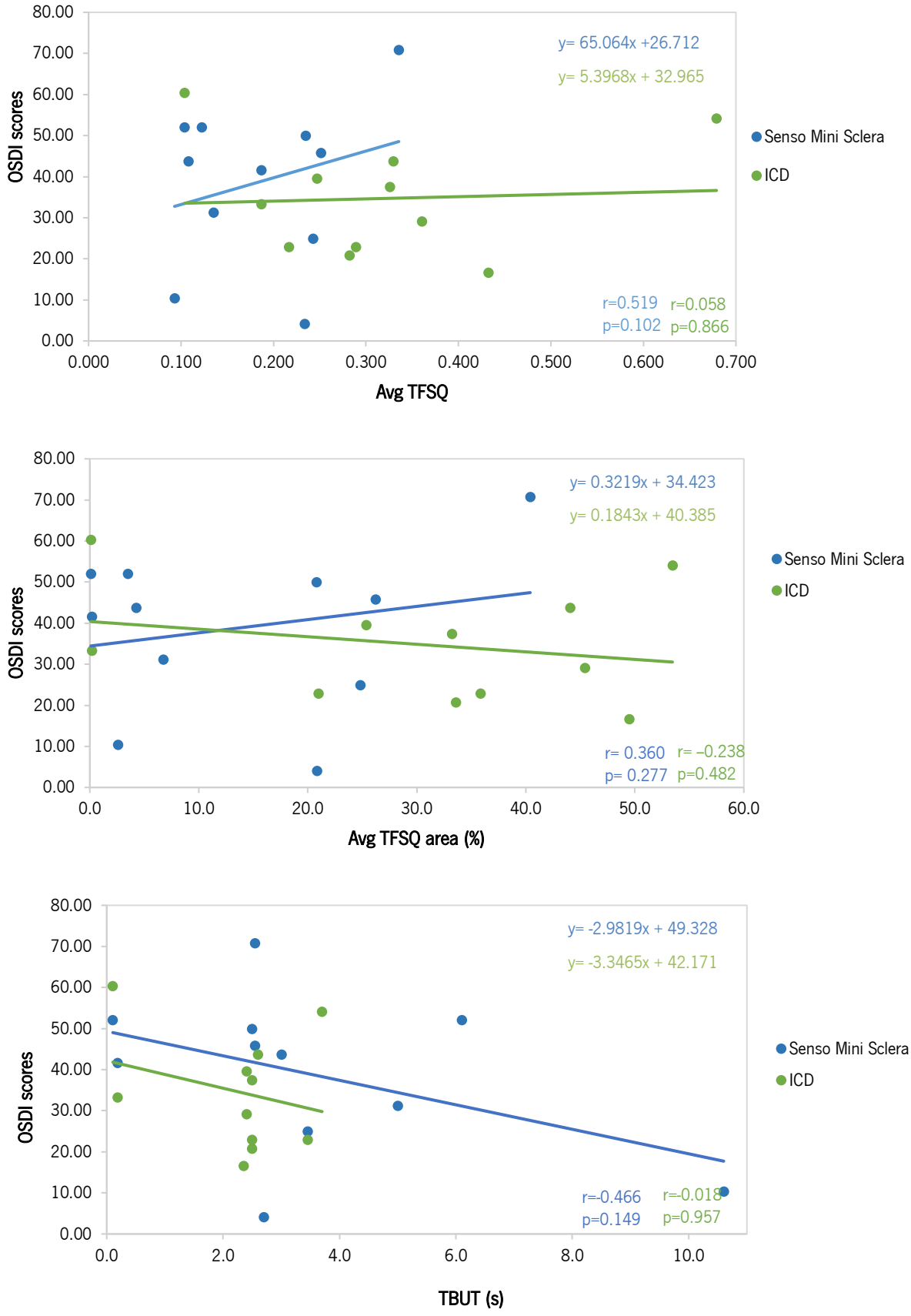

Figure 4.11 Correlations between OSDI scores and TFSQ parameters.

4.12 VAS response and Visual Acuity

The scores of the question regarding the visual acuity after 8h of lens use were compared to HCVA and LCVA for both lenses. The correlations between both variables are presented on **Figure 4.12.**

For Senso Mini Sclera lens, it was observed a fairly statistically significant correlation between question H and LCVA (r=0.477, p=0.029, Spearman correlation) but the same was not observed to HCVA (r=-0.326, p=0.149, Spearman correlation). For ICD lens, HCVA (r=0.298, p=0.189, Pearson correlation) as well as LCVA (r=0.254, p=0.267, Pearson correlation) did not show a statistically significant correlation with the select question of VAS questionnaire.

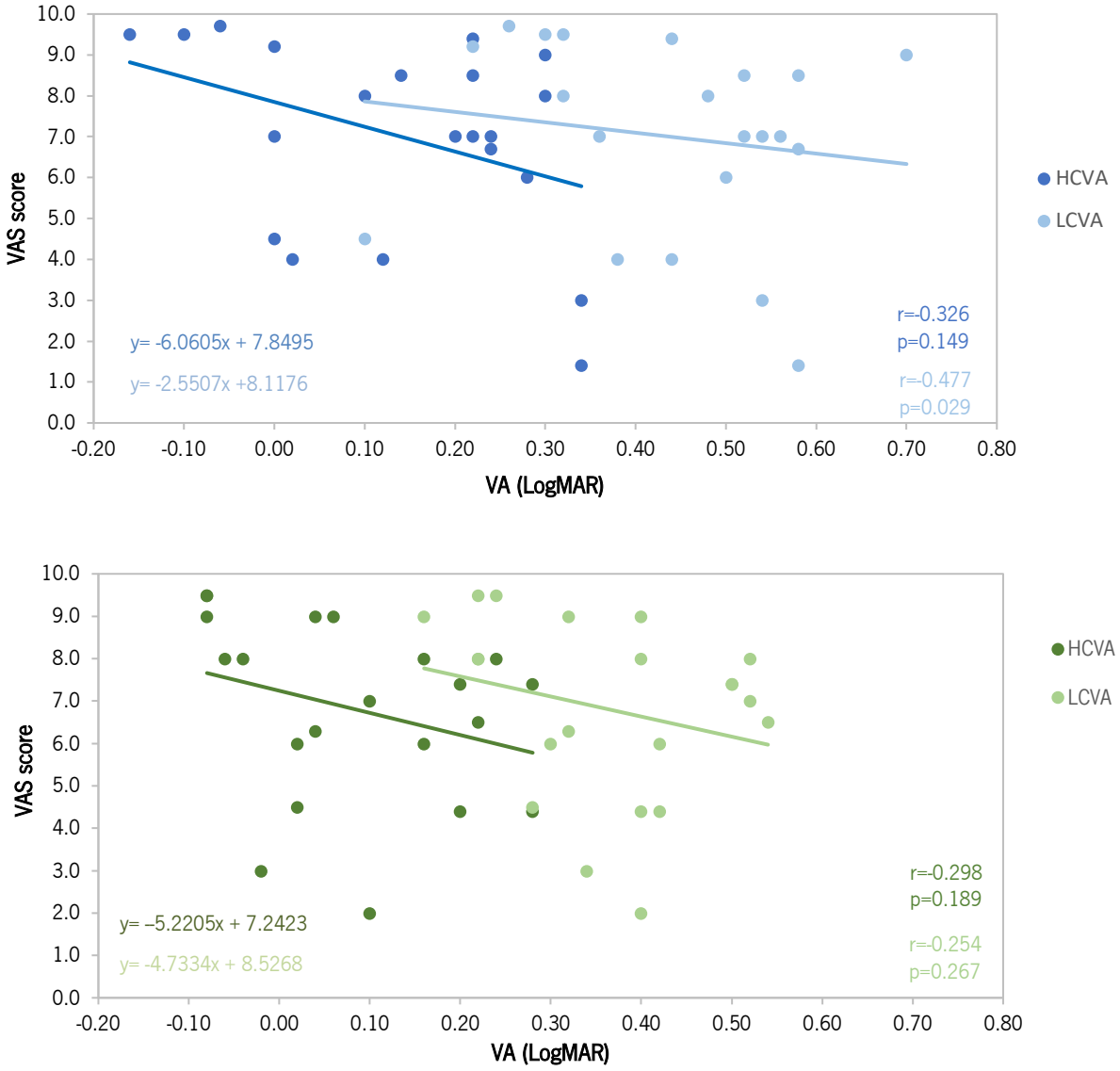

Figure 4.12 Correlation between VAS score and VA with Senso Mini Sclera (top) and ICD (down).

5. DISCUSSION

5.1 Fitting characteristics

One of the goals of this project was to analyze the topographic differences between measurements performed 5 minutes after SL removal or after 3 days of scleral lens wear discontinuation in order to evaluate the necessity to make an interruption in SL wear to perform a new fitting.

The results of the present work showed a statistically significant difference between ocular sagittal height measured immediately after Senso Mini Sclera removal and after 3 days discontinuation of the same SL. The value of sagittal height was higher after SL discontinuation; however, this difference was very small (12μm) and it was not clinically relevant.

The values of sagittal height, measured on 6mm chord, 3 days after lens removal were correlated with diagnostic and final ICD sagittal depth. A fairly and moderately strong correlation was found between sagittal height on 6mm chord and diagnostic and final ICD sagittal depth, respectively.

A retrospective analysis performed by *Macedo-de-Araújo et al* [96] enrolling 126 eyes with primary corneal ectasia, penetrating keratoplasty, post-surgical ectasia or regular corneas with high refractive errors, showed weak correlations between ocular sagittal height at 10mm and 12mm chord and SL sagittal depth. In this study we compared ocular sagittal height on 6mm chord with first diagnostic ICD sagittal depth and with final ICD sagittal depth. A fairly statistically significant correlation (r=0.480) between sagittal height on 6mm chord and first diagnostic ICD sagittal depth was found. Additionally, the correlation value increased when sagittal height on 6mm chord was associated with final ICD sagittal depth, showing a moderately strong significant relation (r=0.735). This seemed not to be in accordance with the study mentioned above. However, there were differences on the sample size and it was not possible to obtain values from some patients on 10mm chord.

A mean of 1.81±0.73 lenses were ordered in order to achieve an acceptable fit. This value seems to be in accordance with the value of 1.8±0.65 lenses described in another study performed with ICD lens in which the lenses were inserted on 39 eyes of patients with irregular corneas and ocular surface disease.[102] However it seems bigger than the value of 1.5 lenses (range 1-3) founded by *Schornack and Patel* [85], who applied the lenses on 30 eyes with Keratoconus.

It was observed that the adjustments on refraction and on landing zone toricity were the main reasons to the reorders. It is well known that the majority of the eyes have an asymmetric sclera which

demands a non- spherical landing zone in order to achieve a better comfort and a better alignment with the ocular surface. In this study, only 3 eyes were fitted with a spherical landing zone while another 18 eyes were fitted with toric peripheral curves, which correspond to 14% and 66% respectively. These values seem to be lower when compared to other studies which found a total of 94.3% and 91% of needed toric peripheral curves. However this sample was smaller than the sample used in these studies and this may explain the difference between these values.[130]

As mentioned earlier, the used diagnostic set only had a standard value of landing zone toricity (LCZ Steep +5.00). When more landing zone toricity was needed, it was necessary to reorder a lens not being certain if the amount of toricity could sufficient. If the reordered adjustment was not enough, it was necessary to reorder another lens. One of difficulties of this study was the fact that the diagnostic set did not allowed to variate and to try another SL with different landing zone toricity before ordering the final lens and this leaded to a higher number of reorders. On the other hand, the number of reorders could also be due to the inexistence of previous experience with this type of lenses by the main investigator, as suggested by other works.[113]

5.2 Optical quality

The important role of scleral lenses for visual rehabilitation is well known and documented on literature. Several studies reported the benefits and the improvements in optical quality with SL wear on many corneal disorders as well as the capacity of to protect ocular surface.[40,49,57,107] One of the main functions of SL is to improve VA due to the lens material and the fluid reservoir capable of mask the corneal irregularities and reduce HOA.

In this study, HCVA and LCVA improved for both monocular and binocular conditions with ICD when compared to Baseline assessments. Nonetheless, after comparing VA with Senso Mini Sclera and VA after 1 month of ICD wear, only the monocular results were statistically significant. For HCVA and LCVA results, the monocular differences between the two lenses were 3 and 4 letters respectively. A minor difference was found on binocular conditions with ICD showing an improvement of 2.5 and 1.5 letters respectively. These values did not correspond even to a one line of visual improvement. In the Baseline visit, an actualized refraction over Senso Mini Sclera lens was not performed in order to understand if it could have some visual improvement with this lens. Once the mean age of the sample was 42.95±7.93, it was not expected that the worst VA with Senso Mini Sclera could be related to the progression of corneal ectasia and consequently to an alteration in over refraction. Once all Senso Mini Sclera lenses had a daily wear superior to 12 months, this decreased on VA with Senso Mini Sclera might be relatively to lens surface degradation over the time.

Relatively to LDA results, the findings showed an improvement on light disturbance perception when the two eyes were open, showing a better optical quality, which was expected. There were no statistically significant differences between the two lenses regarding LDA results. However, the monocular results of BFCIrregSD with ICD seemed to be the only ones which were in line with the better results of ICD in visual acuity. Despite ICD lens presents higher values of HOA, which was not in accordance with VA, these could be explained by the instability of the tear film with the new lens. If the tear film was more unstable with ICD, when tear disrupted it caused light diffusion and consequently there was a dispersion phenomenon of light. However, even if ICD lens added some light dispersion due to the lens dehydration, the values with ICD lens were much better than those without lens.

It was mentioned earlier that SL could decentered due to the typical asymmetric sclera. This decentration may induce HOA, manly horizontal and vertical coma. If the decentration is slight, this HOA may not have visual and clinical significance.[131] Observing aberrometry results, a lower value was obtained for HOA RMS with Senso Mini Sclera, coma RMS and spherical RMS. Despite Senso Mini

Sclera presented better results, the general standard deviation of the two lenses had a higher value, which explained the non-statistically significant differences reported.

Two of the 8 questions of VAS questionnaire were related to subjective vision. The results showed that there were not subjective differences between ICD and Senso Mini Sclera, with the last one obtaining a higher punctuation. When the scores of the question regarding the visual acuity after 8h of ICD wear were correlated to HCVA and LCVA, after 1 month of daily wear, it was observed a statistically significant correlation of 0.477 between these questions and LCVA. The results might indicate that LCVA was more sensible to patient's subjectivity and it allowed to understand that sometimes subjects reported a good vision with high contrast optotypes, but they continue to have complaints.

HCVA and LCVA with Senso Mini Sclera and with ICD were correlated to LDI and $BFC_{irregSD}$. For both lenses, statistically significant correlations were found when VA was compared to LDI values, but the same did not happen with $BFC_{irregSD}$. The results with Senso Mini Sclera showed a statistically significant r value of 0.664 and 0.570 to HCVA and LCVA respectively. These values indicated that 44% of the HCVA results and 32% of the LCVA results were explained by this correlation. With ICD lens lower correlations values were found than those with Senso Mini Sclera. Approximately 27% of the HCVA values and 30% of the of LCVA values were explained by light disturbance.

Also, there was a statistically significant correlation between VA and HOA RMS for both lenses. Senso Mini Sclera showed a fairly correlation with HOA RMS for HCVA and for LCVA. It seemed that, to this lens, 21% of the HCVA results and 24% of the LCVA results were influenced by HOA RMS. These values increased with ICD lens, where it was observed a moderately strong correlation between HCVA and LCVA and HOA RMS. Apparently, 40% of the HCVA results and 36% of the LCVA results were influenced by HOA RMS.

The correlations between LDA and aberrometry did not reveal statistically significant results for both lenses, which meant that the values obtained with LDA were not directly associated and depended of corneal aberrations.

With these results it is reasonable to say that these two scleral lenses are comparable in terms of optical quality which is in agreement with the power profiles reported under methods section, with small differences in power across the optical zone in both cases. The designs of both lenses are very similar and once the results showed a lower and non-statistically significant value of visual improvement,

this small difference may be due to the fact that the new lens had a new and clean surface without any deposits or risks provoked by the lens wear, handling and disinfecting process.

It is important to note that this experimental study did not have the purpose of showing which lens provides better results. A goal that should be approached by fitting a significantly larger number of patients with both lenses, randomly, instead of consecutively.

5.3 Topography

The comparison of the topographic parameters after 3 days of scleral lens wear discontinuation and 5 minutes after SL removal showed a statistically significant flattening of 0.15±0.01mm only for Steep K values, when the measure was performed immediately after lens removal. It seemed that the lens wear induced a surface flattening which was recovered if the lens wear is discontinued. There are a few studies in literature reporting alterations on central corneal curvature after SL wear. A study conducted by *Bleshoy and Pullum* [132] showed a small flattening of corneal curvature after a 5h period of scleral lens wear (0.14 mm for the Flat K and 0.01 mm for Steep K). Another study performed by *Vincent and colleagues* [100], in subjects with normal corneas, showed a small but statistically significant flattening on corneal curvature (0.02±0.01mm) after an 8h period of scleral lens wear, which increased as long as corneal diameter increased too. However, this value was not clinically significant. With these results the authors concluded that eye care professionals should pay attention to the measures obtained after SL removal once the fluid reservoir influenced anterior surface topographic measures. Another study by the same authors revealed a statistically significant difference of 0.02±0.03 mm between the moment immediately after lens removal and after 3h of lens removal with the results showing a flatter value on the first moment in the vertical meridian. *Vincent and colleagues* [97] believed that these changes could be due to the mechanical interaction between the cornea, the lens and the upper eyelid.

However, all these studies reported results to normal and healthy corneas and the findings should not be compared to irregular corneas, once there are differences on corneal structure that may affect the final results. *Soeters et al* [133] evaluated curvature parameters immediately after lens removal and 1 week prior to lens removal in Keratoconous patients. It was observed a significant flattening of Steep K and Flat K immediately after lens removal when compared to the values 1 week after lens discontinuation. It seemed this study showed a concordance with our study relatively to the direction of the differences on the steepest meridian comparing the moment immediately after lens removal and 3 days after lens removal. The differences on the sample, the moment in which the measurements were taken and the different devices used to obtain the data may explain the variances of the results. On the other hand, this study analyzed patients who are regular users of SL for a period superior to 12 months, and all the parameters were taken considering this wearing time.

Comparing the Steep K and Flat K values after ICD removal with different wearing times (3h and 6-8h), it was observed a steepening of the corneal curvature but with no statistically significant differences. This seemed to differ from a recent study performed by *Severinsky, et al* [134], where it was observed a significant flattening of anterior corneal curvature in keratoconous patients with and without CXL, after 2h

and 5h of SL wear. However, in this study, there was not a previously daily use of SL, i.e the SL was inserted for the first time and the measures were taken after the mentioned period, which differs from the present study due to the wearing time of the users.

In the present study, the values of SAI, SRI and IS index were evaluated as well. It seemed that the discontinuation of SL could affect these irregularity indexes, however the differences were not statistically significant. The same was observed for different wearing times of ICD but the results did not show statistically significant differences. In this study, the variations of these indexes were not consistent and did not happen in the same direction. In all articles mentioned above, none revealed the differences on irregularity parameters and it was not found literature where these indexes were analyzed to different wearing times of SL and after SL discontinuation. This may be because the alterations on anterior corneal surface induced by SL wear are not enough to induce significant modifications on these indexes. But further investigation is necessary to understand if these factors could lead to an alteration on these values as there are no other studies reporting this information.

With these results it was found that, there were not significant differences, to the majority of the measured parameters, between 3 days after SL discontinuation and immediately after Senso Mini Sclera removal. However, subjects should discontinue the use of the previous lens in order to let the ocular surface make a rest before a new strange body interact with it.

5.4 TFSQ and subjective response

The tear layer is the primary barrier that light founds when it passes through ocular surface and it has an important role on optical quality. When a CL is over the corneal surface, the pre corneal tear layer divides itself in pre lens tear film and post lens tear film. In the case of SL wear, the way tear spreads over the SL surface will impact on image perception.

There is still minimal information in literature relative to the dynamics of tear film over a SL with a long-term use but there are some results on short term wear. One studies of *Carracedo et al* [99] compared TBUT values in 26 subjects with Keratoconus before and after an 8h use of ICD and did not found statistically significant differences. This seemed to be in accordance with what was found in this study when the values of Baseline visit were compared to the values of ICD+1month.

In a recent study performed by *Serramito et al* [104], 49 patients with Keratoconus were fitted with ICD lens and TFSQ was analyzed after 1 month of lens wear. The authors did not find statistically significant differences between Baseline visit and 1 month after ICD wear, with the last one showing the worst value, which combines with the results from this study, where it was possible to see higher values in the last visit. The authors justify these values by the maintenance of the lens wettability. In this study, some patients reported wettability problems and described the symptoms as "cloudy vision". These symptoms were confirmed by slip lamp examination where it was observed a poor tear spreading over the SL that probably caused light diffusion and dispersion. In order to improve these symptoms and the quality of vision, patients were advised to remove SL and to clean the anterior and posterior lens surface, making a manually rub (to eliminate deposits and improve wettability) and then to reinsert the lens. As described by *Melissa Barnett* [67] this strategy is time consuming and for some patients it was difficult to find a proper and cleaned local to make these steps properly in their daily job. Another followed strategy was to clean the anterior lens surface with a cotton swab moistened with the manufacturer solution with the lens on eye. As described by the same author "*Patients with certain ocular surface diseases are especially at risk for poor surface wettability".* Notwithstanding there are other reasons that could lead to these findings, in particular the use of make up or oil-based skincare products such as lotions, makeup removers and hand soaps with moisturizing agents. According to a recent review performed by *Vincent and Fadel* [131], the initial poor wettability founded in ICD lenses could be explained by the laboratory issues such as over-polishing or the adherence of residual substances from the manufacturing process, or handling throughout shipment or in-office.

The poor tear spreading over SL may have an influence on results: TFSQ was obtained by the projection of Placido's rings on lens anterior surface and if the rings were not well reflected on lens anterior surface, the values probably will differ from those with a well humected lens. In this study, TFSQ was accessed with the different lenses and after a 3 days discontinuation of Senso Mini Sclera. In all the parameters obtained with dynamic topography, there were statistically significant differences between Senso Mini Sclera and ICD. There were already statistically significant differences between Baseline visit and Senso Mini Sclera to all the evaluated parameters (Avg TFSQ, Avg TFSQ (%) and TBUT) with the results showing the better performance of Senso Mini Sclera over ICD.

Even with a new fitting, patients showed better tear film quality values with Senso Mini Sclera than with ICD after 3 hours and 1month of lenses wear. These findings could be explained by the long-term use of Senso Mini Sclera (equal or superior to 12 months), which provideed a higher biocompatibility between this lens and the ocular surface. It could be interesting to repeat these TFSQ measures after a long-term use of ICD lens and comparing it with the values obtained with Senso Mini Sclera in order to understand if the differences were really explained by the biocompatibility question or if those were due to the different material of the two scleral lenses.

Relatively to the responses of VAS questionnaire, a higher punctuation in the questions of visual quality was observed for Senso Mini Sclera, however without statistically significant differences between this lens and ICD. This seems to be in discordance with forced choices of VAS questionnaire, performed in the last visit, in which 75% of the subjects reported a better vision with ICD lens.

OSDI results were in agreement with VAS results: there were not statistically significant differences between dryness with both lenses and 50% of the subjects felt higher dryness with Senso Mini Sclera while another 50% felt higher dryness with ICD.

When trying to correlate OSDI scores and TFSQ parameters, no meaningful neither statistically significant differences were found.

With these results it is reasonable to say that, in general, there was a good subjective response to the new fitting and that the subjects did not feel much subjective differences between the two lenses. Although, a largest number of eyes are needed to understand if these results are consistent.

5.5 Ocular surface response

The majority of the values of Baseline visit (after a 3 days discontinuation of Senso Mini Sclera lens) showed statistically significant differences when compared to those immediately after lens removal. These findings seemed normal once it was made a 3-day rest of the SL previous to Baseline visit.

Bulbar hyperemia, limbal hyperemia, bulbar staining, limbal staining and corneal staining were evaluated in all visits after lenses removal. It was observed that ICD lens showed lower values than Senso Mini Sclera lens for all the analyzed parameters, however limbal hyperemia, bulbar staining and limbal staining were the only ones where statistically significant differences were found.

These findings could be explained by the lifetime of Senso Mini Sclera and by the gradual degradation of lens material over time which may lead to some type of reaction of ocular surface. Another possible reason could be the differences on lenses materials: Senso Mini Sclera is made of Hexafocon A while ICD material is Paflufocon D.

With differences on lenses materials, lenses care products had to be changed. The habitual solution used with Senso Mini Sclera was Boston Simplus (Baush+Lomb) and Boston Advance Cleaner (Baush+Lomb).Boston Simplus is a sterile, aqueous, buffered solution that contains poloxamine, hydroxyalkylphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%) and polyaminopropyl biguanide (0.0005%) and Boston Advance Cleaner is a sterile, concentrated, homogeneous surfactant solution containing alkyl ether sulfate, ethoxylated alkyl phenol, tri-quaternary cocoa-based phospholipid and silica gel as cleaning agents, with titanium dioxide.

Apparently these two products are contraindicated by the manufacturer for ICD care. Subjects started to use Hefilcon solution (Lenticon) and Duolens surfactant (Lenticon). Hefilcon solution contains sodium schloride, boric acid, sodium tetraborate, hydroxypropyl methylcellulose, poloxamer, disodium edetate (0.1%) and polyhexamethylene biguanide (0.0004%) in purified water and Duolens surfactant contains boric acid, sodium tetraborate, hydroxyethylcellulose, disodium cocoamphodiacetate, isopropyl alcohol (20.0%) and disodium edetate (0.1%) in purified water.

The composition of the liquids and the surfactants are different, and this probably had influence on ocular surface response.

6. CONCLUSIONS

This study allows us to conclude that:

- There is large possibility of refiting habitual scleral lens users with another scleral lens, despite the different characteristics;

- There is significant correlation between sagittal height on 6mm chord and sagittal depth of ICD lens that subjects are wearing;

- Both Senso Mini Sclera and ICD lens provide similar visual results and the small differences can be due to the lifetime of Senso Mini Sclera;

- A 3 days discontinuation of the SL wear of just induces a significative alteration on Steep K;

- TFSQ shows better results with Senso Mini Sclera lens and tends not to alter after 1 month of ICD daily wear;

- In this sample, LDI is correlated with HCVA and LCVA;

- Habitual SL users should discontinue SL wear before performing a new fitting in order to allow a rest to the ocular surface;

- A good and actualized diagnostic set is very important in order to achieve a better fitting and it could be essential to reduce the number of reorders. However, the previous experience with this type of fittings might influences the number of the reorders.

7. FUTURE WORK

- To include a larger sample with more clinical conditions (i.e. PMD, dry eye disease, etc) in order to understand if the findings between the two lenses could show more representative results;

- Validate in a larger sample the algorithm of first lens sagittal height selection for ICD 16.5 based on the 6 mm chord diameter corneal height derived from the topographer;

- To evaluate the clinical performance of the ICD lens in the longer term;

- Conduct a parallel clinical trial with random allocation to both interventions in order to assess the clinical performance on a prospective trial.

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9. APEENDIX

Attachment 3 Approved protocol by Ethics Subcommittee for Health and Life Sciences (SECVS) of the University of Minho.

Universidade do Minho

SECVS

Subcomissão de Ética para as Ciências da Vida e da Saúde

Identificação do documento: SECVS 171/2014

Título do projeto: Clinical performance and biological interactions in scleral contact lens wear

Investigador(a) responsável: Doutor José Manuel González-Méijome, da Escola de Ciências, da Universidade do Minho, e Rute Juliana Araújo, aluna do Mestrado da Escola de Ciências da Universidade do Minho Subunidade orgânica: Escola Ciências, Universidade do Minho

PARECER

A Subcomissão de Ética para as Ciências da Vida e da Saúde (SECVS) analisou o processo relativo ao projeto intitulado *"Clinical performance and biological interactions in scleral contact lens wear".*

Os documentos apresentados revelam que o projeto obedece aos requisitos exigidos para as boas práticas na experimentação com humanos, em conformidade com o Guião para submissão de processos a apreciar pela Subcomissão de Ética para as Ciências da Vida e da Saúde.

Face ao exposto, a SECVS nada tem a opor à realização do projeto.

Braga, 19 de janeiro de 2015.

A Presidente

MARIA CECÍLIA DE LEMOS PINTO ESTRELA LEÃO

Digitally signed by MARIA CECÍLIA DE LEMOS PINTO ESTRELA LEÃO
DN: c=PT, o=Cartão de Cidadão, ou=Cidadão Português, ou=Assinatura Qualificada do Cidadão, sn=DE LEMOS PINTO ESTRELA LEÃO, givenName=MARIA CECÍLIA, serialNumber=BI014512203, cn=MARIA CECÍLIA DE LEMOS PINTO ESTRELA LEÃO
Date: 2015.01.20 13:21:32 Z

Attachment 2 Consent Form signed by every participant in this project.

Título do estudo: Optical and visual quality of two scleral lenses

Enquadramento: O projeto será desenvolvido nas instalações da Escola de Ciências da Universidade do Minho, no âmbito da Dissertação de Mestrado em Optometria Avançada, sob a orientação do Professor Doutor José Manuel González Méijome e da Doutora Rute Araújo.
O presente documento e os procedimentos a que diz respeito, respeitam a "Declaração de Helsínquia" da Associação Médica Mundial (Helsínquia 1964; Tóquio 1975; Veneza 1983; Hong Kong 1989; Somerset West 1996 e Edimburgo 2000, Seul 2008).

Explicação do estudo

Este estudo tem por objetivo adaptar uma lente de contacto de apoio escleral disponível no mercado a utilizadores prévios deste tipo de lente, com o propósito de:

- analisar a capacidade de readaptação de uma lente de geometria semelhante à anterior, mas com algumas diferenças de desenho;
- compensar uma irregularidade da córnea (tecido transparente localizado na parte anterior do olho) derivada de uma patologia ocular que se desenvolveu (queratocone, degeneração marginal pelúcida, complicação cirúrgica, acidente, etc);
- compensar uma irregularidade corneal que poderá ter surgido em consequência de uma cirurgia ocular;
- compensar um erro refrativo elevado em casos onde não seja possível uma acuidade visual normal com outros tipos de lentes de contacto (por exemplo, astigmatismos regulares elevados);
- Perceber qual a lente idónea para a prescrição final.

Deste procedimento farão parte avaliações objetivas e subjetivas com a lente anterior e com a nova lente.

A adaptação consistirá em aplicar diferentes lentes até ser encontrada aquela que melhor compensa o problema da visão e fazer a devida avaliação clínica. Para isso realizar-se-ão procedimentos de avaliação visual, que são comuns na rotina clínica. Será ainda essencial aplicar um corante na

lágrima (fluoresceína) para avaliar a adaptação da lente, que não perturbará a visão. Seguidamente irão ser dadas instruções para uma correta e saudável utilização das lentes esclerais e

será iniciada uma utilização regular das mesmas. Assim são necessárias as seguintes consultas de acompanhamento, que iram ser calendarizadas pelo profissional da visão (sem prejuízo de serem alteradas para conveniência do paciente e do profissional):

- Consulta 3 dias depois da lente antiga ser retirada para a adaptação da nova lente escleral e avaliação da qualidade ótica e visual com a lente anterior;
- Consulta para adaptação da lente de teste, e posterior avaliação da adaptação;
- Consulta 3-5 semanas após a adaptação da lente para avaliar o seu estado e prescrição da lente final.

Riscos Potenciais

Com as lentes poderá sentir, principalmente nos primeiros dias de uso os seguintes sintomas:

- Ligeiro desconforto;

- Vermelhidão ocular leve (se for intensa deve contactar o investigador principal);

- Em casos raros, a lente poderá provocar uma ligeira lesão na córnea que será devidamente avaliada e se for necessário deixará de utilizar as lentes por algum tempo até se resolver a situação. Em casos menos frequentes a lente poderá provocar uma lesão mais profunda na córnea limitando temporariamente a visão;

- Em casos raros o uso de lentes de contacto poderá provocar uma infeção corneal sendo a frequência desta ocorrência de 1 a 20 casos em cada 10.000 usuários de lentes de contacto. Desses casos, uma percentagem baixa poderá experimentar diminuição definitiva da visão no olho afetado mesmo após a resolução da infeção;

- É importante que informe o investigador se notar qualquer alteração repentina de conforto ou aparência dos seus olhos;

- Para minimizar os eventos anteriores, deve cumprir todas as indicações dadas pelo investigador.

Por favor, leia com atenção a seguinte informação. Se achar que algo está incorreto ou que não está claro, não hesite em solicitar mais informações. Se concorda com a proposta que lhe foi feita coloque as iniciais do seu 1º e último nome à frente de cada afirmação.

1. Concordo que me foi prestada a informação necessária, e foi igualmente dada oportunidade de colocar qualquer questão, tendo sida respondida de modo satisfatório; ☐

2. Concordo que os dados obtidos sejam analisados e utilizados para efeitos de investigação sem que, em qualquer momento, a minha identidade seja revelada; ☐

3. Concordo em que seja realizado o procedimento que consiste na adaptação de umas lentes esclerais para compensar o meu problema de visão e os exames necessários para a sua realização; ☐

4. Compreende que o tratamento proposto e a avaliação por nós realizada não impede que consulte outros profissionais da visão, nomeadamente o médico oftalmologista para acompanhamento complementar do seu estado de saúde ocular; ☐

5. Compreende que existem outras alternativas para a compensação do seu problema de visão e que no caso de alternativas cirúrgicas deverá consultar o médico oftalmologista para avaliar se se aplicam ao seu caso concreto; ☐

6. Compreende que é importante para a sua saúde ocular seguir as instruções dadas pelo seu profissional da visão, utilizar as lentes esclerais conforme for recomendado e assistir no período previsto para a realização das consultas de acompanhamento conforme combinado. ☐

Em _____, a _____ de _____ de 201__

O paciente: _____ Assinatura:_____

O investigador: Ana Luísa Moreira Marques Assinatura: _____

Contactos do investigador principal: Ana Luísa Moreira Marques
luisamarques96@hotmail.com Tlm: 917945345

Este documento é composto por 3 páginas e feito em duplicado: uma via para o/a investigador/a e outra para a pessoa que consente.

Attachment 3 VAS Questionnaire

Inquérito Subjetivo para comparação das duas lentes

Data: ___ /___ /___

1.Responda às seguintes questões marcando com uma linha horizontal a sua resposta a cada lado da escala vertical, lado direito para a lente direita (➔) e ao lado esquerdo para a lente esquerda (🡐):

A.Facilidade de manuseamento das lentes

B.Conforto com as lentes logo após a inserção

C.Conforto com as lentes às 4 horas de uso

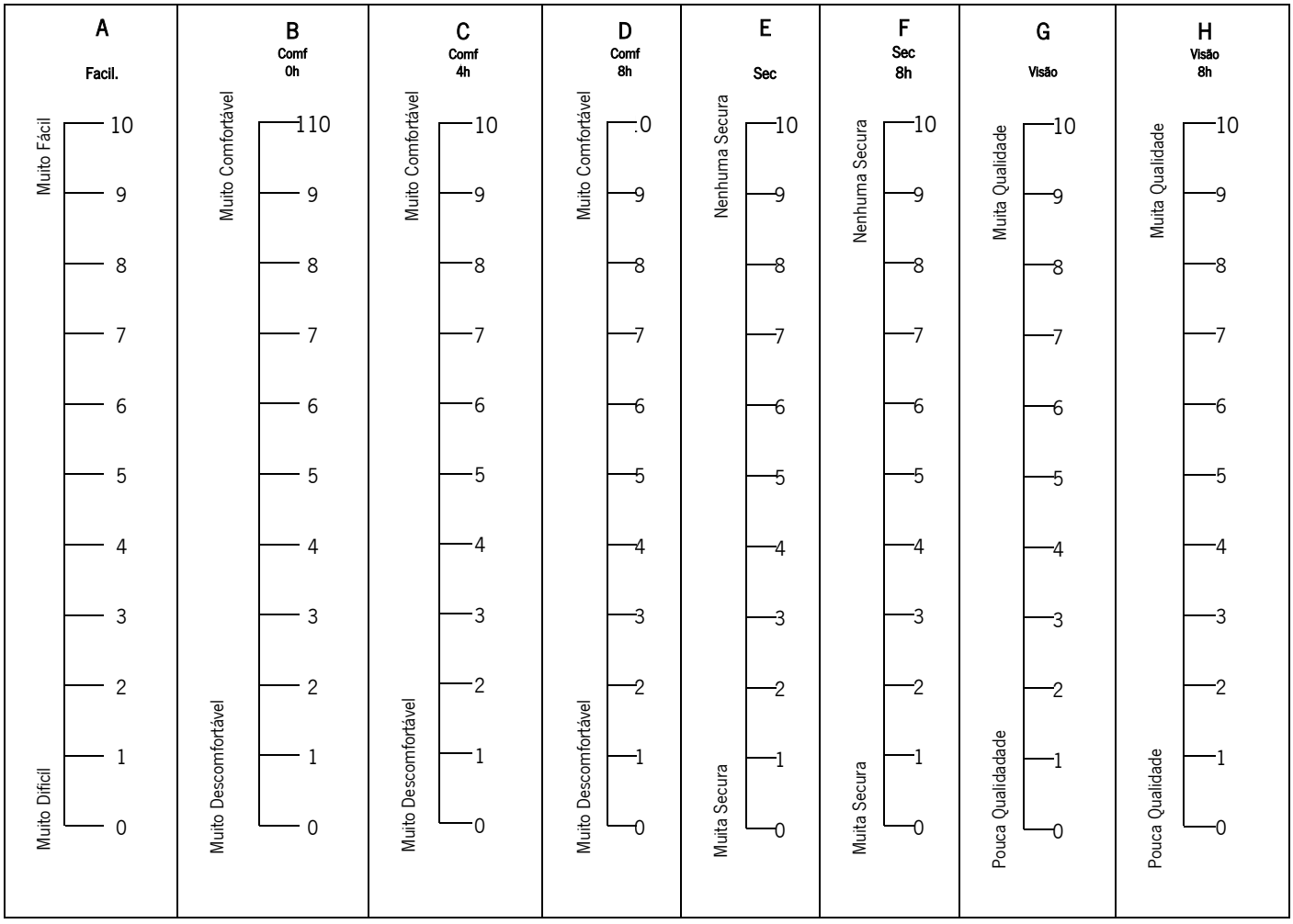
D.Conforto com as lentes às 8 horas de uso

E.Grau de secura durante o dia

F.Grau de secura depois de 8 horas de uso

G.Visão com as lentes durante o dia

H.Visão com as lentes depois e 8 horas de uso



2. Com qual das lentes sentiu maior secura ocular?

Lente Antiga ◯ Lente Nova ◯

3.Qual a lente que preferiu em termos de conforto?

Lente Antiga ◯ Lente Nova ◯

4.Qual a lente que preferiu em termos de visão?

Lente Antiga ◯ Lente Nova ◯

5.Em termos globais, qual a lente que preferiu?

Lente Antiga ◯ Lente Nova ◯