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Case Report

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# Four Years of Observation to Evaluate Autonomy and Quality of Life after Implantation of a High-Add Intraocular Lens in Age-Related Macular Degeneration Patients

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## Keywords

Age-related cataract · Age-related macular degeneration · Magnifying surgery · Quality of life · Self-autonomy

## Abstract

Visual impairment resulting from advanced dry age-related macular degeneration (AMD) limits the ability to perform activities required for independent living and adversely affects quality of life. We aimed to determine changes in these parameters in patients with AMD-related geographic atrophy who underwent magnifying cataract surgery (MAGS) using a foldable, bifocal high-add intraocular lens (IOL). The high-add IOL (LENTIS® MAX LS-313 MF 80, Oculentis) was implanted in the better seeing or dominant eye of eligible patients with clinically significant cataract, best corrected distance visual acuity 1.3–0.5 logMAR (20/400–20/63), best corrected near visual acuity >0.8 logMAR (20/125), and stable advanced dry AMD. Self-reported feasibility of performing routine activities and change in quality of life were the main outcome

measures. Eleven of 15 operated patients had complete follow-up to 48 months. There were no significant intraoperative or postoperative complications. AMD converted from dry to wet in 2 patients. All patients reported functional gains in the first 3–6 months after surgery, and 10/11 patients reported improved quality of life. From baseline to 48 months, functional performance remained improved in all patients, and quality of life remained improved in the 9 patients with stable AMD. Best corrected distance visual acuity and uncorrected near visual acuity improved in all cases after surgery. **Conclusion:** Implantation of the high-add IOL was safe and resulted in durable functional and quality of life benefits. To our knowledge, our report describes the longest prospective follow-up (4 years) of a series of patients undergoing MAGS for rehabilitation of low vision related to advanced AMD. Data are needed from larger cohorts, but our experience supports giving consideration to MAGS in appropriately selected patients with low vision related to advanced dry AMD. We encourage further industry development of this technology and additional clinical research to collect more outcomes data to determine its potential to help patients maintain highly valued autonomy and quality of life.

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## Introduction

Age-related macular degeneration (AMD) is the leading cause of blindness in developed countries, and its prevalence is expected to increase [1]. Although the wet form of AMD is responsible for up to 90% of AMD-related vision loss, the dry form accounts for the vast majority of AMD, and in its advanced stage with the development of geographic atrophy, dry AMD is also associated with significant visual disability leading to loss of autonomy and impaired quality of life [2, 3].

Vision impairment in eyes with advanced dry AMD is characterized by central scotoma that interferes with the ability to recognize faces, read, drive a car, and complete numerous other routine daily activities that are essential for independent living [3]. Although magnifying aids and vision rehabilitation techniques that train patients to utilize the intact peripheral retina can help individuals cope with their central vision loss, these strategies suffer drawbacks that make them less than ideal [4].

Cataract, another age-related eye disease, is a common comorbidity in patients with dry AMD. Performing cataract surgery in patients with advanced AMD has been controversial based on the idea that it might offer no benefit and could promote AMD progression [5, 6]. Findings from recent studies, however, indicate that cataract surgery undertaken with modern methods increases visual function without worsening AMD [5–7].

The functional benefit of cataract surgery is explained by replacement of the cloudy “greyish” lens with a clear intraocular lens (IOL) that allows for improved peripheral vision. Beyond this “lightening effect,” implantation of a high-add IOL after cataract removal may offer patients with dry AMD an opportunity for low vision rehabilitation. We have coined the term “magnifying surgery” (MAGS) to describe this subset of cataract surgery.

## Case Series

The primary objective of this study was to investigate the effect of MAGS with implantation of a high-add IOL (LENTIS® MAX LS-313 MF 80; Oculentis, Berlin, Germany) on the autonomy and quality of life of patients with advanced dry AMD.

All patients were informed in detail about the clinical trial and the high-add IOL at least 4 weeks before surgery. In all cases, a written informed declaration of consent was obtained.

Patients were eligible for the surgery if they had best corrected distance visual acuity (BCDVA) 1.3–0.5 logMAR (20/400–20/63), best corrected near visual acuity (BCNVA) >0.8 logMAR (20/125), clinically significant cataract, and dry AMD with geographic atrophy that was stable for >3 months on optical coherence tomography (OCT). Exclusion criteria were wet AMD, active hemorrhage, neovascularization, cystic edema, glaucoma, astigmatism >1 dpt, and ametropia >2 dpt.

The biometric examination was performed using the IOLMaster 500 (Carl Zeiss Meditec AG, Jena, Germany) and repeated at least twice to confirm measurement consistency before calculating IOL power. The IOL was implanted in the better or dominant eye with a target refraction of emmetropia through a 2.4-mm clear cornea incision using a Viscoject Bio 2.2 injector (Medicel AG, Altenrhein, Switzerland) (Fig. 1). Standard postoperative treatment consisted of topical corticosteroid and nonsteroidal anti-inflammatory drug drops.

Patients were instructed to begin doing exercises for 15 min daily after surgery that are designed to facilitate circular movements of the head and eyes around the target aggravated by central scotoma. The exercises included focusing; moving the right thumb with outstretched arm from right to left and left to right and simultaneously moving the eyes; and looking at large numbers and letters on a close-up board and recognizing six-digit numbers. In addition, patients were encouraged to try to recognize faces of persons depicted in a photo album.

The impact of the high-add IOL on patient autonomy was assessed using a questionnaire that was completed at baseline and at 3, 6, and 48 months after surgery. The questionnaire listed 10 routine activities that involve central vision and/or pertain to independent living (reading, recognizing photos, eating and cooking, operating a telephone, daily hygiene rituals, brushing teeth, cutting nails, operating household appliances, manual work, and use of low-vision aids [e.g., magnifying glasses]). Patients indicated whether each activity was feasible or not using a scoring system of 1 or 0, respectively, and a total score was calculated. Quality of life was evaluated with a questionnaire completed at 3 and 48 months after surgery that asked patients to rate whether their current state was very clearly better, clearly better, slightly better, equal to the state, or worse than before surgery.

Moreover, visual acuity, posterior capsule opacification (PCO), conversion of dry AMD to wet disease and the impact of the high-add IOLs on the feasibility of funduscopy and quality of OCT examinations was determined.

The LENTIS® MAX LS-313 MF 80 IOL (Fig. 1) received the CE mark in 2014. It is a modification of the rotationally asymmetric refractive bifocal LENTIS® Mplus LS-313 MF 30 (Oculentis, Berlin, Germany) that includes the same near segment on the anterior surface but also incorporates an equivalent near segment on the posterior side to provide a near addition of +8.0 dpt (+6.0 dpt at the spectacle plane). The bifocal properties of the LENTIS® MAX LS-313

MF 80 enable good distance vision and approximately  $\times 2.5$  magnification for near, which might minimize the need for near-field magnification by patients with advanced AMD.

The LENTIS® MAX LS-313 MF 80 is a foldable, aberration-neutral, one-piece IOL with a plate haptic design. It has a 6.0-mm biconvex optic and a total diameter of 11 mm. The haptics and optics are a copolymer acrylate (Hydrosmart® Copolymer) with 25% water content consisting of a hydrophilic acrylate with a hydrophobic surface. The lens has a 360° haptic-optic square edge barrier to prevent PCO.

## Results

A total of 15 patients underwent cataract surgery and implantation of the high-add IOL between March and December 2015. All surgeries were completed successfully without complications, and all patients had an uncomplicated postoperative course with normal IOP and wound healing. Four patients did not return for consistent follow-up because of reduced general state of health, age or relocation to another city. These patients were excluded from the analyses for this study. Demographic and clinical characteristics of the 11 patients whose data were included are summarized in [Table 1](#).

The 11 patients had a mean age of 80.6 years. Final refraction was  $\pm 0.75$  dpt of target in all cases. During follow-up, no IOLs showed evidence of calcification. YAG laser capsulotomy for PCO was performed between 21 and 36 months after surgery in 4 cases. Two patients converted to wet AMD and started intravitreal anti-VEGF therapy at 35 and 27 months after surgery, respectively.

Scores from the activity questionnaire are shown in [Figure 2](#). Before surgery, 10 of the 11 patients were not able to perform 50% or more of the listed activities. In all patients, the total score increased from baseline to 3 months, indicating functional gains, and the score for all patients at 6 months was stable ( $n = 5$ ) or further improved ( $n = 6$ ). At 48 months, the activity score was improved from baseline in all patients, although it decreased from the 6-month value in 6 patients, including the 2 patients who had converted to wet AMD.

The quality of life ratings showed a clear treatment benefit with all patients reporting that their quality of life was “very clearly better” ( $n = 7$ ) or “clearly better” ( $n = 3$ ) than before surgery except for 1 patient who reported no change ([Fig. 3](#)). At 48 months, 9 of the 11 patients still rated their quality of life as “very clearly better” ( $n = 6$ ) or “clearly better” ( $n = 3$ ) than before surgery. Both patients who reported worsening had experienced conversion of their AMD to wet disease.

[Table 2](#) shows visual acuity data for each patient. Improvement from preoperative BCDVA was seen at 3 months in all patients, and BCDVA remained stable throughout follow-up in all patients except for the 2 patients whose AMD converted to wet disease. Additionally, uncorrected visual acuity at 3 months was better than BCDVA preoperatively in all patients. Similarly, uncorrected near visual acuity at 3 months was better than preoperative BCNVA in all patients, and uncorrected near visual acuity remained relatively stable throughout follow-up in all patients except 1 patient who had converted to wet AMD.

Cataract removal afforded improved posterior segment visualization. Fundoscopy, contact lens examination, and OCT also remained feasible in all patients throughout follow-up.

## Discussion

To our knowledge, our report describes the longest prospective follow-up (4 years) of a series of patients undergoing MAGS for rehabilitation of low vision related to advanced AMD. Our data show that after cataract removal and implantation of the high-add IOL, patients had increased ability to perform a variety of routine tasks involving central vision and maintained the benefit for up to 48 months. Corresponding with the results of the activity questionnaire,  $\geq 90\%$  of patients reported that their overall quality of life was improved after MAGS, both in the early postoperative period and after long-term follow-up. The patients also demonstrated early improvements in distance and near vision that were generally maintained after 48 months. The improved near vision can be attributed to the higher dioptric effect of the two rotationally asymmetric segmented near parts of the bifocal IOL. The finding that between months 3 and 6 postoperatively the majority of patients demonstrated further gains in their ability to carry out everyday activities is particularly remarkable. Therefore, in our opinion neuroadaptation and training after surgery is particularly important in these cases. The good (above-average) support from the doctor/clinic is decisive. Patient and doctor must function as a team here. It must be emphasized that MAGS procedures and this new IOL in an eye with diagnosed advanced AMD is still not a standard procedure. Special care must be taken before and after the surgery. Furthermore, the indication must be checked very carefully. Even though our results are very pleasing, depending on the condition of the macula, improvement cannot be promised in advance.

IOLs intended to provide a surgical vision rehabilitation option for patients with maculopathy-related low vision have been available for a number of years [8]. Because of their size and design, the implantation procedure for some of these devices is technically challenging, complex, and requires incision enlargement. Consequently, their use can result in astigmatism induction as well as more serious complications, including pupillary block with IOP elevation and damage to intraocular tissues [8–10].

There were no intraoperative or postoperative complications related to the IOL in our series, which is a foldable lens implanted in a routine approach with a universal injector through a 2.2-mm or larger clear cornea incision [11]. Similarly, Qureshi et al. [4] reported favorable safety and visual acuity improvement in a study of another injectable AMD IOL. Not only is the LENTIS® MAX LS-313 MF 80 IOL an injectable lens, but it is built on the same platform as several existing presbyopia-correcting IOLs (LENTIS® Mplus MF 20 and MF 30, LENTIS® Comfort, OSD Medical, Germany). Among surgeons using the latter lenses, familiarity with the technology would be expected to enable operating theater workflow efficiency.

Visually significant calcification has been reported with some IOLs made of the same copolymer material as the high-add implant [12, 13]. Although we did not encounter any such reactions, our series is small and longer follow-up is needed because the opacity may develop after 4 years [12, 13].

The small number of patients in our series is clearly a limitation, whereas the long follow-up of 4 years is a benefit and the longest observation of high-add IOLs to the best of our knowledge. Patient age, however, makes participant retention challenging in an AMD cohort, and 4 of 15 patients who underwent surgery with the high-add IOL were excluded from our analyses after loss to follow-up. The noncomparative design of our study is another limitation because we cannot determine how much of the observed benefits are attributable to the high-

add IOL versus from the “lightening effect” expected after cataract removal. Therefore, it would be important and necessary to conduct studies in the future that directly compare groups implanted with a high-add IOL or a monofocal, “standard” IOL.

## Conclusion

The onus to find solutions that help patients with advanced dry AMD maintain autonomy and quality of life is increasing as the number of affected individuals is expected to continue to rise with population aging. In our opinion, it is time to rethink management for these patients because ideas that cataract surgery is potentially harmful or that nothing can be done to improve their visual function represent antiquated thinking.

Patients with low vision-related to advanced dry AMD should not be dismissed as hopeless cases. At the very least, they can benefit from replacing their cloudy lens with a clear IOL. Based on the promising experience that is accumulating with injectable AMD IOLs, we encourage further industry development of this technology and additional clinical research to collect more outcomes data to determine its potential to help patients maintain highly valued autonomy and quality of life.

## Statement of Ethics

The current study adhered to the tenets of the Declaration of Helsinki and all patients gave their written informed consent to publish their case. In this case report, standard procedures and devices with CE mark were used.

## Conflict of Interest Statement

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## Author Contributions

Both authors (A.F.B., E.M.B.) provided substantial contributions to conception and design, data acquisition, or data analysis and interpretation. They drafted the article and critically revised it for important intellectual content. They both approved the final version to be published.

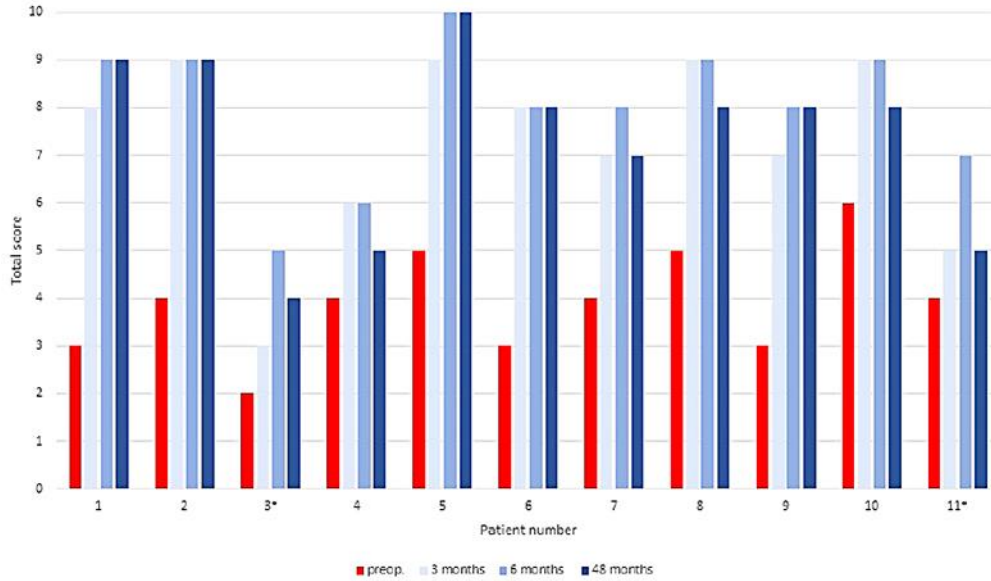


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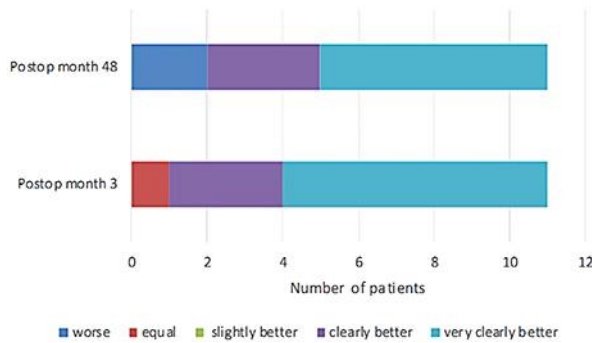
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**Fig. 1.** Medical Viscoject Bio injector system (Medicel, Switzerland) and Lentis LS-313 MF80 (Oculentis, Germany, renamed in OSD Medical, Teleon Surgical, Germany) with sector shaped optic design and 360° square edge.



**Fig. 2.** Total activity feasibility scores from questionnaires completed preoperatively and at 3, 6, and 48 months after surgery. Possible score range is 0 (no activities are feasible) to 10 (all activities are feasible). \* denotes patients who converted to wet AMD.



**Fig. 3.** Summary of patient ratings of change in quality of life from baseline to postop months 3 and 48. Both patients (No. 3 and 11) reporting worsening at month 48 had converted to wet AMD.



**Table 1.** Patient demographics, postoperative refraction, and clinical characteristics

Patient	Gender	Age at surgery, years	Refraction	AMD status (48 months)	YAG capsulotomy (48 months)
1	female	80.2	-0.75 +0.50×020°	dry	no
2	female	79.9	-0.50 +0.00×000°	dry	no
3	male	75.6	+1.75 +0.25×110°	dry → wet 4× IVOM, starting at 35 months	no
4	female	74.5	-0.75 +0.50×085°	dry	no
5	male	82.3	+1.25 +0.50×090°	dry	at 26 months
6	female	81.5	+1.00 +0.00×000°	dry	at 30 months
7	female	79.4	-0.75 +0.25×065°	dry	no
8	female	79.6	+1.00 +0.75×095°	dry	at 23 months
9	male	84.8	+0.75 +0.00×000°	dry	no
10	female	82.5	+0.50 +0.50×145°	dry	no
11	female	86.1	+1.25 +1.00×115°	dry → wet 6× IVOM, starting at 27 months	at 31 months

AMD, age-related macular degeneration; IVOM, intravitreal ophthalmic medication.

**Table 2.** Preoperative and postoperative distance and near visual acuity

Patient	Distance visual acuity, logMAR					Near visual acuity, logMAR			
	BCDVA				UCVA	BCNVA	UCNVA		
	preop	month 3	month 6	month 48	month 3	Preop	month 3	month 6	month 48
1	0.72	0.37	0.37	0.34	0.41	0.90	0.64	0.52	0.60
2	0.69	0.31	0.30	0.31	0.37	1.00	0.66	0.54	0.61
3*	0.90	0.44	0.50	0.64	0.48	1.10	0.94	0.88	0.94
4	0.74	0.39	0.34	0.40	0.39	1.30	0.56	0.55	0.60
5	0.50	0.28	0.22	0.31	0.30	0.80	0.62	0.62	0.61
6	0.61	0.30	0.28	0.34	0.32	0.80	0.72	0.68	0.80
7	0.71	0.28	0.30	0.32	0.34	1.40	0.84	0.70	0.91
8	0.65	0.24	0.20	0.21	0.30	1.00	0.54	0.60	0.40
9	0.79	0.40	0.30	0.43	0.42	1.30	0.52	0.40	0.62
10	0.66	0.18	0.18	0.20	0.20	1.20	0.66	0.60	0.53
11*	0.59	0.22	0.20	0.71	0.29	0.90	0.68	0.66	0.91

BCDVA, best corrected distance visual acuity; UCVA, uncorrected visual acuity; BCNVA, best corrected near visual acuity; UCNVA, uncorrected near visual acuity. The asterisks indicate cases with transition from dry to wet AMD.