UNIVERSITY OF LATVIA
FACULTY OF PHYSICS AND MATHEMATICS
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CUSTOM-MADE SOFT CONTACT LENSES FOR COMPENSATION OF OCULAR ABERRATIONS

BACHELOR THESIS

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ANOTĀCIJA

Darbs uzrakstīts angļu valodā uz 63 lapām. Tas satur 46 attēlus, 1 tabulu un 53 atsauces uz literatūras avotiem.

Mērķis. Novērtēt agstāko kārtu aberāciju (HOA) ietekmi uz redzes funkcijām un acs optisko kvalitāti FOOT kontaktlēcu (KL) nēsātājiem.

Metodes. Tika izmērīts redzes asums gadījumos (RA), kad acī ievietotas FOOT KL un parastās gāzu caurlaidīgās KL. Tika izmērītas visas aberācijas (TA) un HOA gadījumā, kad ievietotas abu veidu lēcas.

Rezultāti. FOOT KL gadījumā RA bija tāds pats kā parasto KL gadījumā, vai augstāks ($p<.01$). FOOT KL gadījumā TA un HOA līmenis bija tāds pats kā parasto KL gadījumā, vai mazāks (p-value $< .01$).

Secinājumi. FOOT KL sniedz augstāku RA nekā parastās KL un samazina TA un HOA līmeni salīdzinājumā ar gadījumu, kad acs nav koriģēta.

Atslēgas vārdi. Augstāko kārtu aberācijas, viļņu frontei pielāgotas KL, FOOT KL.

ABSTRACT

Thesis is written in English on 63 pages. It contains 46 figures, 1 table and 53 references.

The aim. To examine visual performance and optical quality with high order aberrations (HOA) after FOOT CLs application.

Method. BCVA with best habitual GP lenses and with FOOT CLs were recorded and compared. Total and HOA for uncorrected eyes and with FOOT CLs were recorded and compared.

Results. All subjects reached the exit criteria of BCVA equal to or better than those with best habitual GP lenses ($p<.01$). All subjects reached the exit criteria of total and HOA equal to or lower than those for uncorrected eye ($p<.01$).

Conclusion. FOOT CLs provide greater BCVA than those achieved with habitual GP lenses and lower total and HOA than those measured for uncorrected eye.

Key words. High order aberrations, Wavefront-Optimized contact lenses, FOOT CLs.

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INTRODUCTION

FOOT Soft Contact Lenses

FOOT soft contact lenses (CL) represent the most advanced in the field of soft contact lenses and are the result of nine years of research. It is patented as type invention (patent number: 001404352) and it is the first contact lens of its kind.

To generate the all-new lens, the IMAGO CONTACT® company introduced a new fully computerized industrial process. This procedure is based on the communication between the total aberrometer Keratron® ONDA, manufactured by the OPTIKON 2000 s.p.a., and the 3D ray-tracing software developed by the same Imago Contact® (Gottardini, 2013; Gottardini & Manganotti, 2013). Data on the ocular wavefront obtained with the aberrometer ONDA, must be compressed into output file with ".ZER" extension and extrapolated from the computer. Subsequently, the ".zer" file must be sent to the company laboratory together with the application parameters, which are TD (total diameter), BOZR (back optic zone radius), diagnostic CL axis and direction of rotation, CL material (Gottardini, 2013). All transmitted data are transferred to the ray-tracing software and properly processed. Finally, this software communicates with an experimental nanometer control CNC lathe, equipped with swinging arm and tolerances of 16 nanometers, which generates the FOOT soft contact lens (Gottardini, 2013). After the acquisition of aberrometric maps, the refractive error data are included in the data packet that is extrapolated from the Keratron ONDA instrument, in the form of low order aberrations (LOAs) and the compensation for them is included in the wavefront-optimized correction. Therefore for the purpose of carrying out FOOT CL, classical preliminary refraction is not required (Gottardini, 2013; Gottardini & Manganotti, 2013).

The great innovation introduced by FOOT wavefront-optimized soft contact lenses, lies in the ability to customize the new front surface of the lens so that it is able to change the wavefront of the eye of each one examined, optimize it to ensure that the visual performance is excellent (Gottardini, 2013). The new front surface is characterized by a "sui generis" shape, totally dissymmetrical (i.e. lack of symmetry), with variable geometry. In correspondence of its front optic zone diameter (FOZD), it is characterized by variable thickness and curvature radii from point to point of acquisition (in reference to aberrometric maps) (Gottardini, 2013). In order to be applied, the front profile of the surface of the CL must be subjected to interpolation, a process of construction of a curve or of a mathematical function that has an exact match with the number of points assigned (Gottardini, 2013).

The front surface is marked with three reference notches, in analogy with toric CLs, distant from each other by 10°. The central reference axis is placed at 270° (see coordinate system shown in figure 1).

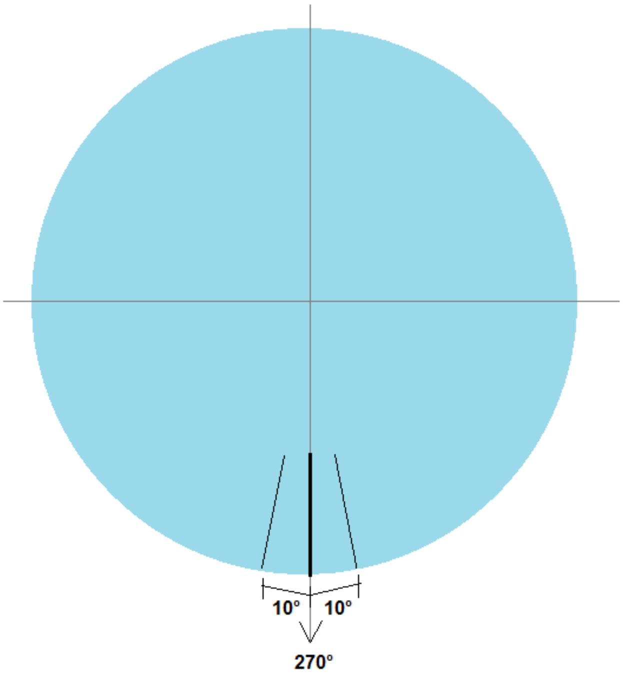

Fig. 1. FOOT CL coordinate system.

These will be used to evaluate and quantify a possible rotation of both trial soft lenses and FOOT CL during the slit lamp examination, with a tolerance of 5° (Lupelli & Petrini, 2016). The axis and the direction of rotation are part of the parameters to be transmitted to the company to carry out the wavefront-optimized correction (Gottardini, 2013; Gottardini & Manganotti, 2013). The posterior surface instead is equipped with a custom aspheric geometry, with hyperbolic periphery, suitable to limbo-scleral support, optimized in thickness, depending on the specific type of lens and the application technique used (materials for the construction and application techniques will be illustrated below) (Gottardini, 2013; Gottardini & Manganotti, 2013). To obviate lens rotation errors that would compromise the compensation of ocular aberrations with optimized wavefront, it has been adopted a prismatic balancing system (Ballast prism) and slab-off (Gottardini, 2013; Gottardini & Manganotti, 2013). A soft CL to ensure good tear flow and replacement and improved oxygenation must continually move when worn. But if a FOOT CL moves too much, it could alters the wavefront correction (De Brabander, Chateau, Marin, G. et al., 2003). The 3D ray-tracing software calculates the final complementary wavefront considering a typical predetermined movement of the lens in situ (Gottardini, 2013; Gottardini & Manganotti, 2013). The purpose of this process is to reduce the decay of the visual quality that occurs as a result of the periodic displacement (post blinking or because of eye movements) of the surface that makes the refractive correction (Gottardini, 2013; Gottardini & Manganotti, 2013). However, a minimum displacement must be present and typically is provided that is approximately 0,5 mm, in full agreement with the scientific literature with which we have faced (De Brabander, Chateau, Marin, G. et al., 2003; Gottardini, 2013; Gottardini & Manganotti, 2013). The application technique that has been defined provides that the displacement of the lens is within these terms (Gottardini, 2013). Furthermore, this value has been established as clinically effective displacement which a soft CL must have in order to avoid that the tear replacement is compromised (De Brabander, Chateau, Marin, G. et al., 2003).

Contact Lens Materials: GMA / 2-HEMA

The choice of the most suitable CL's material for the construction of wavefront-optimized lenses represents a fundamental step. The minimum characteristics that the material must possess include, first of all the dimensional stability. It must be emphasized that a dimensional instability of the polymer would result in decreased visual quality. Other characteristics are respect constant comfort, a continuous oxygenation, a suitable wettability, the best resistance to deposits and the consequent decrease of the possibility of developing infections (Gottardini, 2013). The sum of these characteristics ensures, together with an effective application technique, the observance of the physiology of the eye tissues by limiting the alterations (Gottardini, 2013).

As an example, the figure 2 shows a right eye corneal topography of a subject using conventional soft CL (Methafilcon) and complained discomfort (Gottardini, 2013). It should be noted a suspicious formation in the vicinity of the pupil, approximately at 80° with respect to the center of the pupil. See CLMI index: magnitude (Ma) is 1,62 D and the presence of keratoconic pattern (PPK) is 4,0%. Right eye parameters are: Sf. -3,50 D Cyl. -1,87 D Ax. 170°, horizontal visible iris diameter (HVID) of 12,20 mm (Gottardini, 2013).

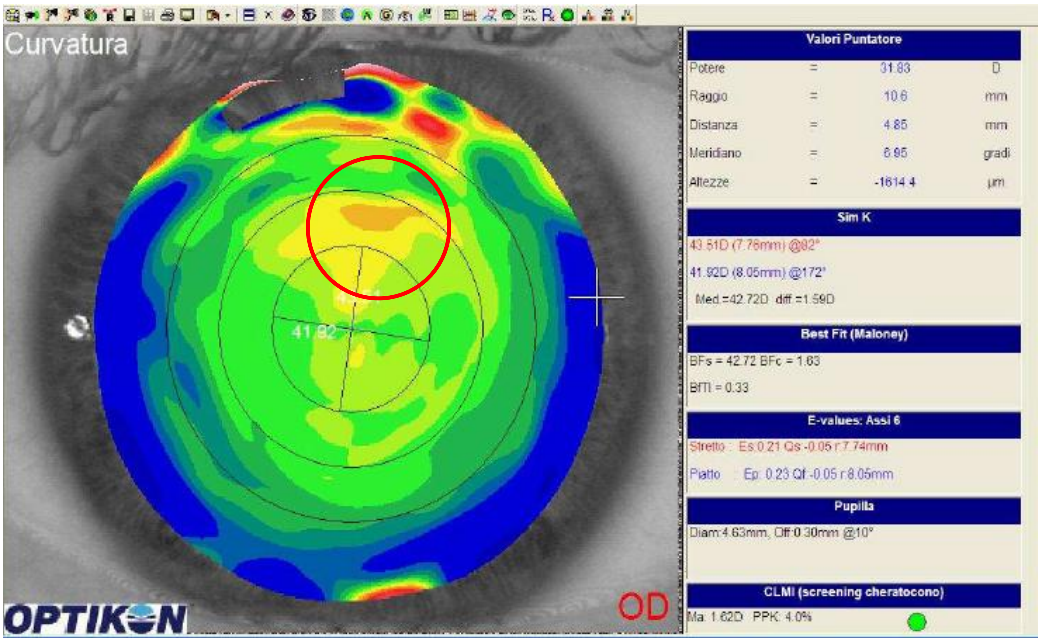

Fig. 2. Right eye corneal topography without CL. It is noted a suspicious formation in the vicinity of the pupil, approximately at 80° with respect to the center of the pupil (Gottardini, 2013).

Found that it was not an artifact highlighted from the map, the subject has been applied to a custom soft contact lens, materials of last generation G4X p-GMA/HEMA (Hioxifilcon D), water content 54% and Dk 23. The applied CL total diameter (TD) was larger than 1,50 mm compared to HVID (MINI 15 technique) (Gottardini, 2013). G4X CL parameters were: TD 13,70 mm and BOZR (back optic zone radius) 8,30 mm. After twenty days a new topographic map was acquired, it is shown in figure 3.

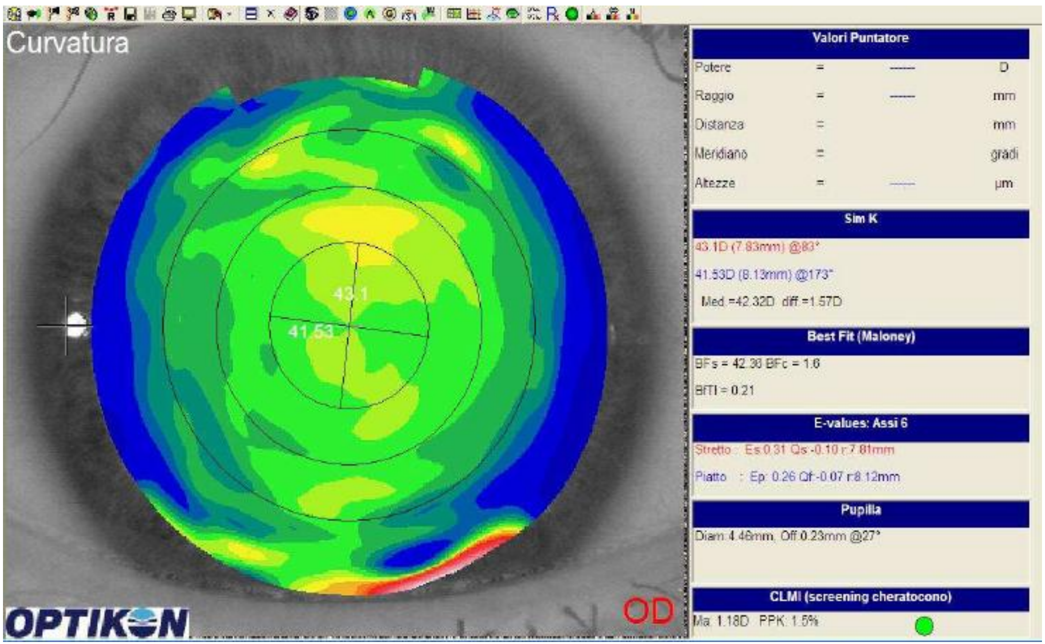

Fig. 3. Right eye corneal topography without CL after twenty days wearing new G4X CL material (Hioxifilcon D). Suspicious formation vanished (Gottardini, 2013).

The suspected formation is no longer present and the values of Ma and PPK are 1,18 D and 1,5% respectively. The subject being examined has no longer complained about discomfort and the recorded visual quality was stably high.

GMA (**Glycerol Methacrylate**) and 2-HEMA (2-hydroxyethylmethacrylate) copolymers are respectively available with water content 49% (Hioxifilcon B), 54% (Hioxifilcon D), 59% (Hioxifilcon A), 72% (G72 HW), 75% (Hybrid Ultra O2 Plus) (Gottardini, 2013). Figure 4. shows GMA/HEMA characteristics declared by the manufacturer (*).

Sigla Materiale	Modello lente	Descrizione materiale	Produttore	% contenuto idrico*	DK*	Color
M1	G4 - G6	*G4X p-GMA/HEMA (Hioxifilcon D)*	BENZ	54%	23	Blue/Clear
M2	G4	*G5X p-GMA/HEMA (Hioxifilcon A)*	BENZ	59%	26	Blue
M4	G4	*G72 HW*	BENZ	72%	42	Blue
M3	G12	*G3X p-GMA/HEMA (Hioxifilcon B)*	BENZ	49%	17	Clear

Fig. 4. Characteristics of GMA/HEMA declared by the manufacturer (*). Extracted from confidential construction list of Imago Contact® (Gottardini, 2013).

All GMA/HEMA lose less than one percent of the total water content during the wear, remain stable in terms of their size and maintain a constant oxygen transmissibility on the eye expressed in Dk/t units (Benz, 2008; Benz & Jose, 2008). From experimental research conducted by Gottardini T. (2013) it showed that these variations, less than 1%, have no effect on the wavefront-optimized correction obtained by FOOT CL.

Basically there are two families of materials available for the construction of custom soft lenses: the first is the family of LIDOFILCON materials, i.e. copolymers of methyl methacrylate (MMA) and N-vinylpyrrolidone (NVP), the second family is that of G-materials. The copolymers of MMA/NVP are available with a water content from 50% to 77% or, in the case of Lidofilcon modified with addition of various monomers, with a water content from 48% to 72% (Benz, 2008). The G-HEMA instead can be divided into: GMA and 2-HEMA copolymers 54% (Hioxifilcon D) and 59% (Hioxifilcon A) of water content; only GMA to 72% (G72 HW) or 75% (Hybrid Ultra Plus O2) of water content (Benz, 2008; Benz & Jose, 2008).

The Lidofilcon lenses show large variations in size and dehydrate very into contact with the eye: they lose from 12% to 18% of water when worn, so as to be smaller and in a steeper application (Benz, 2008; Benz & Jose, 2008). The GMA/HEMA contact lenses, however, do not show significant dimensional changes or water loss when in contact with the eye. Figure 5 shows the variation of the ON-EYE water content of a lens Acuvue (Ethafilcon, water content stated in the blister between 55% and 60%) and a lens of high performance G5XES (Hioxifilcon A, said water content 59%) (Benz, 2008). The Acuvue contact lens loses about

13% of the stated water content, while the G-5XES lens does not undergo significant variations. Figure 6 displays the ON-EYE dimensional variations of two types of contact lenses compared (Lidofilcon A, ES 70 and Hioxifilcon A, G-5XES) (Benz, 2008). The latter does not undergo significant changes during the port, contrary to what happens for the ES 70 lens.

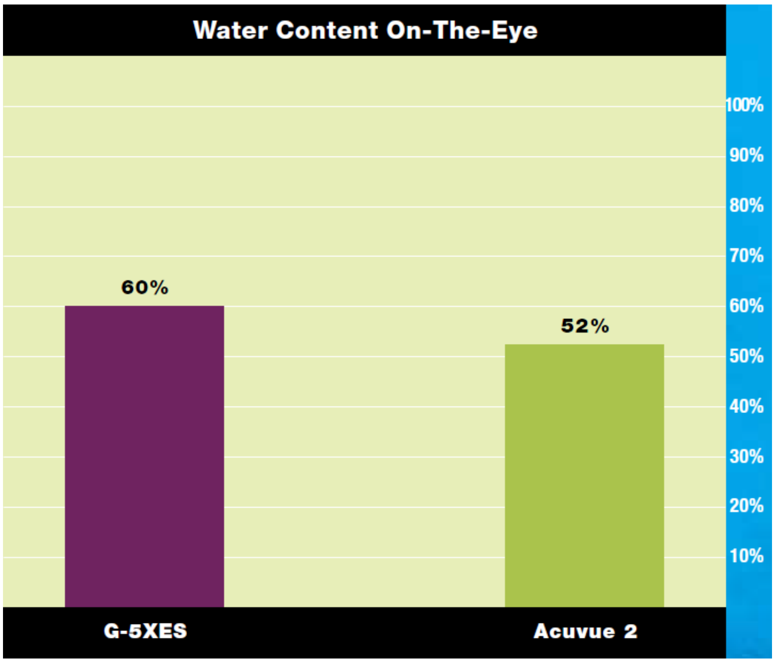

Fig. 5. ON-EYE water content variation between a Acuvue CL (Ethafilcon, water content between 55% and 60%) and a G-5XES CL (Hioxifilcon A, water content 60%) (Benz, 2008).

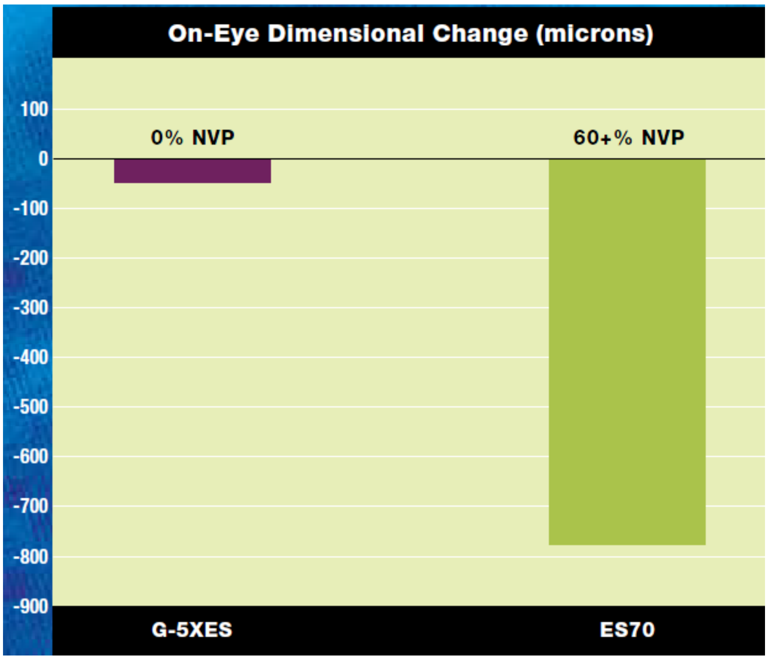

Fig. 6. Dimensional changes during the wear of two types of soft contact lenses: Hioxifilcon A (G-5XES) and Lidofilcon A (ES 70) (Benz, 2008).

With regard to the oxygen transmissibility expressed in Dk/t units, Brennan et al. studies have shown that the percentage of corneal oxygen consumption is at its maximum when the contact lens worn, for daytime use, it has a Dk/t equal to or greater than 20 units (Benz, 2008).

Therefore it is evident that a Dk/t of at least 20 units ON-EYE should be a must for a customized contact lens made from high-performance materials. Figure 7 shows three types of G-materials, produced by the firm BENZ, that meet this criterion, G4X, G-5XES and Ultra Plus O2 (Benz, 2008).

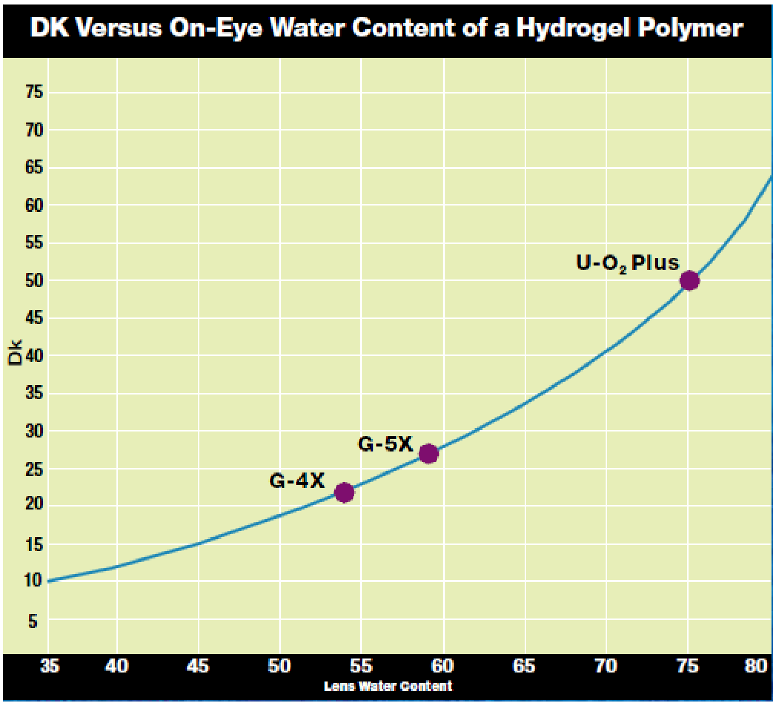

Fig. 7. G4X, G-5XES e Ultra O2 Plus, ON-EYE water content and Dk (Benz, 2008).

The dehydration of the contact lens, as well as to affect the Dk of the same, causes a variation in the geometry itself, altering both the diameter and the base curve. Starting from a base curve of 8,70 mm, a variation of saturation equal to 87% implies a variation of base radius of 0,27 mm. To this, we must add the phenomena of alteration of the mechanical properties and wettability of the CL (Benz, 2008; Benz & Jose, 2008). Clinically has value only the water content of the CL when worn, i.e. on the eye, and not the one referring to CL still sealed in the container (Benz, 2008; Benz & Jose, 2008). In Figure 8 the saturation level during the wear of a Acuvue contact lens (Lidofilcon A) is compared with that of a G-5XES lens (Hioxifilcon A).

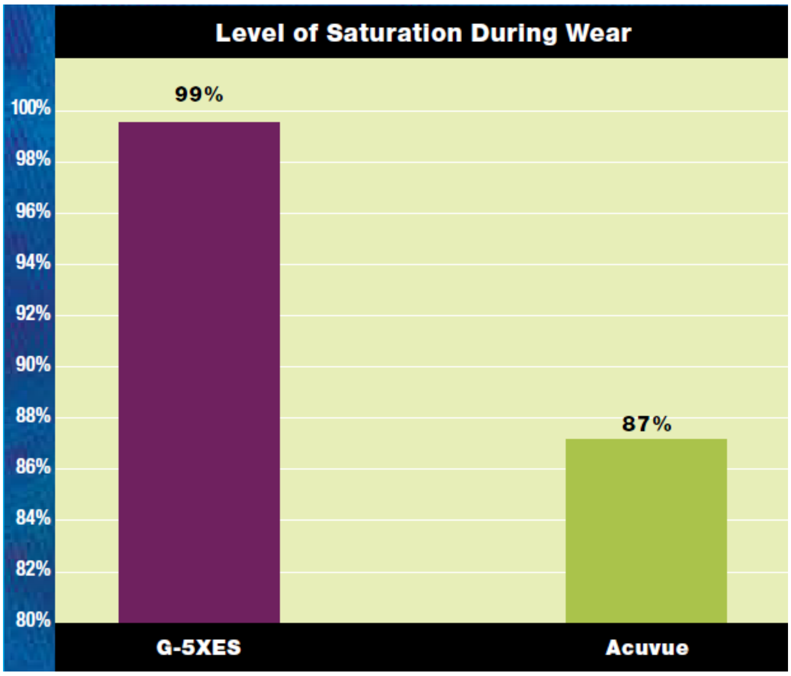

Fig. 8. Comparison between the ON-EYE saturation level of a high-performance CL (G-5XES) and a low-performance CL (Acuvue) (Benz, 2008).

The high-performance Hioxifilcon A lens maintains a saturation level of 99% against 87% of the Acuvue during the port (Benz, 2008).

The Lac a value of permeability to oxygen on the eye (Dk) hydrogel parameter is influenced by the average thickness (t) of the lens itself (inversely proportional) (Benz, 2008). When we consider the Dk as a function of the average thickness of the CL, we are considering the oxygen transmissibility (Dk/t) of hydrogel CL. Therefore, compatibly with the mechanical strength, the thickness of the CL must be relatively content (Benz, 2008). Figure 9 presents a graph showing the relationship between the Dk/t on the eye and the average thickness of four contact lenses: G4X, 54% H_2O; G-5XES, 59% H_2O; G72 HW, 72% H_2O; U-O2 Plus, 75% H_2O (Benz, 2008) .

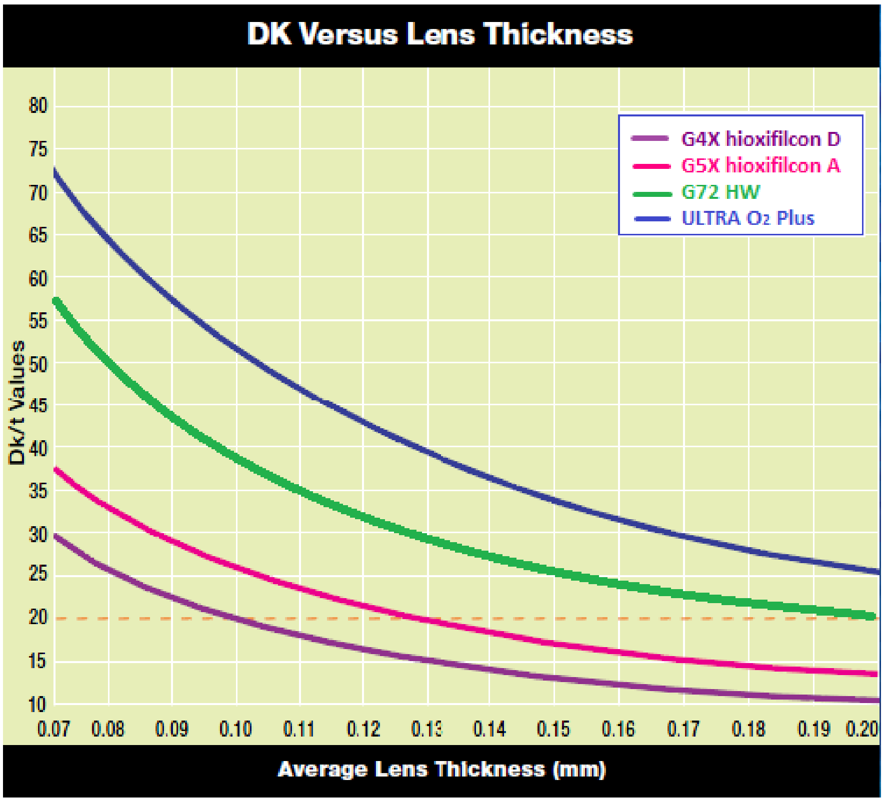

Fig. 9. Dk/t vs Average lens thickness (Benz, 2008).

For example, a CL on the eye with 54% water content (G4X material, Hioxifilcon D) to provide a Dk/t of 20 requires an average thickness of at most about 100 µm; a CL on the eye with water content of 59% (G-5XES material, Hioxifilcon A) to provide a Dk/t of 20 requires an average thickness of at most about 130 µm; a CL on the eye with water content of 72% (G72 HW material) to provide a Dk/t of 20 requires an average thickness of at most about 200 µm; a CL on the eye with water content of 75% (ultra O2 Plus material) to provide a Dk/t of 20 requires an average thickness of at most about 300 µm (Benz, 2008). This means that by using the G-materials it is possible to obtain high-performance custom-made contact lenses, which retain their water content on the eye as no other material commercially (Benz, 2008).

Who they are for?

The wavefront-optimized contact lenses FOOT are addressed to all those who, regardless of age, have high order aberrations in the eye and that can potentially get an increase in visual performance (Gottardini, 2013; Gottardini & Manganotti, 2013). The set of ideal wearers is made up of subsets that include respectively:

- Monolateral applications;
- keratoconus; initial keratoconus treat with CXL (i.e. Cross-linking); keratoglobus;
- refractive surgery with poor quality of vision; post refractive surgery ectasia;
- post transplant irregular astigmatism;
- different causes of corneal irregularity (infectious or traumatic) without opacities;
- regular cornea but with complex defects that penalize the visus;
- alterations of the corneal profile caused by allergies or intolerances;
- lenticonus; lens luxation; aphakia;
- aniridia; coloboma;
- staphyloma; corectopia; pellucida;
- scars; opacities;
- hemangioma; limbus dermoide;
- pinguecula; pterigium; warpage;
- low performance hydrogel CL wearers; intolerance to GP lenses;
- subjects with high order aberrations; individuals who want or would benefit from a high visual acuity (professional athletes, police, special forces, etc.).

(Agarwal, Agarwal, & Soosa, 2007; Gottardini, 2013; Gottardini & Manganotti, 2013; Wang, 2007).

1. REVIEW OF LITERATURE

1.1. High Order Aberrations

Ocular aberrations could be divided in corneal aberrations, responsible for 70-80% of ocular or total aberrations, and internal aberrations, due for example to the lens, vitreous body and other intraocular means, responsible for 20-30% of total aberrations (Mattioli & Camellin, 2006). The term aberrations means all the differences that an optical system, in our case the eye, introduces between object characteristics and the image created by the optical system (Pintus, 2009). If we consider instead an aberrometer like the Keratron ONDA, aberrations can be considered as difference between the actual wavefront and a plane wavefront (this makes mathematical calculations simpler) (Carnevali, 2013).

From this statement it is clear that even the ametropias are aberrations and as such are classified. But these are offset aberrations with the spherical lenses and / or in combination with suitably oriented cylindrical lenses (Pintus, 2009). More precisely ametropias are defined as Low Order Aberrations, LOAs (Carnevali, 2013; Pintus, 2009). High Order Aberrations (HOAs), instead, represent about 15-20% of total aberrations, are classified starting from the third order, and because of their characteristics are not offset with corrective revolution symmetry lenses (Lucente, 2011; Carnevali, 2013; Pintus, 2009). The exact HOAs incidence on retinal image quality is still under study, also because of the tremendous variability of aberrations in general that exists between individuals. But it was reported that, in a normal healthy eye, they could contribute to approximately 7% (Jason, Antonio, Ian, & David, 2001; Sheila & Holly, 2009).

The HOAs interfere in the vision and are mainly influenced by pupil dimension, which is affected by various factors such as environment illuminance where measurements are made, the optotype and the distance which is proposed, the use of trial glasses or the phoropter, etc. Miosis increases the depth of focus of the eyepiece optical system and, if this system is affected by aberrations, also reduces the disc of confusion that is generated for each image point allowing to improve the overall visual acuity or more properly to reduce the minimum angle of resolution (MAR) (Pintus, 2009).

In the general population it was found a considerable presence of high-order aberrations. One study showed that 96% of short-sighted and 77% of emmetropes show significant levels of HOAs (Pintus, 2009). The presence of not corrected HOAs can report very specific symptoms, such as ghosting, lack of contrast, attenuation in colour vision, glare sensitivity, driving problems at night, halos and / or the perception of comets around the light sources and not least fatigue in prolonged near vision (Pintus, 2009). According to experts when HOAs are correct can be reached very high visual acuity even higher than 16/10 (the neural limits is 20/10). This would allow to prescribe corrective lenses with which we could reach the so-called "Super-Vision" (Pintus, 2009). It has been shown that clinically relevant high-order aberrations which can impair vision, irrespective of the correction of defocus and astigmatism (LOAS), are those between the third and sixth order including, as the human eye is able to perceive the effects of distortion up to the sixth order (Lucente, 2011; Pintus, 2009).

1.1.1 Aberropia

Studies conducted by Agarwal A, Agarwal A. e Soosan (2007) on high-order aberrations have allowed to coin the term "Aberropia", which it refers to refractive errors attributable to own HOAs. More precisely, the definition of **Aberropia**: "a refractive error that results in a decrease in the visual quality that can be attributable to higher-order aberration*"*. This new refractive error would be due to the superposition of the harmful effects of different types of aberrations (Agarwal, Agarwal, & Soosa, 2007). It should be recalled that for the aberrations is not worth the overlap of the visual effects, i.e. they are not summable in increasing complexity, because it may verify an elision between the different expressions (Gottardini & Manganotti, 2013; Gottardini, 2013; Lupelli & Petrini, 2016; Lucente, 2011). Thus the correction of Aberropia, through the modification or elimination of harmful aberrations, may be fulfilled, as appropriate, getting an error of the total wavefront equal to zero (expressed in terms of RMS) or getting an error different from zero. Both situations would imply, in relation to a specific case, a better visual performance (Agarwal, Agarwal, & Soosa, 2007). Know the nature of HOAs and define them more and more precisely is crucial to simplify their correction, either by using special lenses, customized CL, either by refractive surgery or intraocular lens implantation (Agarwal, Agarwal, & Soosa, 2007; Jason, Antonio, Ian, & David, 2001). There are two classification systems proposed for Aberropia, one based on the aetiology (Figure 1.1.) and one based on the amount of aberropia (Figure 1.2.) (Agarwal, Agarwal, & Soosa, 2007).

Classification of Aberropia based on etiology

1. Congenital Aberropia:
The person is born with these aberrations. If unilateral and large enough to interfere with normal binocular interaction between the two eyes, these could possibly lead to amblyopia in that eye.

2. Acquired Aberropia:
A) Postoperative
Corneal:
- Post-penetrating keratoplasty
- Post-refractive surgery

Lenticular:
- IOL induced aberrations: either inherent in the IOL or due to malpositioned IOL
- Aberrations due to capsular abnormalities

B) Other
Corneal:
- Keratoconus and other ecstatic disorder
- Corneal trauma, scars, etc.
- Other causes of irregular astigmatism

Lenticular:
- Incipient cataract
- Lenticonus
- Subluxated lens, coloboma lens

Vitreous:
- Vitreous opacities and floaters

Retinal:
- Thickened posterior hyaloid
- Very fine ERMs not causing traction on the retina

Source Agarwal A

Fig. 1.1. Classification of Aberropia according to aetiology. *ERMs means Epi-retinal Membranes (Agarwal, Agarwal, & Soosa, 2007).

Classification of Aberropia based on magnitude

Higher-range aberropia
Keratoconus, post-penetrating keratoplasty, corneal trauma, lenticonus, etc. Here the visual performance has a good correlation with the amount of higher-order aberrations.

Lower-range aberropia
Majority of normal and refractive surgery patients, where the correlation between the range of aberrations and the visual performance is no longer present. This loss of correlation is due also to interaction between the different aberrations, besides other factors such as neural transfer function, Stiles-Crawford profile of the macula, etc.

Source Agarwal A

Fig. 1.2. Classification of Aberropia based on the amount (Agarwal, Agarwal, & Soosa, 2007).

1.1.2 Zernike polynomials

Any aberration can be decomposed into basic types of aberrations described by Zernike polynomials or another set of polynomials. In particular, Zernike polynomials are independent of each other (in other words, they are orthogonal to each other); it is this their important feature that make them linearly summable to obtain any type of aberration. The polynomials are graphically represented by the formulas, maps can use chromatic scales or exploit the outlook for the representation of three-dimensionality. The polynomials are described by the following notation Z_n^m. The index ***n*** is called radial order of polynomial and represent the value of the highest exponent of the polynomial describing the radial function of the Zernike. The index ***m***, that can assume both positive and negative values, represent the azimuth frequency of polynomial with which the entire radial profile waxes and wanes and changes sign rotating section. Figure 1.3. shows Zernike polynomials. Going down the pyramid increases the radial order of the polynomial (***n***), while moving from the center to the right or to the left increases the absolute values of the azimuth frequency (***m***) positive and negative, respectively (Carnevali, 2013).

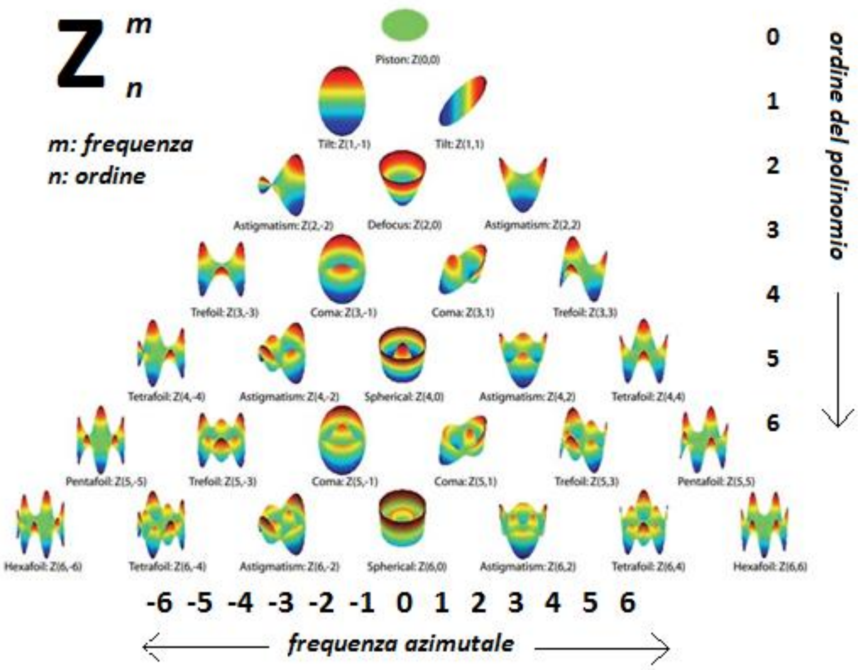

Fig. 1.3. Three-dimensional representation of the Zernike pyramid (Pintus, 2009).

The polynomials are theoretically infinite, we may in fact continue indefinitely adding higher orders. Generally does not exceed the seventh order, and this is usually the highest represented by the instruments, as in the case of Keratron ONDA (Carnevali, News, 2013). Adopting the Zernike polynomials is possible to evaluate the influence that have each eye aberration on the quality of the retinal image, and as each is independent of the others, this allows us to understand what aberration have greater effect on total ocular aberration and what impact it has on image quality (Carnevali, News, 2013). The Zernike polynomials can be quantified graphically, in microns, as a Root Mean Square (RMS), or in diopters (Mattioli & Camellin, 2006). Clinically relevant representation is the "Summary of aberrations" (Figure

1.4.) (Mattioli & Camellin, 2006). Here the additional terms, the opposite sides of the pyramid of the OSA, Optical Society of America, (with index m, respectively positive and negative), are not listed as individual parameters, but which RMS sum two by two (Mattioli & Camellin, 2006).

Mappa | Raggio | PSF | Visus | MTF | Zernike

Zernike	Micron	Diottrie	Asse°	Descrizione aberrazioni
z(2, 0)	-0,84	0,93	---	Defocus
z(2, ±2)	0,341	-0,53	159,	Astigmatismo
z(3, ±1)	0,27	0,3	236,	Coma
z(3, ±3)	0,094	0,1	42,	Trifoglio
z(4, 0)	-0,548	0,61	---	Aberrazione sferica
z(4, ±2)	0,053	0,06	117,	Asigmatismo secondario
z(4, ±4)	0,214	0,24	36,	Quadrifoglio
z(5, ±1)	0,128	0,14	219,	Coma secondario
z(5, ±3)	0,067	0,07	77,	Trifoglio secondario
z(5, ±5)	0,058	0,06	27,	Pentafoglio
z(6, 0)	-0,057	0,06	---	Sferica secondaria
z(6, ±2)	0,019	0,02	161,	Astigmatismo VI ordine
z(6, ±4)	0,052	0,06	41,	Quadrifoglio VI ordine
z(6, ±6)	0,092	0,1	45,	Esafoglio

Fig. 1.4. Summary of aberrations. Picture extracted from Keratron ONDA.

The OSA pyramid is shown in Figure 1.5.

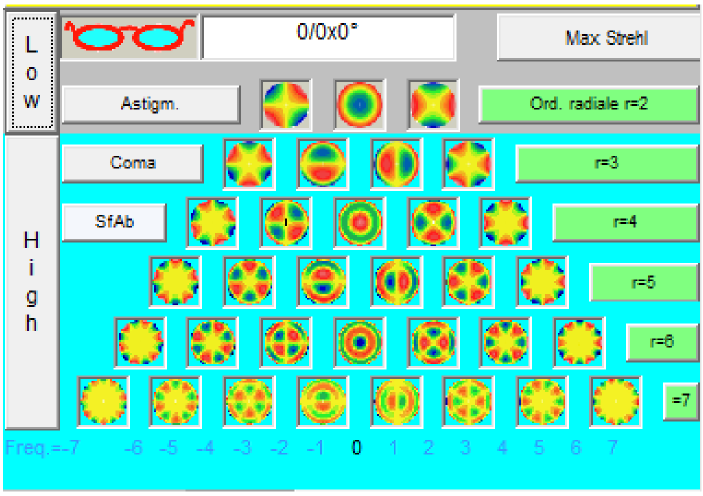

Fig. 1.5. The OSA pyramid of Zernike. Picture extracted from Keratron ONDA.

These RMS amounts are expressed in the "Summary" as in microns or as "defocus equivalent" (Deq) in diopters and axis. The equivalent defocus proposed by Prof. L. Thibos, is an amount that allows you to express the variance of the wavefront or any of its components in more familiar dioptric terms (Mattioli & Camellin, 2006).

1.1.3 Root Mean Square (RMS) value

Root Mean Square (RMS, Figure 1.6.) can be estimated from the wavefront total aberration or by a set of Zernike polynomials. It is often used as a measure of optical quality in relation to a precise pupil diameter. Pupil size must be specified when providing the RMS value. For an ideal wavefront, the RMS is equal to zero (RMS=0); for an aberrated wavefront the RMS value is always positive, greater than zero (RMS>0) (Mattioli & Camellin, 2006). Subtracting the low-order aberrations it is possible to minimize the RMS, which now represent the aberrations from the third order onwards (Figure 1.7.) (Mattioli & Camellin, 2006).

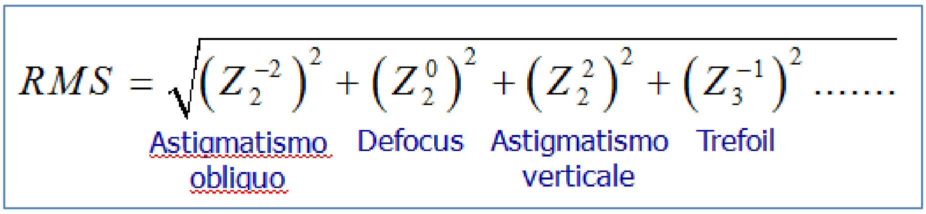

Fig. 1.6. Definition of the RMS sum of Zernike with OSA normalization (Mattioli & Camellin, 2006).

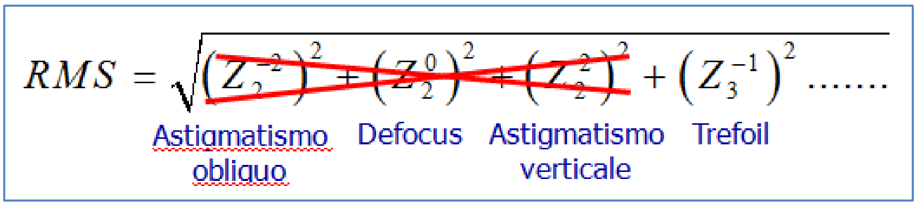

Fig. 1.7. RMS without the low-order aberrations (Mattioli & Camellin, 2006).

1.1.4 Point Spread Function (PSF) and Sthrehl Ratio

Point Spread Function, it is a method to figure out how to actually see a person who has aberrations (Pintus, 2009). Consider a point light source located at an infinite distance, projecting its image in one eye. If the objective is completely free of aberrations, the image of the point will focus on the retina and all the light intensity will be located in a point-like space at the fovea. If, instead, the eye is affected by aberrations we will have a dispersion of the light rays in an area more or less extensive. Consequently its intensity will be reduced, with a maximum value in correspondence of the fovea, then progressively going to shrink gradually as you move away. What has just been described applies to the defocus, for all other aberrations we will always have a dispersion of light on an area more or less wide, but its intensity will not go decreasing smoothly from the center to the periphery but it will be more concentrated in some areas than others and the surface that describes the characteristic will have a more complex shape (Carnevali, 2013; Pintus, 2009). Through complex calculations, which take account of aberrations expressed in terms of RMS, and the pupil diameter, it is possible to determine which would be the best possible PSF for each examined optical system, which is that which would occur in the complete absence of aberrations. The Strehl Ratio value expressing the ratio of the Point Spread Function of the examined system and that of a system with the same features but in the complete absence of aberrations and determined by the presence of only the diffraction phenomena. The result is a value which varies between 0 and 1. The higher in value and the smaller the aberrations. A value of 0,8 is generally considered good (Carnevali, 2013).

1.2. Wavefront-Guided soft Contact Lenses

Wavefront-Guided soft contact lenses are experimental contact lenses realized for research purpose at some specialized laboratories. They most resemble FOOT contact lenses. This kind of soft contact lenses seem able to correct ocular aberrations of the examined eye introducing a predetermined amount of aberration such as defocus, tilt, trefoli, coma, etc. (Marsack, Parker, & Applegate, 2008; Lòpez-Gil N. , et al., 2002). Correction of total ocular aberrations could be obtained inserting the same amount of aberration but of opposite sign (Lòpez-Gil, Castejòn-Mochòn, & Fernàndez-Sànchez, 2009). If to do so, we use contact lenses, the correction induced wavefront must be exactly complementary to the wavefront measured in the same plane. So, the wavefront coming from an axial point, object to the retina, is totally spherical and centered in the fovea (Lòpez-Gil, Castejòn-Mochòn, & Fernàndez-Sànchez, 2009). Figure 1.8. shows in a schematic way as just described.

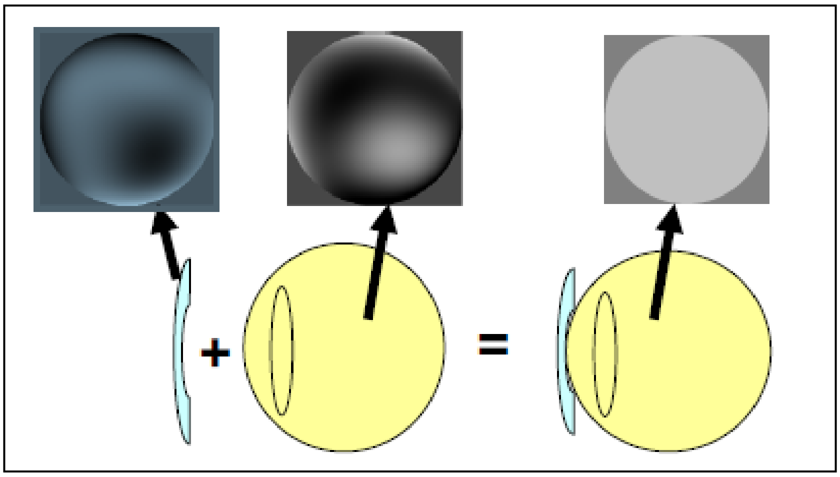

Fig. 1.8. Principle of aberration correction using contact lenses (Lòpez-Gil, Castejòn-Mochòn, & Fernàndez-Sànchez, 2009).

In 1961, M. S. Smirnov first proposed the idea to change the ocular wavefront using customized soft contact lenses (Smirnov, 1961; Lòpez-Gil, Castejòn-Mochòn, & Fernàndez-Sànchez, 2009). For this purpose have been developed soft contact lenses with aspherical and asymmetric front surface able to generate the complementary wavefront detected for each eye (Lòpez-Gil, Castejòn-Mochòn, & Fernàndez-Sànchez, 2009). Some clinical trials shown that in subjects suffering from keratoconus a custom made soft CL corrections, which takes account of the low and high order aberrations, can dramatically enhance visual performance, even in the presence of typical movements such as those of a soft CL (De Brabander, Chateau, Marin, G. et al., 2003; Marsack, Parker, & Applegate, 2008; Lòpez-Gil, Chateau, Castejòn-Mochòn, & Artal, 2003). In support of these claims, from literature we learn that a patient with moderate keratoconus whose habitual correction was a soft toric lens, and that was reapplied with custom wavefront-guided soft lens had an improvement in visual acuity of at 1,5-line and a 50% reduction of higher order aberrations (Marsack J. D., Parker, Niu, Pesudovs, & Applegate, 2007).

Other simulations have confirmed that the correction of ocular aberrations, in particular those belonging to the fifth order, improves the visual performance of the majority of subjects with keratoconus (Marsack, Pesudovs, Sarver, & Applegate, 2006). More recently, Yoon e Jeong (2005) have proposed the use of this technique not only in the presence of keratoconus, but also in the post-keratoplasty cases and in the presence of normal eyes. The main limitation imposed to a precise correction of aberrations with these lenses is represented by the rotation and the translation of the same lenses (Barry & DeNaeyer, 2012; Lòpez-Gil N. , et al., 2002). So specific for higher-order aberrations correction, they must be well positioned on the cornea and the alignment requirements must also be stricter than those adopted with toric soft lenses (Thibos, Cheng, & Bradley, 2003). In particular, the translational errors must not exceed 0,5 mm (De Brabander, Chateau, Marin, G. et al., 2003). A further limitation is imposed by the variability of aberrometric maps that prevents to know the true structure of ocular aberrations (Thibos, Cheng, & Bradley, 2003). It should be remembered that the eye is a biological system that changes over time for normal physiological reasons, therefore, the uncertainty in the measurement of the maps because of these factors will make difficult, but not impossible, to get a full optical correction with a contact lens (Thibos, Cheng, & Bradley, 2003). To reduce the level of uncertainty associated with any measurement is essential that more maps are acquired following a protocol that includes the realignment of the instrument used (Thibos, Cheng, & Bradley, 2003).

1.3. Previous studies on FOOT Soft Contact Lenses

Previous studies on the wavefront optimized technology were conducted by Dr. Alberto Manganotti (2011), Ophthalmologist, and more recently by Dr. Daniele Petrini with Professor Luigi Lupelli (2016). They are described below and are included the results obtained from each study.

In the study led by Dr. Manganotti A. (2011), 21 eyes were involved. The subjects who took part in the study were all wearing contact lenses: 19 contact lenses "thickened" in patients with keratoconus from the first to the third stage, fifteen of which were previously treated with CXL (i.e. cross-linking); 2 GP contact lenses made with "Calco" system in subjects with outcomes of PRK (i.e. Photo-Refractive Keratectomy) with a small optical zone and decentralized. The average age was 36,4 years. Wavefront-optimized soft CL (p-GMA/HEMA hioxifilcon D, 54% H_2O) were applied to all participants recording a success rate of 85% (i.e. success in 18 cases of 21). Measurements necessary to generate FOOT CL were acquired by the Keratron ONDA total aberrometer, after which the output files with ".zer" extension was sent to the company together with the basic parameters of each eye (HVID, horizontal visible iris diameter; BOZR, back optic zone radius). Mean contrast sensitivity noted with FOOT CL was medium to high. The overall comfort has been listed as high by most participants. The mean visual acuity recorded in 19 eyes with keratoconus, in different conditions, is shown in the graph of Figure 1.9.

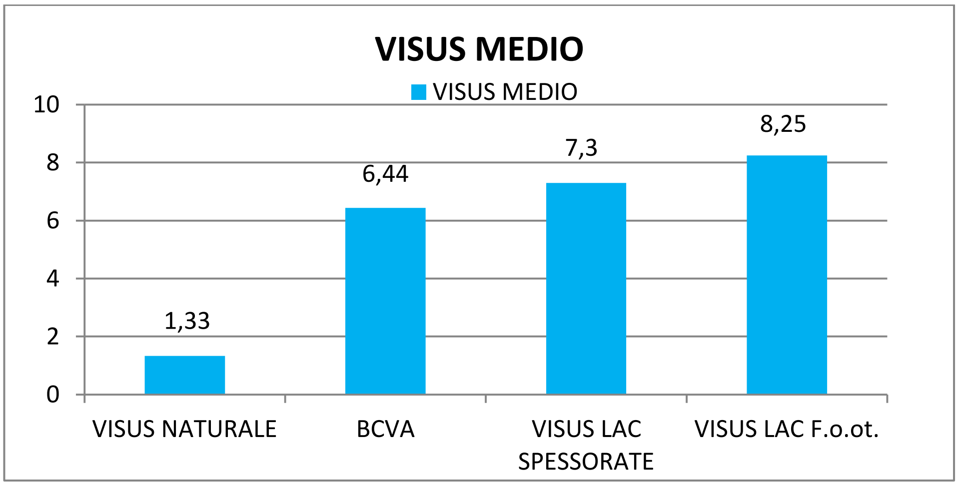

Fig. 1.9. Chart shows the average visual acuity for 19 eyes with keratoconus in different situations (Manganotti, 2011).

Figure 1.10. shows the graph that compares the average amount of coma aberration for the 19 eyes with keratoconus in conditions "without contact lenses" and "with FOOT CL". The pupil diameter was normalized and is equal to 4,50 mm.

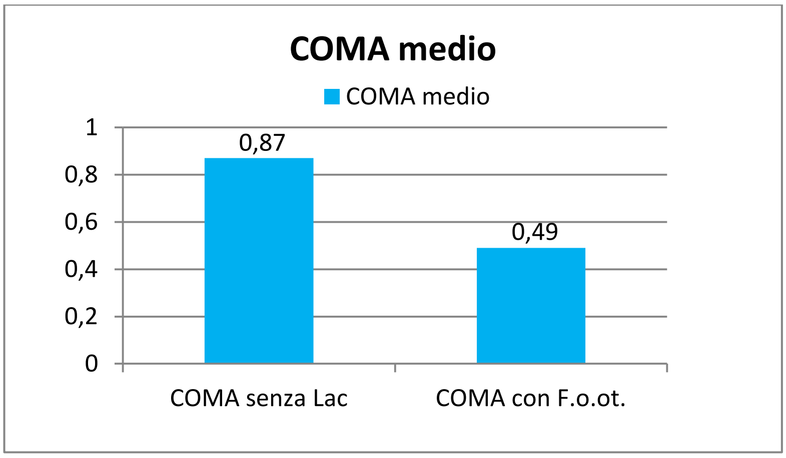

Fig. 1.10. Comparison of Coma average in 19 eyes with keratoconus, without CL and with FOOT CL. The pupil diameter is normalized to 4.50 mm (Manganotti, 2011).

In addition, participants with keratoconus was asked to give a score from 1 to 3 (where 1 means the worst, 2 corresponds to the same, 3 matches best) to FOOT lenses in terms of overall comfort, total time of use, visual acuity from a distance and night vision compared to those made thicker. Figure 1.11. shows a graph with the individual scores for each category. The responses indicate that FOOT lenses were found to be equal or better than the thickened lenses in all categories (Manganotti, 2011).

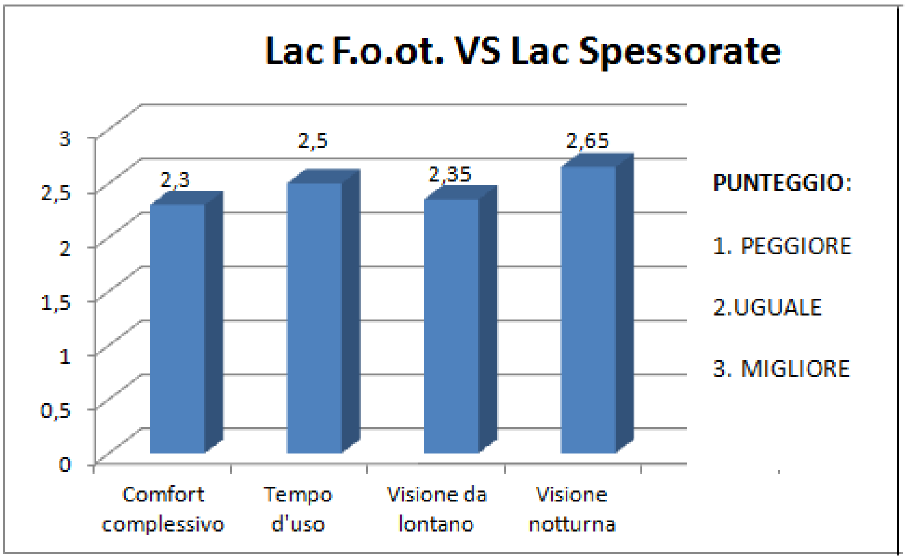

Fig. 1.11. Comparison between FOOT and thickened CLs (Manganotti, 2011).

As for the two eyes with results of PRK with small and decentralized optical zone applied with "Calco" GP lenses, preliminary data were: visual acuity 20/20 in both eyes, but complained about the perception of night halos. With wavefront-optimized technology visual acuity remained unchanged and evening halos disappeared (Manganotti, 2011).

In the study led by Dr. Petrini D. and by Professor Lupelli L. (2016), a group of 10 Caucasian patients was recruited (16 eyes; ages from 18 to 59-years average 34,8 years). The general inclusion criteria were: patients with mild to severe corneal irregularities for pathological or iatrogenic reasons; absence of inflammatory or infectious disease such as not to be able to apply CL; already satisfied wearers of soft shimmed CLs (Lupelli & Petrini, 2016). The purpose of the study was to evaluate the effects on visual performance of soft shimmed CL, Med Keratoplus with 0,40 mm center thickness, and wavefront-optimized soft CL, FOOT For such research the hydrogel Benz G4X has been chosen as material for both types of lenses applied. Preliminary measurements to determine the parameters for the construction of aberrometric soft lenses were: corneal topography and total ocular aberrometry performed with the instrument Keratron ONDA without CL. Only in cases of rotation more than 5° (clockwise or anti-clockwise), it proceeded to determine the parameters of a new CL tending into account only the magnitude of such rotation (Lupelli & Petrini, 2016). Then were measured visual acuity at high contrast, monocular and binocular, at a distance of 6 meters from the optometric table and contrast sensitivity, monocular and binocular, at a distance of 3 meters from the optometric table, in conditions that would result in photopic adaptation. The average values of visual acuity at high contrast, Sthrehl ratio and RMS for left and right eyes measured with shimmed and F.o.ot CLs are shown in Figure 1.12. (Lupelli & Petrini, 2016).

	AV (logMAR)	Strehl Ratio	RMS (Deq)
Thick O.D.	0,10	0,01216	1,48
F.o.ot. O.D.	0,10	0,01416	1,13
Thick O.S.	0,00	0,01338	1,26
F.o.ot. O.S.	0,00	0,01680	1,00

Fig. 1.12. The average values of visual acuity at high contrast, Strehl ratio and RMS for left and right eyes measured by the thicked and FOOT CL (Lupelli & Petrini, 2016).

The results of contrast sensitivity were indicated with conversion numbers representing the logarithm of the threshold contrast inverse (Log 1/c). Three comparison charts were processed (Figure 1.13., 1.14., 1.15.) (Lupelli & Petrini, 2016).

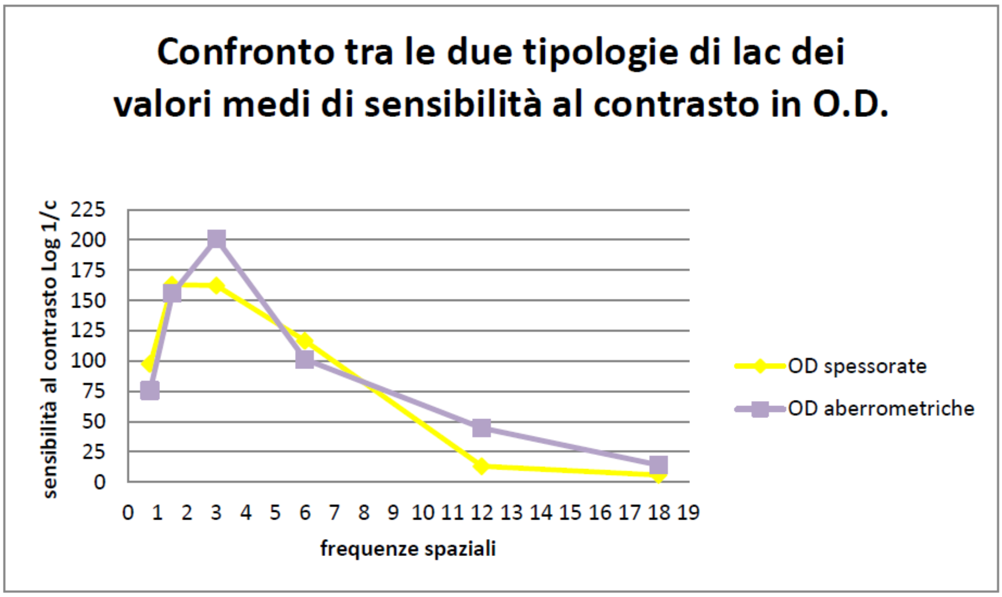

Fig. 1.13. Comparison between the average values of the contrast sensitivity in OD of the two types of CL (Lupelli & Petrini, 2016).

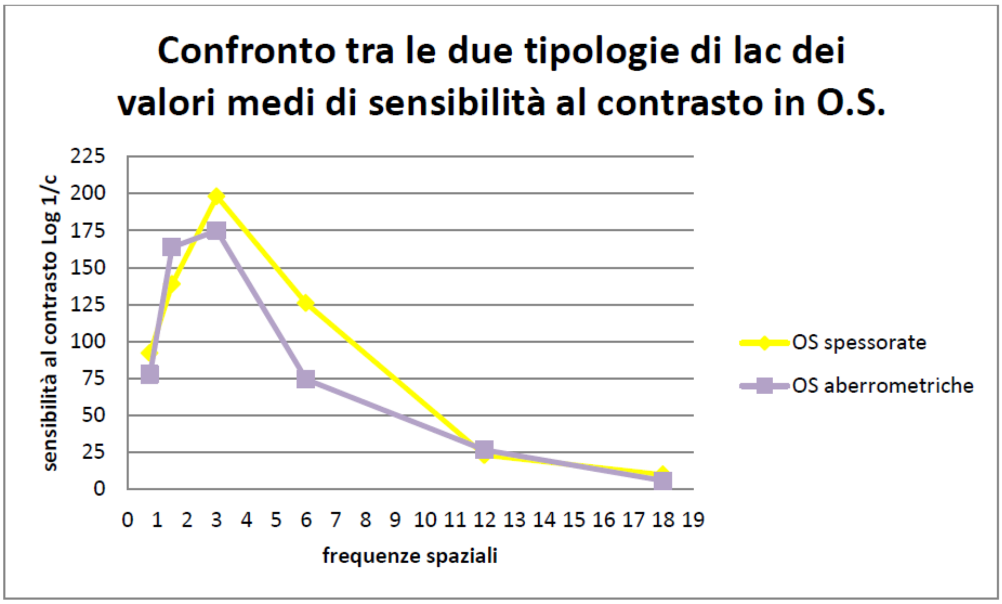

Fig. 1.14. Comparison between the average values of the contrast sensitivity in OS of the two types of CL (Lupelli & Petrini, 2016).

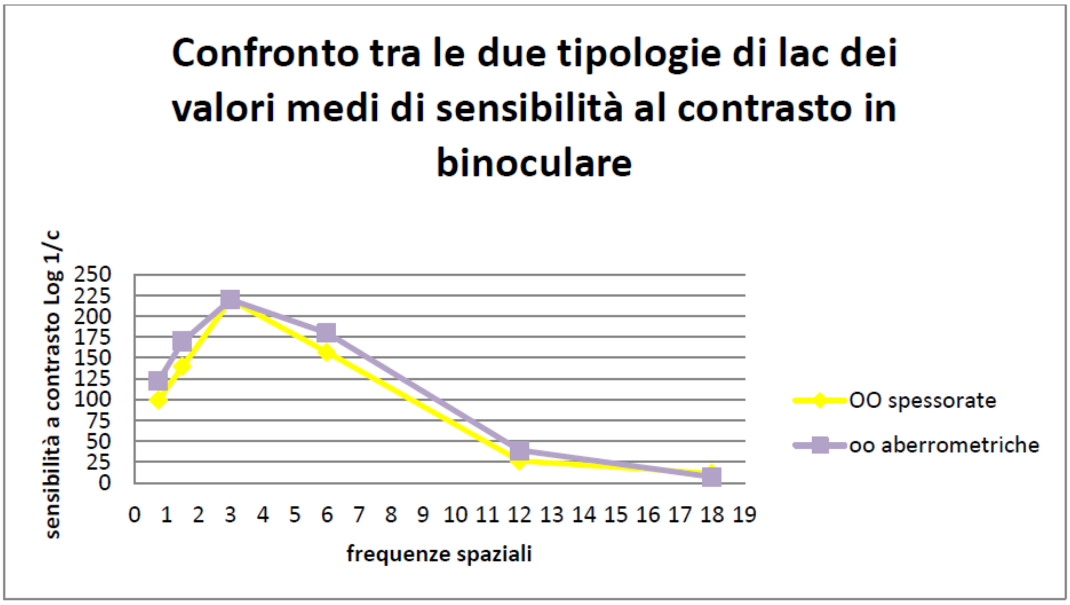

Fig. 1.15. Comparison between the average values of the contrast sensitivity in both eyes of the two types of CL (Lupelli & Petrini, 2016).

Analysis of the data showed that both solutions in hydrophilic material are useful and effective even in the presence of particularly aberrated ocular wavefronts due to corneal irregularity for pathological or iatrogenic reasons (Lupelli & Petrini, 2016). Both types of Lac confirmed two clinically relevant aspects: although physically rigid CL represent the highest optically performing solution in the presence of corneal irregularities (Casco, 2011), soft lenses, specifically made for the optical compensation of corneal irregularity, very often find particular consensus by the holder, both in relation to the visual quality they produce and in relation to the perceived comfort (Lupelli & Petrini, 2016). As regards FOOT CL the main problem in relation to their purpose remains the stability and centering, in a much more influential than the normal soft toric lenses (Lupelli & Petrini, 2016). Given the limitations related to the centering and the rotational stability of the lens in the eye and in agreement with the literature (De Brabander, Chateau, Marin, G. et al., 2003; Marsack J. D., Parker, Niu, Pesudovs, & Applegate, 2007) it was possible to say that the F.o.ot. lenses are able to partially compensate the high-order aberrations (Lupelli & Petrini, 2016). In connection with the change in total ocular aberrometric data the differences found between the two types of CL were minimal, although present. The first value measured was Sthrehl ratio, detecting a minimum value of the improvement in favor of the aberrometric CL. The second measured value was the Root Mean Square, the reduction of the RMS with aberrometric CL than shimmed CL tends to favor the FOOT CL (Lupelli & Petrini, 2016).

2. RESEARCH

2.1. Aim and Tasks of research

Aim. Evaluate the effects of applying FOOT customized soft contact lenses in subjects with total ocular wavefront characterized by higher-order aberrations (HOAs).

Tasks

1. Total ocular wavefront aberrometric maps acquisition.
2. To compare best corrected photopic high contrast logMAR visual acuity (monocular and binocular) measured with habitual GP contact lenses (BCVA GP) and with FOOT CL (BCVA F.o.ot.).
3. Evaluation of subjects examined optical quality highlighting both total aberrations and high order aberrations, by comparing the mean Root Mean Square (RMS) and Strehl Ratio (Str) relative to total and high order aberrations measured for uncorrected eye and with FOOT lens applied, with a normalized pupil diameter of 4 mm and 6 mm (Guirao, Porter, Williams, & Cox, 2002; Sheila & Holly, 2009; Casco, 2011).

2.2. Participants

For the purposes of this study were recruited eight Caucasians, from October 2016 to March 2017, age from 30 to 45 years (mean age 35,25 years), for a total of 16 eyes (8 right eyes, 8 left eyes). Candidates have voluntarily participated in the study, they were informed about the research motive and were able to leave the study at any time. All the participants signed a permit for this research's realization: this research is supervised by the University of Latvia Scientific Research Ethics Commission.

The general inclusion criteria were:

- Subjects with total ocular higher-order aberrations (HOAs) greater than those recorded for a 6 mm pupil by Wang and Koch (2003) and by Wei, Lim, Chan & Tan (2006), respectively for individuals screened for refractive surgery (mean 6 mm HOAs RMS value: $0{,}305 \pm 0{,}095\ \mu m$) and for a population of Chinese with myopia (mean 6 mm HOAs RMS value: $0{,}490 \pm 0{,}160\ \mu m$).
- Lack of contraindications to the port of CLs, certified by Ophthalmologist physician.

The exclusion criteria, however, were:

- Subjects who have total ocular higher-order aberrations lower than those recorded for a 6 mm pupil by Wang and Koch (2003) and by Wei, Lim, Chan & Tan (2006).
- Contraindication to the port of contact lenses.

All enrolled subjects were evaluated at the Gottardini Vision optometric office of Trento. The material employed in this study with which the FOOT lenses were made is the G72 HW, 72% water content with a Dk of 42 units (figure 2.1.).

G72-HW Specifications	
Water Content (%)	72
Dk (35°C, Fatt Units)	42
Refractive Index Dry	1.513
Refractive Index Hydrated (35°C)	1.384
Linear Expansion (mm)	1.560
Radial Expansion (mm)	1.560
Hardness (Shore D)	84
% Transmission (@500 nm)	>95

Fig. 2.1. G72HW Technical detail (Benz, 2008).

2.3. Methods

The preliminary measurements carried out in each subject were:

- Subjective best corrected photopic high contrast logMAR visual acuity with the best habitual GP correction (BCVAGP), monocular and binocular, at a distance of 5 meters, with the digital MOS Light optometric table.
- A minimum of eight corneal topographies for each eye, performed with the Keratron Onda, and selection of the best considered map from which to extrapolate the corneal parameters (HVID, Apical radius at 3 mm) useful for subsequent receiving of the geometric parameters of the final FOOT CL (TD and BOZR).
- Acquisition (as minimum) of eight aberrometric maps of the total ocular wavefront to the uncorrected eye in order to evaluate the optical quality of the participants and specifically the high order aberrations.

The visual acuity achieved with GP CLs was detected under photopic condition. Instead, the FOOT contact lenses, produced subsequently, were evaluated in low ambient lighting conditions, so as to obtain aberrometric lenses that allow the best visual acuity in these conditions. These CLs, when evaluated in photopic adaptation conditions, allow to achieve even better photopic high contrast visual acuity due to the decrease of HOAs as a result of the pupil constriction, in accordance with what was stated by Pintus (2009).

The sights used with the digital MOS Light optometric table were letters of Sloan (S O C D K V R H N Z) designed according to the standard suggested by Snellen, presented low crowding, arranged in three rows for each screen. The level of visual acuity was recorded on a logarithmic scale.

The aberrometric maps of the total ocular wavefront were performed in scotopic conditions prior to the uncorrected eye, for each candidate, in order to get the aberrometric parameters related to basic optical quality of the participants. These data will be compared with those obtained for the same scotopic conditions after the application of FOOT CLs.

At the end of the realization of the first FOOT CL was necessary to follow these steps:

- Selection, implementation and evaluation, using a CSO slit lamp, of the best trial CL for right eye and left eye. The dynamics of the trial lens must meet the criteria imposed by the producer in order to allow an effective wavefront optimized correction: periodic movement of the CL not more than 0,5 mm; benchmarks consistent with those of the diagnostics CL.
- Amplitude and direction of rotation registration of the in vivo trial CL.
- Professional Acquisition of 8 aberrometric maps of the total ocular wavefront with the best trial CL in vivo, for each analyzed eye, 20 minutes after application of the diagnostic lens. They have been applied and examined, for each subject, before the right eye and then the left. (Lupelli & Petrini, 2016).
- Elaboration and Selection of the best total ocular wavefront map with the best trial CL in situ, for the right eye and the left eye, according to the selection criteria established in agreement with the manufacturer.
- Output file with the extension ".zer" extraction from Keratron software.
- Sending the following information to the company laboratory: CL material; desired application technique with TD and BOZR of FOOT CL to realize; amplitude and direction of rotation of the diagnostic CL; ".zer" file.

Here follows in more detail the steps above.

2.3.1 Detection of the Horizontal Visible Iris Diameter (HVID)

To get the HVID I used the "extrapolates diameter" function available within the Keratron software installed on my computer. The useful diameter is reported to the anterior cornea, therefore, it must be acquired in correspondence with the limbus, where it terminates the cornea and the sclera starts (Gottardini, 2013; Gottardini & Manganotti, 2013). Graphically, from topographic maps acquired with the Keratron Onda, the sclera appears gray / white while the end portion of the horizontal visible iris is represented by a shade of gray colour which progressively fits into the sclera. Figure 2.2. shows a topographical map in which are highlighted the "extrapolation" function, the sclera and the colour gradient which delimits the horizontal visible iris from the sclera.

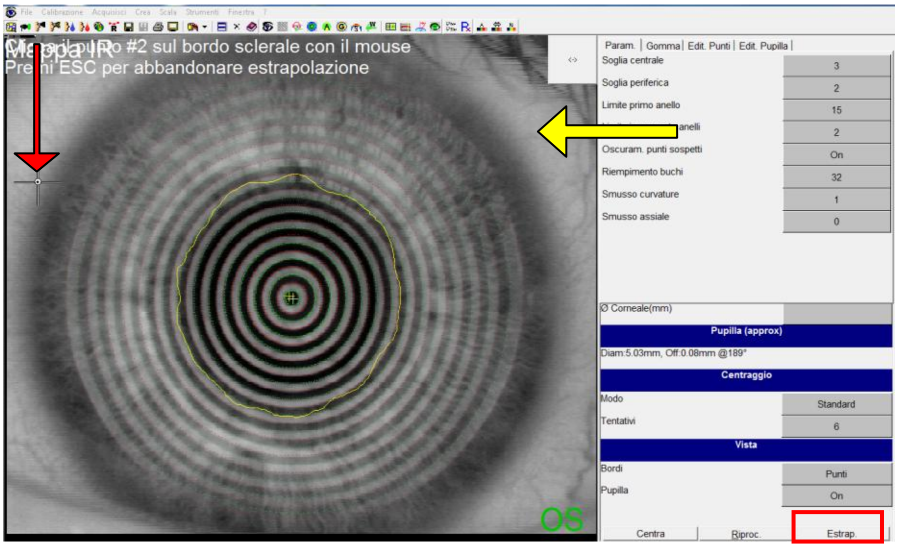

Fig. 2.2. "Extrapolation" function (red rectangle); sclera (yellow arrow); colour gradient which delimits the horizontal visible iris from the sclera (red arrow).

The HVID 's detection procedure involves first placing the mouse cursor to the outermost part of the limbus, the one that graphically looks just like a nuance (Figure 2.2.). Click your mouse in the desired place, you will see a white dot at the center of a symbol in the shape of a cross. Always in Figure 2.2. the cursor has been placed properly and carries the mentioned symbol (highlighted by the arrow in red). Repeat the operation and place the cursor on an area similar to the previous one, again belonging to the gradient visible from the topographic map, as shown in Figure 2.3. At this point it will appear on the screen a variable-size circle described by a dotted line (Figure 2.3.). By moving the mouse to select the third and last point where you put the cursor, it will form a circular area that will enable us to acquire the horizontal visible iris diameter. By pressing the mouse button the area will be highlighted by a red colour circle and diameter will thus be measured and displayed on the screen (red rectangle). As just described is shown in Figure 2.4.

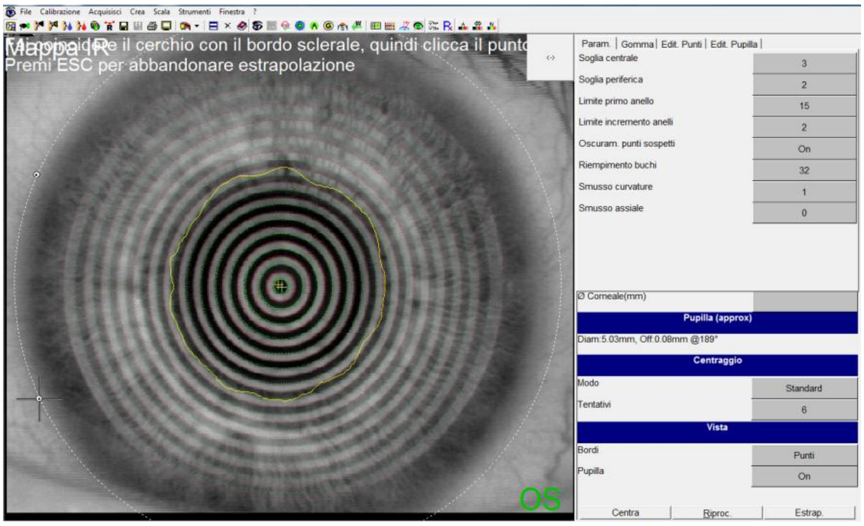

Fig. 2.3. By moving the cursor and selecting the second point it will form a circle of variable size.

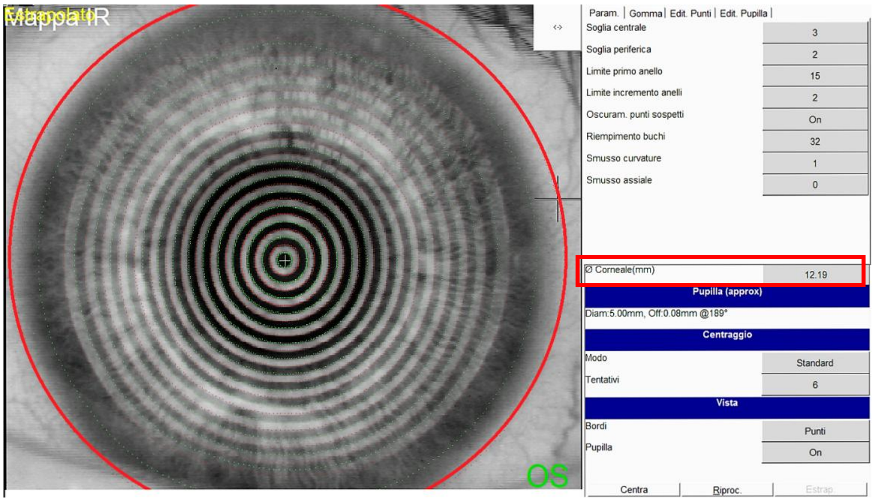

Fig. 2.4. The red circular area delimits the HVID measured following the procedure described. HVID is highlighted by the red rectangle.

2.3.2 Apical radius at 3 mm detection (Flat K)

The detection of apical radius has the aim to determine the BOZR of CL to be applied. They are offered by way of explanation, only a few examples: in the case of relatively smooth cornea, as a reference has been chosen the apical radius (K plate) to 3 mm Keratron detected directly from the instrument. The apical radius value expressed in millimeters was then inserted into an experimental software and was flanked by the desired application technique, in such a way that the program, taking into account the relative coefficient of flattening, would provide the value of BOZR expressed in millimeters of lens to apply. Otherwise, the presence of irregular corneas is not easy to understand which is the correct starting radius of curvature. Thanks to the experimental software, which considers in general four types of irregular surfaces and suggests specific and pre-set flattening coefficients, starting from K plate always measured at 3 mm, it was possible to obtain the BOZR of CL to be applied. The reference surface profiles are essentially: cornea bearer of Central keratoconus, with high positive eccentricity; cornea bearer of decentralized keratoconus; "trapezoidal" cornea post-keratoplasty; cornea with negative eccentricity post refractive surgery (Gottardini, 2013). The method used, which is based on clinical experience and the research carried out by Gottardini (2013), allows a quick selection of the parameters of the CL. In this way you can proceed by taking test set a lens that has a BOZR derived from the above considerations, and in the next step you can proceed to redefine the essential parameters of the FOOT custom CL. Once applied, all the lenses must meet the fitting requirements imposed by the wavefront optimized correction, therefore, must always be evaluated in slit lamp (Gottardini, 2013; Gottardini & Manganotti, 2013).

2.3.3 Selection, Application and Evaluation of trial CLs

Once determined the parameters of the most suitable trial lens for the acquisition of the total ocular wavefront with CL in vivo, it picks up the CL selected by the trial set available and proceed to the application starting right eye (Gottardini, 2013; Gottardini & Manganotti, 2013). After 20 minutes of port evaluating the centering and the dynamics of CL in the slit lamp, paying particular attention to the periodic movement of the CL and rotation (Lupelli & Petrini, 2016). They must be recorded the amplitude and direction of the CL rotation that will be communicated to the laboratory. At this point the application technique, with the TD and the desired BOZR and the material with which realize the FOOT CL are determined.

Below are proposed professional acquisition rules of the total ocular wavefront with the best trial lens inserted and the selection rules of the most suitable aberrometric map for generating the first FOOT CL.

2.3.4 Total ocular wavefront Professional Acquisition and Selection of the most suitable aberrometric map for generating the first FOOT CL

FOOT soft lenses application protocol provides that aberrometric maps are acquired after that a specific trial lens has been inserted and properly assessed. When the trial lens has stabilized, typically after twenty minutes, we can start the acquisition (Lupelli & Petrini, 2016).

In order to facilitate the choice of the first trial lens, Imago Contact® has developed a trial set. The sample set consists of five plano contact lenses (power of 0,00 diopters), with a thickness of 0,23 mm at the center and bending radii that start from 7,60 mm up to 8,40 mm, with step of 0,20 mm, G72HW material. The chosen diameter is 14,20 mm, assuming that the average corneal diameter is from 11,80 to 12,20 mm and lens desired by us has to be from 2,00 to 2,20 mm larger than the cornea (Gottardini, 2013). The trial contact lens is intended to simplify the application and to make the corneal surface as homogeneous as possible before performing the aberrometric map (Gottardini, 2013; Gottardini & Manganotti, 2013). In this case it will be the trial lens to interpolate the corneal surface. Acquire the aberrometric map with a soft contact lens in situ of the same material of the final lens simulates the patient's final condition: the optimized wavefront will held into account the interaction of the polymer with the tear film and with the corneal surface (Gottardini, 2013; Gottardini & Manganotti, 2013; Sheila & Holly, 2009). Finally, applying a trial lens we have the possibility to evaluate in advance the presence of any translations and / or rotations of the CL. The changes of the parameters of the trial lens to be applied on the first lens FOOT, are intended to limit the periodic shifts of the CL within the limits set by the manufacturer (0,5 mm of allowed movement).

With the best trial lens inserted (Casco, 2011; Sheila & Holly, 2009) by 20 minutes, after having evaluated in slit lamp and having recorded amplitude and direction of rotation of the reference signs, we proceed to the total ocular wavefront professional acquisition, first in right eye and then repeating the procedure for the left eye: check that the instrument is calibrated; in a totally dark environment (make sure the instrument is away from other light sources, to avoid interfering with such sources with the Keratron Onda sensors and to obtain the maximum pupil midriasis), accommodate the subject and instruct it on the target to be fixed ; instill 1 drop of tear stabilizer in order to laminate the surface of the diagnostic CL and eliminate any artifacts that might interfere with the acquisition (Gottardini, 2013; Gottardini & Manganotti, 2013); wait for 1 minute and in the meantime arrange the face of the subject on the instrument pocket; select the "Topo-aberrometry" detection mode from the initial Keratron screen; proceed to the acquisition of (a minimum of) number 8 aberrometric maps. All images should be acquired approximately one second after ocular blinking to standardize the measurements and limit variations due to the tear film alteration (Lupelli & Petrini, 2016).

Entering "Topo-aberrometry" mode, wait a few seconds to recalibrate the optic motors that compensate for the defocus and fogging of the eye (Optikon, 2010). The Keratron® ONDA submits the patient to a progressive focus of the target, from near to far, which proceeds until it occurs a certain release of accommodation for far vision ("Fogging"). At the end of each or both of these operations, if the eye has not moved too far and is still in the "far-near" range, the capture starts automatically (Optikon, 2010). If, during the acquisition, the patient's eye had moved away or approached too quickly from the ideal focal point of the cone, the software signals the unreliability of the acquisition (Optikon, 2010).

Below, in Figure 2.5. the capture screen of the Keratron® Onda is shown. On the screen in Figure 2.5. in addition to the live image, the following are displayed: OD/OS eye examination (1), super-luminescent diode beam (SLD) position depicted by a yellow circle (2), wavefront sensor image (3) and eye distance reporting via the EPCS (4), with the selection of the Near or Far photocell pair (5) (Optikon, 2010).

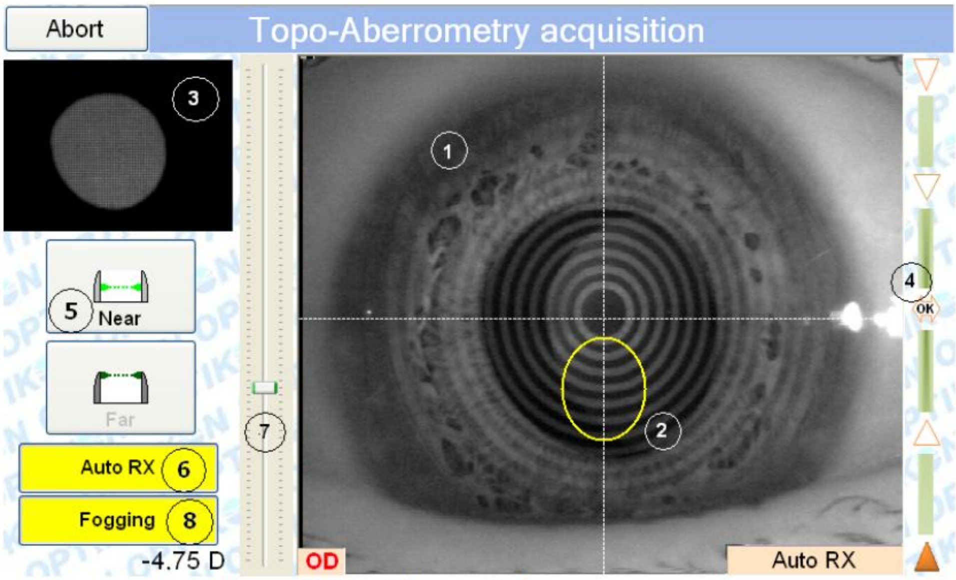

Fig. 2.5. Elements that make up the topo-aberrometry screen (Optikon, 2010).

When you capture an image and immediately afterwards, it is essential to ensure that the wavefront sensor (3) is uniform and without artifacts. The sensor allows the operator to realize whether the retinal reflection is adequate or whether the image should be centered so that the SLD beam is correctly inserted into the pupillary area (Optikon, 2010). Below, in Figure 2.6., is given the image of the wavefront sensor with the presence of reflections (1) and opacity (2), which makes it not adequate and the suspect image, and with proper aspect respectively (3).

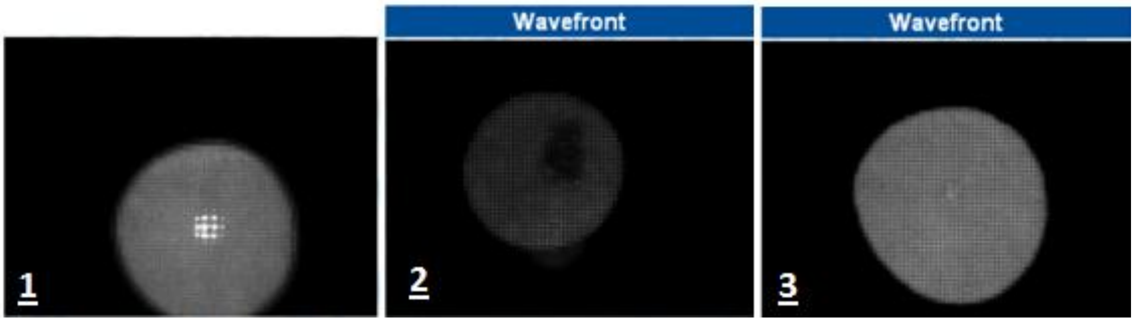

Fig. 2.6. Wavefront sensors (Optikon, 2010).

Attention should also be paid to the sharpness of the image and to the distance of the Placido rings, which should not be too close, otherwise the image must be discarded and acquired a second time (Gottardini, 2013; Gottardini & Manganotti, 2013). Proceed in this way until you get 8 suitable images that need to be sent to your computer for processing. In Figure 2.7. you can see how maps appear after processing.

To focus our attention on HOAs, low order aberrations have been mathematically removed from the maps (Thibos, Cheng, & Bradley, 2003), but at the time of extrapolation of the ".zer" output file of the best map, all the polynomials of Zernike up to the seventh order were included in the file and sent to the lab.

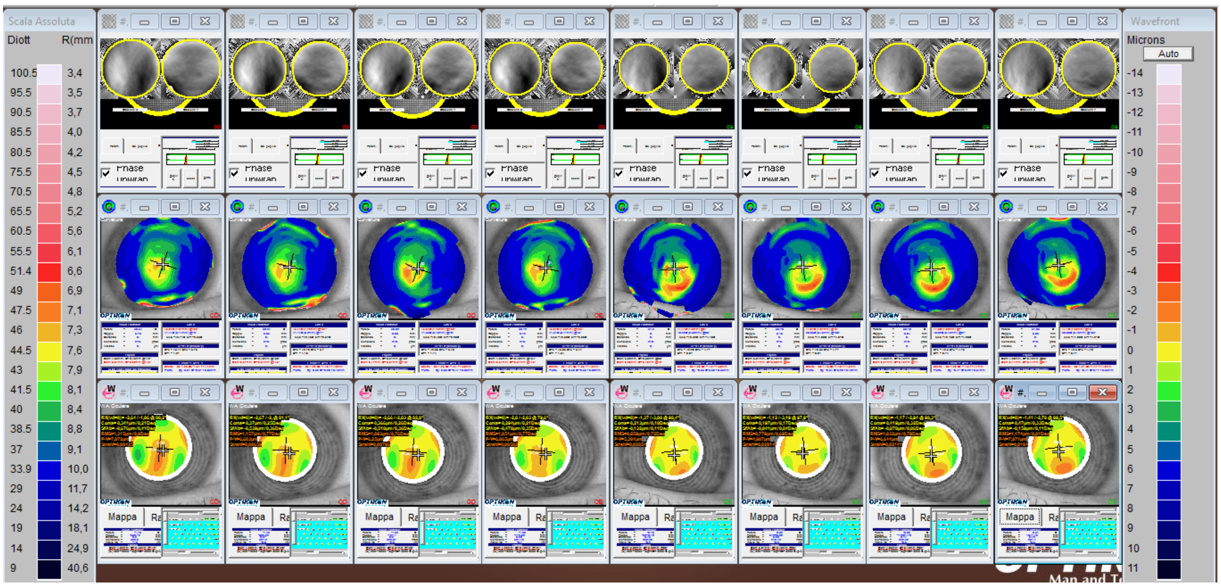

Fig. 2.7. Above, X and Y gradient maps; in the middle, topographic maps; bottom, Total ocular wavefront maps (these show the “aberrometric profile”).

We believe it is important to emphasize that Keratron software does not have a specific function for aberrometric maps that allows verification of repeatability of acquisitions, as is the case with corneal topography. To overcome this failure, the operator must execute the image capture procedure accurately demonstrating a certain level of practicality and knowledge of the instrument, and must also check that the data provided by each map is comparable to each other before proceeding with the next steps.

It is possible to select the most suitable total ocular wavefront map with in vivo Trial CL to generate the FOOT CL using the following criteria in order of importance:

1. ***Comparison of the aberrometric profile of the eight total ocular wavefront maps*:** discard the aberrometric maps that show a clear graphical inconsistency over the other. This step was done by mathematically removing the LOAs from the aberrometric maps, highlighting the aberrometric framework of the HOAs.

2. ***Evaluation of the reliability of X and Y gradients:***
   for the same aberrometric profile consistency, discard the maps in which the gradients show imperfections within the pupillary area, marked by a yellow circle.

Figure 2.8. compares gradients X and Y when they are characterized by imperfections (A) and when they are homogeneous (B).

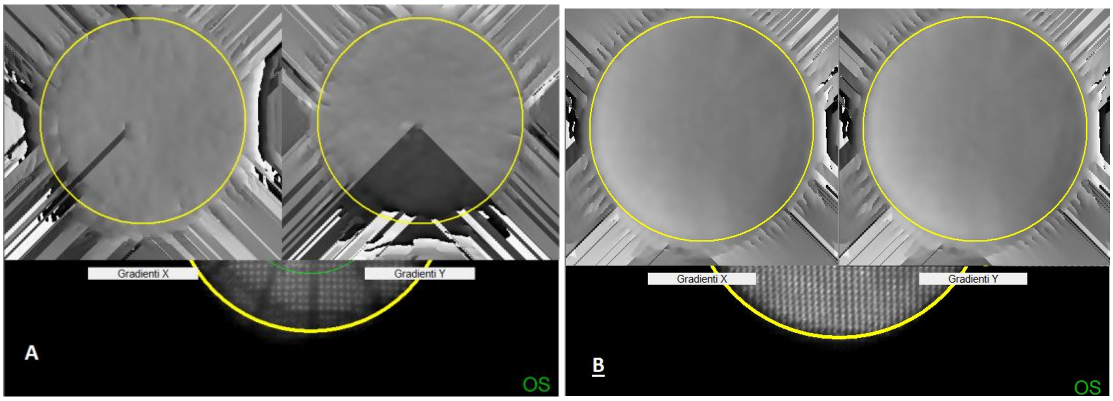

Fig. 2.8. Gradients X and Y when they are characterized by imperfections (A) and when they are homogeneous (B). See area within the yellow circle.

3. ***Greater pupil Diameter:***
   for the same aberrometric profile consistency and reliability of X and Y gradients, prefer the map with greater pupil diameter.

4. ***More positive or less negative refractive value:***
   for the same aberrometric profile consistency, reliability of gradients X and Y and greater pupil diameter, select the map with the most positive or less negative refractive value.

When the most suitable total ocular wavefront map has been selected, extrapolate its output file with ".zer" extension. At this point, we have all the information needed to produce the FOOT CL.

2.3.5 FOOT CL Evaluation

Upon arrival of the first FOOT lenses, application is carried out and after 20 minutes the CLs are evaluated in slit lamp to verify the fitting, dynamics and position of the reference marks. If the CLs respect the parameters and application criteria that were set forth, they are delivered to the candidate. All subjects who participated in this study were evaluated after 7 days of wear and on the day of the check they presented with CLs inserted for 2 hours.

Measurements for the evaluation of FOOT contact lenses were:

- Monocular and binocular BCVA FOOT in low ambient light condition.
- Monocular and binocular BCVA FOOT in high ambient light condition (these results are those used to make comparisons with BCVAGP).
- Slit lamp evaluation of the fitting, dynamics and the position of the reference marks.
- Professional acquisition of number 8 maps of the total ocular wavefront with FOOT CLs in vivo, in order to evaluate vision quality.

If BCVA FOOT, monocular and binocular, is adequate and accepted by subjects and slit lamp evaluation shows coherent reference marks position with those of the diagnostic CL, the lenses are delivered to the subjects.

If BCVA FOOT, monocular and binocular, is NOT adequate and:

1. The position of the reference marks is consistent with that of the diagnostics CL, an "over-aberrometry" is performed. The new data packet must be sent to the lab that will generate a new lens or a pair of lenses. When the lenses are available, the FOOT CLs evaluation procedure must be repeated.

2. The position of the reference marks is not consistent with that of the diagnostics CL, you need to register the new position of the reference marks and perform an "over-aberrometry". The data should be sent to the lab. When the lenses are available, the FOOT CLs evaluation procedure must be repeated.

During the evaluation FOOT CLs it was possible to modify the application technique, TD and BOZR so that the application was optimal.

The procedures just described represent the application protocol of FOOT lenses, aiming to guide the clinician toward a successful application. As mentioned earlier, these guidelines do not want to be definitive, but pave the way for successive proposals and modifications, perhaps simpler and more effective, in the field of eye aberrations correction.

2.4. Results and analysis of data

2.4.1 Analysis of data

BCVAGP and BCVA FOOT data were collected for both monocular and binocular conditions.

The aberrometric low and high order data were collected for each eye without correction and with FOOT CLs in situ (Casco, 2011; Sheila & Holly, 2009), normalizing the pupil diameters at both 4 mm (Guirao, Porter, Williams, & Cox, 2002) and 6 mm (Sheila & Holly, 2009). All data were organized and processed using "Microsoft Excel". We performed a parametric statistical analysis (Student T-Test) to study the differences between the mean values of the sample. We used an online free calculator at www.socscistatistics.com .

As for aberrometric data, statistical analysis focused on total aberrations and HOAs (Thibos, Cheng, & Bradley, 2003), from the third to the seventh order, including the extremes, has considered and compared the values of RMS and Strehl Ratio (Lupelli & Petrini, 2016) of uncorrected eye and with FOOT CLs applied, with 4 and 6 mm normalized pupil for each condition.

2.4.2 Results

In table 2.1. a legend is proposed with all the abbreviations used in data processing.

Acronims	
BCVA	Best Corrected photopic high contrast logMAR Visual Acuity
Odx	Right eye
Osx	Left eye
Bino	Binocular (Both eyes)
GP	Gas permeable contact lens
F.o.ot.	Wavefront-optimized soft contact lens (FOOT)
RMS	Root Mean Square
Str	Strehl Ratio
Tot	Total Aberrations
HOAs	High Order Aberrations
MSE	Mean standard error
No CL	Uncorrected eye (without contact lens)

Tab 2.1. Legend.

2.4.2.1 Best Corrected Photopic High Contrast logMAR Visual Acuity

The graph of Figure 2.9. shows the monocular BCVA average values measured for right and left eyes with GP lenses (Odx: $0{,}16 \pm 0{,}02\ logMAR$; Osx: $0{,}19 \pm 0{,}03\ logMAR$) and with FOOT CLs (Odx: $-0{,}13 \pm 0{,}03\ logMAR$; Osx: $-0{,}13 \pm 0{,}02\ logMAR$) in comparison. BCVA average values with FOOT CL applied are statistically better than those measured with GP lenses, both for right and left eyes ($p < 0{,}01$).

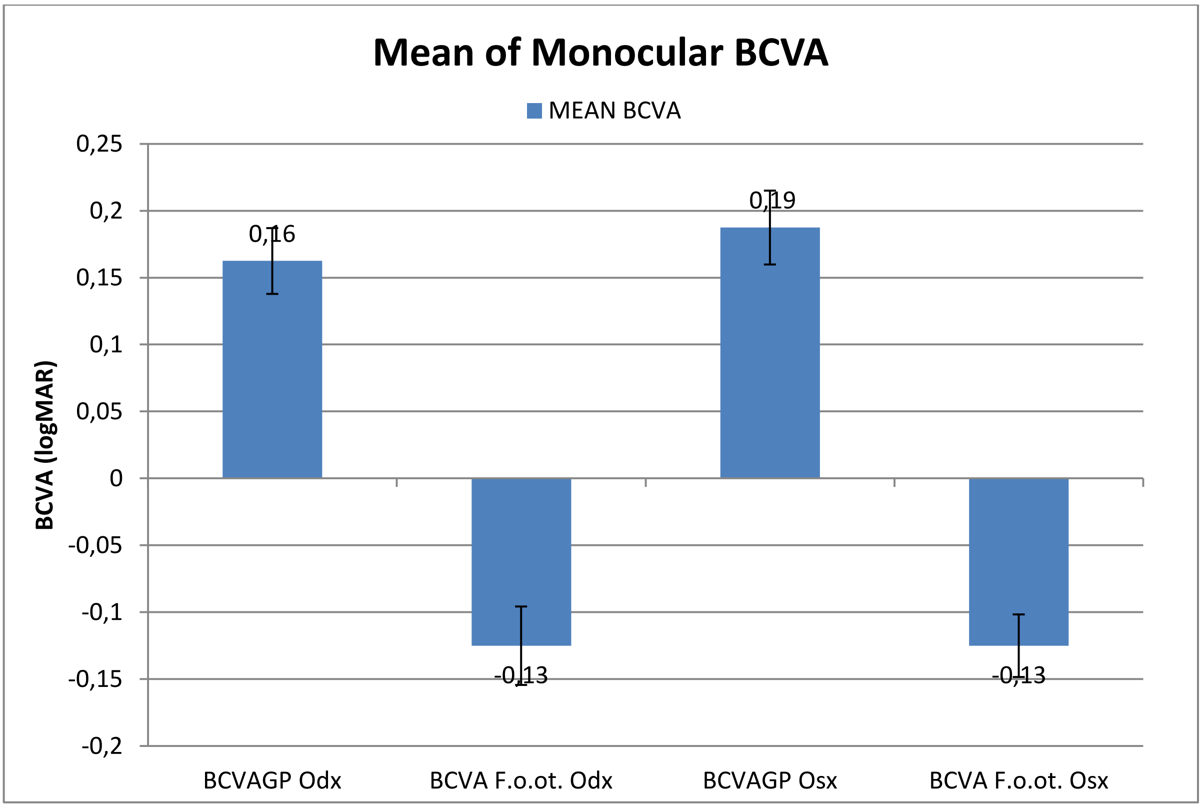

Fig. 2.9. Monocular BCVA average values measured with GP lens and with FOOT CL, in comparison.

The graph of Figure 2.10. shows, in comparison, the binocular average values of BCVA measured with GP lenses ($0{,}10 \pm 0{,}03\ logMAR$) and with FOOT CLs ($-0{,}19 \pm 0{,}01\ logMAR$). Binocular BCVA average value with FOOT CLs is statistically better than the one for GP lens condition ($p < 0{,}01$).

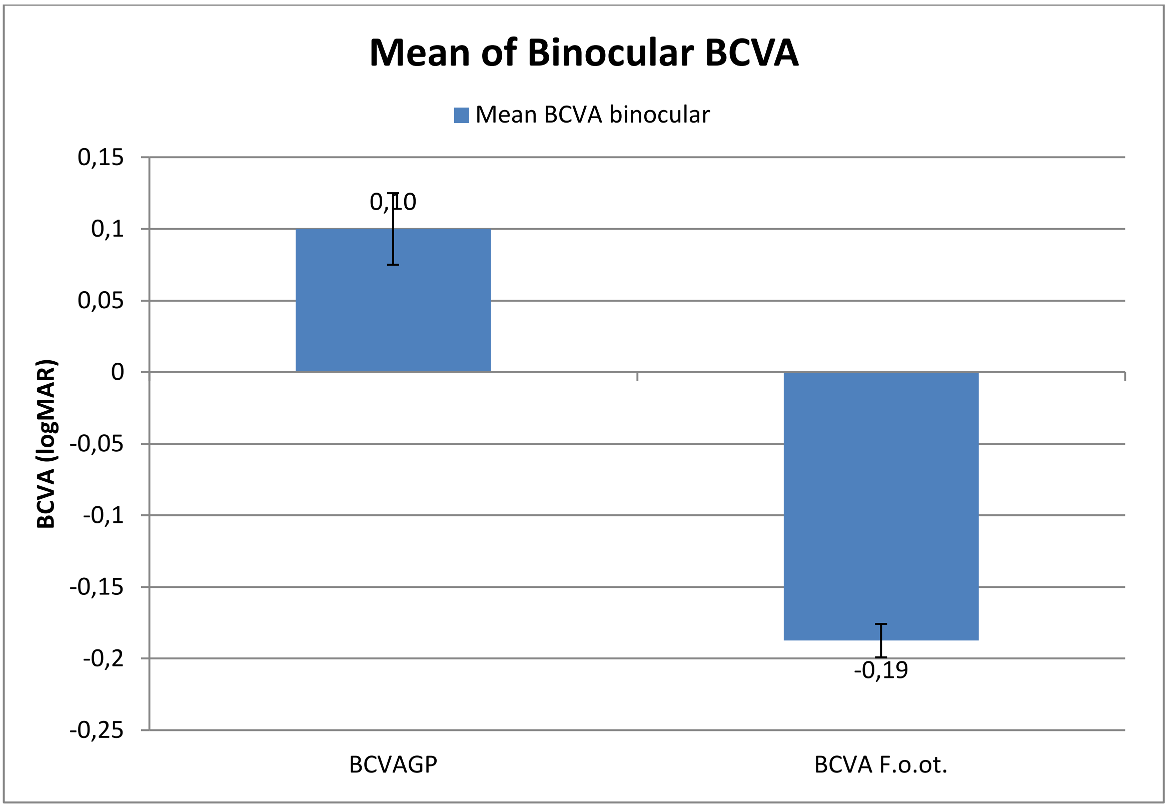

Fig. 2.10. Binocular average values of BCVA with GP lenses and with FOOT CLs, in comparison.

2.4.2.2 RMS and Strehl Ratio for Total Aberrations

The RMS values for total ocular aberrations (total RMS) detected in each right and left eye, without any CLs and with FOOT CLs, with a standard pupil diameter of 4 mm and 6 mm, were recorded.

The average 4 mm total RMS value measured for the uncorrected and with FOOT CLs right eyes were respectively $2{,}375 \pm 0{,}419\ \mu m$ and $0{,}322 \pm 0{,}043\ \mu m$ ($p < 0{,}01$). The average 6 mm total RMS value measured for the uncorrected and with FOOT CLs right eyes were respectively $5{,}194 \pm 0{,}987\ \mu m$ and $0{,}731 \pm 0{,}125\ \mu m$ ($p < 0{,}01$).

The average 4 mm total RMS value measured for the uncorrected and with FOOT CLs left eyes were respectively $2{,}247 \pm 0{,}387\ \mu m$ and $0{,}376 \pm 0{,}058\ \mu m$ (p < 0,01). The average 6 mm total RMS value measured for the uncorrected and with FOOT CLs left eyes were respectively $5{,}113 \pm 0{,}907\ \mu m$ and $1{,}064 \pm 0{,}131\ \mu m$ (p < 0,01).

In all eyes examined, the RMS value for total aberrations measured for uncorrected eye and with FOOT condition decreases if the pupil diameter decreases, according to scientific literature (Pintus, 2009). The total RMS value tends to zero more effectively when FOOT CLs are applied, if compared to the uncorrected eye condition. The average values of total RMS are compared and presented in graphs of Figure 2.11. and 2.12.

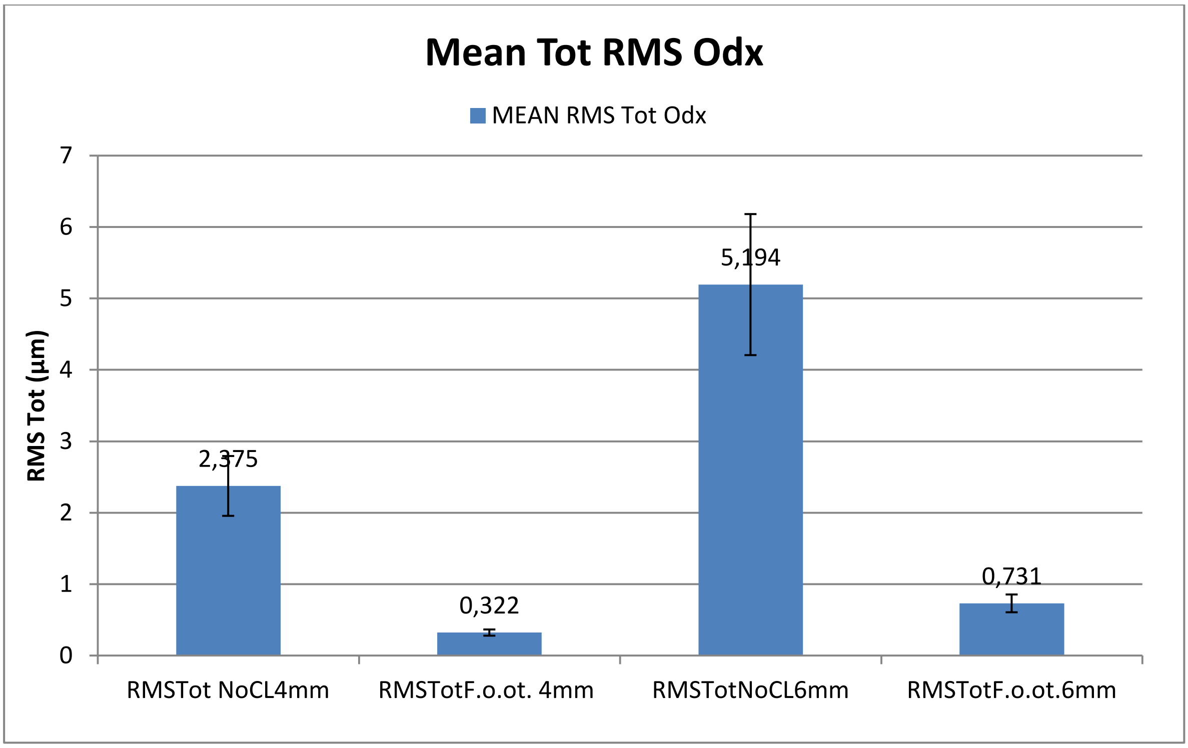

Fig. 2.11. Comparison between the average values of total RMS in the right eyes, for uncorrected and with FOOT CLs conditions, 4 mm and 6 mm standard pupil.

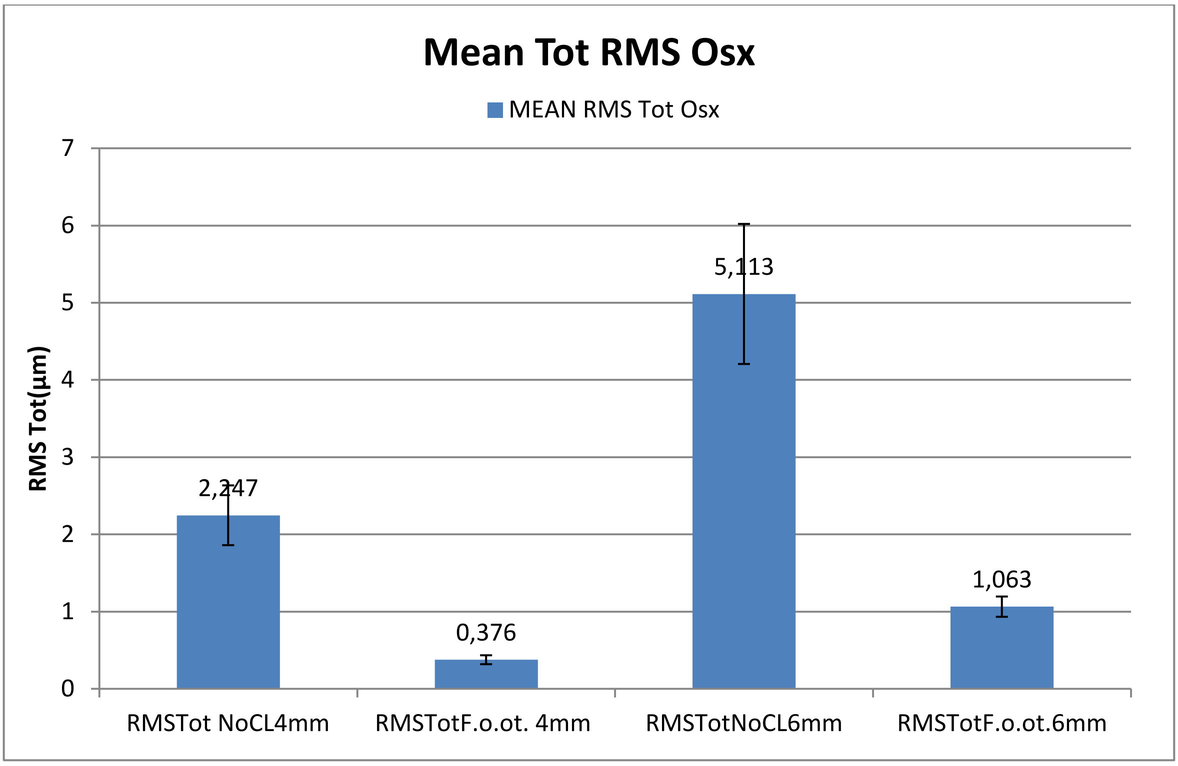

Fig. 2.12. Comparison between the average values of total RMS in the left eyes, for uncorrected and with FOOT CLs conditions, 4 mm and 6 mm standard pupil.

The total RMS average values for all 16 examined eyes measured for uncorrected and with FOOT conditions, with normalized pupil of 4 mm and 6 mm, are shown in figure 2.13.

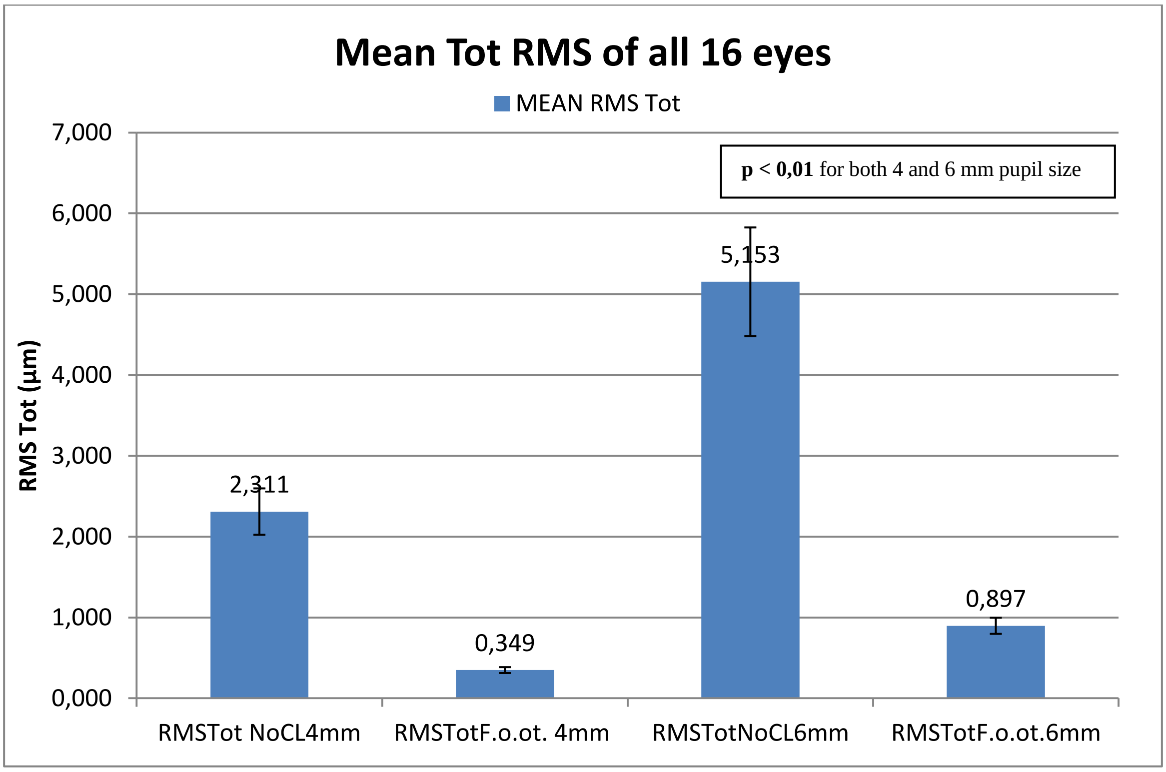

Fig. 2.13. Comparison between the average values of total RMS measured for all 16 eyes (right and left), uncorrected eye and with FOOT, 4 mm and 6 mm normalized pupil.

Strehl Ratio values for total ocular aberrations (total Str) detected in each right and left eye, without any CLs and with FOOT CLs, with a standard pupil diameter of 4 mm and 6 mm, were recorded.

The average 4 mm total Str value measured for the uncorrected and with FOOT CLs right eyes were respectively $0{,}00667 \pm 0{,}00446\ \mu m$ and $0{,}08088 \pm 0{,}02363\ \mu m$ (p < 0,05). The average 6 mm total Str value measured for the uncorrected and with FOOT CLs right eyes were respectively $0{,}00368 \pm 0{,}00182\ \mu m$ and $0{,}02395 \pm 0{,}00658\ \mu m$ (p < 0,01).

The average 4 mm total Str value measured for the uncorrected and with FOOT CLs left eyes were respectively $0{,}00541 \pm 0{,}00232\ \mu m$ and $0{,}06319 \pm 0{,}01237\ \mu m$ (p < 0,01). The average 6 mm total Str value measured for the uncorrected and with FOOT CLs left eyes were respectively $0{,}00220 \pm 0{,}00077\ \mu m$ and $0{,}01752 \pm 0{,}00384\ \mu m$ (p < 0,01).

In all eyes examined, the Strehl Ratio value for total aberrations measured for uncorrected eye and with FOOT condition increases if the pupil diameter decreases, according to scientific literature (Pintus, 2009). The total Str value tends to one more effectively when FOOT CLs are applied, if compared to the uncorrected eye condition. The average values of total Strehl Ratio are compared and presented in Figure 2.14. and 2.15.

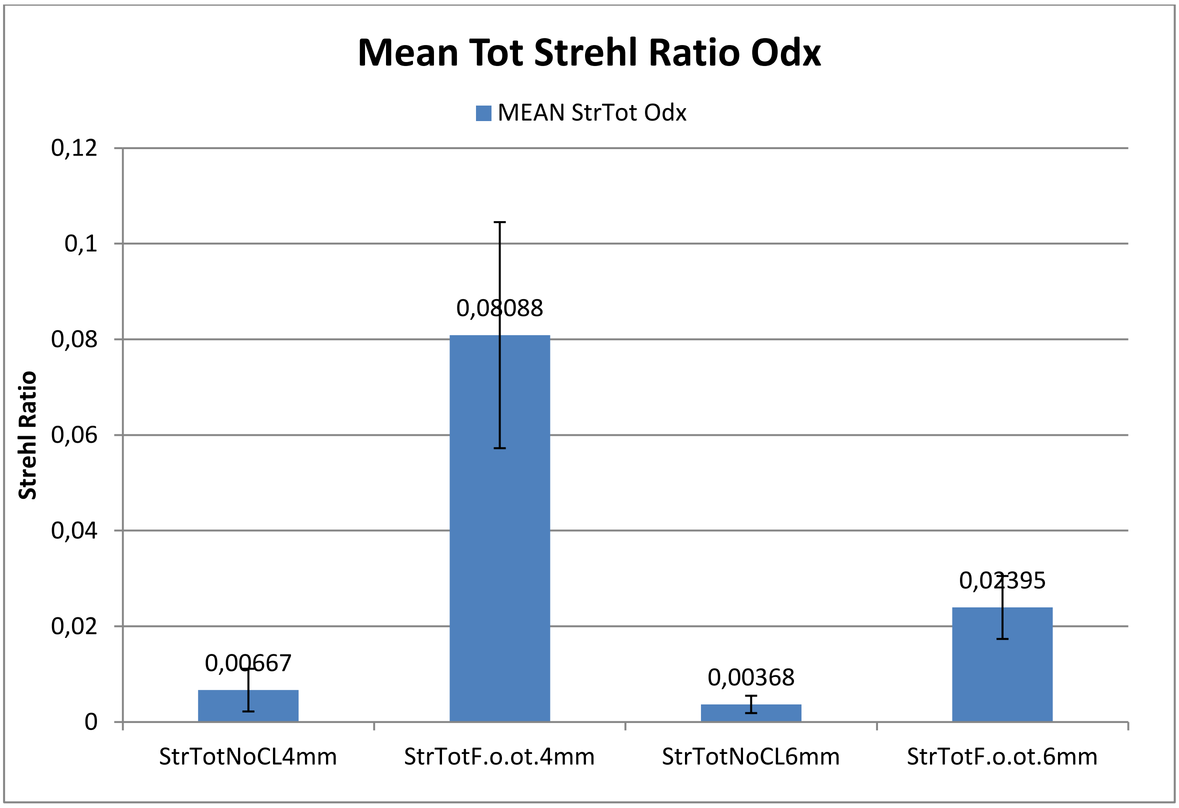

Fig. 2.14. Comparison between the average values of Tot Strehl Ratio in the right eyes, for uncorrected and with FOOT conditions, 4 mm and 6 mm standard pupil.

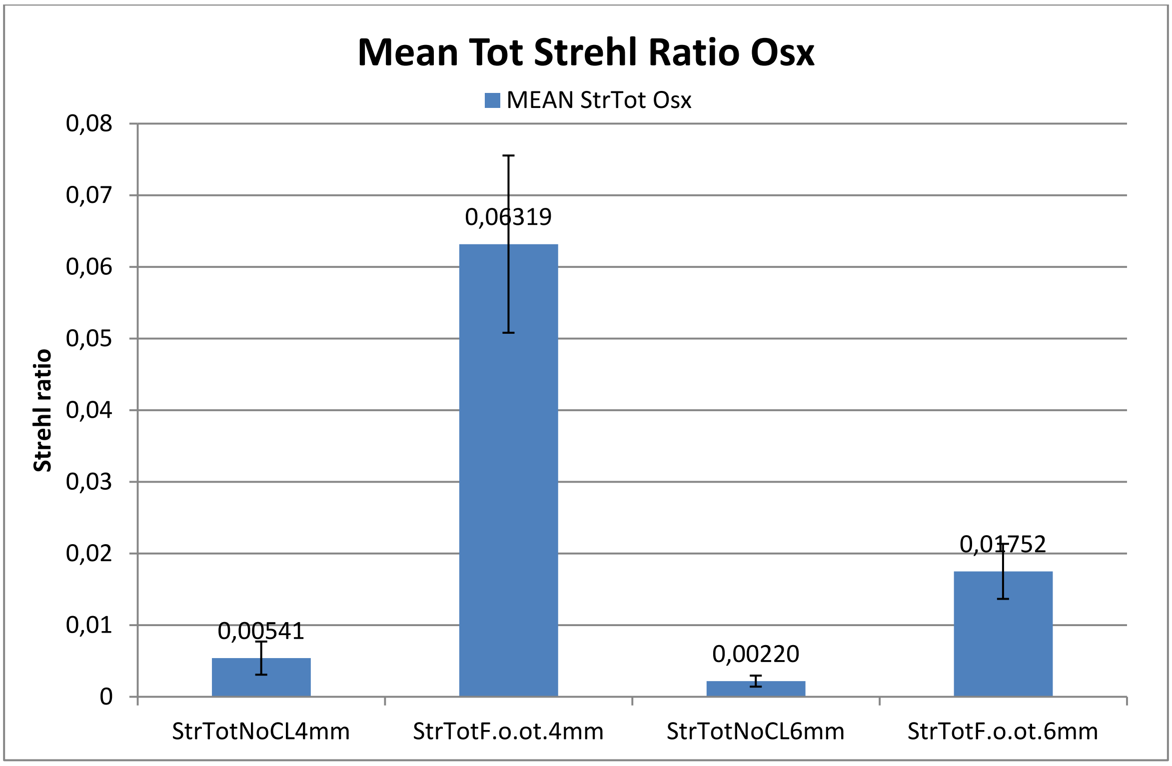

Fig. 2.15. Comparison between the average values of Tot Strehl Ratio in the left eyes, for uncorrected and with FOOT conditions, 4 mm and 6 mm standard pupil.

Total Strehl Ratio average values for all 16 examined eyes measured for uncorrected and with FOOT conditions, with normalized pupil of 4 mm and 6 mm, are shown in figure 2.16.

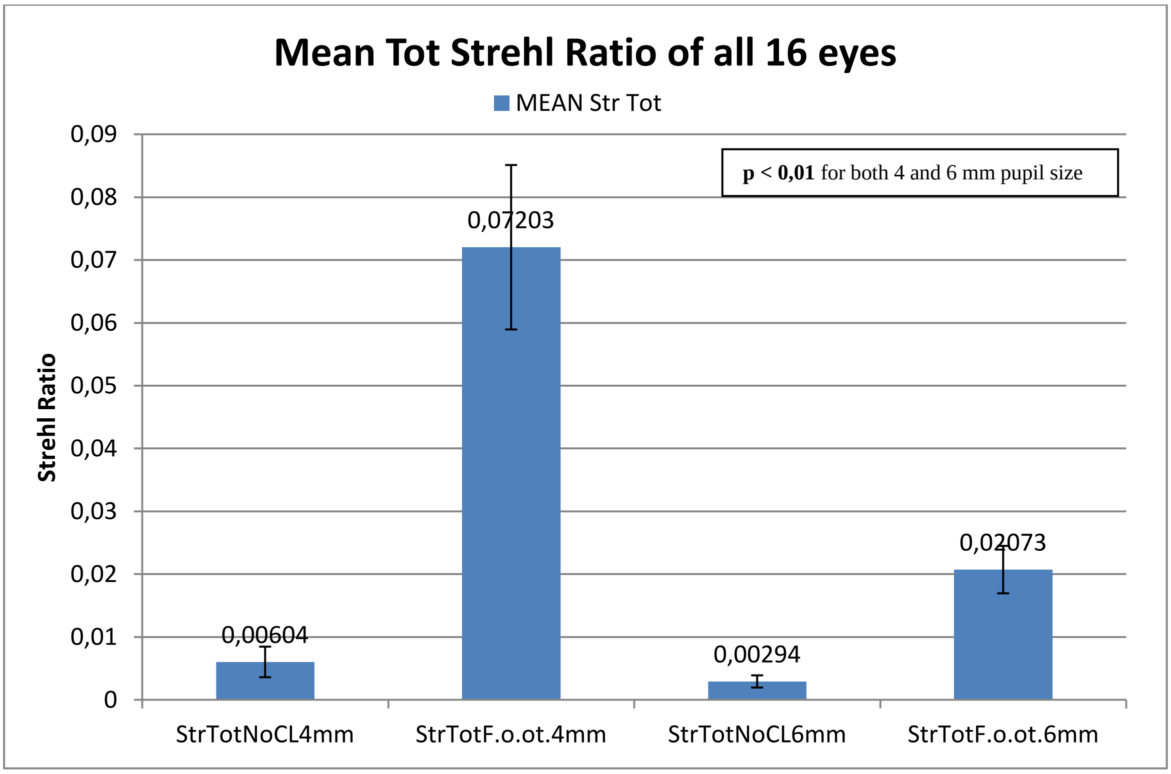

Fig. 2.16. Comparison between the average values of total Str measured for all 16 eyes (right and left), uncorrected eye and with FOOT, 4 mm and 6 mm normalized pupil.

2.4.2.3 RMS e Strehl Ratio for High Order Aberrations

The RMS values for high order aberrations (HOAs RMS) detected in each left and right eye, without any CLs and with FOOT CLs, with a standard pupil diameter of 4 mm and 6 mm, were recorded.

The average 4 mm HOAs RMS value measured for the uncorrected and with FOOT CLs right eyes were respectively $0{,}274 \pm 0{,}031\ \mu m$ and $0{,}145 \pm 0{,}019\ \mu m$ ($p < 0{,}01$). The average 6 mm HOAs RMS value measured for the uncorrected and with FOOT CLs right eyes were respectively $0{,}799 \pm 0{,}050\ \mu m$ and $0{,}377 \pm 0{,}053\ \mu m$ ($p < 0{,}01$).

The average 4 mm HOAs RMS value measured for the uncorrected and with FOOT CLs left eyes were respectively $0{,}462 \pm 0{,}051\ \mu m$ and $0{,}181 \pm 0{,}038\ \mu m$ ($p < 0{,}01$). The average 6 mm HOAs RMS value measured for the uncorrected and with FOOT CLs left eyes were respectively $1{,}380 \pm 0{,}122\ \mu m$ and $0{,}559 \pm 0{,}073\ \mu m$ ($p < 0{,}01$).

In all eyes examined, the RMS value for high aberrations measured for uncorrected eye and with FOOT condition decreases if the pupil diameter decreases, according to scientific literature (Pintus, 2009). The HOAs RMS value tends to zero more effectively when FOOT CLs are applied, if compared to the uncorrected eye condition. The average values of HOAs RMS are compared and presented in graphs of Figure 2.17. and 2.18.

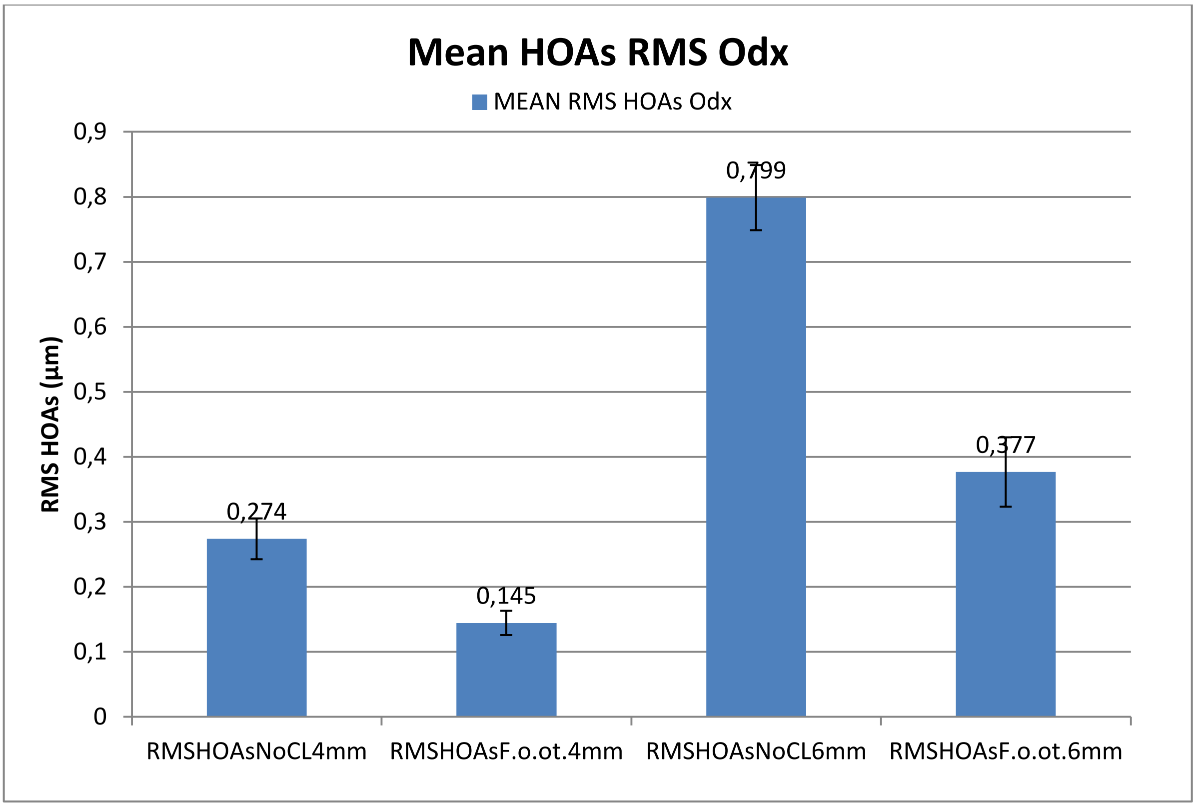

Fig. 2.17. Comparison between the average values of HOAs RMS in the right eyes, for uncorrected and with FOOT CLs conditions, 4 mm and 6 mm standard pupil.

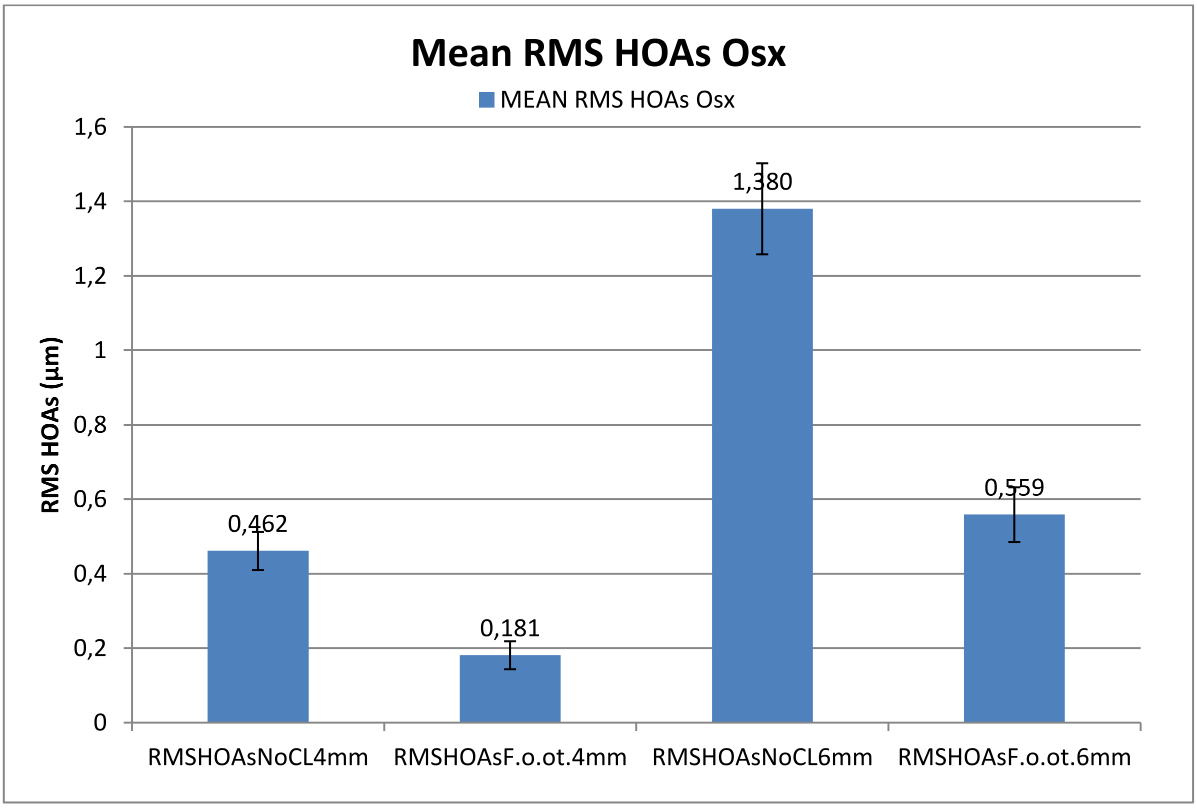

Fig. 2.18. Comparison between the average values of HOAs RMS in the left eyes, for uncorrected and with FOOT CLs conditions, 4 mm and 6 mm standard pupil.

The HOAs RMS average values for all 16 examined eyes measured for uncorrected and with FOOT conditions, with normalized pupil of 4 mm and 6 mm, are shown in figure 2.19.

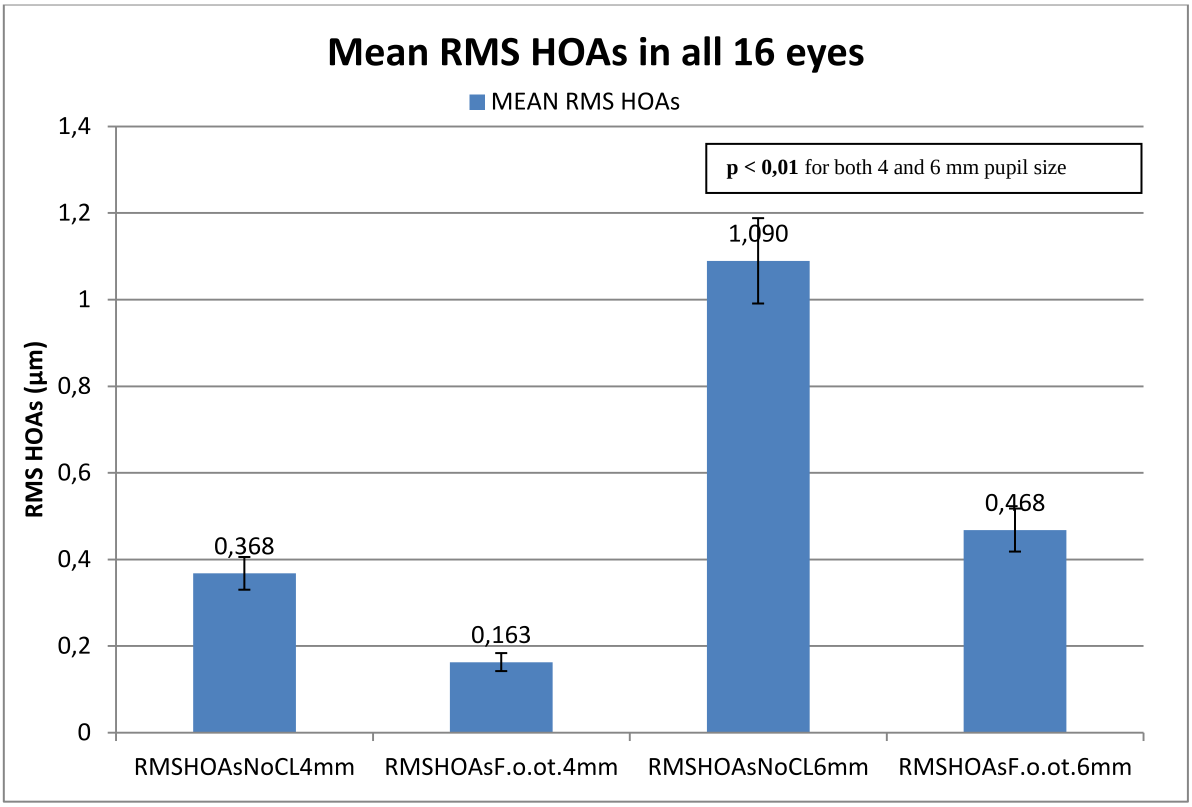

Fig. 2.19. Comparison between the average values of HOAs RMS measured for all 16 eyes (right and left), uncorrected eye and with FOOT, 4 mm and 6 mm normalized pupil.

Strehl Ratio values for high order aberrations (HOAs Str) detected in each right and left eye, without any CLs and with FOOT CLs, with a standard pupil diameter of 4 mm and 6 mm, were recorded.

The average 4 mm HOAs Str value measured for the uncorrected and with FOOT CLs right eyes were respectively $0{,}08532 \pm 0{,}01249\ \mu m$ and $0{,}19614 \pm 0{,}04667\ \mu m$ ($p < 0{,}05$). The average 6 mm HOAs Str value measured for the uncorrected and with FOOT CLs right eyes were respectively $0{,}01372 \pm 0{,}00211\ \mu m$ and $0{,}04979 \pm 0{,}01380\ \mu m$ ($p < 0{,}05$).

The average 4 mm HOAs Str value measured for the uncorrected and with FOOT CLs left eyes were respectively $0{,}03684 \pm 0{,}00945\ \mu m$ and $0{,}22165 \pm 0{,}07880\ \mu m$ ($p < 0{,}05$). The average 6 mm HOAs Str value measured for the uncorrected and with FOOT CLs left eyes were respectively $0{,}00599 \pm 0{,}00103\ \mu m$ and $0{,}03367 \pm 0{,}00963\ \mu m$ ($p < 0{,}05$).

In all eyes examined, the Strehl Ratio value for high aberrations measured for uncorrected eye and with FOOT condition increases if the pupil diameter decreases, according to scientific literature (Pintus, 2009). The HOAs Str value tends to one more effectively when FOOT CLs are applied, if compared to the uncorrected eye condition. The average values of HOAs Strehl Ratio are compared and presented in Figure 2.20. and 2.21.

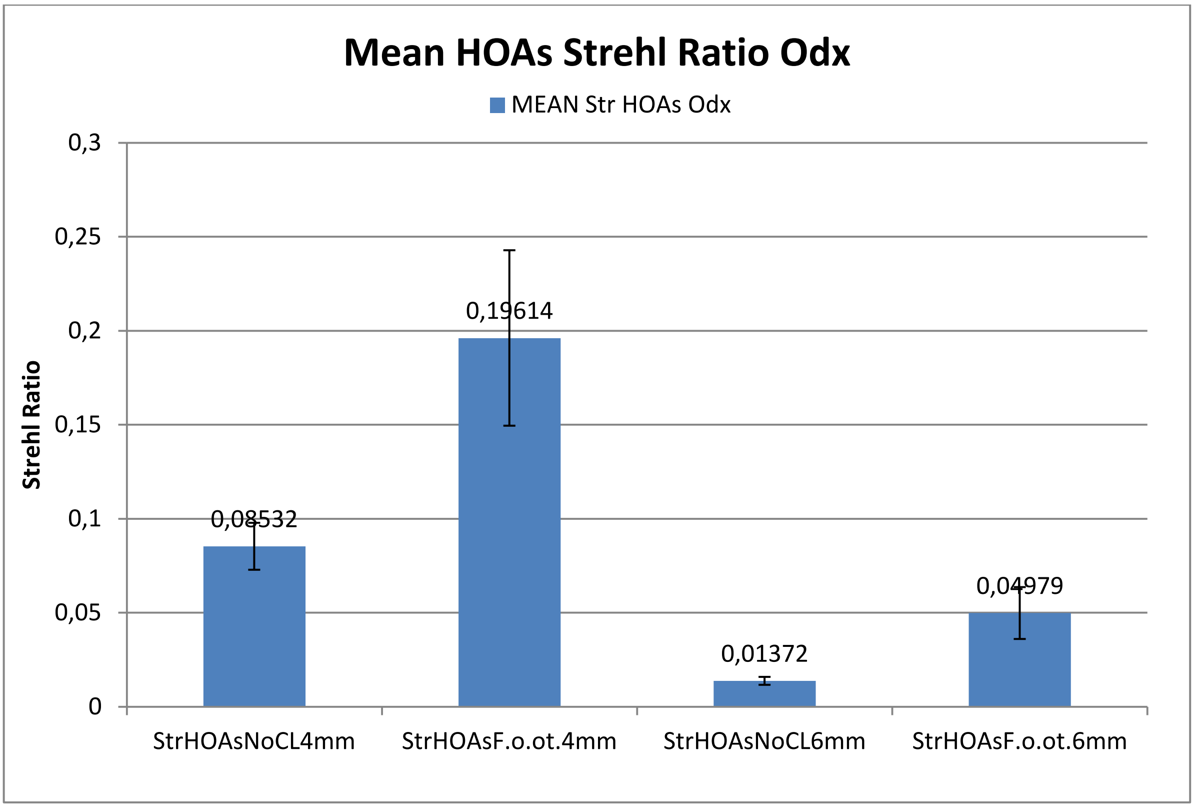

Fig. 2.20. Comparison between the average values of HOAs Strehl Ratio in the right eyes, for uncorrected and with FOOT conditions, 4 mm and 6 mm standard pupil.

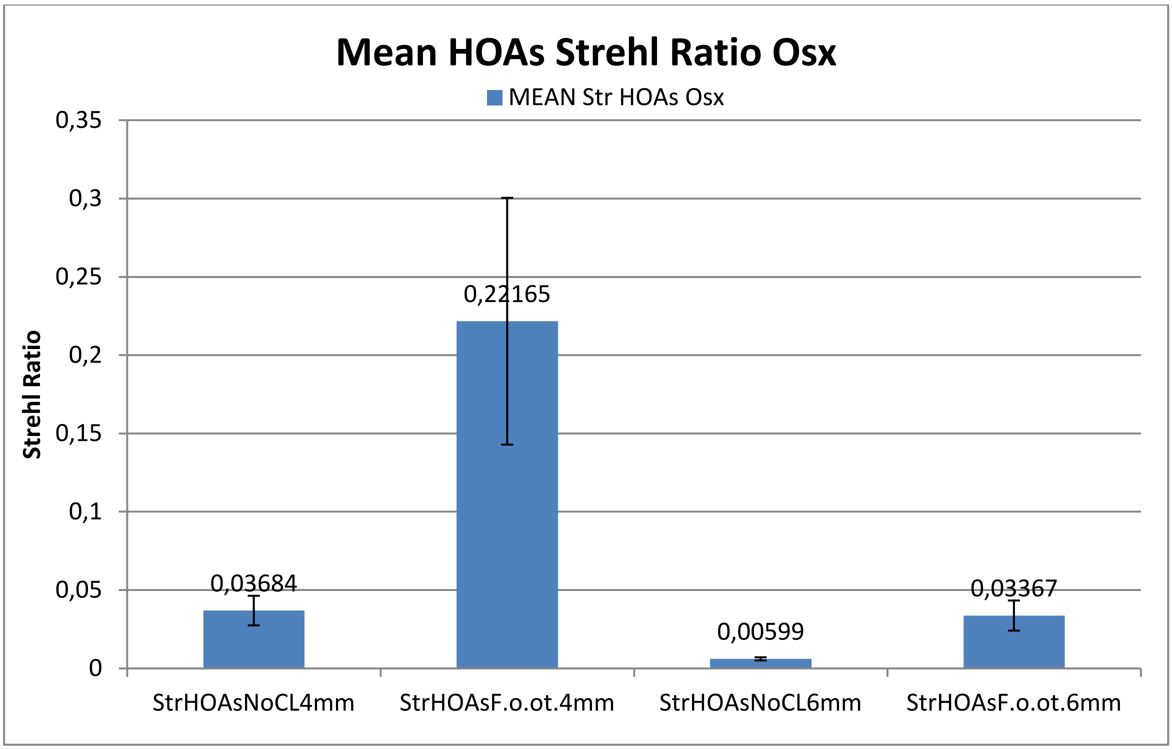

Fig. 2.21. Comparison between the average values of HOAs Strehl Ratio in the left eyes, for uncorrected and with FOOT conditions, 4 mm and 6 mm standard pupil.

HOAs Strehl Ratio average values for all 16 examined eyes measured for uncorrected and with FOOT conditions, with normalized pupil of 4 mm and 6 mm, are shown in figure 2.22.

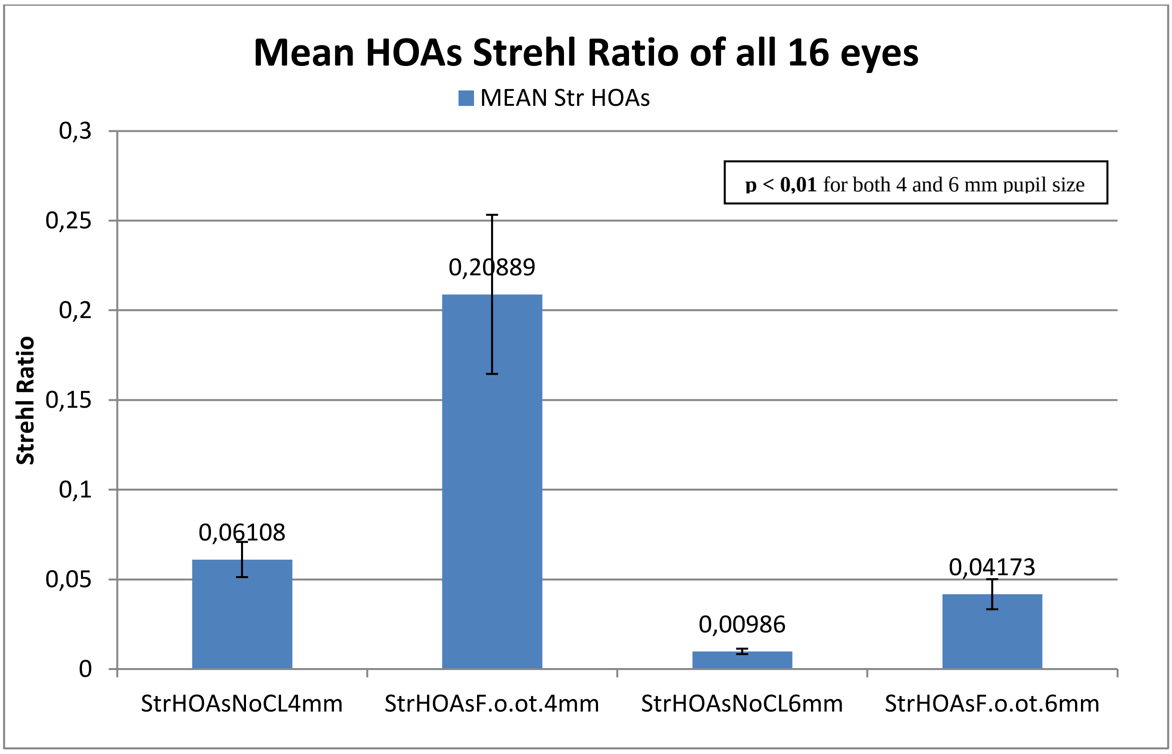

Fig. 2.22. Comparison between the average values of HOAs Str measured for all 16 eyes (right and left), uncorrected eye and with FOOT, 4 mm and 6 mm normalized pupil.

2.5. Discussion

Best Corrected photopic high contrast logMAR Visual Acuity measured with FOOT CLs, both monocular and binocular, is significantly higher ($p < 0{,}01$) than the one obtained with habitual GP lenses, in accordance with what previously stated by Lupelli & Petrini (2016) and by Manganotti (2011). In our case the BCVA values obtained with FOOT are better than those obtained previously by other authors, thanks to the improvement of the production process and the introduction of the concept of over-aberrometry.

The mean RMS and mean Strehl Ratio values obtained for total ocular aberrations and HOAs are better when FOOT lenses are applied if compared to uncorrected eye, in full agreement with Lupelli & Petrini (2016). Again, our study shows results that are superior to the previous ones (Lupelli & Petrini, 2016), which is again attributable to improvements to the wavefront-optimized technology used for our study.

Total ocular aberrations RMS mean values for a 6 mm pupil we recorded for each right, left and all-eyes uncorrected eyes conditions are greater than $4{,}000 \pm 2{,}450\ \mu m$ that is the average total ocular aberrations RMS value for a 6 mm pupil reported by Netto, Ambrósio, Shen & Wilson (2005) in a normal refractive surgery population. When FOOT CLs are applied, total ocular aberrations RMS mean values we measured for a 6 mm pupil become respectively $0{,}731 \pm 0{,}125\ \mu m$ for right eyes, $1{,}063 \pm 0{,}131\ \mu m$ for left eyes and $0{,}897 \pm 0{,}100\ \mu m$ for all-eyes, which are all lower than that reported in 2005 by Netto et al. and also are lower than that reported by Castejo´n-Mocho´n, Lo´pez Gil, Benito & Artal in 2002 for a young normal vision population (total ocular aberrations RMS mean value for a 6 mm pupil of 2,200 μm).

Total ocular aberrations RMS mean values for a 4 mm pupil we recorded for each right, left and all-eyes uncorrected eyes conditions are greater than that reported for the same pupil size by Castejo´n-Mocho´n, Lo´pez Gil, Benito & Artal (2002) for a young normal vision population: total ocular aberrations RMS mean value for a 4 mm pupil of 0,940 μm. However, when FOOT CLs are applied all our data of total ocular aberrations RMS mean values (right, left and all-eyes condition) for a 4 mm pupil are lower than 0,940 µm: $0{,}322 \pm 0{,}043\ \mu m$ for right eyes, $0{,}376 \pm 0{,}058\ \mu m$ for left eyes, $0{,}349 \pm 0{,}037\ \mu m$ for all-eyes condition.

Salmon T. and van de Pol C. (2006) established that the average value of HOAs RMS for a 6 mm pupil in a normal-eye population is 0,330 µm. They have also stated that measurements greater than double the mean, found in less than 10% of the normal population, would be suspicious (higher-order RMS value for a 6 mm pupil greater than 0,660 µm). Higher-order aberrations RMS mean values for a 6 mm pupil we recorded for uncorrected eyes in our study, they all exceed that 0,660 µm. This is because our sample comprehends subjects that cannot be included in the normal-eye population considered by Salmon T. and van de Pol C. (2006). While, when FOOT CLs are applied all data are lower than 0,660 µm for every condition (right eyes, left eyes and all-eyes). HOAs RMS mean values for a 6 mm pupil we recorded with FOOT CLs in situ are $0{,}377 \pm 0{,}053\ \mu m$ for right eyes, $0{,}559 \pm 0{,}073\ \mu m$ for left eyes and $0{,}468 \pm 0{,}050\ \mu m$ for all-eyes respectively. Also, they are lower than or comparable to the average value suggested by Lim & Fam (2009) in a refractive surgery Chinese-eye population ($0{,}525 \pm 0{,}354\ \mu m$).

Salmon T. and van de Pol C. (2006) suggested a reference value also for higher-order aberrations measured in a normal-eye population for a 4 mm pupil: $0{,}100 \pm 0{,}044\ \mu m$. As previously stated for 6 mm pupil, also in this case authors suggested that measurements greater than double the mean would be suspicious (higher-order RMS value for a 4 mm pupil greater than 0,200 µm). Higher-order aberrations RMS mean values we measured for a 4 mm pupil in the uncorrected eyes conditions are greater than 0,200 µm. Instead, when FOOT CLs are applied our HOAs RMS mean values for a 4 mm pupil are lower than 0,200 µm: they are $0{,}145 \pm 0{,}019\ \mu m$ for right eyes, $0{,}181 \pm 0{,}038\ \mu m$ for left eyes and $0{,}163 \pm 0{,}021\ \mu m$ for all-eyes.

Data on the mean Strehl Ratio for total and higher-order aberrations recorded for both 4 and 6 mm pupil are quite low for all uncorrected-eye conditions (right and left eyes; all-eyes condition). Considering the same data and conditions but when FOOT CLs are applied, we observed for each condition a significantly increase (see sub-chapters 2.4.2.2 and 2.4.2.3 for p-values) in the mean Strehl Ratio for both total and higher-order aberrations. The Strehl Ratio data obtained in this research with FOOT lenses are still quite low if compared to the reference value of a normal and healthy eye (generally a value of 0,8 is considered good – Carnevali, 2013). But, they are still comparable to or greater than those reported by Petrini and Lupelli in 2016 for a irregular-cornea population.

The data obtained confirms the hypothesis of Marsack, et al. (2008) and Lòpez-Gil N., et al. (2002) for the correction of aberrations with soft contact lenses: these would be able to correct ocular aberrations of the examined eye introducing a predetermined amount of aberration but of opposite sign. FOOT contact lenses represent the concrete realization of these hypotheses.

CONCLUSIONS

In the light of what has just been stated, we can state that:

- FOOT lenses are effective and have achieved the expected results, even in the presence of particularly aberrated wavefronts (for which no satisfactory results were achieved with GP contact solutions);
- Although rigid contact lenses are still considered to be the most effective optical solution in the presence of corneal irregularities (Casco, 2011), FOOT soft contact lenses have proved to be an equally valid solution and in our case a better one for correcting complex visual defects caused by higher-order aberrations;
- They find particular consensus among the carriers about the excellent visual quality that they produce both in relation to the perceived comfort;
- Where total eye aberrations are mainly determined by internal wavefront and not by corneal surface irregularities, these soft lenses represent the most appropriate corrective solution (as the physically rigid lenses do not compensate for internal aberrations as stated by Kenneth, 2008);
- It has been found that aberrations can be measured with soft lenses inserted into the eye, according to Sheila & Holly (2009), and that the obtained data can be used to produce a contact correction based on the aberrometric profile of the optical system considered;

FINAL WORDS

The main difficulty we have faced lies in the need to comply with the stability and centering criteria that the FOOT lens must have in order to fulfil its purpose. These latter, in fact, have a greater influence on the visual quality than they would if we consider the traditional soft toric lenses (De Brabander, Chateau, Marin, G. et al., 2003). However, in view of the practical difficulties expressed and provided that the guidelines outlined in the protocol are met, we can state that FOOT lenses are capable of offsetting high-order aberrations, minimizing the total aberrometric framework without producing negative effects on it.

We are satisfied with the promising results achieved and the application protocol developed for the use of FOOT lenses. We believe that in order to assert with greater certainty the effectiveness of soft contact lenses with optimized wavefront, it is indispensable to conduct further studies on the visual performance achievable with these lenses considering more specimens with different characteristics, such as subjects exclusively with keratoconus; subjects with regular cornea, but with internal aberrations, or patients with functional amblyopia. In this regard, supported by Agarwal, Agarwal, & Soosa (2007) hypotheses, with reference to Congenital Aberropia, a fair number of amblyopic subjects could be grouped and an in-depth analysis of the ocular wavefront could be performed. Breaking down the wavefront of the eye in its corneal and internal parts you could investigate whether, and to what extent, the aberrations participate in describing the clinical picture of an amblyopic subject, and especially what aberrations play a decisive role. It would be useful to ascertain whether by eliminating the cause of congenital aberropia by compensating the aberrated wavefront, it would be possible to obtain an improvement in the visual performance of amblyopic subjects and at least partially restore their binocularity. It remains certain to us that if the origin of a particular functional amblyopia was of aberrometric nature, that condition could be solved or at least improved with the use of FOOT lenses.

We believe it is indispensable to continue studying aberrations to allow the formation of more accurate reference scales and universally accepted values, despite the varying nature of the aberrations themselves (Sheila & Holly, 2009). This would, for example, contribute to the construction of aberrometers of a precision such as to provide an extremely accurate description of the eyepiece wavefront (Salmon & van de Pol, 2006), with which it would be possible to produce wavefront-optimized soft contact lenses with an almost absolute precision.

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