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Visual quality after implantation of bioanalogic intraocular lens in cataract patients: 3 months results from international observational registry

Session Title: Pseudophakic IOLs: Multifocal & Accommodative
Session Date/Time: Monday 07/09/2015 | 08:00 — 10:30
Paper Time: 10:12
Venue: Room 1
First Author: E. Mrukwa-Kominek, POLAND
Co Author(s): R. Ang, M. Ilavska, L. Hans, C. Lenis

Purpose:
Clinical evaluation of functional results and quality of vision after bilateral implantation of a bioanalogic, polyfocal, accommodative intraocular lens.

Setting:
Department of Ophthalmology, Silesian University of Medicine, Katowice, Poland

Methods:
A prospective, international, multicenter case study comprised 126 eyes of 63 patients treated due to cataract and presbyopia who underwent phacoemulsification followed by WIOL–CF® (Medicem) implantation. Follow-up was 3 months after surgery of the second eye. Binocular and monocular visual acuity for distance, intermediate and near vision (reading table), subjective refraction, glare and halos rate analysis, PCO, depth of focus and overall satisfaction of patients were analyzed.

Results:
63 cataract patients, mean age 61.9±10.6 year, were implanted with bioanalogic intra-ocular lens WIOL–CF® Mean post-operative UCDVA was 0.96±0.14 decimal. Mean UCNVA was 0.24±0.15 logMAR. Only 5% of patients reported moderate glare/halo, 95% of patients were spectacle independent for daily activities, driving and reading, 98% were satisfied or very satisfied. Postoperative improvement in UCDVA, BCDVA, UCNVA in comparison to preop value were observed in 98% of eyes.

Conclusions:
The implantation of polyfocal, bioanalogic intraocular lens is interesting option for patients who wants to be totally independent of glasses after cataract surgery. WIOL–CF® brings back full, natural vision via combination of multiple mechanisms of action, that are similar to those of natural crystalline lens.

Financial Interest:
One of the authors travel has been funded, fully or partially, by a competing company.

Long term visual performance with polyfocal, bioanalogic IOL: 1 year results

Session Title: Pseudophakic IOLs: Multifocal & Accommodative
Session Date/Time: Monday 07/09/2015 | 08:00 — 10:30
Paper Time: 10:18
Venue: Room 1
First Author: P. Studeny CZECH REPUBLIC
Co Author(s): J. Urminsky, D. Krizova, T. Novotny, M. Hlozanek

Purpose:
Clinical evaluation of functional results and quality of vision after bilateral implantation of a bioanalogic, polyfocal intraocular lens with extended depth of focus.

Setting:
1 Department of Ophthalmology, University Hospital Kralovske Vinohrady and 3rd Medical Faculty Prague, Czech Republic 2 Department of Ophthalmology, T. Bata Regional Hospital Zlín, Czech Republic

Methods:
Patients who have underwent bilateral implantation of bioanalogic, polyfocal IOL (WIOL–CF® Medicem) were examined one year after surgery including uncorrected and corrected visual acuity (VA) for far, near (40 cm) and intermediate (70 cm) distances on reading tables and subjective refraction. The quality of vision, glare, halos, spectacle independence and the personal satisfaction of the patients was assessed with a questionnaire.

Results:
One year follow up available for 62 patients (124 eyes) from 9 centres in this non-interventional, multicentre, prospective observational registry. Mean age 62.8±8.3 years, (median 63; 47–82 years). One year after bilateral implantation mean uncorrected distance VA was 0.96 (decimal) and 92% of patients are better than 0.8 (decimal). Mean value of uncorrected intermediate (70 cm) and near (40 cm) VA is 0.15±0.12 logMAR and 0.29±0.16 logMAR respectively. 88% patients did not need glasses for daily activities, driving and reading. 93% of patients is one year after surgery without serious/disturbing optical phenomena.

Conclusions:
The WIOL–CF® intraocular lens provides excellent and predictable functional results for far and intermediate vision and near vision within range of social reading for majority of patients. Excellent contrast sensitivity and low level of severe/disturbing glare and halo is a base for high patient satisfaction and spectacle independence rates. WIOL–CF® should be considered as very promising IOL for refractive and cataract surgery, correcting presbyopia.

Financial Interest:
NONE
Prospective study to evaluate the visual outcomes after femtosecond laser-assisted cataract surgery and bilateral implantation of a polyfocal bioanalogic intraocular lens

First Author: R. Ang, PHILIPPINES

Purpose:
To evaluate the refractive outcomes and the distance, intermediate and near visual acuity achieved by patients after bilateral implantation of a bioanalogic, polyfocal intraocular lens.

Setting:
Asian Eye Institute, Makati City, Philippines

Methods:
This is a prospective study of patients who underwent femtosecond laser-assisted cataract surgery and implantation of a polyfocal bioanalogic IOL. Patients 40 years and above with bilateral cataracts were recruited. The polyfocal bioanalogic IOL is a new concept which resembles the natural crystalline lens by the material and optical design. Follow-up examinations included uncorrected and corrected visual acuity (VA) for far, near (40 cm) and intermediate (70 cm) distances, subjective refraction and contrast sensitivity under different lighting conditions. The quality of vision, glare, halos, spectacle independence and the personal satisfaction of the patients was assessed with a questionnaire.

Results:
10 patients (20 eyes) have reached six month follow up. Mean age was 62.3 years, (48–72 years). At six month, the mean sphere was +0.44D, mean cylinder was –0.73D and mean spherical equivalent was +0.05D. Mean monocular UDVA is 0.02 logMAR, UIVA 0.08 logMAR and UNVA 0.25 logMAR. Mean binocular results UDVA –0.02 logMAR, UIVA 0.04 logMAR and UNVA 0.2 logMAR. Patients contrast sensitivity photopic and mesopic results are excellent (on or above population norm). 100 % patients did not need glasses for daily activities, driving and reading. Only 10 % of patients reported Grade 4 Halo (measured on glaremeter).

Conclusions:
Study results at six months showed that refractive outcomes achieved were near emmetropia and monocular and binocular uncorrected distance, intermediate and near vision were very good. Femtosecond laser provide large, round capsulotomy, better centration and stable positioning. Consistency in surgical technique can help give consistent surgical outcomes. Polyfocal, bioanalogic intraocular lens provide seamless range of vision from distance to intermediate to near, less glare, haloes, and excellent contrast sensitivity. It seems to be rational choice because it addresses the drawbacks of multifocality.

Financial Disclosure:
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Correction of presbyopia at cataract surgery with polyfocal intraocular lens WIOL–CF®: one year experience

First Author: M. Ilavska, SLOVAKIA

Purpose:
Clinical evaluation of functional results and quality of vision after the bilateral cataract surgery with implantation of a bioanalogic, polyfocal intraocular lens.

Setting:
Medilux Eye Centrum, Galanta, Slovak Republic

Methods:
The cataract surgery was done by incision 2.75 mm, capsulorhexis 6 mm, implantation by injector in to the capsular bag. Binocular uncorrected visual acuity (UNVA) was evaluated for distance, intermediate (70 cm) and near (40 cm) on reading tables. The contrast sensitivity was examinated by the Pelli-Robson test. The quality of vision, spectacle independence and personal satisfaction of patients was assessed by completing a questionnaire (the Visual function test NEI–VFQ14).

Results:
13 patients, (26 eyes), underwent uneventful cataract surgery during the period 06/2013—12/2014. Mean binocular UNVA 3 month after surgery was 0.895 (Snellen optotypes) (range 0.63–1.0). Binocular UNVA for 70 cm was 0.16 logMAR and for 40 cm 0.22 logMAR. The mean binocular contrast sensitivity was 2.69 %, (average logCS 1.575) for the size of letters 4/125. Any patient with binocular implantation of WIOL–CF® need a spectacles for daily activities, driving and reading. Two patients gave an account of light phenomenon at night.

Conclusions:
Clinical results are very promising. Lens provides 100 % spectacle independence on all distances and excellent contrast sensitivity with low level of optical phenomena and high subjective satisfaction of patients. The next follow-up of the stability of results is necessary.

Financial Disclosure:
NONE
**Autorefractometer vs manifest refraction after implantation of bioanalogic polyfocal intraocular lens**

First Author: D. Krizova, CZECH REPUBLIC  
Co Author(s): P. Studeny, M. Hlozanek  

**Purpose:**  
To evaluate whether autorefractometry values after implantation of a bioanalogic, polyfocal, intraocular lens (WIOL–CF®, Medicem) correlate with manifest refraction values. This information is important mainly for post-operative follow up of patients where autorefractometers are widely used.  

**Setting:**  
Department of Ophthalmology, University Hospital Kralovske Vinohrady and 3rd Medical Faculty Prague, Czech Republic.  

**Methods:**  
Eyes that underwent cataract surgery with implantation of a bioanalogic, polyfocal IOL were retrospectively evaluated in this study. Values from the autorefractometer (Nidek) were compared with the manifest refraction values to determine the correlation between the 2 methods. Spherical and cylindrical refractive errors were collected minimum one month after the surgery.  

**Results:**  
16 eyes of 8 patients were included in this study. The mean spherical refractive error was +3.57±1.649 diopters (D) measured by autorefractometer and –0.03±0.195 D in manifest refraction. The mean cylinder value was –1.69±0.93 D and 0.00 D, respectively. The mean SE was +2.72±1.29 D and –0.03±0.195D, respectively. No statistical correlation was found comparing measurements by autorefractometer and manifest refraction.  

**Conclusions:**  
The results show that postoperative values measured by autorefractometer cannot be used to estimate the manifest refraction in eyes with bioanalogic, polyfocal IOL.  

**Financial Disclosure:**  
NONE  

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**Binocular improvement of near visual acuity in eyes implanted with polyfocal bioanalogic intraocular lens**

First Author: M. Hlozanek, CZECH REPUBLIC  
Co Author(s): P. Studeny, D. Krizova, K. Liehneova  

**Purpose:**  
To evaluate the effect of binocular summation on near visual acuity in patients who have undergone bilateral implantation of a polyfocal bioanalogic intraocular lens.  

**Setting:**  
Department of Ophthalmology, University Hospital Královské Vinohrady and 3rd Medical Faculty, Charles University, Prague, Czech Republic.  

**Methods:**  
Fifty four patients with an average age of 62.6±8.3 years (range: 47 to 82 years) underwent bilateral standard cataract surgery with implantation of a polyfocal bioanalogic IOL (WIOL–CF®, Medicem). Uncorrected monocular and binocular near visual acuity (UNVA) was measured on average 12 months following the surgery of the second eye using the standard reading chart (logMAR, 40 cm). Difference between binocular and better eye monocular near visual acuity was compared to evaluate the effect of binocular summation.  

**Results:**  
Mean ± standard deviation UNVA was 0.34±0.17 and 0.44±0.16 logMAR comparing the better and worse eye, improving to 0.28±0.15 logMAR binocularly. Binocular summation, defined as the difference between the binocular and better eye monocular near visual acuity, was found to be statistically significant (P<0.05).  

**Conclusions:**  
The results of the study showed, that there was statistically significant benefit of bilateral implantation of polyfocal bioanalogic IOL in terms of improved near visual acuity.  

**Financial Disclosure:**  
NONE
Retinal straylight measurements in patients with implanted bioanalogic polyfocal lens

First Author: K. Liehneova, CZECH REPUBLIC
Co Author(s): S. Ovesna, E. Adamusova, M. Hlozanek

Purpose:
This paper aims to compare intraocular light scattering in pseudophakic eyes of patients with implanted bioanalogic polyfocal lens and in healthy eyes of corresponding age. The main sources of retinal straylight are: corneal scatter, iris and sclera transparency, lens, and fundus scatter. The light scattering reduces the contrast of the retinal image, and consequently decreases the quality of image projected on the retina.

Setting:
1 Department of Ophthalmology, University Hospital Královské Vinohrady and 3rd Medical Faculty Prague, Czech Republic 2 GEMINI Eye Clinic Zlín, Czech Republic 3 Medicem Institute, Kamenne Zehrovice, Czech Republic

Methods:
Patients were measured by a straylight meter C-Quant (Oculus). All patients had binocularly implanted bioanalogic polyfocal lenses WIOL–CF® (Medicem). This dataset was statistically analyzed using statistical software QC.Expert version 3.3 (TriloByte Statistical Software) aiming to compare pseudophakic and healthy eyes of corresponding age. WIOL–CF® data were compared to recently published retinal straylight values in patients with monofocal and multifocal intraocular lens (IOL).

Results:
Twelve patients (24 eyes) from 2 centers in the Czech Republic were measured (age: 65±6 years). The retinal straylight in eyes implanted with WIOL–CF® was statistically significantly better than healthy population standard of corresponding age (P<0.05). The mean value of retinal straylight in WIOL–CF® eyes was 1.09±0.25. Recently published retinal straylight values in pseudophakic eyes implanted with monofocal and multifocal IOLs were 1.16±0.23 (age: 67±9 years) and 1.23±0.21 (age: 66±8 years), respectively. The difference in retinal straylight between eyes implanted with multifocal IOLs and polyfocal IOLs (WIOL–CF®) was statistically significant (P<0.01).

Conclusions:
The study showed, that WIOL–CF® had comparable results to monofocal IOLs and better results than multifocal IOLs in retinal straylight. If we supposed that four of five sources of straylight were identical in pseudophakic and phakic eyes, it could be concluded that the difference would lay mainly in the lens properties and consequently, the retinal straylight induced by WIOL–CF® would correspond to the straylight induced by natural crystalline lens of lower age. This suggests that polyfocal WIOL–CF® should be less susceptible to disturbing optical phenomena at low light under glare conditions than multifocal IOLs.

Financial Disclosure:
One or more of the authors research is funded, fully or partially, by a company producing, developing or supplying the product or procedure presented.

Visual outcomes after implantation of polyfocal, bioanalogic intraocular lens

First Author: R. Mach, CZECH REPUBLIC
Co Author(s): J. Kopriva

Purpose:
To evaluate visual outcomes in patients who have undergone bilateral implantation of a polyfocal, bioanalogic intraocular lens.

Setting:
Department of Ophthalmology, Hospital Most, Czech Republic

Methods:
Three months after surgery, the distance and near visual acuities; spherical equivalent; residual refractive astigmatism were evaluated. A patient satisfaction and visual phenomena questionnaire was administered to all patients.

Results:
14 patients (15 eyes) with an average age of 71.1±8.7 years (range: 53 to 86 years) underwent mono or bilateral implantation of a polyfocal bioanalogic IOL (WIOL–CF®, Medicem). Three months after surgery, the mean monocular uncorrected distance visual acuity (logMAR) was 0.11±0.07 at 4 m, and J 3–4 at 40 cm

Conclusions:
Implantation of polyfocal, bioanalogic, large optics IOL in patients with cataract was a simple, safe, and accurate option. Extended depth of focus design and biocompatible material provides surgeons with a feasible option for meeting patient expectations of an enhanced lifestyle resulting from long term decreased spectacle dependence.

Financial Disclosure:
One or more of the authors is employed by a competing company.
Relationship between lens optical characteristics, preoperative biometric data and clinical outcomes of patients implanted with bioanalogic polyfocal IOL

First Author: R. Chaloupka, CZECH REPUBLIC
Co Author(s): J. Kopriva, V. Stoy

Purpose:
The main goal of this paper is elucidation of relation 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.

Setting:
Medicem Institute, Czech Republic and Medicem International, Czech Republic

Methods:
Statistical analysis of clinical results of implantations (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 (40 cm), intermediate (70 cm) and distance (4–6 m), for photopic and mesopic contrast sensitivity and other clinical outcomes.

Results:
Statistical analysis of clinical data using linear regression shows that the means of both the photopic and mesopic contrast sensitivity in patients implanted with WIOL–CF® having the highest negative spherical aberration equals or exceeds the population norm for healthy eyes of the corresponding age group. The photopic contrast sensitivity does not depend on the amount of WIOL–CF® negative spherical aberration, whereas the mesopic contrast sensitivity at lower spatial frequencies is spherical aberration dependent at the significance level of 0.05. However, the observed effect is not statistically significant at 18 cycles/degree.

Conclusions:
Excellent visual acuity and very good contrast sensitivity can be achieved even with an IOL having controlled amount of negative spherical aberration. 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. 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.

Financial Disclosure:
One or more of the authors is employed by a for-profit company with an interest in the subject of the presentation.

Comparison of the bioanalogic IOL material WIGEL® with various IOL materials

First Author: J. Kopriva, CZECH REPUBLIC
Co Author(s): V. Stoy, E. Adamusova

Purpose:
WIGEL® is a bioanalogic synthetic polymethacrylate hydrogel with fixed negative charge developed specifically for long-term ophthalmic implants. WIGEL® is now used for production of bioanalogic polyfocal intraocular lens WIOL–CF®. The aim of the current study is to compare this proprietary material with different materials used in IOL manufacturing; namely with hydrophobic and hydrophilic acrylic, silicone and Collamer.

Setting:
WIGEL® was compared in vitro with standard IOL materials — hydrophobic and hydrophilic acrylic, PMMA, silicone and Collamer, which is another hydrogel developed specifically for long-term ophthalmic implants. Comparison was made on basis of refractive index, water content and interaction of material with human cultured fibroblasts.

Methods:
The water content and refractive index were determined for all materials using gravi-metry and refractometry. Selected materials were tested for in-vitro interaction with cultured human fibroblast cells. The cell viability in the vicinity of the materials and adhesion, spreading and proliferation of the cells to the surface was evaluated.

Results:
The refractive index (RI) of WIGEL® was 1.43, which is similar to Collamer but lower than the RI of other IOL materials tested in this study. The equilibrium water content of WIGEL® material was higher than in other IOL materials. The in-vitro cytotoxicity of WIGEL® is comparable to other IOL materials but fibroblasts adhere much less to the surface of WIGEL® than to other materials. Fibroblast spreading and proliferation was most pronounced on the hydrophilic acrylate, very low on Collamer and almost zero on WIGEL®.

Conclusions:
This study demonstrated that RI of WIGEL® is more similar to the effective RI of human crystalline lens than RI of most other tested materials. In contrast to some other tested IOL materials, WIGEL® is highly resistant to cells attachment, spreading and proliferation on its surface. This is the underlying reason for WIGEL’s resistance to PCO and biofilm formation that is caused by adhesion and proliferation of fibroblasts. These findings fully support bioanalogic concept of intraocular lens WIOL–CF® that is produced from this unique material.

Financial Disclosure:
One or more of the authors is employed by a for-profit company with an interest in the subject of the presentation.
Bioanalogic Hydrogel Intraocular Lens, WIOL-CF®, is a foldable, polyfocal one-piece, full-size optic lens.

- Total overall diameter: 8.6 mm – 8.9 mm
- Central thickness: 0.6 mm – 1.8 mm, depending on diopter
- Nominal refractive index: 1.43
- Water content: 42 ± 2% (w)
- Refractive power: +10 D to +33 D in 0.5D increments

Refractive powers outside the specified range are supplied only based on a specific request.

The nominal A-constant is located on the outside of the package and it is only an estimation. If available, use an optimized IOL constant.

Please visit http://www.augenklinik.uni-wuerzburg.de/ulib/c1.htm to get most up to date optimised constants for IOL Master. Lens power can be also calculated using online calculator at: www.wiols.com. This calculator is optimized for IOL Master with Keratometric Index of 1.3375.

Store at +5 °C to +30 °C. Protect from direct sunlight and humidity.

Material of the lens is made by polymerization of the following components: 2-hydroxyethyl methacrylate, methacrylic acid, 2-hydroxy-(methacryloyloxy) bezophenone (UV absorber), diethylene glycol dimethacrylate and triethylene glycol dimethacrylate.