

Monofocal plus lens – a perfect solution for (nearly) every patient? Surgeons' own experience with RayOne EMV



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ABSTRACT

Objective: This article aims to briefly characterise the most popular IOLs on the market and focus on Rayner EMV: monofocal plus lens being a very good compromise between a good deal of spectacle independence, its price and coexisting ocular conditions allowing for its implantation. Setting the postoperative refraction at minimonovision as was done in this study allows for even greater depth of field and thus minimalizes the need for glasses when performing most everyday activities.

Methods: To summarise the IOLs characteristics a literature search was conducted. In the second part of the article surgeons' own experience is shown together with postoperative results and patients' satisfaction survey.

Results: Uncorrected binocular visual acuity was very high: 74% of patients reached 6/6 on Snellen chart or better, and for 96% of patients mean UCVA both eyes was 6/6.5 or better. Mean binocular UCVA both eyes was 6/5.5. Near visual acuity score: 43% of patients did not require spectacle correction for near reading and 91% of patients were able to read line D-0,75 or more on Snellen reading chart. Halo or glare effect were noted in 5 cases but only in two of them resulted in lower score in patients' satisfaction questionnaire (to 64 and 79% of maximum score). In three remaining cases patients gave 95% of maximum score and stated that even though they noted halo and / or glare it did not comprise their visual quality. In patients' satisfaction questionnaire score given by drivers was 90%; non-drivers were even more satisfied and gave 92% of maximum score – it shows very high percentage of satisfied patients in both groups

Conclusion: Rayner EMV IOL is an affordable and valuable option for patients who would like to increase their spectacle independence postoperatively and should be considered along with premium multifocal IOLs. Reducing spectacle dependence with the pseudophakic mini-monovision technique could improve the functionality, independence and quality of life for many patients.

Key words: cataract surgery, IOL, monofocal plus, minimonovision, Rayner EMV

HIGHLIGHTS

Cataract surgery nowadays is not only about restoring visual acuity but also about allowing at least some degree of spectacle independence – and that is why premium IOLs are becoming more and more popular. This article presents a relatively new product on the market: monofocal plus intraocular lens with its benefits and limitations from a surgeon's point of view.

INTRODUCTION

The world is changing fast and not surprisingly changes include our attitude towards cataract surgery. Nowadays after the operation patients expect not only better visual acuity but also at least some degree of spectacle independence – and often they are prepared to pay for it. Due to relatively easy access to surgical procedures, higher expectations and longer life expectancy patients are willing to undergo cataract extraction much earlier in life, often when they are still working and thus their expectations concerning their quality of life seem to be higher than they were 20 years ago.

In response to these demands companies are presenting wider and wider range of premium intraocular lenses (IOLs), made of high-quality biomaterial, with aspheric design and modified optical properties. The purpose of implanting those lenses, in contrast to so-called 'standard ones', is to improve uncorrected visual acuity from near to far distance with good intermediate vision in between, not to mention additional correction of astigmatism, if needed. All the above: constant increase in patients' demands and growing IOL market force the specialists to do thorough research before presenting their patients with a choice of appropriate lenses so that together, the doctor and the patient, can choose the "perfect" one. The key to success seems to consist of a mix of understanding of the patient's needs, possibilities (both financial and neural), and personal characteristics together with presenting different IOLs' including their advantages and disadvantages. And since it is the specialist's role to narrow down the choice of IOLs that they are offering to their patient, it seems crucial to best understand what possibilities and limitations have specific types of lenses. Thus, this article aims to present a brief description of one of the lens' types together with a surgeon's own experience to make the process of IOL choice a bit easier. Our goal is to present a relatively new product on the market: a monofocal plus lens produced by Rayner (Worthing, UK) and designed in cooperation with Professor Graham Barrett: the RayOne EMV IOL.

LENSES WITH EXTENDED DEPTH OF FOCUS

When talking about premium IOLs, the ones that first come to mind are multifocal/trifocal lenses and lenses with extended depth of focus (EDOF). In the first type their multifocality is achieved by creating diffraction rings (in so called 'diffractive lenses') or different refractive zones in the lens' optical zone (refractive type) [1], while in EDOF lenses single focal point is elongated to create extended depth of focus [2]. Despite the high efficacy of these implants for the restoration of distance, intermediate and near visual function, the perception of unwanted visual phenomena, such as glare or halos, is still considered one

of their most relevant limitation. Indeed, this is one of the main causes of dissatisfaction after cataract surgery with multifocal IOL implantation, especially the trifocal lenses [3–5]. EDOF IOLs were developed to overcome this limitation: the idea behind its construction is that in theory it should create less dysphotopsias due to the smoother transition between foci. However, although they can provide good distance and intermediate visual outcomes as well as a functional near visual outcome, they are not completely free from photic phenomena depending on their optic design [6–9] and the near vision is not as good as what can be achieved with trifocal lenses [8]. The near vision with EDOF lenses can be improved with mini-monovision when choosing a target refraction for the non-dominant eye from -0.5 to -0.75 D. This however does not resolve the problem of photic phenomena especially with diffractive EDOF lenses – though less common with non-diffractive EDOF than trifocal lenses, dysphotopsia still affects around 30% of patients after IOL implantation [5]. And here seems to be a good opportunity to bring the monofocal plus lenses to the market. These new lenses include (but are not limited to) Tecnis Eyhance (Johnson&Johnson Vision), enVista (Bausch + Lomb), ISOPURE (BVI) and RayOne EMV (Rayner) – the latter was introduced in 2020. One of the existing classification of lens' types, especially the EDOF IOLs is based on criteria set by American Academy of Ophthalmology and focuses especially on intermediate visual acuity which is a critical factor for classifying IOLs as EDOF or "monofocal-EDOF" or "monofocal plus" IOLs [10]. The latter type of lens have been described as a mix between very good distance visual acuity (as with standard monofocal lens) and intermediate visual acuity but also very low profile of dysphotopsias [11]. They use changes in curvature or spherical aberration to extend the depth of focus. The lenses are also more tolerant of refractive error and extend intermediate vision to about 2.0 D of defocus. Enhanced monofocal IOLs effectively improve unaided intermediate vision maintaining a similar distance performance compared to conventional monofocal IOLs. This is achieved without compromising the contrast sensitivity or inducing photic phenomena [12].

It is a good choice for patients not qualified or not willing to undergo a surgery with trifocal or diffractive EDOF lenses yet seeking a reasonable degree of spectacle independence without increasing the risk of dysphotopsias. When set to emmetropia, the monofocal plus lens give very good distant and intermediate vision but by introducing micro- or minivision (0.5 to 1.5 D difference) most patients are able to achieve quite good near vision as well. Mini-monovision in cataract surgery results in high patient satisfaction and considerable reduction in spectacle dependence [13, 14].

RayOne EMV

RayOne EMV is a non-diffractive lens with positive spherical aberration to extend the range of vision and, by introducing monovision, giving further elongation of depth of field. It offers high patients' satisfaction with relatively little compromise on their quality of vision [15–17]: the rate of dysphotopsias [15, 16] and level of contrast sensitivity [16, 17] are comparable to those expected with monofocal lenses. The idea behind the RayOne EMV's optic design is that its aspheric anterior surface induces controlled positive spherical aberration which work together with the natural positive aberration of the human cornea to extend depth of vision and blended edge reduces longitudinal spherical aberration to maintain visual acuity and contrast sensitivity even in low-light conditions. The non-diffractive optics are intended to reduce unwanted photic phenomena when compared to diffractive IOLs. There are several benefits of using positive instead of negative spherical aberration (as in other monofocal plus IOLs, i.e. Tecnis Eyhance) with the RayOne EMV IOL. One is the completion of the natural positive spherical aberration of the human (virgin) cornea. Another one is the superiority over negative spherical aberration in case of some level of IOL decentration and especially tilt. Finally the RayOne EMV comes with the benefits of the rotationally stable RayOne platform [18], which additionally helps to maintain a high visual quality and performance.

AIM

The aim of this paper is to show clinical outcomes and surgeons' own experience with patients operated for cataract in both eyes with RayOne EMV set for mini-monovision with target refraction set for emmetropia in the dominant eye and between -0.75 and -1.25 D in the non-dominant eye. Apart from measuring uncorrected distance visual acuity (UDVA) and uncorrected near visual acuity (UNVA), in (both measured in photopic lighting conditions), patients' satisfaction and the ability and comfort performing everyday activities without optical aids were assessed using a modified VF-14 questionnaire.

PATIENT'S QUALIFICATION

There is no exaggeration in saying that a proper qualification for surgery is a key to success. One must be careful choosing the best possible option for the patient also taking his or her age into account. The population of cataract patients is younger and these patients have higher expectations compared to patients operated a decade or two ago [19].

One of the aspects to further consider are different personality types. Rudalevicius et al. published a paper in which they established that patients' level of satisfaction (or dis-

satisfaction) after implanting multifocal IOL was closely related to certain personality traits: the group that was the least satisfied with their surgery's results were patients with neuroticism and high criticism; on the other hand, the ones with conscientiousness and agreeableness were highly satisfied with postoperative outcome – and the level of satisfaction was not directly correlated with objective outcome measured with visual acuity [20].

Irregular astigmatism is a key factor when choosing between monofocal and multifocal lens as well. It is well known that higher degree of residual astigmatism (above 0.75 D) will most likely decrease visual function of multifocal IOL by creating unwanted optical phenomena [21, 22]. Thus, multifocal IOL are contraindicated in corneas with irregular astigmatism [9]. And here is an advantage of monofocal and monofocal plus lenses, as they are much more "forgiving" in cases of residual astigmatism [23].

Pupil's diameter is another factor that must be considered when deciding which lens type should be implanted. Pupil narrower than 3 mm in photopic conditions or wider than 6 mm in mesopic conditions should be a warning flag for diffractive EDOF or trifocal lenses as patient can experience lower contrast sensitivity or higher degree of dysphotopsias respectively [22]. On the other hand, the diffractive-free design of monofocal plus IOL results in lower dependence of pupil size which once again makes it a good choice in larger group of patients.

METHODS

Patients' characteristics

Patients were eligible for inclusion in the study if they were diagnosed with cataract in both eyes and were willing to perform the surgery in the second eye within 2–4 weeks after the first eye, and if the following conditions were present: axial length (AL) between 21.0 and 27.0 mm, and mean corneal power between 41.0 and 47.0 D. Further, the patients must have had a proper understanding of how mini-monovision works and previously consented to undergo a bilateral surgery set for a monovision with target refraction of non-dominant eye set for -0.75 to -1.25 D.

Regarding exclusion criteria, the following conditions were considered: age below 18 years; insufficient understanding to comply with study procedures and/or complete patient questionnaires; inability or unwillingness to complete follow-up or comply with study procedures; possibly complicated cataract surgery (e.g. combined with another ocular procedure); factors known for increasing the risk of refractive error (i.e. AL <21.0 mm or >27.0 mm, more than 1.5 mm difference between both eyes, non-normal keratometry readings, history of refractive surgery, degenerative myopia); lens luxation or other serious irregular lens status, se-

rious ocular comorbidities (i.e. advanced glaucoma, diabetic retinopathy with macular oedema, retinal detachment).

Patients who were willing to participate and met the inclusion and exclusion criteria were qualified by the surgeon (DK) to the implantation of the RayOne EMV (Rayner, Worthing, UK) in both eyes. The follow-up duration per patient was up to two months after second eye surgery.

Preoperative examination

All patients had a complete preoperative ophthalmic examination including subjective and objective refraction, biomicroscopy of the anterior and posterior eye segments, intraocular pressure (IOP), macular optical coherence tomography (OCT, Carl Zeiss Meditec), automated keratometry, optical biometry (IOL Master 700, Carl Zeiss Meditec), and had their non-dominant eye determined. Patients with corneal astigmatism higher than 1 D in IOL Master keratometry were qualified for EMV toric lens.

Surgical technique

Pseudophakic mini-monovision was chosen for this study. For purposes of this study, the definition of mini-monovision is the non-dominant/near eye calculated for a postoperative spherical equivalent between -0.75 and -1.25 D. In all patients the dominant eye was corrected for distance vision (plano). Toric IOLs were used on patients who had preoperative corneal astigmatism greater than 1.0 D. The same experienced surgeon (DK) performed all surgeries under topical anaesthesia using a standard sutureless microincision phacoemulsification procedure. Surgeries were initiated after instilling intracameral anaesthesia and mydriasis by performing a main corneal incision at the temporal or superior location. The next step was creation of the capsulorhexis and the performance of the phacoemulsification. After this, the IOL was inserted into the capsular bag through the main incision using the preloaded RayOne injector developed by the manufacturer.

A standard postoperative topical therapy was prescribed: antibiotic 4 times daily for 1 week and steroid starting from 5 times daily and tapering the dose during 4 weeks after the surgery; patients were also advised to use preservative-free artificial tears.

Postoperative examination

Routine postoperative examinations were performed 1 day, 3 weeks and 2 months after surgery. These included visual acuity testing for distance, intermediate and near vision, IOP, subjective and objective refraction and biomicroscopy of the anterior and posterior segment. Near vision was tested with the near vision chart shown in Appendix B. On this chart line D-0.5 represents small print similar to the one found in daily newspapers (font size 9) and D-0.75 represents an average book font (font size 11–12). Patient

reading line D-1.0 – D-1.25 is usually able to comfortably read PC screen.

The main study outcomes were assessed at the last follow-up visit. At two months postoperative the patient was asked to complete the modified VF-14 questionnaire. Outcomes included visual acuity, patient reported questionnaire data on performing common daily activities without optical correction and presence of dysphotopsias.

Patients' questionnaire

At the last follow-up visit (2 months after the second eye surgery) patients were asked to answer questions about their ability to perform everyday activities without using glasses. Patients were asked about how well they were able to read small print, books and newspaper, larger print like newspaper's headlines, use their smartphones (close-distance activities), recognize faces, prepare meals, play chess, watch TV, use laptop/PC (intermediate-distance activities) and recognize road signs, or read a bus number plates (long-distance activities). Each activity could be described as easily performed or performed with mild, moderate and high difficulty. Altogether there were 12 questions for all patients and 2 additional ones for car drivers about possible difficulties when driving during day or night, plus a question concerning possible halo and glare effect. Maximum number of points was 48 (or 56 for drivers) – the more points scored, the easier the activities were performed. Presence of halo and glare was described in 0/1 scale (0 for "I don't experience such thing" and 1 for "I notice halo and/or glare effect"). The questionnaire is shown in Appendix A.

POSTOPERATIVE RESULTS AND STATISTICAL ANALYSIS

A total of 46 eyes of 23 patients with a mean age of 71.9 years (SD: 5.8, median: 72.0, range: 60–83 years) were enrolled. The sample comprised 11 males (48.0%) and 12 females (52.0%).

In general, uncorrected binocular visual acuity was very high: 74% of patients reached 6/6 on Snellen chart or better, and for 96% of patients mean UDVA both eyes was 6/6.5 or better (fig. 1). Mean binocular UDVA both eyes was 6/5.5. Also near visual acuity score was satisfying: 43% of patients did not require spectacle correction for near reading and 91% of patients were able to read line D-0.75 or more on Snellen reading chart (fig. 2).

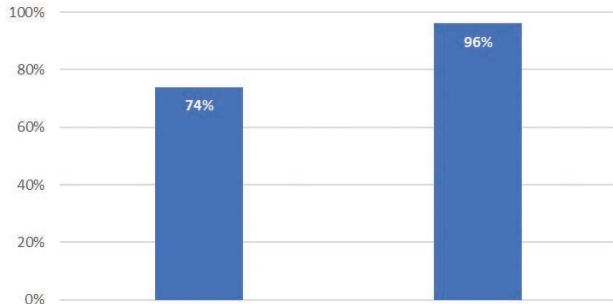
Halo or glare effect were noted in 5 cases but only in 2 of them these phenomenon resulted in lower score in patients' satisfaction questionnaire (to 64 and 79% of maximum score). In 3 remaining cases patients gave 95% of maximum score and stated that even though they noted halo and/or glare it did not comprise their visual quality (fig. 3).

In patients' satisfaction questionnaire score given by drivers was 90%; non-drivers were even more satisfied and gave

FIGURE 1

In 74% of cases mean UDVA both eyes was 6/6 on Snellen chart or better, in 96% of cases mean UDVA both eyes was 6/6.5 on Snellen chart or better.

BINOCULAR UDVA

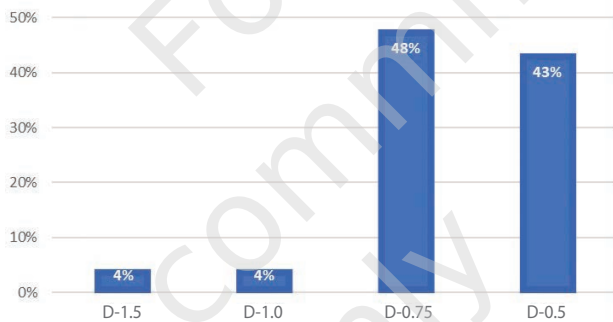


UDVA – uncorrected distance visual acuity.

FIGURE 2

43% of patients did not require spectacle correction for near reading. 91% of patients were able to read line D-0.75 or more on Snellen reading chart.

BINOCULAR UNVA

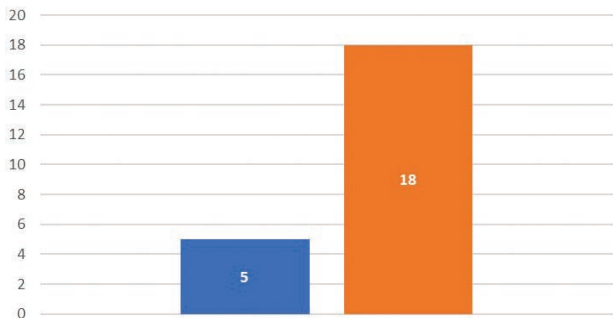


UNVA – uncorrected near visual acuity.

FIGURE 3

Halo or glare effect were noted in 5 cases but only in 2 of them these phenomenon resulted in lower score in patients' satisfaction questionnaire (to 64 and 79% of maximum score).

Dysphotopsias



92% of maximum score – it shows very high percentage of satisfied patients in both groups (fig. 4, 5).

FIGURE 4

In patient's satisfaction questionnaire score given by drivers was 90% of maximum.

Patient's questionnaire - drivers

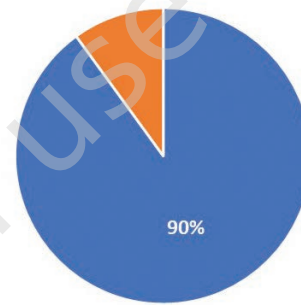
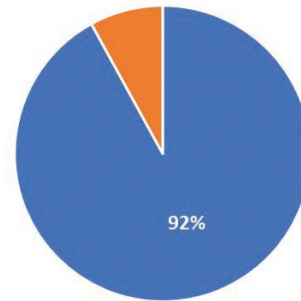


FIGURE 5

In patient's satisfaction questionnaire score given by non-drivers was 92% of maximum.

Patient's questionnaire - non-drivers



CONCLUSION

The Rayner RayOne EMV IOL set to mini-monovision seems to offer a very good visual quality for both distance and intermediate and quite well near vision which gives a reasonably high degree of spectacle independence with relatively low risk of dysphotopsia at a moderate price. It is a good option for patients who are not willing to accept high cost of trifocal or EDOF IOLs but who are expecting they will be able to get rid of glasses for most of their everyday activities while accepting spectacles for a small print or longer reading under low light conditions.

From the surgeon's point of view it is a good quality lens, easy to implant, while offering a stable intracapsular positioning and rotation, which is especially important when implanting the toric version of the same IOL. It offered good intracapsular centration, stability and the preloaded

cartridge sped up the implantation process and at the same moment did not create any problems while implanting the lens. The IOL power calculation with the IOL Master 700 was precise and the post-operative refraction was within the desired values. For toric IOLs there was no case of unwanted lens rotation during the follow-up.

To sum up, this technique is an affordable and valuable option for patients who would like to increase their spectacle independence postoperatively and should be considered along with premium multifocal IOLs as an option availa-

ble for patients based on their needs, preferences and clinical indications. Reducing spectacle dependence with the pseudophakic mini-monovision technique could improve the functionality, independence and quality of life for many patients who are unsuitable or are unable to pay additional fees associated with premium multifocal IOLs.

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APPENDIX A. PATIENT'S QUESTIONNAIRE

Please answer all the questions below. They all concern situations when you are not wearing glasses (neither reading nor ones for the distance).

- (1) Do you have any difficulty reading small print, such as labels on medicine bottles, a telephone book, food labels?
- (2) Do you have any difficulty reading a newspaper or a book?
- (3) Do you have any difficulty reading a large-print book or large-print newspaper or numbers on a telephone?
- (4) Do you have any difficulty recognizing people when they are close to you?
- (5) Do you have any difficulty seeing steps, stairs or curbs?
- (6) Do you have any difficulty reading traffic signs, street signs, or store signs?
- (7) Do you have any difficulty doing fine handwork like sewing, knitting, crocheting, carpentry?
- (8) Do you have any difficulty playing games such as bingo, dominos, card games, chess?
- (9) Do you have any difficulty taking part in sports or rehabilitation exercises?
- (10) Do you have any difficulty watching television?
- (11) Do you have any difficulty using computer?
- (12) Do you have any difficulty using your smartphone?

Response Points:

4. none	3. a little difficulty	2. a moderate amount of difficulty	1. a great deal of difficulty	0. I am not able to do this
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Driving

(13) Do you currently drive a car?

if Yes, go to 14 if No, go to 16

(14) How much difficulty do you have driving during the day because of your vision?

(15) How much difficulty do you have driving at night because of your vision?

Response Points

4. none	3. a little difficulty	2. a moderate amount of difficulty	1. a great deal of difficulty
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(16) Do you experience glare and / or halo (effect of strong light like camera flash or bright circles around light source)?

1. Yes	0. No
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APPENDIX B. NEAR VISION CHART

D - 0.5

Liczba chorych na cukrzycę wzrasta lawinowo, a Światowa Organizacja Zdrowia uznała tę chorobę za epidemię XXI wieku. W Polsce, według raportu NFZ z 2019 roku, z cukrzycą żyje blisko 3 mln osób (9,1% populacji). Średnio u co trzeciego chorego dojdzie do rozwoju retinopatii cukrzycowej. Częstość jej występowania zwiększa się wraz z czasem trwania choroby podstawowej.

D - 0.75

Czynniki zwiększającymi ryzyko rozwoju retinopatii cukrzycowej są: brak wyrównania metabolicznego choroby podstawowej, nieprawidłowy profil lipidowy, a także nadciśnienie tętnicze. Niestety, u części chorych na cukrzycę, pomimo prawidłowych parametrów wymienionych badań, dojdzie do rozwoju

D - 1.0

mikroangiopatii. Komórki śródbłonna wyścielają wewnętrzną powierzchnię wszystkich naczyń krwionośnych, w tym naczyń kapilarnych siatkówki. Powierzchnia śródbłonna jest pokryta mieszaniną

D - 1.25

glikoprotein i proteoglikanów określaną jako glikokaliks. W przebiegu cukrzycy jeszcze przed wystąpieniem widocznych w badaniach diagnostycznych/obrazowych wykładników morfologicznych uszkodzenia ciągłości

D - 1.5

i funkcji śródbłonna dochodzi do ścięnięcia warstwy glikokaliks w łożysku naczyniowym w tym naczyniach siatkówki. W cukrzycy wykazano

D - 2.0

ścięczenie warstwy glikokaliksu w śródbłonku naczyń krwionośnych, co powodowało większą

D - 2.25

przepuszczalność ich ściany

D - 3.0

dla makrocząsteczek.

Authors' contributions:

Dorota Maria Kaczmarek: conceptualization, methodology, validation, formal analysis, investigation, writing, review and editing, project administration.

Radosław Kaczmarek: conceptualization, review and editing, supervision.

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Conflict of interest:

None.

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Ethics:

The content presented in the article complies with the principles of the Helsinki Declaration, EU directives and harmonized requirements for biomedical journals.