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ORIGINAL ARTICLE

# Optimising image quality with EyeMax Mono lens in dry age-related macular degeneration

**Hamidu Hamisi Gobeka**[1] · **Tansu Erakgün**[2]

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## Abstract

**Background** To investigate clinical outcomes in patients with dry age-related macular degeneration (AMD) after intracapsular implantation of a novel EyeMax Mono macular lens.

**Methods** In this study, 22 phakic eyes of 19 moderate to advanced dry AMD patients with macular disciform scar and/or macular atrophy who were followed up for ≥ 3 months after surgery were studied. A thorough pre-operative ophthalmological examination was performed, including measurement of corrected distance visual acuity in logMAR and ETDR. Following phacoemulsification, the EyeMax Mono lens was implanted intracapsularly via a 2.2-mm clear corneal incision to improve retinal image quality in all areas of the macula ≤ 10° from the central fovea. Main outcome measures included optimisation of corrected distance visual acuity and surgical safety.

**Results** Male-to-female ratio was 13:6. Mean age at surgery was 68.37 ± 10.23 years. The mean duration of post-operative follow-up was 7.91 ± 3.42 months. The mean post-operative refractive spherical equivalent improved to + 2.31 ± 1.56 D with significant visual improvement as early as 3 months post-operatively. Post-operative corrected distance visual acuity improved significantly from 1.05 ± 0.45 to 0.72 ± 0.43 logMAR ($P < 0.001$), equivalent to mean ETDRS of 49.55 ± 20.05 ($P < 0.001$). There were no major surgical complications, either intra- or post-operatively, except in two patients who experienced intra-operative haptic rupture.

**Conclusions** Extended macular vision lenses appear to have a comparable safety profile as standard IOLs in the short to medium term. It could be the preferred lens for improving and preserving visual acuity in moderate to advanced dry AMD patients.

**Keywords** Cataract · Dry age-related macular degeneration · EyeMax Mono macular lens · Visual acuity

## Background

Age-related macular degeneration (AMD) and cataracts are age-related disorders that can occur concurrently in the elderly. Loss of the central visual field and deterioration of contrast sensitivity are associated with progressively lower visual performance and reading ability, both of which have a significant impact on living standards. Cataract extraction by phacoemulsification is a safe and effective procedure that may improve vision without increasing the risk of progression to exudative AMD [1–3].

Generally, AMD patients undergoing cataract extraction frequently are provided with standard monofocal IOLs, prism IOLs or telescopic IOLs [4–7]. The EyeMax Mono™ (London Eye Hospital Pharma, London, UK), on the other hand, is a novel category of injectable, soft acrylic, expanded macular vision lenses using a hyper-aspheric model to expand a breadth of focus and boost the retinal image quality provided throughout the macula area at ≤ 10° retinal eccentricity [8, 9]. It has been reported to generate excellent image quality at 4° and 7.5° of retinal eccentricity when compared to standard monofocal IOLs [8]. There are, if any, very few literary articles with expertise in the clinical implementation of this very novel intraocular device and its subsequent visual outcomes.

✉ Hamidu Hamisi Gobeka
hgobeka@gmail.com

Tansu Erakgün
terakgun@hotmail.com

[1] Department of Ophthalmology, Afyonkarahisar Health Sciences University Faculty of Medicine, Afyonkarahisar, Turkey

[2] Kaşkaloğlu Eye Hospital, Izmir, Turkey

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The purpose of the current study was to investigate the short- and medium-term clinical outcomes following a novel EyeMax Mono macular lens intracapsular implantation in dry AMD patients.

## Materials and methods

### Study design and participants

This interventional study included 22 phakic eyes of 19 moderate to advanced dry AMD patients who were followed up for ≥ 6 months at Kaşkaloğlu Eye Hospital in Izmir, Turkey. The study procedure complied with the ethical standards of the Helsinki Declaration and was completely approved by the Ethics Committee of the Institutional Review Board. Before obtaining consent, each patient was told of the study.

Patients with dry AMD who had ≥ 3-month post-operative follow-up period were studied. However, patients with the following conditions were excluded from the study: (a) comorbidities that could be exacerbated by IOLs and/or render IOLs ineffective, including corneal and retinal disorders; (b) glaucoma; (c) pseudo-exfoliation syndrome or pre-existing zonular pathology; (d) a history of uveitis (anterior, intermediate, posterior or pan-uveitis) and white-to-white measures < 11.5 mm; (e) a corrected distance visual acuity ≥ 20/40 and (f) an involvement of sub-retinal or intraretinal fluid consistent with exudative AMD.

All eyes had moderate to advanced dry AMD with macular disciform scar and/or macular atrophy. And, they were regarded as having stable dry AMD once clear of any active choroidal neovascularisation for ≥ 3 months with no need for intravitreal anti-vascular endothelial growth factor therapy. Peri-operative complications were identified parallel with the rates listed for major complications in the American Academy of Ophthalmology Preferred Practice Pattern for Adult Cataract (2016) [10].

### Participant assessment

A complete pre-operative ophthalmological evaluation was performed, including corrected distance visual acuity measurements in logarithm of the minimum angle of resolution (logMAR) and Early Treatment Diabetic Retinopathy Study (ETDRS), Goldmann applanation tonometry intraocular pressure (IOP, Goldmann; Haag-Streit AG, Köniz, Switzerland) and an anterior–posterior segment slit-lamp biomicroscopy. Pre-operative evaluation of the anterior segment with Pentacam (Pentacam HR, Oculus, Wetzlar, Germany) and fundus photography, as well as macular analysis using SPECTRALIS® optical coherence tomography (Heidelberg Engineering, Heidelberg, Germany) was also performed. The following parameters were measured during the pre- and post-operative periods: (a) full refractive spherical equivalents (SEs), (b) corrected distance visual acuity, (c) IOP and (d) macular optical coherence tomography (total maculopathy area relative to optic disc area). Complications that occurred during the intra- and post-operative periods were also documented. The implant's location was determined post-operatively using anterior segment optical coherence tomography (Visante® OCT, Carl Zeiss).

### The EyeMax Mono lens specifications

The EyeMax Mono™ macular lens is an implantable device that consists of a soft, single-piece hydrophobic acrylic lens delivered in a pouched blister pack. Each lens comes with its own lens injection system, which includes one single use soft-tipped injector and one single use cartridge. Following the removal of the crystalline lens, a modified C loop haptic lens is injected into the eye and positioned intracapsularly via a 2.2-mm corneal incision. The lens surfaces are produced with distinctive wave-front features that create high-quality images on all areas of the neighbouring retina that AMD patients are using for vision, i.e. proprietary hyper-wave-front modification for pan-macular optic design. The EyeMax Mono™ macular lens is also intended to be used in combination with traditional external spectacles to magnify objects on the retina, thereby boosting vision even further. This method is an exquisite and efficient approach to allow greater magnification for close objects (10–30%), thereby enhancing reading or smartphone use. If the patients' macular disease worsens, they can proceed to use various preferred retinal locus throughout the whole macular area as long as visual function is preserved. As a result, providing a high-quality image with decreased blur in areas of the macula extending up to 10° from the central fovea, at which photoreceptor cell densities are still high, may still offer better visual acuity. Image quality delivered to the macula can be improved even further by reducing chromatic aberration. Moreover, this implant has the following physical characteristics: 6.00-mm optic diameter; 13.00-mm overall length; 0° haptic angulation; ultraviolet and high-energy blue light filtration capability and a refractive index of 1.525. An estimated A-constant using optical biometry SKT is 119.2 or SRKII is 119.6. Powers are available in 2 D steps from 11 to 25 D, and refractive target ranges from plano to + 3.00 D post-operatively.

### Pre-operative IOL power determination

This implant typically requires a reasonable post-operative refractive target for a magnification of up to 1.2 D, which can sometimes be adjusted at the surgeon's discretion depending on the extent of maculopathy. The IOL Master® 500 (Carl Zeiss Meditec) was used for pre-operative biometric

assessments in this study. As previously stated, the lens power was determined using the SKT formula with an A-constant of 119.2 to achieve a post-operative refraction of 0 to + 3.00 D.

### Surgical intervention

All surgical procedures were performed under topical anaesthesia by the same surgeons (HHG and TE) using standard cataract extraction techniques. Following pupil dilation with topical mydriatic agents, two-step clear cornea main incision was positioned at 12 o'clock using a metal keratome (slit knife, 2.2-mm angled, Alcon, Fort Worth, TX), while the single-plane side-port incisions were positioned at 9 and 3 o'clock using a metal keratome (1.2-mm sideport knife, dual bevel, Alcon). Instillation of 1% sodium hyaluronate solution (Healon, Abbott Medical Optics, Santa Ana, CA) into the anterior chamber for endothelium protection was done, followed by a 5-mm capsulotomy and phacoemulsification procedure using Alcon's Centurion Vision System (Alcon laboratories, Inc. Fort Worth, TX) through the clear cornea main incision. A cohesive ophthalmic viscoelastic device was delivered into intracapsular space and the IOL was loaded into an injector cartridge, followed by intracapsular implantation, lens centration and ophthalmic viscoelastic device/balanced salt solution exchange. After diligent ophthalmic viscoelastic device aspiration and intracameral corticosteroid and anti-biotherapy administration, all eyes were patched.

The standard post-operative treatment regimen was prescribed with topical dexamethasone 0.1% and topical antibiotics eight times daily for the first week, and the dose was slowly reduced over a period of 1 month. Subjective refraction was performed at least 1 month post-operatively.

### Statistical analysis

Decimalised corrected distance visual acuities were converted to logMAR and ETDRS values. Categorical data were described using observed frequencies and percentages, and continuous variables were summarised by their means and standard deviations (or medians and interquartile ranges in case of serious deviations from normality) with statistical package (SPSS Inc., version 25.0, Chicago, IL, USA). Non-parametric Brunner and Langer model (F1-LD-F1) was used to test group and dependent time effects by using a web-based software (R software, version 3.5.2, package: nparLD, R Foundation for Statistical Computing, Vienna, Austria; http://r-project.org). Depending on the results, comparisons between matching pre- and post-operative variables were performed using either the paired two-tailed *t*-test (in case of normal distribution) or the Wilcoxon matched-pairs signed rank test (when non-parametric test was required). Post-operative corrected distance visual acuity was compared using the Kruskal–Wallis *H* test among patients with cataract grade 2, grade 3 and clear crystalline lens. The non-parametric Spearman correlation method was conducted to analyse the correlation between post-operative corrected distance visual acuity and patient age. The statistical significance level was set at $P < 0.05$.

## Results

Twenty-two eyes of 19 moderate to advanced AMD patients, the majority of whom were males (68.41%), were studied. Table 1 summarises the demographic features of the patients. The mean pre- and post-operative IOPs were $4.60 \pm 2.96$ and $14.18 \pm 2.75$ mmHg, respectively ($P = 0.277$). Only two patients (9.1%) experienced intra-operative IOL haptic rupture, which was resolved instantaneously by replacement with another IOL. No complications were identified during the entire post-operative follow-up period.

### Refractive SEs

The overall mean post-operative refractive SE improved significantly compared to pre-operative refractive SE ($P < 0.001$). This was accompanied by a strong positive correlation between overall mean pre- and post-operative refractive SEs ($P = 0.001$; $r = 0.911$) (Table 2; Fig. 1). There was also a significant correlation between post-operative SE and follow-up time ($P = 0.029$; $r = 0.466$).

**Table 1** Demographic features of the patients

| | |
|---|---|
| Mean age (years) | $68.37 \pm 10.23$ (min. 45; max. 80) |
| Males/females | 13 (68.41%)/6 (31.57%) |
| Laterality (right:left) | 13 (59.10%):9 (40.90%) |
| Follow-up period (months) | $7.91 \pm 3.42$ (min. 3; max. 16) |
| Cataract grade | |
| Grade 2 | 16 (72.70%) |
| Grade 3 | 3 (13.60%) |
| Clear crystalline lens | 3 (13.60%) |
| Maculopathy | |
| Macular atrophy | 7 (31.80%) |
| Macular scar | 15 (68.20%) |
| Size of centre-involving maculopathy with either atrophy or scar | |
| Less than 3 optic disc area | 13 (59.10%) |
| Greater than 4 optic disc area | 9 (40.90%) |
| Prior therapy | |
| Aflibercept or ranibizumab | 11 (50.00%) |
| None | 11 (50.00%) |

**Table 2** Pre- and post-operative changes in refractive SEs and mean corrected distance visual acuity in dry AMD patients

| Refractive SE | | | |
|---|---|---|---|
| Eyes | Pre-operative | Post-operative | *P* value* |
| Myopes ($n=10$) | $-3.00 \pm 2.87$ | $-0.38 \pm 0.18$ | 0.001 |
| Emmetropes ($n=2$) | $0.00 \pm 0.00$ | $0.00 \pm 0.00$ | |
| Hypermetropes ($n=10$) | $2.57 \pm 1.49$ | $2.59 \pm 1.36$ | 0.001 |
| Overall ($n=22$) | $-0.19 \pm 3.45$ | $2.32 \pm 1.56$ | 0.001 |
| Corrected distance visual acuity | | | |
| Eyes | Pre-operative (logMAR) | Post-operative (logMAR) | *P* value* |
| Macular scar | $1.27 \pm 0.34$ | $0.913 \pm 0.389$ | 0.001 |
| Macular atrophy | $0.59 \pm 0.26$ | $0.317 \pm 0.139$ | 0.018 |
| Overall | $1.05 \pm 0.450$<br>ETRDS $33.409 \pm 21.009$<br>ETDRS difference<br>$16.136 \pm 8.155$ | $0.724 \pm 0.433$<br>ETDRS $49.545 \pm 20.054$ | 0.001 |

*Wilcoxon signed ranks test, *AMD* age-related macular degeneration, *SE* spherical equivalents, *n* number of eyes, *logMAR* logarithm of the minimum angle of resolution, *ETDRS* Early Treatment Diabetic Retinopathy Study chart

## Corrected distance visual acuity

The overall mean pre-operative corrected distance visual acuity improved from $1.05 \pm 0.45$ logMAR to $0.72 \pm 0.43$ logMAR (ETDRS: $49.55 \pm 20.05$) post-operatively ($P < 0.001$), equating to an average ETDRS gain of $3.22 \pm 1.63$ lines (Table 2; Fig. 2). No significant correlation between post-operative corrected distance visual acuity and patient age was observed ($P = 0.675$; $r = -0.103$).

### Size of the centre-involving maculopathy versus post-operative corrected distance visual acuity

Patients with less than three and greater than four optic disc areas of maculopathy with either atrophy or scar had mean post-operative corrected distance visual acuities of $0.59 \pm 0.41$ logMAR and $0.91 \pm 0.41$ logMAR, respectively ($P = 0.069$).

### Cataract grade versus post-operative corrected distance visual acuity

Patients with grade 2 cataract, grade 3 cataract and clear crystalline lens had median post-operative corrected distance visual acuities of 0.75 logMAR (min: 0.20, max: 1.80), 0.50 logMAR (min: 0.30, max: 1.00) and 0.70 logMAR (min: 0.20, max: 0.80), respectively ($P = 0.728$, Kruskal–Wallis *H* test).

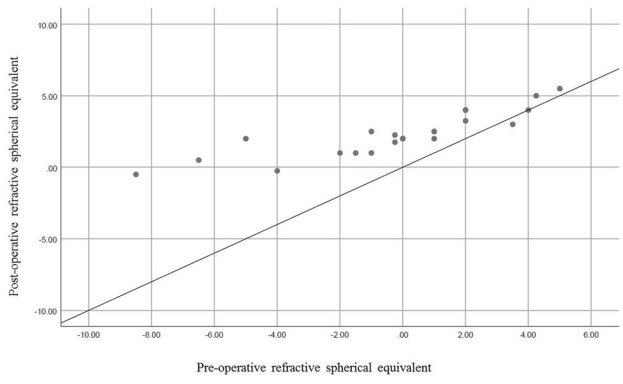


**Fig. 1** Illustration of a strong positive correlation between the overall pre- and post-operative mean refractive spherical equivalents

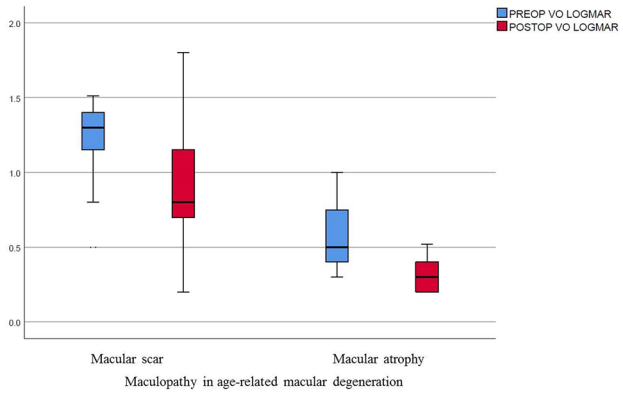


**Fig. 2** Illustration of a significant improvement in post-operative mean corrected distance visual acuity in eyes with macular scar and atrophy, respectively

### Prior AMD therapy versus post-operative corrected distance visual acuity

The mean post-operative corrected distance visual acuities in patients with prior therapy (aflibercept or ranibizumab) and naïve patients were 0.85 ± 0.31 logMAR and 0.60 ± 0.52 logMAR, respectively ($P = 0.068$).

### Bilateral EyeMax Mono lens implantation

Six of the nine pseudophakic eyes with prior implanted EyeMax Mono lenses in the contralateral eye, accounting for 27.3% of the total investigated eyes, were associated with comparatively better mean post-operative corrected distance visual acuity [0.88 logMAR (range: 0.20–1.80)] than unilateral EyeMax Mono lens implantation (Fig. 3a, b).

## Discussion

The current study describes the clinical outcomes of a novel EyeMax Mono lens implantation in dry AMD patients. This implant is a single-piece, hydrophobic acrylic lens designed to improve the retinal image quality provided by standard IOLs, allowing patients with single or multiple preferred retinal locus to extract maximum benefit from the healthiest parts of the macula. It is referred to as a new category of a

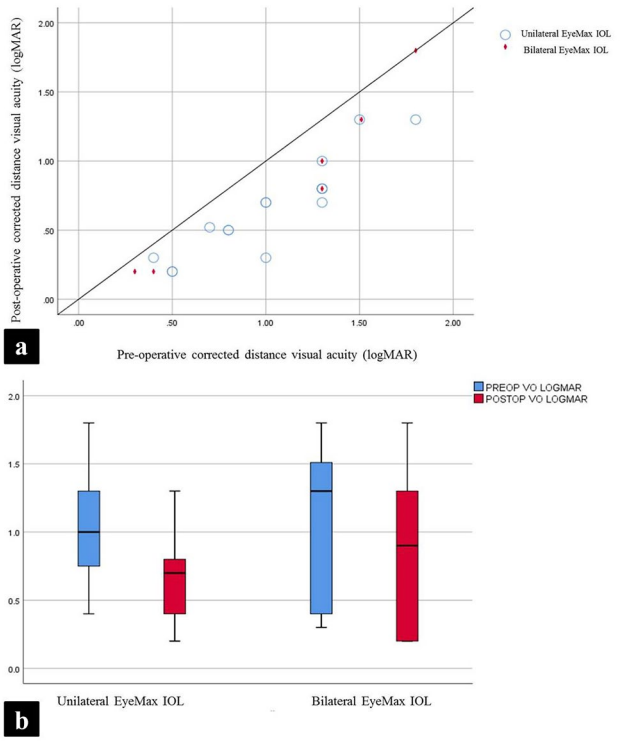


**Fig. 3** Illustration of the relationship between a bilateral implantation of the EyeMax Mono lens and a comparatively improved post-operative mean corrected distance visual acuity relative to a unilateral implantation in the **a** scatter plot and **b** box plot

'widened macular vision' IOL, with the goal of maximising image transmission to the broad macula and not only to the central fovea [11].

With the number of AMD patients anticipated to rise significantly in the foreseeable future, along with an increased aged population, the socio-economic burden of AMD, which accounts for 8.7% of blindness cases globally, is inescapable [12, 13]. Treatment alternatives are typically restricted to a subset of patients with choroidal neovascularisation. Other interventions are basically supportive, including visual assistances or preventive actions such as dietary supplementation [14]. The functional and optical disadvantages of portable and spectacle-mounted visual assistances led to the development of intraocular telescopes [15, 16].

More than 22 million people suffer from age-related cataracts in the USA [17], with the number expected to rise to around 30 million by 2020 [18]. Thus, several AMD patients aged over 60 years are likely to undergo cataract surgery as the disease progresses [19]. The surgical alternatives for such patients are typically restricted to standard IOLs developed to deliver a tightly focused image at the central fovea and telescopic IOLs with an implantable miniature telescope (IMT; VisionCare Ophthalmic Technologies) [20], the IOL-VIP™ (Soleko) [21] and iolAMD® (London Eye Hospital Pharma) [22–24] that have less desirable risk/benefit characteristics, which involve elevated incidence of both intra- and post-operative concerns, resulting in decreased peripheral visual field, which in some cases restricts their usage to a single eye only [25]. None of the above alternatives promotes patients' natural propensity to develop an emerging preferred retinal locus in areas of the macula remaining fairly undamaged by geographical atrophy or macular scar [7]. Earlier reports revealed that both standard IOLs and natural crystalline lenses could potentially degrade visual function in AMD patients due to a massive decline in the retinal image quality created beyond fovea, although the cone density is still significantly greater [3, 5, 26].

While cataract surgery appears to be safe in short- to medium-term in AMD patients, guidelines for surgery, particularly dry AMD with the centre-involving large macular atrophy and/or scar, remain poorly established. Hence, further studies are required to assess its position regarding visual recovery and long-term consequences on the visual function in this group of patients [3, 27]. The extended macular vision technology, on the other hand, may provide considerable advantages over standard IOLs in promoting patients' natural adaptive mechanisms and may appear to preserve visual function longer in progressive disease without necessitating eccentric vision training, additional surgery and/or preventive procedures. A consecutive case series [8] in which 244 eyes with dry/stable wet AMD and VA ≥ 0.3 logMAR were implanted with iolAMD EyeMax Mono recorded safety results that were comparable to those

found after standard IOL implantation [28–30]. These results corresponded favourably with cataract surgery outcomes in AMD patients implanted with standard IOLs, as seen in a recent meta-analysis revealing that corrected distance visual acuity increased by 6.5–7.5 ETDRS letters after 6–12 months [3].

Consistent clinical results were observed in the current study, including significantly improved post-operative refractive SE within a reasonable post-operative refractive target of + 2 D to + 3.5 D for magnifications up to 1.2 D. In addition to a significant correlation between the overall pre- and post-operative refractive SEs, there was a significant correlation between post-operative refractive SE and follow-up time ($P = 0.029$; $r = 0.466$). This may point to a neuro-adaptive aspect to the new intraocular implant's visual improvement.

Moreover, the overall mean post-operative corrected distance visual acuity improved significantly, equivalent to an average ETDRS increase of $3.22 \pm 1.63$ lines. Patients with macular scar, however, were associated with a considerably improved post-operative visual recovery compared to those with macular atrophy. This an unanticipated finding might have arisen as a consequence of less centre-involvement of the macular scar, the number of patients with macular scar being more than twice as high as those with macular atrophy, which could have led to an unsuspected disparity in statistical outcomes, or the majority of patients with macular scar being over 60 years of age, reflecting relatively healthier retinal tissue, and thus, improved post-operative visual recovery. Notably, the improvements in corrected distance visual acuity with this implant tend to be significantly variable, depending on the severity and pattern of the residual functioning macula. Thus, additional large-scale long-term prospective studies are needed to collect more data.

The visual recovery spectrum is also anticipated to have a desirable cost–benefit and risk–benefit ratio relative to current AMD therapies, as with ranibizumab which produce less corrected distance visual acuity lines over an approximate time span and consequently leads to no visual recovery from pre-intervention over a 5-year period [31–33]. Therefore, improved corrected distance visual acuity found in the current study appears to be mainly due to the sophisticated optics of the EyeMax Mono lens.

Bilateral implantation of the EyeMax Mono lens is also expected to have a summative outcome, as experienced with standard IOLs, which can lead to more progress not just in reading capacity but also in several other daily tasks [34]. This hypothesis has been also supported by the current study that included AMD patients in which six of the nine pseudophakic contralateral eyes had previously implanted EyeMax Mono lenses, accounting for 27.3% of the total investigated eyes. Prior implanted EyeMax Mono lenses in the contralateral eye were associated with comparably more improved mean post-operative corrected distance visual acuity than unilateral EyeMax Mono lenses. It has also been proposed that both eyes be implanted with the EyeMax Mono lens in a brief amount of time to prevent dysphotopsia and/or diplopia. However, no such complaints were observed in patients with unilateral EyeMax Mono lenses in the current study. This indicates that there could be other mechanisms underlying these complaints, including peri-operative complications such as decentralisation due to novice surgeons, varying severity of AMD and accompanying comorbidities, prior ocular surgery as well as trauma affecting the entire ocular optical axis.

To our knowledge, no literature study on the EyeMax Mono lens has investigated clinico-pathological relations in AMD patients with respect to post-operative visual acuity and dry AMD-related factors, including age, AMD severity, level of scar and/or geographical atrophy, cataract severity and pre-operative AMD therapy. In this context, the current study found no significant correlation between post-operative corrected distance visual acuity and patient age ($P = 0.675$; $r = -0.103$). As anticipated, greater centre-involving maculopathy with either atrophy or scar was associated with a relatively lower mean post-operative corrected distance visual acuity, comparable to cataract severity, although the difference was not significant ($P = 0.069$ and $P = 0.728$, respectively). Moreover, compared to patients who had prior anti-vascular endothelial growth factor therapy, naive dry-AMD patients had a slightly better post-operative corrected distance visual acuity, though the difference was not significant ($P = 0.068$). Overall, while the findings are likely to differ significantly among AMD patients, especially because they almost always vary with retinal eccentricity, the density of cone photoreceptors varies markedly among patients and also with ageing [26]. Thus, pre-operative type and severity of AMD could be primarily potential determining factors of post-operative visual recovery extent of a patient.

The current study has some limitations. As far as AMD patients with differing centre-involving maculopathy are concerned, residual influence factors could have contributed to an unexplained analytical preference. Size of the study population was just not high enough to improve the study efficacy. Thus, long-term large-scale comparative studies with other telescopic lenses, to determine the efficacy and effectiveness of this novel extended macular IOL technology, could lead to different significant clinical outcomes. The role of extended macular vision technology in the treatment of other disorders ranging from diabetic macular degeneration to glaucomatous visual field loss and other forms of macular diseases, including myopic macular degeneration, macular holes and hereditary retinal degeneration such as Stargardt's dystrophy, has yet to be explored.

Despite its limitations, the current study has some advantages. As far as the EyeMax Mono lens intracapsular

implantation in moderate to advanced AMD patients is concerned, this could be the first study in which a wide range of enrolled patients' ages with wider centre-involving maculopathy were investigated. Aside from comprehensive exclusion criteria for clinical results accuracy, very low to zero intra-operative and post-operative complications were another encouraging sign that reinforced the safety and efficacy of this implant. Furthermore, investigation of clinico-pathological associations between post-operative corrected distance visual acuity and dry AMD-associated factors is among the factors that strengthen the current study.

## Conclusions

The extended macular vision IOL designed to improve retinal image quality in eyes with moderate to advanced AMD has a safety profile comparable with standard IOLs in the short to medium term. This implant could become the lens of choice for optimising and maintaining visual acuity in dry AMD with varying degrees of centre-involving maculopathy. Increasing the breadth of focus and image quality in areas of functioning macula at $\leq 10°$ of retinal eccentricity may lead to improved visual function and, as a result, optimised daily activities in AMD patients.

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**Author contribution** Both HHG and TE contributed significantly to the conception and design of the current study; acquisition, analysis and interpretation of the data; the drafting and essential revision of the manuscript for relevant intellectual content and the endorsement of the final version of the manuscript.

## Declarations

**Ethics approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

**Consent to participate** Informed consent was obtained from all individual participants included in the study.

**Conference presentation** The abstract of this original study was presented at the 18th BSOS TIOC Congress, 19–20 December 2020 in Tbilisi, Georgia.

**Conflict of interest** The authors declare no competing interests.

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