On relationship between lens optical characteristics, preoperative biometric data and clinical outcomes of patients implanted with bioanalogic polyfocal IOL

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Bioanalogic approach to IOL design – WIOL-CF

Inspiration from young Natural Crystalline Lens (NCL)

For a long time, people are trying more or less successfully to find ideal replacement for the natural crystalline lens, which would ensure functional vision at all distances from far to near. Currently, the most widely used solution to the problem is the use of refractive or diffractive multifocal IOLs. This purely technical solution, however, has several unpleasant consequences for the patient resulting from the presence of transitions between optical zones, including low contrast sensitivity especially at mesopic conditions and occurrence of photic phenomena. It can be suggested that these difficulties are linked to incompatibility of IOL design and retinal&neural image processing needs. WIOL-CF is looking for an alternative to achieving sufficient depth of focus by seeking inspiration in the nature assuming better compatibility with retinal&neural image processing patterns. Spherical aberration (SA) seems to be a good (and retinal&neural image processing compatible) mean to achieve sufficient depth of focus since NCL of a important part of the population has negative SA at a young age.


WIOL-CF

- refractive power is maximal in the center and gradually decreases to the periphery

Polyfocal optics with negative spherical aberration is used in order to extend the depth of focus and consequently, to achieve good vision at all distances from far to near. Moreover, the focus changes continuously with changing aperture without the presence of transitions between optical zones.
Introduction

The main goal of this paper is elucidation of relationship between patient’s biometric data, optical properties of the implanted IOL, and quality of vision in patients implanted with bioanalogic polyfocal intraocular lens (WIOL-CF, Medicem). This bioanalogic IOL is made of an optically homogeneous hydrogel and its polyfocality (wide depth of focus due to controlled amount of negative spherical aberration) is achieved strictly by geometry of its optical surfaces.

Methodology

Statistical analysis of clinical results of implantations (clinical trial 2012-2013/210 eyes, post-op follow-up from 3 to 12 months) complemented by WIOL-CF optical characteristics using statistical software QC.Expert version 3.3 (TriloByte Statistical Software) aiming to find the most important predictors for good visual acuity at near (40cm), intermediate (70cm) and distance (4-6m), for photopic and mesopic contrast sensitivity and other clinical outcomes.

Multidimensional linear regression was used in order to test whether the individual clinical outcomes depend on 7 possible predictors: gender, age, biometric data including axial length (AL), anterior chambre depth (ACD), keratometry (K1/K2) and manufacturing data including value of IOL spherical aberration (SA).
Factors influencing visual acuity (VA) in WIOL-CF patients

Monocular and binocular UCVAs at all distances in WIOL-CF patients can be found in the table below. These values demonstrate very good vision at far and intermediate distances and good functional vision at near distance. The difference between binocular and monocular UCVAs nicely illustrates the effect of binocular summation.

<table>
<thead>
<tr>
<th>Table: UA/UCVA in WIOL-CF patients</th>
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<tbody>
<tr>
<td>UDVA</td>
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<tr>
<td>abs</td>
</tr>
<tr>
<td>gender</td>
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<tr>
<td>age</td>
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<td>SA</td>
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<td>AL</td>
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<tr>
<td>ACD</td>
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<td>K1/K2</td>
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<tr>
<td>average</td>
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<tr>
<td>UDVA (dec)</td>
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<tr>
<td>0,94</td>
</tr>
<tr>
<td>UIVA (logMAR)</td>
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<tr>
<td>0,82</td>
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</table>

Statistical analysis of clinical data using multidimensional linear regression shows that:

- UDVA is influenced by patient’s age and slightly also by the value of spherical aberration (SA).
- UIVA and UNVA depend on preoperative anterior chamber depth (ACD) (they are better in patients with lower ACD) and do not depend on patient’s age.

This effect of ACD on near and intermediate vision should be taken into account in patients with greater ACD.

Figure: Age distribution of WIOL-CF patients in the study.
Factors influencing contrast sensitivity (CSF) in WIOL-CF patients

Polyfocal IOL can achieve **sufficient depth of focus without compromising contrast sensitivity** whereas multifocal technology decreases substantially the contrast sensitivity (see the graph below). It can be seen that the mesopic CSF of WIOL-CF patients exceeds population norm for healthy eyes of the corresponding age group.

Multidimensional linear regression demonstrates that both **mesopic and photopic contrast sensitivities of WIOL-CF patients** (see tables) **depend on patient’s age**. It is not very surprising, since the population norm for healthy population is also age dependent. Moreover, **mesopic CSF decreases slightly with the value of spherical aberration**. Other factors including gender and biometric data influence neither photopic nor mesopic contrast sensitivity. **Since the mesopic CSF exceeds the population norm, it seems that slight decrease of mesopic CSF with SA is clinically inconsequential.**

**Figure:** The graphs show mean values of contrast sensitivity, error bars correspond to standard deviations.

*Alio, J.L. “Experiences with multifocal IOLs FineVision (Physiol): 1st trifocal Diffractive IOL” ESCR 2012 Milan*  
IOL design with controlled amount of negative spherical aberration can lead to good vision at all distances without compromising the contrast sensitivity

Statistical analysis revealed important predictors for good clinical outcomes:

- Better clinical outcomes including UDVA, UIVA, photopic and mesopic contrast sensitivity (CSF) and occurrence of photic phenomena can be achieved in patients of lower age. It could be due to the fact that postoperative CYL value at all distances is significantly higher in older patients.
- Pre-operative anterior chambre depth (ACD) influences exclusively UIVA and UNVA, better vision at intermediate and near distances can be achieved in WIOL-CF patients with smaller preoperative ACD.
- Spherical aberration (SA) of WIOL-CF influences slightly UDVA and mesopic contrast sensitivity (CSF). Nevertheless, even so the mesopic CSF of WIOL-CF patients exceeds population norm of corresponding age group. The slight impairment of mesopic CSF and UDVA can be expected in patients requiring WIOL-CF with higher negative SA value, as compared to WIOL-CF patients with lower SA value. This trend can be taken into account in WIOL-CF patient selection, but it is clinically inconsequential since all SA values used in WIOL-CF provide good visual acuity at all distances and excellent CSF even at mesopic conditions.

Overall, the data demonstrated that:

- UCVA at all distances are very good in WIOL-CF patients
- Photopic as well as mesopic CSF of WIOL-CF patients exceed population norm
- WIOL-CF shows low incidence of glare and halo

Conclusions

Although one can assume that lenses with spherical aberration should cause lower contrast sensitivity (particularly at mesopic conditions), the polyfocal WIOL-CF do not suffer from this adverse effect. Excellent visual acuity and very good contrast sensitivity can be achieved even with an IOL having controlled amount of negative spherical aberration. The WIOL-CF spherical aberration has detrimental effect neither on photopic nor on mesopic contrast sensitivity, and provides an indisputable advantage of vision at all distances from far to near. We explain this effect by high compatibility of the retinal and neural image processing system for images projected by polyfocal optics.