Visual function after bilateral implantation of bifocal versus monofocal IOLs in children below 5 years of age

Bifocal IOLs in children

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ABSTRACT:

PURPOSE: To evaluate visual results after bilateral implantation of bifocal versus monofocal IOLs in children with congenital cataract aged 1-5 years.

SETTING: Center for Pediatric Ophthalmology, Warsaw, Poland

DESIGN: Prospective clinical study.

METHODS: Fifty children between 1 and 5 years of age with bilateral cataract in whom after cataract removal implantation of an bifocal IOL -Lentis Mplus^{x}, Oculentis GmbH, Germany (25 children-group A) or monofocal IOL - C-flex Aspheric Monofocal, Rayner Intraocular Lenses Limited, UK (25 children- group B) were implanted in both eyes. Distance corrected visual acuity, distance corrected near visual acuity, binocular vision using the Worth 4-dot test, stereopsis using the TNO stereotest and subjective symptoms such as glare and halos were evaluated after 12 months of follow-up.

RESULTS: At the final follow-up visit after 12 months, the mean best corrected distant visual acuity was not significantly different between group A and B but the best corrected near visual acuity, binocular vision and stereopsis were significantly superior in patients in Group A as compared to Group B. The parents of the both of both operated children have not reported that operated patients complained about halos or glare later than 3 months after the surgery.

CONCLUSION: Implantation of a bifocal IOL in children aged 1 to 5 years with bilateral cataract provides a better level of near vision and considerably improves the development of stereopsis in comparison with children after monofocal IOL implantation.

Keywords: pediatric cataract surgery, bifocal IOLs, monofocal IOLs, distance visual acuity, near visual acuity, binocular vision, stereopsis.

Implantation of multifocal IOLs is nowadays widely used method of aphakia correction after cataract surgery in adult patients[1, A] A new generation of multifocal IOLs has demonstrated their safety and efficacy.[2,3] In pediatric patients implantation of IOLs is now accepted as an optimal method of visual rehabilitation after cataract surgery. However, pediatric ophthalmologists prefer to implant monofocal IOL in children. These IOLs provide excellent distance vision correction but for near vision additional reading spectacles with monofocal or bifocal glasses are required. It is known that loss of accommodation has a great effect on the development of visual function in the pediatric patient.[4,5,6] It affects considerably the development of binocularity and stereopsis in a child and might worsen amblyopia (especially in unilateral pseudophakia).[4] The visual world of our youngest patients is primarily at arm's length, so it is important to provide the child with a focused image of a toy, bottle, or mother's face. Therefore, implantation of multifocal IOLs should theoretically offer much better conditions for the development of visual functions in children. However, these IOLs still have their drawbacks: considerable loss of light (diminished contrast sensitivity), glare and halos, disturbed night vision, simultaneous vision of 2 images on the retina (diffractive IOLs), small visual fields of far and near segments and necessity of continuous searching of distant or near picture (refractive IOLs). It is still unknown how multifocality (and its drawbacks) might influence the development of binocular vision. All these problems cause that pediatric ophthalmologists still prefer to implant monofocal IOL and our experience of multifocal IOL implantation in children is very limited. In the literature one can find only a few papers concerning this problem.[7,8,9,10] and their authors encourage surgeons who have implanted multifocal IOLs in children to report their experience to increase the

number of cases reported and hence improve the discussion of the possible benefits and drawbacks of this type of surgery.[8]

In recent years new concept of multifocal IOL was developed - bifocal, asymmetric, refractive IOL (Lentis Mplus, Oculentis GmbH, Germany). This IOL is one-piece zonal refractive lens with plate haptics and two refractive segments – a larger, upper and central zone for distance and smaller, lower segment with addition+3,0D for the near. (Fig 1) Because of optic design Lentis Mplus offers much better contrast sensitivity and much smaller light loss than rotationally symmetric IOLs, is pupil indipendent and only one image is focused at the same time on the retina. So, many drawbacks of previous multifocal IOLs, which deterred pediatric ophthalmologists from their implantation in children, have been corrected.

The aim of the study was to evaluate visual results after bilateral implantation of bifocal, asymmetric versus monofocal IOLs in children aged 1-5 years.

PATIENTS AND METHODS

Patient Selection

Fifty children aged 1-5 years with bilateral congenital cataract have been enrolled for the study in Center for Pediatric Ophthalmology in Warsaw/Poland from May 2012 to November 2013. Indications for surgery was visual acuity 0,4 or worse (in older children) or dense central lens opacification bigger than 3 mm obscuring visual axis (in younger, illiterate children). The main exclusion criteria were: recurrent chronic uveitis, previous ocular trauma and existent or suspected corneal, iris and retinal or optic nerve pathologies. Prospective enrollment of patients was done during the study. Selection of bifocal or monofocal IOL was done after discussion with child parents and patients were divided into two groups – Group A

implanted with bifocal IOL in both eyes and Group B implanted with monofocal IOL in both eyes.

Preoperative examination

Before surgery, a comprehensive ophthalmological and systemic examination was performed. It included Snellen's visual acuity assessment for distance (letters or numbers) for older children or figure optotypes for younger children (Precision Vision chart no. 2503), near vision assessment using reading cards with cord for 40 cm (Precision Vision charts no. 2508 or no. 2709), intraocular pressure (IOP) measured by Perkins applanation tonometry, assessment of ocular deviations using synoptophore or PlusoptiX SO4 device (PlusoptiX GmbH, Germany)), cycloplegic refraction assessment and keratometry (using handheld autorefractometer Retinomax 3 (Righton Co., Japan), portable slit-lamp biomicroscopy and fundus evaluation under dilation with binocular indirect ophthalmoscopy. Binocular function was evaluated with the Worth 4 dot test (Gulden Ophthalmics, USA) and stereoacuity for near with TNO stereotest (Laméris Ootech BV, Netherlands). Worth test was performed at the 5 m distance with the use of handheld Worth 4 dot test at 5 m distance. With the TNO test, the booklet was held at 40 cm perpendicular to the subject's visual axis and the screening plates from 480 to 15 seconds of arc were gradually presented until the child was able to identify three-dimensional shape correctly.

Axial length and anterior chamber depth were measured using ultrasound technique (AL-4000,Tomey Corporation, Japan) and IOL power calculation was performed using Hoffer Q formula corrected to the age. [11]

Intraocular lens

Foldable, bifocal, asymmetric, refractive IOLs (Lentis Mplus and Lentis Mplus^{x} (since October 2013), Oculentis GmbH, Germany) were implanted in both eyes of 25 children

(group A) Fig 1 and foldable monofocal IOLs (C-flex Aspheric Monofocal, Rayner Intraocular Lenses Limited, UK) were implanted in both eyes of 25 children (group B).

Figure 1

Surgical technique

All cataract surgery were performed by a single experienced surgeon (M.E.P.) under general anesthesia. Standard surgical technique of C-flex Aspheric Monofocal IOLs included: limbal corneal approach, manual continuous curvilinear capsulorhexis, hydrodissection, phacoaspiration of the nuclear and cortical lens material, posterior capsulectomy of 4 mm and anterior vitrectomy through the main incision using vitrector, injection of an ophthalmic viscosurgical device (OVD) to open widely the capsular bag and in the bag IOL implantation. After OVD removal, the main wound was closed with one 10.0 nylon suture.

In children with implantation of Lentis Mplus IOLs different technique was used. Lentis Mplus IOLs have plate design and have different unfolding pattern during removal from the cartridge noozle which caused difficulties in precise placement of IOL in the peripheral parts of the capsular bag after posterior capsulectomy and anterior vitrectomy. Therefore, in these children surgical technique included: limbal corneal approach, manual continuous curvilinear capsulorhexis, hydrodissection, phacoaspiration of the nuclear and cortical lens material, injection of an ophthalmic viscosurgical device (OVD), in the bag IOL implantation and pars plana posterior capsulectomy of 4 mm and anterior vitrectomy using vitrector. After OVD removal, the main wound was closed with one 10.0 nylon suture and pars plana wound with one 8/0 absorbable suture.

At the conclusion of surgery pupil was constricted by intracameral injection of acetylcholine, 1g of cefuroxime was injected into the anterior chamber and a sub-conjunctival injection of 4 mg of dexamethasone was given.

Figure 2

Postoperative care

Postoperatively, all the patients received topical moxifloxacin 0.5 % four times for 7 days and loteprednol etabonate 0,5% five times daily for 2 weeks and titrated further over a period of next two weeks. A clear protector was worn for 2-3 weeks after surgery to avoid possible trauma.

Postoperative examinations included distant and near visual acuity, IOP measurements, biomicroscopy of the anterior segment, eye fundus examination after pupil dilation, binocular vision and stereoacuity measurements and assessment of ocular deviations (with the previously mentioned methods) and were performed at 3, 6, 9 and 12 months.

Occlusion therapy and binocular vision training was started in the postoperative period depending on the presence or absence of amblyopia and on development of binocular vision.

Because children were only 1-5 years old it was not possible to evaluate the occurrence of glare and halos but their parents were asked to interrogate them for the presence of these visual symptoms later than 3 months after the surgery.

Statistical analysis

Mann–Whitney U test for non-parametric data was used for comparison of best corrected distant visual acuity**,** best corrected near visual acuity an results of TNO tests and chi-squared test χ^2 test for Worth 4 dot test.

RESULTS

Patients

Mean age of children at the time of surgery was 2,3 years (range 1,1 to 5 years) in Group A and 2,6 years (range 1,3 to 5 years) in group B.

Surgical results

No complications occurred intraoperatively or postoperatively in all operated children. In one children with implanted Lentis Mplus IOL it was necessary to perform surgical capsulectomy because of LEC proliferation and phimosis of the primary posterior capsulectomy. Visual axis of all other children was clear during the follow-up period.

Distant visual acuity

Before the surgery, it was possible to measure distant visual acuity in 14 children in group A and 17 children in group B. After the surgery, the measurements were performed in 23 children in group A and 24 in group B.

The best corrected distant visual acuity was not significantly different between group A and B one year postoperatively ($p=0.565$, Mann–Whitney U test). (Tab. 1)

Near visual acuity

Before the surgery, it was possible to measure near visual acuity in 15 children in group A and 18 children in group B. After the surgery, the measurements were performed in 23 children in group A and 24 in group B.

The best corrected near visual acuity was significantly superior in patients in Group A as compared to Group B ($p<0.02$,Mann–Whitney U test). (Tab. 2)

Worth test

Before the surgery, it was possible to perform Worth test in 17 children in group A and 19 children in group B. After the surgery, the measurements were performed in 23 children in group A and 24 in group B.

Binocular function evaluated with the Worth 4-dot test was significantly superior in patients in Group A as compared to Group B A (chi-squared test χ^2 test, =4,8, df=1, p=0,028) (Tab. 3)

TNO test

Before the surgery, it was possible to measure stereoacuity for near in 14 children in group A and 12 children in group B. After the surgery, the measurements were performed in 23 children in group A and 24 in group B. (Tab.4)

Stereoacuity for near was significantly superior in patients in Group A as compared to Group B ($p<0.002$, Mann–Whitney U test).

The occurrence of glare and halos

The parents of the both operated children have not reported the occurrence of glare and halos later than 3 months after the surgery.

Discussion

In the literature one can find only a few papers concerning the results of implantations of multifocal IOLs in children.[7,8,9,10] All these papers reports encouraging results. However, in some of these papers both unilateral and bilateral cases were included in the study [7,10] and only small group of five children with unilateral cataracts were evaluated.[8] The only report comparing homogenous large enough groups of pediatric patients was paper of Ram et al. who evaluated visual results and complications after bilateral implantation of multifocal versus monofocal IOLs in 21 children.[9] In these papers different multifocal IOLs were implanted, but all of them have similar drawbacks (as mentioned above) which deter most pediatric ophthalmologists from implanting them in children. Some years ago the new multifocal IOL - bifocal, asymmetric, refractive IOL (Lentis Mplus, Oculentis GmbH,

Germany) was introduced. This IOL has low loss of light of about 7% comparing to other refractive and diffractive IOL which have light loss of 14-22%.[B] Contrast perception with the Lentis Mplus is equivalent to that of a 20-year-old with healthy eyes.[C] The IOL is pupil indipendent and only one image is focused in the same time on the retina. Recently Oculentis company has introduced new IOL – Lentis Mplus[x] with improved optics which simplifies neuronal image interpretation by the retinal rods and cones due to additive paraxial asphericity and surface design optimization which has enlarged the near vision section making the IOL more pupil independent and provides better reading conditions. According to the manufacturer this IOL should have very low loss of light of 5% only. [D] Therefore, the author, after many years of considerations whether to implant multifocal IOLs in children, decided to use this IOL in children.

The implantation technique of Lentis Mplus IOLs is more difficult than other multi- or monofocal IOLs in children. Usually posterior capsulectomy and anterior vitrectomy is performed through the main incision using vitrector and then IOL is implanted in the bag with the help of spatula which direct the lower haptics into the remaining peripheral bag. Lentis Mplus IOLs are have plate design and different, more vigorous unfolding pattern with marked IOL bending into the vitreous cavity when upper haptics is released from the cartridge noozle. It cause difficulties in precise placement of IOL in the peripheral parts of the capsular bag after posterior capsulectomy and anterior vitrectomy. Therefore the author has changed the technique of IOL implantation performing posterior capsulectomy and anterior vitrectomy through pars plana after in the bag implantation of IOL. Lentis Mplus IOL has asymmetric optic so it must be very precisely positioned in the bag. It has also good in the bag stability so its dialing is difficult comparing with other IOLs.

Examination of visual functions after one after the IOL implantation have shown that the best corrected distant visual acuity was not significantly different between group A and B. However, children with implanted bifocal IOLs have significantly better near vision and first

of all binocular vision and stereopsis (Worth and TNO tests). The same tendency was observed also in other studies in children with implanted symmetric multifocal IOLs. [7,8,9,10] Also in adult patients multifocality does not deteriorate stereoacuity after the surgery.[12] We do not know the exact cause of better development of these visual functions in children with bifocal IOLs. However, this can be explained by the more prolonged use of near vision by these children. Children with monofocal IOLs require second eyeglasses or bifocal eyeglasses for near activity. Both solutions are troublesome for the patients and their parents: monofocal near eyeglasses need frequent changes; children's bifocal eyeglasses are not widely accepted because of their appearance. Therefore, in practice focused near vision activity of these children is limited (long periods of defocused near vision). Because the visual world of youngest patients is concentrated primarily at near distance, the development of visual functions in children should be less effective. Bilateral implantation of bifocal IOLs increases the time of focused near vision (it can be obtained with wearing of monofocal eyeglasses only) and offers much better conditions for the development of near vision, binocular vision and stereopsis.

The author has not found publications concerning implantation of bifocal IOLs in children. However, the analysis of optical properties of bifocal IOLs (better contrast sensitivity and small light loss, pupil indipendency and only one image is focused at the same time on the retina) make them more suitable for the implantation in children than rotationally symmetric multifocal IOLs. The results of this study indicate that implantation of bifocal IOLs offer much better conditions for the development of visual functions in children after cataract surgery than monofocal IOLs. It was the reason that the author have chosen bifocal IOLs as the standart IOLs for the implantation in pediatric cataract surgery.

In conclusion, implantation of bifocal IOLs in small children aged 1-5 years with bilateral cataract provide better near vision and considerable improves the development of binocular vision and stereopsis. Although it was not possible to evaluate it directly, the reports of the

parents of these children indicate that photic phenomena such as glare and halos are not a problem after implantation of bifocal IOLs.

WHAT WAS KNOWN

* Pediatric ophthalmologists prefer to implant monofocal IOL in children with congenital cataracts because it is still unknown how multifocality (and its drawbacks) might influence the development of binocular vision.

* Our experience of multifocal IOL implantation in children is very limited and in the literature one can find only a few papers concerning this problem. There are no publications about the results of implantation of the novel multifocal IOL - bifocal, asymmetric, refractive IOL type of bifocal IOLs in children.

WHAT THIS PAPER ADDS

* Analysis of optical properties of bifocal IOLs suggests that these IOLs will be more suitable for the implantation in children than other types of multifocal IOLs.

* Implantation of bifocal IOLs in small children aged 1-5 years with bilateral cataract provide better near vision and considerable improves the development of binocular vision and stereopsis than implantation of monofocal IOLs.

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Figure legends

Fig. 1 Foldable, bifocal, asymmetric, refractive IOL Lentis Mplus^{x}

(Courtesy Oculentis GmbH, Germany)

Fig. 2 Lentis Mplus^{x} IOL after implantation in 1,5 year old child.