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A CA system for RGP contact lens design

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Abstract

Purpose:

Development of procedures aimed at assisting lens designer when RGP lenses are to be prescribed to a patient.

Method:

Procedures have been partly developed and partly adapted, (i) to choose the most suitable lens shape category for a specific visual defect, and (ii) for determining lens geometrical parameters. In some cases lens designer is asked to choose among two alternatives.

Result:

The program covers all the more widespread lens categories and is ready for testing by the potential users.

Discussion & Conclusion:

This work originates from the objective of reducing the number of trials before the definitive lens is produced. The initial idea to develop a dedicated CAD/CAM system is at the moment in standby, as lens manufacturers distrust optician solutions.

1 Introduction

The work presented is part of package aimed at improving the actual procedures for designing and manufacturing rigid gas permeable (RGP) contact lenses.

RGP contact lenses are a niche in the field of contactology. They are actually a newer technology than soft lenses and represent the natural evolution of rigid lenses, thanks to the availability of new and more suitable materials. They are similar to rigid lenses with whom they share a low tendency to absorb liquids, but transmit more oxygen to the eye than do traditional soft contact lenses (although some newer silicone hydrogel soft lenses are comparable to RGPs in oxygen transmission). RGPs can also provide better vision, durability, and deposit resistance than soft contact lenses. On the other hand, soft lenses are instantly comfortable to wear, while RGPs require an adaptation period before they can be comfortable.

RGPs are frequently the answer for people who do not obtain acceptable vision with soft lenses. This includes:

- Individuals who are very fussy about the quality of their vision.
- Some people with astigmatism for whom soft contacts do not produce the desired visual acuity.
- People with presbyopia, because RGPs come in numerous bifocal and multifocal designs. Different bifocal designs work well for different people, so having many choices is a real plus. Also, many people find that the best combination of near and distance acuity is obtained with RGP bifocals.
- People who have a condition called keratoconus, where the cornea is cone-shaped and causes extreme visual distortion [1].

In Italy opticians, less frequently ophtalmologists, are the designers; then lenses are manufactured at specialized companies through turning operations on dedicated lathes and lapping to reduce surface asperities.

2 Lens morphology

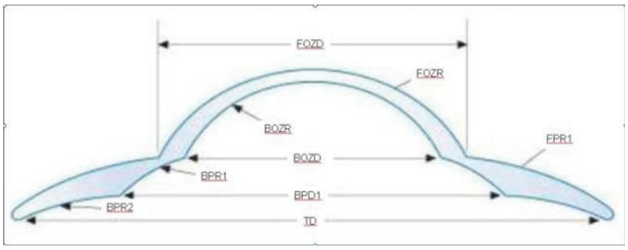


Fig. 1 A cross section of a contact lens (adapted from [2]).

Before describing the tools currently used to select lens shape and dimensions, it is opportune to introduce the way a lens is structured. Both the inner and the outer surfaces are divided in a central part, called respectively Back Optic Zone (BOZ) and Front Optic Zone (FOZ), and a periphery, inner and outer flanges. The optical zones are responsible for the quality of vision, while the inner flanges must assure (i) a stable lens support on the cornea surface, (ii) an acceptable tear film turnover between lens and cornea and (iii) an easy lens lifting. At the same time, the lens thickness at the edge should not interfere with the natural eye blinking.

In Fig. 1 both the IOZ and the OOZ are described by a single arc of a circumference. On the external surface there is only one flange, while two flanges compose the inner periphery.

3 Cornea analysis

Lens design starts from analysis of the patient cornea; since the cornea is normally responsible for some 70% of the eye's refractive power, its topology is of critical importance in determining the quality of vision. To this aim, an ophtalmometer or a topographer could be used. Both tool categories take advantage of the cornea reflective capability.

The former tool is more widespread, due to its usage simplicity and lower cost. Through a zoom of the cornea, it allows a circumscribed measurement of the central area through which it is possible to measure cornea curvature along a specific meridian, as if it were an arc of a circumference. To some extent, it is also possible a direct measurement of the dioptric power of the cornea. Since an ophtalmometer gives an approximate description of the cornea shape through few geometrical parameters, it is a more appropriate tool to deal with regular cornea shapes.

When the cornea is affected by local defects or it is characterized by an irregular shape, an ophtalmometer is no longer suitable to determine the cornea profile and a topographer is a better choice because it makes it possible to know in detail the thorough cornea topology. A computer provides the necessary analysis, typically determining the position and height of several thousand points across the cornea. The topographical map can be represented in a number of graphical formats, such as a sagittal map, which color-codes the steepness of curvature according to its dioptric value [2], an example being given in Fig. 2.

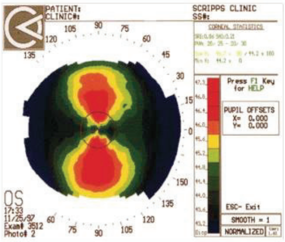


Fig. 2 An example of a sagittal map [3].

A very useful aid to define an appropriate lens shape is fluorescein eye stain. This is a test that uses orange dye (fluorescein) and a blue light, originally introduced to detect foreign bodies in the eye. When a test lens is put on the cornea, this test makes it possible to determine where the lens is in contact with eye and, to some extent, the thickness distribution of the tear film between lens and cornea.

4 Previous activities

In this paragraph steps that preceded the work presented are quickly sketched, because they are considered useful for a better comprehension of the environment.

- A questionnaire was sent to nearly all Italian RGP lens manufacturers. Those companies are all equipped with CNC lathes for lens manufacturing, but they usually do not develop NC programs; instead they use a set of parametric programs, at each one being associated a lens category. Opticians are forced to ask only for lenses which are within one of categories, otherwise the lens shape must be changed.
- The next step was conditioned by a few pieces of information relevant to the optician category which is opportune to highlight. Most opticians are equipped with ophtalmometers, they usually do not have a deep informatics knowledge and cannot invest much money to buy commercial packages.
- The first aim was the development of a CAD/CAM tailored for RGP lenses, in such a way that an optician could send to a manufacturer a file intelligible by the lathe numerical control. As the numerical controls of the lathes for lens manufacturing utilizes proprietary languages, no commercial postprocessors are available for them. In addition, lens shapes are simple, therefore a commercial CAD system would be heavily underutilized. From the above consideration derived the idea of developing a CAD/CAM system from scratch.
- Java was chosen as the programming language because (i) it is free, (ii) a large number of libraries are available, (iii) in internet it is easy to find information and suggestions and (iv) it is possible to develop user-friendly user interfaces.
- A CAD/CAM system has been partly developed [4], its main lack being a preprocessor suitable for lathe numerical controls. Aimed at developing a preprocessor and at testing it, several lens manufacturers were contacted, but the choral answer was that they do not want to produce lenses as opticians ask for. It seems that opticians are considered unable to design lenses.

As a consequence of the above point, it was decided to develop a computer program to assist opticians in the lens designing activity. The program is divided into two sections. The main part is aimed at supporting a lens designer in deciding the suitable lens category, depending on the eye shape, and in determining lens dimensions. Afterwards, the fluorescein eye stain is opportune, to verify decisions correctness. The latter part of the program can only be used when an optician is equipped with an ophtalmometer and is aimed at simulating the fluorescein eye stain, so that the patient only need to wear few test lenses, just to tune the choice.

5 Procedures for lens design

The following procedures are to be intended as an aid for the lens designers who are only equipped with an ophtalmometer. This tool analyses cornea cross sections to obtain (i) the apical radius and (ii) the p-value, also called shape factor which, in the general equation to all the conic sections, is given by Baker's equation [5] as:

$$y^2 = 2r_0x - px^2 \tag{1}$$

where y is the semi-chord, r_0 is the apical radius and x is the sag of the section. Cornea cross sections are typically ellipsoidal and it is possible to identify two of them characterized by the largest and the smallest apical radius, conventionally called the flat and the steep meridians.

From a geometrical point of view, the simplest lenses are spherical. It means that on a cross section a lens is described by a small number of circumference arcs, like the one in Fig. 1, and it is axisymmetric. In addition, all centres of curvature lies on the optical axis. It has been assumed that when the corneal astigmatism is below 2 dioptres a spherical lens is well supported by the cornea, that is to say there is a stable contact along a whole annulus without excessive cornea deformation.

The second situation taken into account by the program is relevant to corneas which underwent a radial keratotomy surgical intervention. In such interventions corneas are heavily flattened, therefore it is better to choose different conic profiles instead of circular ones for contact lenses (aspheric lenses).

When the corneal astigmatism is over 2 dioptres, an axisymmetric lens is no longer suitable to be coupled with such a cornea and it is necessary to choose a toric lens which, on an axial section is elliptic.

At the moment no procedures have been determined for lens designing when a cornea is affected by keratoconus.

5.1 Spherical lenses

To begin the procedure, the necessary data are the apical radius and the shape factor of both the flat and the steep meridians. To warrant lens centring, it is necessary to analyse the distance between eye lids; the 3 possible configurations are shown in Fig. 3. The procedure can deal with 2 possible fitting philosophies, "interpalpebral fitting" and "lid attachment". The latter indicates that the lens is partly below at least one lid; this choice is preferred when lids partly cover cornea, as in the first and the second configurations of Fig. 3 [6]. Obviously the lens must be quite thin at the edge.

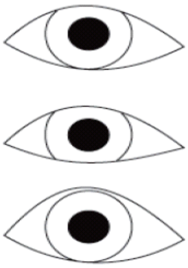


Fig. 3 Possible lid configurations.

Once the fitting strategy has been chosen, it is possible to choose the lens diameter (Total Diameter = TD). Please refer to Fig. 1 to see the main geometrical parameters of a contact lens.

The BOZ dimensions are defined starting from the radius of curvature of the flat meridian. The BOZ diameter (BOZD) is chosen in such a way that the lens touches the cornea along the flat meridian, in the lens area between the BOZ and the first flange, as sketched in Fig. 4.

Fig. 4 A possible contact configuration between lens and cornea.

The BOZ radius of curvature (BOZR) is calculated in such a way that an adequate Tear Layer Thickness (TLT) is between lens and cornea at the cornea apex, so that cornea is always wet. The user is asked to choose a value for TLT are between 0.015 and 0.025 mm. Obviously, the BOZR must be compatible with the BOZD, and is determined according to the following [7]:

$$BOZR = \frac{(BOZD/2)^2 + s_{1,FLAT}^2}{2 s_{1,FLAT}} \qquad (2)$$

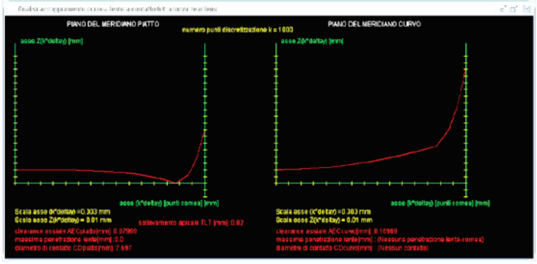
Where $s_{1,FLAT}$ is the BOZ sag at BOZD/2 distance from the optical axis.

To begin the design of the peripheral back surface, the number of flanges, between 1 and 3, is suggested as a function of TD, but user is allowed to change it. Then the user must specify the Axial Edge Lift (AEL) of a lens, which is the distance between lens and eye at the lens edge. This distance is necessary to make easier lens removing from an eye and is shared among flanges in such a way that flanges closer to the optical axis gives a higher contribution. For instance, in the case of 3 flanges, the suggested share is, as follows [8]:

- AEL_1 = 50%
- AEL_2 = 33%
- AEL_3 = 17%

In addition, the program suggests the increments between diameters of adjacent flanges, so that the geometrical definition of the flanges is possible.

At this point a user is allowed to verify the distance distribution between lens and cornea by means of a graphic where the cornea profile is rectified. Fig. 5 shows 2 of such distributions referred to the flat (left) and to the steep (right) meridian. The cornea profile is supposed to coincide with the horizontal axis, while the red lines represent lens profiles. As previously planned, the lens only touches the cornea on the flat meridian, at the point between the BOZ and the first flange, because the cornea is supposed perfectly rigid, which is not true. As ophtalmometers do not give information on the whole cornea shape, the implied hypothesis is that the geometrical information of the cornea apex can be extended to the whole surface. Only when a user is equipped with a topographer, graphics in Fig. 5 give reliable information.



Scala asse (k*deltay) =0.303 mm
Scala asse Z(k*deltay) = 0.01 mm
sollevamento apicale TLT [mm] 0.02
clearance assiale AECpiatto[mm] 0.07989
massima penetrazione lente[mm]:0.0
diametro di contatto CDpiatto[mm] 7.697

Scala asse (k*deltay) =0.303 mm
Scala asse Z(k*deltay) = 0.01 mm
clearance assiale AECcurvo[mm] 0.10989
massima penetrazione lente[mm] : (Nessuna penetrazione lente-cornea)
diametro di contatto CDcurvo[mm] : (Nessun contatto)

Fig. 5 Distance distributions between cornea and lens on the flat (left) and steep (right) meridians.

The front profile of a lens is determined by both its back profile and the required optical power, because the difference between the BOZR and the FOZR determines the optical power of a lens, once the refraction index of its material is known. As no other requirements must be satisfied by a front surface, its profile could be a single arc of circumference.

When a high power is required, either positive or negative, a too thick lens would result at the apex or at the edge; as a consequence, in both cases a double curvature of the forward profile helps in reducing lens largest thickness. We speak of positive or negative power lenticulated lenses depending on the front surface resulting concave or convex, as shown in Fig. 6.

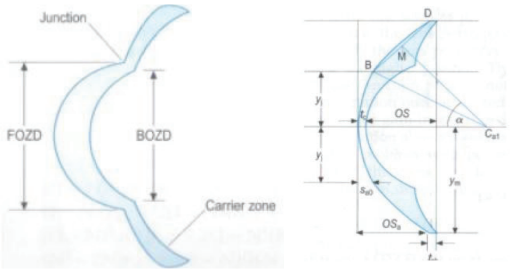


Fig. 6 Cross sections of positive (left) and negative (right) power lenticulated lenses [2].

The program suggests a positive power lenticulated lens design when the required Back Vertex Power (BVP) is below -5.00 dioptres and a negative one when BVP must be over -2.00.

Once defined the general shape of the front profile, its design begins deciding the lens thickness at its apex. The generally accepted smallest value is 0.15 mm, but an increment is suggested depending on the oxygen permeability (D_k) of lens material and on the dioptric toricity of a lens.

In case of lenticulated lenses, the FOZD must be decided. No suggestions were found; an analysis of a lens shape DB allowed to determine that (i) the FOZD is less than BOZD of 0.5-1.6 mm and that (ii) the difference increases together with BOZD. Another parameter to be chosen with lenticulated lens is the edge thickness, whose default value is 0.08 mm.

5.2 Aspherical lenses

Under this general term a number of axisymmetric lens categories are collected, all being oriented to follow cornea shape more accurately than spherical lenses. Aspherical lenses are sometimes chosen for higher comfort or better lens centring, but they often become necessary when a cornea has been heavily flattened by a radial keratotomy surgical intervention.

The program assists a user in designing 3 categories of aspherical lenses:

- offset continuous bicurve,
- polynomial and
- fully aspherical lenses.

Moving along the above list from the first item to the third, freedom increases to design a lens more faithfully tailored for a specific eye.

As the procedure for design of spherical lenses is used whenever possible, only those steps which are different will be presented.

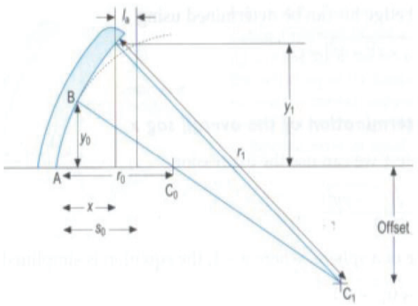


Fig. 7 Cross sections of an offset continuous bicurve lens [2] .

Fig. 7 shows a cross section of an offset continuous bicurve lens. It differs from a spherical lens as the peripheral back profile is still an arc of circumference, but its centre is no longer on the optical axis.

Once defined the Back Optical Zone and the lens Total Diameter, the offset is determined in such a way that the 2 arcs of the back profile are tangent. It is usual that, at the monitor, lens profile intersects the cornea profile. Lens designer is in charge to decide if pressure on cornea surface should be considered acceptable.

In polynomial lenses the peripheral back profile is described by an elliptic profile, as given by law as the following [2]:

$$Z = Ay^2 + By^4 + Cy^6 + Dy^8 + ... \qquad (3)$$

Where the number of coefficients A, B, C, D, … to be determined is the same as the known conditions which must be satisfied by the curve. Often an equation is used with four coefficients, like the (3), therefore four conditions are needed. The curve must obviously pass through the initial and the final points, which are known; another point could be selected in such a way to define the contact arc between lens and eye along the flat meridian. The last required condition often is tangency between the Back Optical Zone and the flange. This procedure needs some refinements aimed at curve smoothing.

When a fully aspherical lens is to be designed, first of all a TLT value is chosen, that typically is 0.02 mm. Then an attempt value must also be chosen for the contact diameter between lens and cornea on the flat meridian, the suggested value being 5 mm. Two other conditions are necessary; one is the last point of the curve, defined by the TD and by the axial distance from the curve apex. The last condition is the centre of curvature on the optical axis.

When all the above information are known, it is possible to calculate the factor form of the curve, usually an ellipse. Then some iterations could be necessary to obtain satisfactory values for both the contact diameter, initially set at 5 mm, and the maximum penetration of the lens inside the cornea, to be decided.

5.3 Toric lenses

RGP lenses are often prescribed to correct astigmatism. This defect is often mainly due to a large difference between radiuses of curvature of the flat and of the steep meridians (corneal toricity). As a consequence, parallel rays fail to meet in a focal point and the resulting image is blurred. The large difference between radiuses of curvature imposes that a non-axisymmetric lens must be used; therefore the previously described lens categories are unsuitable.

According to [9], 5 possible lens designs are suggested to cope with astigmatism, the choice depending on both the residual astigmatism and the corneal toricity. The residual astigmatism is the astigmatic component of a lens required to fully correct an eye wearing a spherical powered RGP lens with a spherical BOZ.

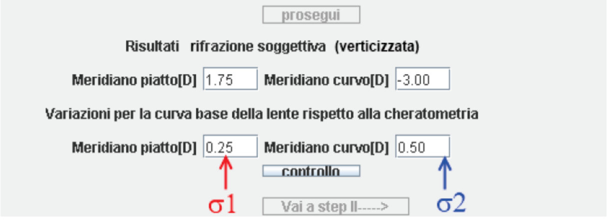
In the program, procedures are implemented to guide user in defining 4 out of the 5 designs, as at the moment it has not been possible to define a complete procedure for front surface toric lenses. The 4 designs are, as follows:

- Toric base/spherical front,
- Bitoric design,
- Spherical Power Effect bitoric (SPE), and
- Cylinder Power Effect bitoric (CPE).

The design of the BOZ of toric lenses is similar to the other lens categories, but the procedure followed for the flat meridian must be replicated also for the steep one. As a consequence, the transverse sections of the BOZ is elliptical. In addition, it is customary that the 2 lens meridians are flatter than the corresponding on the cornea, so that the tear turnover is increased. The suggested values are 0.25 D flatter for the flat meridian and a value between 0.75 and 1.00 D for the steep one.

The design of the back lens periphery could be spherical or toric. In the former situation the main advantage is a simpler shape, but in general the lens is less steady, therefore the program suggests use of toric peripheries having the same toricity level of the lens BOZ. This solution also gives a simpler transition between BOZ and back periphery, positioned on a transverse section.

Toric base/spherical front lenses are relatively cheap because, once machined the back surface, there is no need to align main meridians to machine the front surface. As concerns input data, the main difference from spheric/aspheric lenses is the need to input curvatures of the cornea flat and steep meridians, as measured through an ophtalmometer, and the respective increments for lens meridians. All data are in dioptres (=m^{-1}). An example of in put data is given in Fig. 8, where 1.75 and -3.00 are the dioptric powers of cornea meridians, 0.25 and 0.50 are the relevant increments for lens meridians, in such a way that the lens is flatter than the cornea.



Risultati rifrazione soggettiva (verticizzata)

Meridiano piatto[D] 1.75 Meridiano curvo[D] -3.00

Variazioni per la curva base della lente rispetto alla cheratometria

Meridiano piatto[D] 0.25 Meridiano curvo[D] 0.50

Fig. 8 Input data for toric lens design.

Criteria for deciding the number of arcs composing the back peripheral profiles are the same already seen for spherical lenses. The program also calculates the highest lens penetration in the cornea. At the same way as previously described for spherical lenses, toric lenses are lenticulated when they are supposed to be too thick; criteria and procedures are the same as for spherical lenses.

When the axis of the residual astigmatism is not the same of the corneal toricity, it is necessary that also the front surface is toric and we speak of bitoric lenses. The main difference from toric base/spherical front lenses is that the front and the back optical zones must be correctly aligned.

Spherical Power Effect bitoric (SPE) are so called because their front surface is made so as to produce the same optical effect on the eye as would a spherical lens. It means that if a refraction test is performed over a SPE bitoric, the same answer is obtained as if the test were performed over a spherical lens having the same overall parameters as the flat meridian of the bitoric.

The design of a tailor-made SPE lens is based on use of sets of SPE lenses. One set must be chosen whose toricity must be close to the corneal toricity. Once selected the most suitable set of test lenses, the user must input the dioptric power of the flat meridian, 43.50 D in the example of Fig. 9, and obtains as output the same information for the steep meridian.

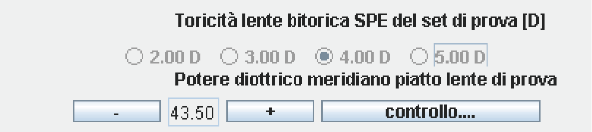
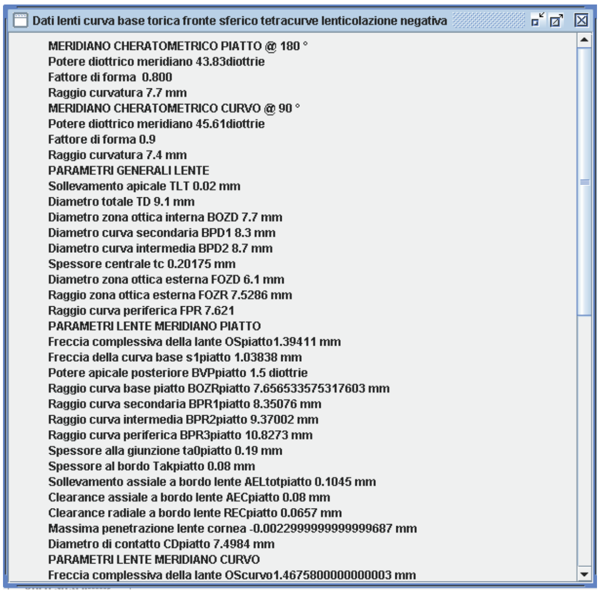

Toricità lente bitorica SPE del set di prova [D]
○ 2.00 D ○ 3.00 D ● 4.00 D ○ 5.00 D
Potere diottrico meridiano piatto lente di prova
43.50

Fig. 9 Selection of the dioptric power for a SPE lens.

The program guides user in performing some other steps, but the final decision is based on refractions with test lenses suggested by the program. When SPE lenses fail in giving a satisfactory vision acuity, it is only possible to try with the next lens design, Cylinder Power Effect bitoric (CPE) lenses.

CPE lenses act much like soft toric in that rotational effects are evident. If lid interaction creates rotation with the blink, transient blur will occur. The design of these lenses is again based on tests with SPE lenses and on fluorescein eye stain. Again user must define σ1 and σ2 corrections on the two main meridians.

Whichever lens category is chosen, the program at the end of all the procedures show a table which summarizes all the geometrical parameters of the new lens, an example is given in Fig. 10.


Dati lenti curva base torica fronte sferico tetracurve lenticolazione negativa

```
MERIDIANO CHERATOMETRICO PIATTO @ 180 °
Potere diottrico meridiano 43.83diottrie
Fattore di forma  0.800
Raggio curvatura 7.7 mm
MERIDIANO CHERATOMETRICO CURVO @ 90 °
Potere diottrico meridiano 45.61diottrie
Fattore di forma 0.9
Raggio curvatura 7.4 mm
PARAMETRI GENERALI LENTE
Sollevamento apicale TLT 0.02 mm
Diametro totale TD 9.1 mm
Diametro zona ottica interna BOZD 7.7 mm
Diametro curva secondaria BPD1 8.3 mm
Diametro curva intermedia BPD2 8.7 mm
Spessore centrale tc 0.20175 mm
Diametro zona ottica esterna FOZD 6.1 mm
Raggio zona ottica esterna FOZR 7.5286 mm
Raggio curva periferica FPR 7.621
PARAMETRI LENTE MERIDIANO PIATTO
Freccia complessiva della lante OSpiatto1.39411 mm
Freccia della curva base s1piatto 1.03838 mm
Potere apicale posteriore BVPpiatto 1.5 diottrie
Raggio curva base piatto BOZRpiatto 7.656533575317603 mm
Raggio curva secondaria BPR1piatto 8.35076 mm
Raggio curva intermedia BPR2piatto 9.37002 mm
Raggio curva periferica BPR3piatto 10.8273 mm
Spessore alla giunzione ta0piatto 0.19 mm
Spessore al bordo Takpiatto 0.08 mm
Sollevamento assiale a bordo lente AELtotpiatto 0.1045 mm
Clearance assiale a bordo lente AECpiatto 0.08 mm
Clearance radiale a bordo lente RECpiatto 0.0657 mm
Massima penetrazione lente cornea -0.0022999999999999687 mm
Diametro di contatto CDpiatto 7.4984 mm
PARAMETRI LENTE MERIDIANO CURVO
Freccia complessiva della lante OScurvo1.4675800000000003 mm
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Fig. 10 Summary table of the lens geometrical parameters.

6 Simulation of fluorescein eye stain

As already anticipated in the 3^{rd} paragraph, the simulation of the fluorescein eye stain is only possible when a lens designer is equipped with an optical topographer. In this work we have referred to the Nidek Magellan topographer, which, after scanning a cornea surface, gives as its output the coordinates of a grid of up to 360 x 60 points. The grid is composed of up to 60 circumferences where the radius is increased of 0.1 mm from one circumference to the successive. When scanning a cornea, the number of circumferences utilised depends on the cornea radius. For each circumference, the position of 360 points is detected, one for each degree. As a consequence, the density of the detected points is much higher close to the centre than at the cornea periphery.

On the other hand, the geometrical description of a test lens is much simpler because it is made of few conic arcs which then rotate around the cornea optical axis.

To simulate the test, an algorithm was developed to create a one-to-one correspondence between lens and cornea points and for each couple of corresponding points the distance is calculated. It is then possible to analyse the distribution of the distance between of corresponding points, an example being shown in Fig. 11.

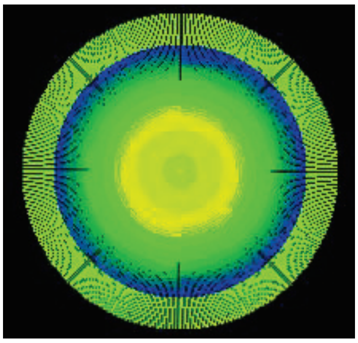

Fig. 11 An example of a fluorescein eye stain simulation.

It is possible to tune the chromatic scale to highlight the range of distances in a specific area. Another option is the possibility to analyse the range of distances in a specific cross section, where the cornea is the reference and, for this reason, is straight. An example is shown in Fig. 12. The green line is the rectified cornea, the green points constitute the lens; where points are at the same height or below the line means that the lens touch the cornea. The user is in charge to decide if pressure on the cornea could be too high.

Fig. 12 An example of a fluorescein eye stain simulation.

Unfortunately, until now it has not been possible a thorough validation of this algorithm because lens producers refused to give us information about the shape and dimensions of test lenses. Some more work could also be useful to improve the default chromatic scale of Fig. 11.

7 Conclusion

The program presented in the paper is intended to assist opticians in the design of RGP lens. Several procedures were developed to cope with the more widespread lens shape categories. Beside spherical lenses, whose design procedure is quite well-established thanks to their simple shape, validation tests will be necessary to verify (i) correctness of the procedures for aspherical and torical lenses and (ii) the percentage of cases when the program does not give any assistance.

It is expected that the most important criterion for potential users to accept to test the program will be user friendliness. To this aim, an option of Java was used, that allows the development of a user interface that automatically adapts to the specific window style of each user on a PC. In addition, the software should run on any PC, independently from the current operating system ("Write Once, Run Everywhere" is a slogan created to describe Java portability).

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