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Mplus/Mplus Toric (Oculentis) Bifocal Successor of Monofocal Lens in Private Medical Centre. Six Years of Experience

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Abstract

A retrospective analysis of parameters of vision and postoperative complaints in 428 patients (606 eyes) undergoing cataract surgery or clear lens extraction with ontime bifocal Oculentis® lens implantation. Artificial lens implantation was performed in one or in both eyes in patients without preoperative eye defect. Subsequent groups included patients with preoperative hyperopia, myopia and with corneal astigmatism. The biggest number of patients received spherical lenses with addition of 3.0 Dsph to near distances, then with addition of 1.5 Dsph, and toric lenses. The other two analyzed groups included patients who needed posterior vitrectomy and who have been preoperatively diagnosed with Age Related Macular Degeneration, dry and exudative changes. The main inclusion criterion was the need to become free of glasses to far and near distances. Almost all of patients obtained satisfactory visual acuity and quality of vision while maintaining the appropriate inclusion criteria. One of the criteria assumed that patients with larger pupil sizes were implanted with lenses with less addition to near distances, and corneal astigmatism was corrected even if the value was below 1 diopter.

***Highlights:** Owing to their simple structure, intraocular bifocal lenses from Oculentis®, when certain qualification criteria are met, can replace monofocal lenses as the product of choice, giving measurable benefits including far and near vision without additional need for correction.*

Keywords: *AMD; bifocal lens; cataract; Oculentis®; posterior vitrectomy; refractive lens exchange.*

Introduction

Cataract surgery is one of the most dynamically developing branches of ophthalmology. Apart from the minimization of tools, reduced surgery time, and improved safety of procedures, there is much focus on the development of intraocular lenses. Regrettably, monofocal lenses remain the product of choice in the majority of ophthalmology centers in Poland, in spite of a huge selection of premium lenses [1,2,3].

To be considered as premium products, lenses should allow patients to see without the need for near, intermediate, or far vision correction, while correcting corneal astigmatism of the eye [3,4,5]. Why are such lenses rarely offered to patients? Is it due to insufficient quality of obtained vision, limited availability, or the purchase price being too high? In the Polish realities, the choice of this class of lenses appears primarily restrained by the fact that the regulations of the insurance provider, the National Health Fund, are unfavorable to patients. Polish regulations do not permit patients to participate in the cost of the procedure. Patient who wants to get premium class intraocular lens have to pay for all the procedure, even if they have an insurance [6].

Yet another cause is the lack of information among patients, who usually obtain information regarding available products from physicians. If the clinician is

well informed and, most importantly, convinced of the prospect to obtain a better quality of vision through the use of premium lenses, their patients will learn it too. At present, ophthalmologists can choose from a broad range of lenses, from bifocal to toric multifocal lenses embedded with extended depth of focus (EDOF) technology [7]. If fully paid treatment is chosen, the offer to implant a monofocal lens is insufficient according to the criteria used at the Silesian Center for Eye Disease Treatment [Śląski Ośrodek Leczenia Chorób Oczu] at Żory, regardless of applied additional features (asphericity, yellow filter etc.). It is worth mentioning that a large new group of prospective patients has just entered the ophthalmological market: persons diagnosed with sight defects who also lost the ability to accommodate. Unfortunately, these patients are forced to wear glasses or contact lenses which they do not tolerate.

Some of them do not use any vision correction in spite of their, frequently severe, vision impairment. Clear lens extraction (CLE) surgery with subsequent implantation of an artificial lens of specific parameters enables the resolution of the above issue through permanent correction of virtually any eye defect [8, 9]. Offering monofocal lenses to patients from this group when there are no contraindications for implantation of premium lenses is contrary to the stated objective of removing the defect.

Therefore, which premium lens is the best? The lens should be possibly uncomplicated in structure while giving the near and far vision capability without the need to wear additional correction. Additionally, it should generate minimal visual impairments due to its structural complexity.

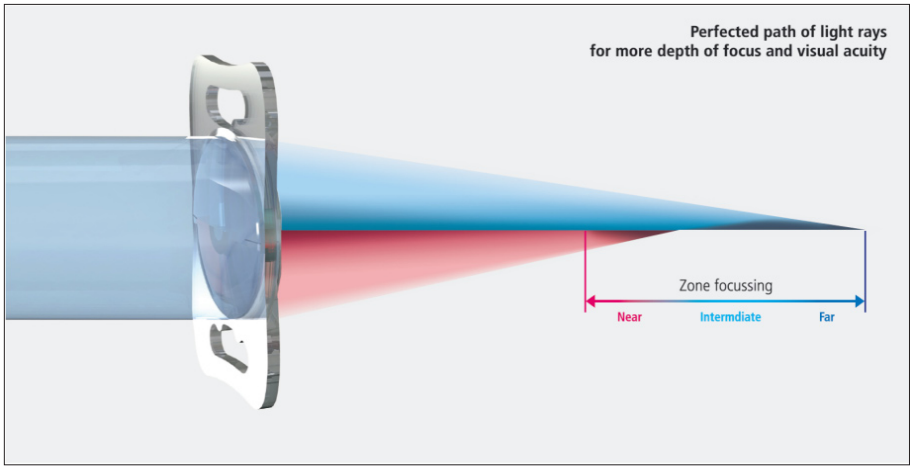

Figure 1. *Model of an Oculentis® bifocal lens showing near and far vision segments in the optical part of the lens*

Most importantly, such a lens should be a product which can be used in virtually any patient. Economic aspect does matter; however, they should only be considered as the last criterion when selecting a product to be implanted in the eye for practically a lifetime.Bifocal lenses from Oculentis® can be seen as a product which meets the above criteria [10]. These lenses were introduced to the international markets around 2009. At the Silesian Center for Eye Disease Treatment, first implantations of spherical lenses with 3.0 Dsph near vision addition of (Mplus®) were performed in January 2013. Lenses from this manufacturer were chosen as the recommended product based mainly on international opinions and reports of their application [11]. It is worth mentioning that Oculentis® lenses were implanted in Western European countries more than 200 thousand times before we decided to use them in our Center. An asymmetric bifocal lens (Fig.1) enables both far and near vision (with 3.0 Dsph addition), while the transitional segment between the two main foci enables additional vision at intermediate distances [12]. The simple structure of the lens only slightly reduces the vision contrast, by about 7%. Other advantages include not being dependent on the size of the pupil and the ability to implant in mass patients. HydraSmart®, the material from which the lenses are manufactured, is yet another asset. Covering the hydrophilic interior with a thin hydrophobic layer ensured excellent vision quality [13,14].

Competitive manufacturers of lenses made from entirely hydrophobic materials stress that the use of

hydrophilic material is associated with the necessity of laser capsulotomy in virtually all patients in order to break down progressive clouding of the posterior capsule. Alas, the authors of these reports overlook one undisputed fact, namely the emergence of air-filled microvacuoles observed in hydrophobic lenses already 3-4 years after the implantation in the eye. This phenomenon causes the so-called glistening, leading to a decrease in visual contrast. In the light of the above, the visual contrast in 40-50-year-old patients decreases, reaching values found in 70-year-old patients already 6-7 years post-implantation [15,16,17].

In time, based on our own experiences associated with the used of Oculentis® lenses, the selection criteria underwent slight but justified changes, allowing the selection to be more precise. In fact, the recent year brought the most significant changes to these criteria. The evaluation of corneal surface for the higher-level aberrations it may generate, mostly affecting twilight and night vision, has become a standard. Additionally, we perform a test to measure the angle kappa and angle alpha in all patients. Angle alpha is the angle between the visual and the optical axes of the eye. Angle kappa is formed by the intersection of the pupillary axis and the optical axis. The evaluation of angle alpha provides information to establish the anticipated location of the central optical segment of the implanted lens. Whereas angle kappa seems to be of less significance in cataract surgery, yet may be of ancillary importance in the cases of hyperopic eyes and high angle alpha values. These tests allow to reduce the risk of post-operative decrease in visual quality associated with the optical axis passing through diffraction and refraction rings (segments) of the lens. Owing to this we can limit the adverse effects on visual quality due to additionally induced higher-level aberrations, which results in improved far vision quality and a higher level of patient satisfaction after the implantation of multifocal lenses. Consequently, there is a lower risk of such adverse symptoms as clouding, shadows, and light reflections, and the feeling of contrast is normal [18,19,20,21].

Material and Method

Between January 2013 and July 2018, 428 patients (606 eyes) underwent the implantation of Oculentis® group lenses, of which in 178 persons the implantation was performed in both eyes. Monocular implantations were performed in 250 persons, using bifocal lenses in each case. The lenses were implanted in virtually any possible combination, from binocular implantation of spherical lenses with 3.0 Dsph near vision addition to combined monofocal or multifocal implants from other manufacturers. Subsequent implantations involved bifocal toric lenses, both monocularly and binocularly, implantations in monocular patients, and implantations combined with posterior vitrectomy. Patients with early diabetic changes and with AMD type changes, both dry (mainly macular drusen) and wet, receiving anti-VEGF treatment, were the next analyzed group.

Based on our own results and information published in medical periodicals, in time we began implanting bifocal spherical and toric lenses with near vision addition of 1.5 Dsph (Comfort line). In virtually all patients the lens was introduced into the capsula.

Qualification for Surgery

The main exclusion criterion was the inability to achieve good near and far vision (also quality-wise). Therefore, all eye pathologies, from severe lacrimal film disturbances, to corneal diseases, to central retinal damage which can lead to decreased visual acuity and quality, disqualified patients from bifocal lens implantation.

Inclusion Criteria

Intent to obtain permanent near and far vision without the need of additional correction (in cataract patients) and to eschew the need for ocular correction in patients with refraction defects who lost the ability to accommodate (patients qualified for refractive lens replacement).

Ability to Obtain Good Near and Far Vision

Medical history included asking about the lifestyle, with a particular focus on night-time functioning hours, when increased width of the pupil may exacerbate adverse changes after the implantation of a complex structure lens.

The evaluation of pupil diameter and position, eye dominance, examination of the anterior and posterior segments and pressure in the eye are the subsequent fixed stages of qualification. When astigmatism was diagnosed, its amount was calculated from the

results of standard refractometry, corneal topography analysis, and the measurements of the intraocular lens taken using an optical biometer. Routinely, the tests to reveal higher-level aberrations and the measurements of angles kappa and alpha were introduced in the final months of qualification.

Toric lenses were calculated using the mathematical formula made available by Oculentis® at the http://www.lentistoric.com website. Delivery time for a customized toric lens is 3-6 weeks. Macular OCT was performed in each case where the central retinal, or macular condition appeared doubtful. The intraocular lens value was mainly calculated using an optical biometer. When the lens opacity was too high, calculations were carried out using rather immersion than contact biometry. The latter method was mostly used in the cases of myopia or mature cataract. While the Haigis formula is the main calculation formula recommended by the Oculentis® manufacturer, four formulae were compared in each case and, if any doubts arose, the lens value most frequently found in the calculations was selected. Cataract surgeries were performed by 2 surgeons (Cywiński, Bednarski). Posterior vitrectomy and combined surgeries with cataract extraction were carried out by one surgeon (Cywiński). The following Oculentis® lens models were implanted in the analyzed group: LS-313 MF30 (Mplus and MplusX with 3.0 Dsph addition), LS-313 MF and 15T (Comfort® with 1.5 Dsph addition), LU-814 MF30 and MF30T (4-hapten).

Results

Table 1 compiles (below) statistical data including information on the number of patients, implanted lenses, patients' ages, observation period, quantitative division into cataract removal and clear lens extraction (CLE) patients, due to pre-operative defect, number of toric implant, pupil diameter, etc.

Visual Acuity and Oculentis® Implants.

Table 1. *Statistical data including information on the number of patients, implanted lenses, age, observation period, number of patients undergoing cataract removal and RLR, broken down by pre-operative defect, pupil diameter.*

Meanage (years)	65+/-13,2
Number of procedures	606
Number of patients - Mplus in both eyes	178
Number of patients -Mplus in one eye	250
An observation time (months)	6-63
Mean observation time (months)	11 +/-9
Number of spherical Mplus implantations	481
Number of toric Mplus implantation	125
Number of Yag capsulotomies	100
Time from surgery to capsulotomy (months)	2-42
Mean time from surgery to Yag capsulotomy (monhts)	13+/-8,9
Number of clear lens extractions	146
Number of cataract extractions	460
Pupil size before surgery (mm)	4,7 +/-3,18
Pupil sizeafter surgery	4,39 +/- 2,76
Number of preoperative hyperopia (eyes)	327
Number of preoperative myopia (eyes)	250
Number of eyes without preoperative eye defect	29
Mean eye length----------	24,72 +/-7,23
Mean anterior chamberdepth	3.41 +/-0,44

Obtained results were compiled in Table 2. (below)

Table 2. *Comparison of far vision (BCVA - logMAR) and near vision (Snellen) visual acuity with the best correction, obtained pre- and post-operatively, without correction, in selected groups.*

	BCVA to far before surgery (LogMAR)	BCVA to near before surgery (Snellen)	BVA to far after surgery (LogMAR)	BVA to near after surgery (Snellen)
Catarct	0,4 +/-0,27	0,75 +/-0,45	0,1 +/-0,22	0,5 +/-0,36
Cataract removal after posterior vitrectomy or combined surgery	0,5 +/- 0,4	0,75 +/-0,53	0,3. +/-0,30	0,75. +/-0,5
Cataract and AMD changes	0,7 +/- 0,87	1,0 +/-0,77	0,3. +/-0,29	0,75. +/-0,63
Maturecataract	Reading letters from 1 meter	x	0,3. +/-0,43	0,75. +/-0,6
Clearlensekstraction	0,0 +/-0,05	0,5	0,0. +/-0,1	0,5. +/-0,06
Clear lens extraction and amblyopia	0,4. +/-0,26	0,5. +/-0,12	0,3. +/-0,19	0,5 +/-0,18

Statistical analysis was carried out using t-Student test to determine if there were any statistically significant relationships between visual acuity measured before and after surgery. Assuming the level of statistical significance $\alpha = 0.05$, the statistical analysis revealed that, in the case of refractive lens replacement patients, the obtained results are statistically significant ($p = 0.00156$), but only with regard to far vision.

The best values, highest stability, and most predictable outcomes were obtained in CLE patients, and the least predictable in mature cataract patients. The patients who already had a monofocal or multifocal implant from another manufacturer in the other eye did not complain of decreased visual quality.

Oculentis® and Posterior Vitrectomy

Combined surgery was performed in 14 persons (eyes), separately in 21 patients (eyes). The causes for vitrectomy were: full-thickness macular hole, vitreo-macular traction, ophthalmic complications of diabetes, and retinal detachment with and without macular involvement.

Oculentis® and AMD

When the prognosis of visual improvement was good, bifocal lenses were implanted even when AMD changes were present. The surgery was performed in 44 eyes, in 25 of which the changes were wet, extrafoveal, and required introducing anti-VEGF treatment. Patients usually received 2-3 injections before surgery, mainly with Bevacizumab. Anti-VEGF treatment was continued after surgery according to a treat-and-extend protocol. Dry AMD usually manifested as macular drusen.

Table 3. *Complications associated with performed surgery*

Time of occurrence	Kind of complication	Number of patients
Intraoperative	-ruptura of the capsula - lens introduced on the anterior capsula-transient haemorrhagia to anterior chamber during lens fixation	3 (3)
	-not completely introduce to the capsula	2(2)
		9(9)
Postoperativeearly	-displacement of the lens relative to the axis	1(1)
	-need to removal bifocal toric lenses	1(2)
Postoperativelate	-retinal detachment	3(3)
	-lens opacifitation (calcification)	2(2)

The majority of the above complications were successfully removed. Unfortunately, in the case of retinal detachment in one patient who underwent a combined surgery of cataract removal and posterior vitrectomy (due to macular pucker), due to a misinterpretation of ultrasound imaging performed at the ER (hemorrhage to vitreous body with accompanying choroid detachment instead of the present retinal detachment), the patient arrived at our Center too late to obtain the attachment effect and restore his vision. In the remaining 2 persons (eyes) reparative surgery was performed, i.e., posterior vitrectomy with silicone oil endotamponade, which ensured permanent attachment. It is worth taking notice of progressive far vision impairment observed 3-7 days post-surgery when the upper part of the lens was not completely introduced to the lens capsula. This situation took place when the pupil diameter before the instant of implantation was smaller than the diameter of anterior capsulorhexis. Far vision was restored by surgical correction, i.e., complete introduction of the lens to the capsula. In 4 cases the lens was removed. The need to remove the bifocal toric lens from both eyes in one patient resulted from reported vision impairments. The examination of angles kappa and alpha revealed very high values, which is a contraindication for this kind of implants. In another 2 persons (2 eyes), a completely opaque (calcified) lens was replaced with the 4-hapten model, introduced on the anterior capsula. It is worth mentioning that the same bifocal lens model implanted into the other eye did not cloud.

Complaints

On postoperative day 1, virtually all patients were satisfied with the obtained results, excluding patients who underwent combined surgery, i.e., cataract removal and posterior vitrectomy with endotamponade, or in the cases of severe pre-operative lens opacity (almost mature and mature cataract).

Already at the next follow-up (6-10 days), many patients pointed out the presence of a semi-circular shadow in the vicinity of light sources, which spontaneously resolved after several to a dozen or so weeks.

It should be stressed here that, in all patients who were examined post-operatively, a refractometer revealed the presence of both a spherical defect and astigmatism, in spite of good near and far vision being preserved without correction. This is due to the complexity of structure of this kind of lenses. Therefore, the discharge report contains additional information saying that it is not necessary to correct the "artificial" post-surgery defect revealed in refractometry. Patients with myopia, particularly average and high, initially complained of problems with near vision reading as they needed to disaccustom themselves from reading from the distance of a few cm and adapt to reading from the distance of 30-40 cm. Similar problems with far vision were observed in persons with slight preoperative hyperopia, mainly in refractive lens replacement cases. These persons, particularly if they have not used the recommended far vision correction for hyperopia, believe that their far vision worsened after surgery. In such cases one should thoroughly consider the validity of suggesting the surgery. Some persons, especially monocular and patients with diabetic and AMD changes, required additional near vision corrections.

It is also worth mentioning the fact that such adverse post-operative symptoms as glare or halo were exacerbated if the surgery was performed during fall or winter. It is associated with periods of prolonged lack of daylight and thus longer physiological mydriasis under scotopic conditions.

Discussion

Is it reasonable to delve deep into a patient examination and, once specific qualification criteria are met, to offer them a complex-structure lens which, in most cases, will provide them with more benefits than a monofocal lens, primarily independence from correction? You could just cut corners, as they say, and with no effort or any greater risk offer a monofocal lens to everyone. The former option is addressed to more ambitious and qualified physicians and more demanding patients. Many times have I heard a reply that "nobody told me it was possible" when I asked a patient with an implanted monofocal lens if they would not prefer to see far and near without the need to wear glasses or contact lenses.

With regard to the adverse visual symptoms and the risk of complications associated with surgery, it is necessary to analyze the adverse symptoms associated with the use of contact lenses, bifocal spectacle lenses, progressive lenses, and the vision impairments

occurring when correcting sometimes huge sight defects. Considering our experience, the total amount of premium lens implantations, including Oculentis® lenses, ranges between 65 and 80% of all implants, depending on the analyzed month. Taking into account the small number of observed complications and the rarely reported and usually receding in time post-operative complaints, and small amount of performed Yag capsulotomies (about 16%), procedures involving Oculentis® bifocal lenses are a good alternative for monofocal lenses. The number of patients who decide to undergo refractive lens replacement is also increasing.

Thus, the demand for this kind of surgery and premium products is growing. It would be worthwhile if physicians without any experience in this matter stopped informing patients that it could not be done, the risk was too great etc. It would suffice to refer them to another doctor who is known to perform such procedures.

Conclusions

Bifocal Oculentis® lenses replaced, one might say ousted, monofocal lenses in our Center, being a product offering measurable benefits to patients, primarily by getting rid of the need to use additional correction. Adequate pre-operative qualification allows minimizing the adverse effects of performed surgery, in a way that is most satisfying to the patients. The presence of AMD changes or pathologies requiring posterior vitrectomy is not a contraindication to implanting this type of a lens if the prognosis with regard to the restoration or preservation of sight is good. The presence of mature cataract is not a contraindication to implantation either, even though, taking visual acuity measurements into account, the most stable and predictable prognosis involves patients who underwent refractive lens replacement.

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