ARTYKUŁ PRZEGLĄDOWY REVIEW ARTICLE

DOI: 10.24292/01.OT.300324.4

Monofocal plus – future or present?

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HIGHLIGHTS

Monofocal plus IOLs allow patients to achieve independence from spectacles.

ABSTRACT

The implantation of extended deep-of-focus intraocular lenses during cataract surgery allows patients to achive spectacles independence. Correct calculation of the power of the lenses and the use of monovision significantly improves the level of satisfaction after the procedure. The choice of the target postoperative refraction of the dominant eye within the limits of emmetropia and the non-dominant eye with slight myopia within the range of -1.0 D can provide satisfactory visual acuity for a long distance, intermediate and near vision, without the need for glasses. Some authors classify some types of monofocal plus on an equal footing with lenses with an extended depth of focus. They are the latest solution in cataract surgery and are characterized by a low tendency to cause side effects typical of multifocal lenses.

Key words: EDOF, monovision, monofocal plus, phacoemulsification

INTRODUCTION

To function properly, our eye needs a clear lens that is correctly positioned. This small structure, located in the eye, is responsible for focusing light to produce a clear image on the retina and for accommodation. The most common reason for replacing the lens with an artificial implant is lens opacity, a condition known as a "cataract", which is now the leading cause of reversible visual impairment in people over 60 years of age [1]. An artificial lens implantation is used to treat angle-closure glaucoma or to correct vision [2, 3].

There are three types of senile cataracts, depending on the anatomical location of the lesions. The most common type is the nuclear cataract, which primarily reduces visual acuity for distance vision while retaining the ability to read at near distance. The cortical location of the opacities causes glare, greater sensitivity to light, and impaired near vision. Patients with posterior subcapsular cataracts, which can be caused by glucocorticosteroids, may have improved visual acuity in low light conditions due to changes in pupil width. Therefore, such patients may experience difficulties while driving or during other activities involving strong eye lighting [4]. Hypermature cataracts can lead to glaucoma, uveitis, or other conditions that may result in vision loss [5]. The most effective treatment for cataracts is to undergo cataract surgery with artificial IOL implantation [6].

The elderly population is living longer, which has led to an increased prevalence of cataracts and a growing need for cataract surgeries. Therefore, surgeons face a major challenge in ensuring postoperative quality of both near and far vision [7]. The World Health Organization estimated that in 2020 a total of 32 million phacoemulsification surgeries were performed, an average of 86,000 per day. These figures highlight the significance of finding optimal solutions for cataract patients [8].

The rapid development of materials engineering and surgical techniques in recent decades has led to the evolution of cataract removal surgery towards one-day surgery with rapid patient recovery and few complications. Thanks to the ongoing research and the development of new intraocular lens solutions, it is now possible to simultaneously treat cataracts, astigmatism, and presbyopia [9]. The increasing ubiquity of digitalization has led to a growing reliance on smartphone screens for online shopping or scheduling medical appointments. Consequently, patients who have undergone cataract surgery are more frequently expecting improved post-operative visual acuity and greater independence from glasses.

TYPES OF INTRAOCULAR LENSES

Currently, patients can choose from monofocal, extended depth-of-focus (EDOF), or multifocal lenses. However, each of these options has its own limitations. Therefore, it is the ophthalmologist responsibility to select the most suitable option based on the patient's anatomical conditions and capabilities. Monofocal plus lenses combine features of monofocal IOLs and EDOFs. Some authors include them in the EDOF group, while others suggest classifying them separately.

Monofocal lenses provide clear vision at only one distance, which means patients may need to use glasses for near or distance vision. A potential solution to this problem may be monovision, where the dominant eye is set to zero refraction for distance vision and the non-dominant eye is set for intermediate or near distances. However, this approach may result in loss of depth perception. Moreover, not all patients are good candidates for monofocal IOLs [10, 11].

However, it is important to note that the traditional use of monofocal lenses is associated with a loss of vision at intermediate distances, which can often impact patient satisfaction with the procedure. Despite these limitations, monofocal lenses remain the most widely used solution due to their affordability and ease of implantation. Monofocal lens manufacturers use four approaches to address asphericity. One approach is to use non-aberration lenses that do not generate spherical aberrations. An example is the RayOne Aspheric IOL with an asphericity of 0.00 µm. This type of implant does not interfere with naturally occurring corneal aberrations (+0.27 µm) and has the advantage of being less prone to causing visual disturbances when the implant is decentered or tilted.

The purpose of negative aberration IOLs is to compensate for the cornea positive spherical aberration. For instance, the Johnson & Johnson TECNIS Monofocal 1-Piece IOL (-0.27 µm) aims to create an aberration-free system in the eye, resulting in a sharp image. However, it lacks depth of focus due to a slight refractive error and lens decentration, which can significantly reduce patient satisfaction. Implants with negative spherical aberration of more than -0.27 µm can expand patient's depth of focus. For example, Johnson & Johnson Vision TECNIS Eyehance IOL (-0.4 µm) falls into this category. Another group of IOLs was designed to increase depth of focus by generating positive aberrations. An example of such IOL is the RayOne EMV with a range of 0.12–0.15 µm. These two groups of lenses are referred to as 'monofocal plus', and some authors classify them in the same category as EDOFs.

The implantation of an artificial intraocular lens during cataract surgery has been associated with the loss of accommodation, which can result in presbyopia. To prevent this, multifocal and extended depth of focus (EDOF) IOLs have been found to be effective. Multifocal IOLs provide good visual acuity for both distance and near vision, but patients may experience issues with intermediate distances [12]. Proper alignment of the lens in the patient's eye is crucial for its optimal functioning, but even then, lower and higher

order aberrations that occur may lead to reduced contrast sensitivity [13, 14].

The lenses that offer optimal distance vision at intermediate distances and are free from the visual disturbances associated with multifocal lenses can fill the gap between monofocal and multifocal lenses. EDOF and monofocal plus lenses meet most of these requirements, and monofocal lenses improve spectacle independence [15].

DIVISION OF EDOF IOLs

Many types of EDOF lenses produce a single elongated focal point that provides vision from different distances [9]. EDOF lenses can be divided into 5 types, each including dozens of different IOLs. This classification helps surgeons understand the differences and choose the optimal solution for their clinical practice [16].

Type 1 EDOF lenses are based on changes in positive and negative spherical aberrations to increase depth. However, the extended focus can decrease the quality of the retinal image. In some cases, explantation of the lens may be necessary, which raises questions about their effectiveness.

Type 2 lenses provide potential only for patients with irregular corneas. These lenses use the pinhole principle, which severely limits peripheral vision (30–60°) and can impede functioning in ambient lighting conditions.

Type 3 lenses offer satisfactory intermediate vision due to the similar defocus curve. However, they are actually multifocal lenses with all their problems and limitations, and a small addition for intermediate distances.

Type 4 lenses combine properties of multifocal IOLs and EDOFs. The extended focus is intended to compensate for some adverse effects commonly associated with multifocal lenses. While they may be beneficial for some patients, further research is needed to determine the actual number of adverse effects.

Professor Alio proposed **type 5** lenses characterized by variations in geometry in the central optical part, resulting in different power at the periphery and center. This group also includes lenses that can extend focus by modulating the light wavefront. This group of lenses does not cause dysphotopic phenomena and provides excellent vision for distant and intermediate distances. In some cases, patients may be fully spectacle independent [16].

TEST RESULTS

One representative of the latter group is the RayOne EMV IOL, launched in 2020 and classified by some authors as monofocal plus. These IOLs are implanted with a preloaded injector system, similar to the standard RayOne monofocal IOL. RayOne EMV IOLs are made of 26% hydrophilic-acrylic material; the overall diameter of the lens is 12.5 mm, and the optical part covers 6 mm. RayOne EMV IOL was designed in collaboration with Prof. Barrett and is the only aspheric lens that induces controlled spherical aberration. Thanks to its properties, it lengthens the optical ability towards hyperopia, which can be crucial for preserving stereopsis and long-distance vision in a non-dominant eye set to a slight disadvantage when choosing monovision. A calculation of this nature and the utilization of an appropriate target postoperative refraction serve to markedly enhance the percentage of patients who are satisfied with the outcome. The lack of reported higher-order aberrations following lens implantation can be attributed to slight differences in optical power in the central region of the lens [17]. Multicenter studies conducted in the United Kingdom, Spain, and Portugal were the first reports on RayOne EMV IOL.

Studies indicate that these lenses are stable in the capsular bag since their properties are not as dependent on pupil width, tilt, or decentration [18]. Ray-One EMVs currently appear to be the optimal solution for patients who have opted for intermediate monovision. In this case, a target refractive value is chosen for the dominant eye within the limits of emmetropia while shifting the non-dominant eye is adjusted toward myopia. The resulting difference of 0.75–1.5 D between the dominant eye providing distance vision and the non-dominant eye allowing to see at intermediate and near distances is very well tolerated.

Laboratory experiments have demonstrated that the RayOne EMV lens provides 1.5 D of extended depth of field, a value that is significantly greater than that of monofocal lenses. It is also noteworthy that, in some cases, researchers have opted not to perform an eye dominance test, and the obtained depth of field of 2.5 D was sufficient to make 70% of patients independent from glasses [19]. At follow-up 30 days after the procedure, none of the patients reported dysphotopic phenomena, halo, haze, or problems climbing stairs [20]. Tecnis Eyhance lens (Johnson & Johnson Vision), referred to as monofocal plus, belongs to the same group of lenses. Ferreira et al. compared Tecnis Monofocal 1-Piece (Johnson & Johnson Vision), Tecnis Eyhance (Johnson & Johnson Vision), Symfony (Johnson & Johnson Vision), AcrySof IQ Vivity (Alcon), and RayOne EMV (Rayner) lenses [21]. The analyzed groups included 30 patients each, who were implanted with the same lenses in both eyes. Authors conducted a comprehensive analysis of defocus curves, dysphotopsia profiles, contrast sensitivity, and patients' independence from glasses. In terms of defocus curves, Vivity and Symfony had very similar properties to RayOne EMV lens.

Tecnis Monofocal 1-Piece and Tecnis Eyhance IOLs did not demonstrate the same properties as other IOLs. In the evaluation of visual acuity, the differences between the three lenses were minimal. Dysphotopsia was virtually absent in

patients with Ray-One EMV, with similar levels reported by patients with Tecnis Eyehance lenses. In the contrast sensitivity evaluation, the Tecnis Monofocal 1-Piece demonstrated superior performance, with a slight advantage over the RayOne EMV. The Symfony and Vivity lenses exhibited inferior results. In the assessment of eyeglass independence, RayOne EMV demonstrated a level of performance that was higher than that of Symfony's EDOF lens and comparable to that of the Vivity lens. It is also worth taking a look at the result of the Eyhance lens, which works on a similar principle to the RayOne EMV, with the only difference being that it uses negative spherical aberrations. The significantly lower independence from glasses proves that positive spherical aberrations are effective [21].

The average spherical aberration in the 6.0 mm optical zone is +0.27 μm. RayOne EMV lenses induce additional spherical aberrations at 0.12 to 0.15 μm, amplifying and complementing positive corneal aberrations to increase depth of field by about 1.5 D. The upper limit of spherical aberrations tolerated by patients ranges from 0.56 μm to 0.6 μm, above which they can cause dysphotopic phenomena, reduced visual acuity, and decreased contrast [21].

The modulation transfer function (MTF) coefficient is employed to assess the optical quality of lenses. For lenses exhibiting positive spherical aberration, the apex of the MTF curve is shifted to the right, resulting in the formation of a tail directed towards hyperopia. Conversely, in the case of lenses with negative spherical aberration, such as the Tecnis Eyhance, the apex of the curve is directed to the left, giving rise to the formation of a tail in the direction of myopia [21]. The defocus curves of the Tecnis Monofocal 1-Piece and Tecnis Eyhance lenses demonstrate that spherical aberrations are not significantly different at a pupil width greater than 2.5 mm. This finding may significantly limit the number of patients who will benefit from Tecnis Eyhance lens implantation. According to Royo et al., all patients were able to cease wearing glasses for intermediate and distance vision after RayOne EMV binaural implantation, with a 1.5 D improvement in near visual acuity [23]. A comprehensive analysis of the economic aspects, patient satisfaction, and safety of the procedure performed has led to the conclusion that this group of lenses has the potential to become a leader in the field. The use of monofocal plus lenses allows ophthalmologists to develop their skills in a straightforward and secure manner, enabling a seamless transition from monofocal lenses to more challenging lenses that provide useful vision at any distance. It has been observed that the level of satisfaction experienced by patients following phacoemulsification is significantly influenced by their ability to perform activities of daily life without the need for ocular correction at intermediate distances. This ability is more useful than the ability to read the finest text from a distance of 30 cm [14].

The number of scientific reports remains limited, and further studies on a larger group of patients are necessary. However, the efforts of manufacturers indicate that monofocal plus lenses may become the standard for every patient undergoing surgical cataract removal in the near future.

OWN EXPERIENCE

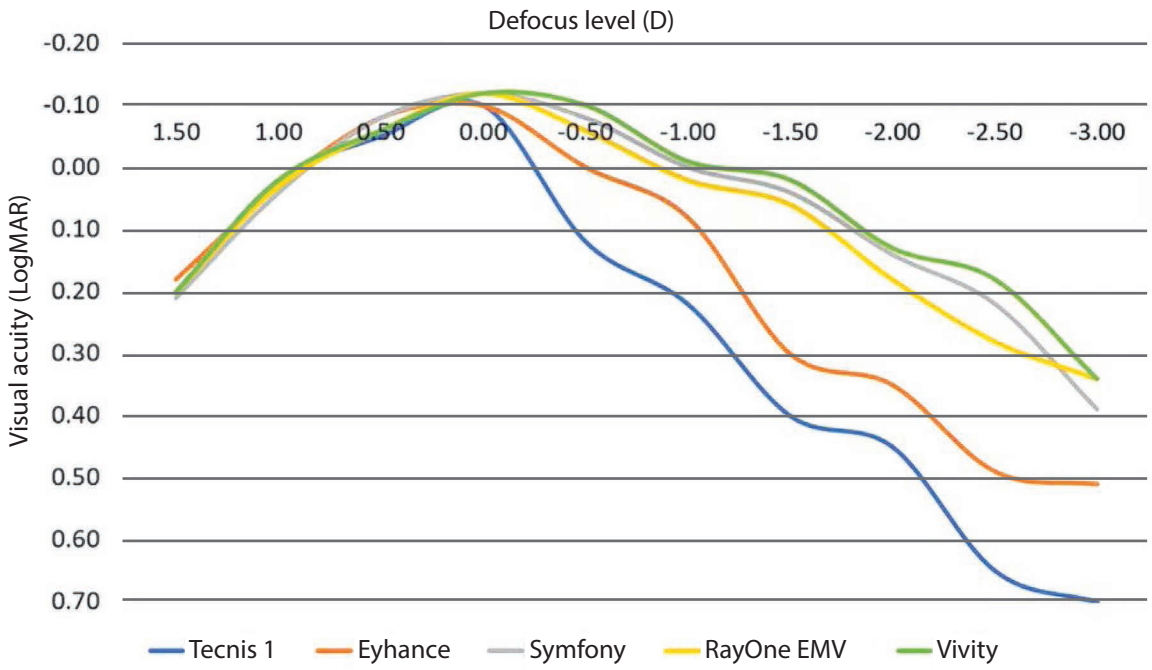
The Ophthalmology Department in District Health Care Center in Będzin offers monofocal plus lenses to all patients undergoing cataract removal surgery, which is fully reimbursed by the Polish National Health Fund. Our institution performs nearly 3,000 lens replacement procedures annually. The initial outcomes of patients treated with the aforementioned solutions have been highly encouraging, substantiating the innovative nature of these techniques. Patient's preoperative preparation, ward stay, surgery, and postoperative period is identical to that of routine interventions. After several hundred treatments, we observed the intended refraction to be correct and noted stable positioning of the RayOne lens in the capsular bag.

Patients who selected a target postoperative refraction close to 0 often achieved a LogMAR visual acuity of 0.0–0.1. The same group of patients had LogMAR 0.35 visual acuity to intermediate distances (about 65 cm) without spectacle correction, allowing them to read medium-sized text with ease. Evaluation from a distance of 40 cm oscillated around LogMAR 0.4. The aforementioned measurements were conducted 30 days following the procedure.

It is also notable that micromonovision, or target postoperative refraction, is well tolerated in the dominant eye within emmetropia, and for the non-dominant eye, approximately -1.0 D. This solution will help optimize the utilization of the offered lens, thereby enhancing the level of services provided. The data presented were of considerable interest, particularly in relation to patients with medium and high myopia who chose to wear corrective glasses even after undergoing surgery. A significant number of patients were able to achieve logMAR 0.1 near visual acuity as early as 14 days after surgery, while simultaneously achieving full visual acuity for distance with the same glasses (-2.0 D), with the expected post-operative refraction of -2.0 D. The use of this enhanced lens led to a high level of patient satisfaction with the resulting outcomes. Both RayOne EMV and RayOne EMV toric implants are employed in conjunction with other surgical procedures for patients diagnosed with glaucoma. A review of the medical literature reveals that the simultaneous performance of lens replacement and micropulse transcleral laser therapy (MP-TLT) using the Cyclo G6 apparatus (IRIDEX, Mountain View, CA, USA) is a safe and effective procedure. The achieved decrease in intraocular pressure and improvement in visual acuity are promising.

FIGURE 1

Binocular photopic defocus curves [22].



CONCLUSIONS

The observation period is short, so definite conclusi ons cannot be drawn. However, there are indications that the proposed solutions may be groundbreaking. The large scale of the undertaking will contribute to a better understanding and further development of cataract surgery. The RayOne EMV monofocal plus lens should be introduced as a standard option for all patients undergoing cataract surgery in public health facilities. This recommendation is based on the positive patient outcomes, high satisfaction levels, and numerous benefits of this lens.

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Authors' contributions:
Adam Kabiesz – idea for the work, development of the material, writing the manuscript; Joanna Grzbiela – collection of literature and linguistic corrections; Damian Skorupka – collection of literature and language corrections; Patryk Zemła – collection of literature and language corrections; Alfred Niewiem – collection of literature and linguistic corrections.

Conflict of interest:
None.

Financial support:
None.

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