Purpose: To report the outcomes of macular add-on intraocular lens implantation in improving reading vision in patients with bilateral advanced diabetic maculopathy.

Methods: In this retrospective study, a supplementary bifocal sulcus intraocular lens (Scharioth Macular Lens) was implanted in the better-seeing eye of five patients. Baseline-corrected distance vision, corrected near visual acuity, a preoperative simulation test, and multimodal imaging were collected. The primary outcome was the uncorrected near visual acuity at a working distance of 15 cm, at a 12-month follow-up.

Results: Study patients included 3 cases of refractory subfoveal exudation and 2 cases of diabetic macular ischemia. A preoperative test to assess the potential gain in near vision showed an improvement of $\geq$2 paragraphs on the RADNER reading chart in all patients. At 12 months, median reading vision (corrected near visual acuity at 15 cm) significantly improved from 20/125 (range 20/50–20/200) preoperatively to uncorrected near visual acuity (at 15 cm) of 20/50 (range 20/40–20/80) ($P = 0.042$; Wilcoxon signed-ranks test). Distance vision remained unchanged in four patients. All patients were able to achieve the size of newsprint (20/50 Snellen equivalent), within the first 3 months.

Conclusion: The macular add-on intraocular lens improves reading vision in visually impaired patients due to end-stage diabetic macular disease.

From the *Department of Ophthalmology, Vajira Hospital, Navamindradhiraj University, Bangkok, Thailand; and †Retina Service, Massachusetts Eye and Ear, Harvard Medical School, Boston, Massachusetts.

For these patients, the ability to maintain central vision depends on a new eccentric fixation point, called a preferred retinal locus (PRL). Therefore, the underlying principle for visual rehabilitation in these patients involves amplification of the PRL by enhancing magnification and encouraging perceptual completion.1 External devices, such as handheld magnifiers and stand magnifiers, have been widely applied to improve reading ability. Nevertheless, these devices have a number of problems in practical use, including restricted field of view from a ring scotoma, requiring a steady hand, and vestibulo-ocular conflict from head movement. An earlier study reported that almost one-fifth of patients abandoned these prescribed devices.2 Various implantable devices have been developed to overcome such problems and improve monocular depth perception. Among such devices, Scharioth Macular Lens (A45 SML; Medicontur, Zsàmbék, Hungary) has several features, which provide some specific advantages. First,
unlike handheld or other physical devices, the SML preserves the peripheral visual field and orientation toward objects. Second, the SML is easily placed through a small 2.2-mm corneal incision and can be implanted in pseudophakic patients. The SML is a foldable hydrophobic square intraocular lens (IOL) designed for ciliary sulcus implantation. This bifocal IOL provides 2 times magnification by adding +10 diopters of power in the central 1.5 mm diameter. The IOL power in the remaining peripheral zone is neutral, and the photic phenomenon is reduced by the round edges of IOL optic.3

End-stage diabetic eye disease is a broad spectrum, which can lead to permanent central scotomas through several mechanisms, such as tractional retinal detachment, chronic subfoveal exudation, and diabetic macular ischemia. Visual recovery in these patients is generally limited even after a variety of treatments. In general, diabetic macular disease affects a younger patient population and thus more often impacts these patients’ ability to work. Therefore, this visual disability may have a greater socioeconomic impact at the national level compared with other bilateral maculopathies such as AMD and is certainly worth pursuing alternative solutions.

A previous study reported favorable outcomes after SML implantation in the better-seeing eye of patients with bilateral advanced dry AMD.3 However, the results of placing this magnifying device in eyes with advanced diabetic disease have never been reported in the literature. In this study, we report the clinical outcomes of SML implantation in improving reading vision in patients with bilateral advanced diabetic maculopathy at 12 months of follow-up.

Methods

The macular add-on IOL was implanted in the better-seeing eye of five patients. All surgeries were performed by a single surgeon (Y.C.) in a university hospital setting. An institutional review board approval was obtained. This study was performed in accordance with the Declaration of Helsinki for research involving human participants. The potential risks and benefits of the surgery were thoroughly explained to every patient before proceeding. The medical charts were retrospectively reviewed from 2015 to 2017.

Inclusion Criteria

1. Patients with bilateral chronic advanced diabetic maculopathy with an average duration of more than 3 years. The maculopathy was further classified into two categories: 1.1 eyes with persistent subfoveal exudation refractory to both laser treatment and intravitreal medications (anti–vascular endothelial growth factor and/or steroids) for at least 12 months before IOL surgery (Figure 1, A–C) and 1.2 eyes with foveal atrophy resulted from diabetic macular ischemia or postdiabetic vitrectomy (Figure 2, A–C). The presence of foveal atrophy was documented using the optical coherence tomography (OCT) (Spectralis OCT2; Heidelberg Engineering, Heidelberg, Germany).

2. Patients with moderate to severe visual impairment according to The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) defined as best-corrected visual acuity of <20/60 to 20/400 in the better-seeing eye.

3. A positive challenge test for the benefit of near vision, defined by improvement of more than two paragraphs of an English version of the RADNER reading chart (Precision Vision, Woodstock, IL) after comparison of near visual acuity in the better-seeing eye with +6.0 diopters at 15 cm and +2.5 diopters added to the distance refraction at 40 cm.

4. Motivated patients with realistic expectations who understand the possible risk of progression of diabetic retinopathy.

Exclusion Criteria

1) Patients with active proliferative diabetic retinopathy within 1 year before surgery. 2) Patients with poor control of their systemic disease and hemoglobin A1c level >7.5%. 3) Photopic pupil of <3.0 mm. 4) Any anterior segment disease precluding sulcus implantation, including uveitis, glaucoma, zonular instability, and anterior chamber depth of <2.8 mm.

All patients understood the importance of postoperative training. They also acknowledged the fact that the working distance would be shortened to 15 cm, whereas distance vision would remain unchanged. A task analysis was performed to tailor the goal of visual rehabilitation to each patient. If a significant cataract was found in the better-seeing eye, the preoperative test for near correction would be repeated after phacoemulsification with posterior chamber IOL implantation had been performed. The SML insertion would be performed at least 3 months after cataract surgery. The primary outcome of this study was an improvement in uncorrected-near visual acuity (UNVA) in the better-seeing eye at a distance of 15 cm.

All surgical procedures were performed under topical anesthesia. A paracentesis was created using a 15-degree angle blade (Alcon, Fort Worth, TX), and the ciliary sulcus was opened by injecting ophthalmic vicosurgical devices into the retroirisis space. An iris spatula was then used to gently open the original cataract wound. The folded SML was loaded within
a cartridge and injected through the previous temporal corneal incision. All haptics were simultaneously placed into the ciliary sulcus using a second instrument, and the SML was then rotated until maximal centration was achieved (Figure 3A). The ophthalmic viscosurgical devices were removed, and wound closure was accomplished by stromal pressurization. None of the patients received surgical peripheral iridectomies. Postoperative visual rehabilitation began 1 month after surgery to allow for immediate postoperative healing and to promote reading ability for all patients.

Data collected from enrolled patients included corrected-distance visual acuity (CDVA), measured
by the Early Treatment Diabetic Retinopathy Study visual acuity charts. Preoperative corrected-near visual acuity (CNVA) and postoperative UNVA were measured by logarithmic reading charts, the RADNER reading chart in English, which is based on the concept of sentence optotypes. A stop criterion of 20 seconds per sentence was chosen in this study as it corresponds to a reading speed of at least 40 wpm. Although this chart was intentionally constructed for distances of 32 cm and 40 cm, reading vision at 15 cm was converted to a form of the logarithmic reading acuity determination (logRAD) for statistical analysis purposes and then converted back for the ease of interpretation.4

Refraction, spherical equivalence, gonioscopy, a test for ocular dominance, and individualized multimodality imaging, including fundus photography, OCT scans, and postoperative horizontal cross-sectional images of the anterior segment taken by the Scheimpflug camera and the Pentacam HR tomographer (Oculus, Wetzlar, Germany), were obtained for every patient. The interlenticular distance and angular width were assessed by the measurement tools (Figure 3D). Fundus fluorescein angiography was performed to determine the macular perfusion status and disease activity in selected cases whose visual acuity did not correlate with the OCT findings. Adverse events and potential surgical complications, such as ocular hypertension, angle closure glaucoma, prolonged iritis, persistent corneal edema, pigment dispersion syndrome, and worsening of diabetic macular edema, were collected at every visit (preoperative and postoperative visits at 1, 2, 3, 6, and 12 months).

Statistical analysis of visual outcomes was computed using Stata, version 13.0 (Statacorp, College Station, TX). Descriptions of the specific statistical tests used are included in the results section below.

Results

Baseline characteristics of patients and clinical results are shown in Tables 1 and 2, respectively. The median follow-up time was 15 months (range = 13–18 months). At 12 months of follow-up, median reading vision (CNVA at 15 cm reading distance) significantly improved from 20/125+2, interquartile range (IQR) = 20/63–20/150, preoperatively to 20/50 (UNVA at 15 cm reading distance), IQR = 20/40–20/502, postoperatively (Z = 2.032, P = 0.042, Wilcoxon signed-ranks test). This improvement could not convert to the Early Treatment Diabetic Retinopathy Study letter as the near visual acuity was measured by the RADNER chart where each Snellen fraction.

Fig. 3. An IOL position of Case 3. Intraoperative view (A) shows the macular add-on IOL on top of the posterior chamber 3-piece IOL in the right eye. At 1-month follow-up, central magnified part of macular add-on IOL (B) (white arrow) with diameter of 1.5 mm was detected by retroillumination, and a slit beam of light illustrates a valve (C) (white arrow) between 2 IOLs. The central interlenticular distance (D) measured by the Scheimpflug camera is 390 μm.
incorporates 82 to 84 characters. All patients were able to achieve the reading acuity of 20/50, the size of newsprint, within the first 3 months postoperatively. In addition, the median spherical equivalence change was $-0.625$ diopter (IQR = $-1$ to $-0.375$ diopter), and the median corneal astigmatism remained unchanged (IQR = 0–0.5 diopter) (Table 2).

Case 1 received 3 monthly injections of anti–vascular endothelial growth factor because of an exacerbation of diabetic macular edema during the early postoperative period. At 8 months follow-up, Case 2 suffered a worsening of diabetic macular ischemia, resulting in decreased CDVA and UNVA at 1 year postoperatively (Table 2). Case 3 and 4 needed to occlude their poorer dominant eye while reading. Case 5 was diagnosed as primary open-angle glaucoma and experienced intraocular pressure (IOP) elevation of more than 25 mmHg in both eyes at 13 months. Successful IOP control was achieved by two IOP-lowering eye drops.

The median perpendicular distance between the central posterior surface of the SML and anterior surface of the PCIOL, measured from the horizontal cross-sectional images of the Pentacam HR, was 300 μm (IQR = 270–380). Pre-existing posterior chamber IOL models included AR40e (Abbott Medical Optics, Santa Ana, CA) in 4 cases and SN60WF (Alcon) in 1 case. All gonioscopy and Pentacam images revealed open-angle configurations in all patients after surgery. None of the patients in this study experienced prolonged iritis or persistent corneal edema by the time of their 12-month follow-up.

**Discussion**

Unlike other intraocular telescopic devices, the SML mainly aims to improve the reading vision, whereas distance vision remains unchanged. The peripheral visual field is generally preserved, as this device is neither based on the principle of the Galilean telescope nor prismatic effect.\(^3\)–\(^8\) Our median outcomes of UNVA at 15 cm (20/50) are slightly inferior to previous reports involving AMD patients (20/40).\(^3\) One possible explanation is that diabetic macular edema has a more diffuse area of reduced retinal function from previous macular grid laser photocoagulation or widespread microvascular abnormalities.\(^9\) Hence, postoperative PRL relocation caused by light deviation can contribute to a better outcome in eyes with geographic atrophy. This theory was confirmed by the microperimetry test after implantation of the injectable telescopic IOL (the IOL-AMD, London Eye Hospital Pharma, London, United Kingdom) in eyes with geographic atrophy.\(^7\) It is worth mentioning that extensive damage to the superior macula may reduce the chances of success with SML IOL implantation, as the corresponding inferior scotoma interferes with downward gaze in the reading position. Nevertheless, none of the patients in this study had such a condition before surgery.

The fact that all 5 cases were able to achieve newsprint reading by the 3-month follow-up visit suggests that patients with preoperative CDVA between 20/63 and 20/200 are capable of benefitting from this IOL surgery. Moreover, we observed that the

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**Table 1. Demographic and Baseline Characteristics of the Patients and Their Better-Seeing Eyes**

<table>
<thead>
<tr>
<th>Case</th>
<th>Sex/Age (years)</th>
<th>Preoperative Diagnosis</th>
<th>CDVA</th>
<th>CNVA at 40 cm</th>
<th>CNVA at 15 cm</th>
<th>Paragraphs Improved From the Simulation Test*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F/55</td>
<td>Chronic subfoveal exudation</td>
<td>20/200</td>
<td>20/300</td>
<td>20/200</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>F/33</td>
<td>Foveal atrophy postdiabetic vitrectomy</td>
<td>20/200</td>
<td>20/300</td>
<td>20/150</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>F/75</td>
<td>Chronic subfoveal exudation</td>
<td>20/80</td>
<td>20/100</td>
<td>20/63</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>M/72</td>
<td>Chronic subfoveal exudation</td>
<td>20/200</td>
<td>20/250</td>
<td>20/125</td>
<td>3</td>
</tr>
<tr>
<td>5</td>
<td>M/55</td>
<td>Diabetic macular ischemia</td>
<td>20/63</td>
<td>20/80</td>
<td>20/50</td>
<td>2</td>
</tr>
</tbody>
</table>

*Comparison of near visual acuity between +6.0 diopters at 15 cm and +2.5 diopters at 40 cm added on distance refraction.

CDVA, corrected distance visual acuity.

**Table 2. Postoperative Results of Better-Seeing Eyes at 12 Months**

<table>
<thead>
<tr>
<th>Case</th>
<th>CDVA at 15 cm</th>
<th>CDVA at 40 cm</th>
<th>UNVA</th>
<th>Time to Achieve M1 Letter (Weeks)</th>
<th>SE Changes (Diopters)</th>
<th>Induced Astigmatism (Diopters)</th>
<th>Postoperative Clinical Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>20/200</td>
<td>20/200</td>
<td>20/50</td>
<td>12</td>
<td>-1.75</td>
<td>0</td>
<td>3 Anti-VEGF injections</td>
</tr>
<tr>
<td>2</td>
<td>20/400</td>
<td>20/400</td>
<td>20/125</td>
<td>8</td>
<td>-0.625</td>
<td>0</td>
<td>Worsening of macular ischemia</td>
</tr>
<tr>
<td>3</td>
<td>20/80</td>
<td>20/80</td>
<td>20/50</td>
<td>4</td>
<td>0.625</td>
<td>0.50</td>
<td>Well-controlled DME</td>
</tr>
<tr>
<td>4</td>
<td>20/200</td>
<td>20/200</td>
<td>20/40</td>
<td>4</td>
<td>-0.375</td>
<td>0</td>
<td>Well-controlled DME</td>
</tr>
<tr>
<td>5</td>
<td>20/63</td>
<td>20/63</td>
<td>20/40</td>
<td>8</td>
<td>-1.0</td>
<td>0.50</td>
<td>Regressed PDR</td>
</tr>
</tbody>
</table>

CDVA, corrected distance visual acuity; SE, spherical equivalence; PRP, panretinal photocoagulation; DME, diabetic macular edema; PDR, proliferative diabetic retinopathy; VEGF, vascular endothelial growth factor.
preoperative simulation test was a good predictor of postoperative visual outcomes. Postoperatively, it is imperative that patients control their systemic glucose to prevent the worsening of diabetic eye disease. It is noted that close ophthalmic monitoring is important during the postoperative period because both cataract surgery and SML implantation can lead to increased intraocular inflammation and subsequently postoperative exacerbation of macular edema (Case 1), which may be a possible adverse effect of the surgery. In addition, postoperative training is critical to maximize the use of the PRL by increasing fixation stability. Patients with a poorer-seeing dominant eye should be informed before surgery that misperception of the implanted eye may occur postoperatively when using binocular reading.

In our study, a slight shift of spherical equivalence and a low degree of induced astigmatism underscore the benefit of small-incision surgery (Table 2). This study successfully demonstrates the safety of this particular sulcus-IOL design, which is consistent with previous reports.3,10 Our mean interlenticular distance (300 μm) is shorter than that in the previous study (680 μm) performing in cadaveric eyes.10 Furthermore, no appositional angle closure was found on gonioscopic examinations in our patients. Of note, we did not find any correlation between the type of preexisting posterior chamber IOL and the final anterior chamber depth.

The position of the magnification portion of the IOL was well centered in the nondilated pupil in all cases (Figure 3B). However, long-term follow-up is necessary to determine whether the IOL will maintain its stability as a previous study showed that Soemmering’s ring formation could potentially affect the final centration of this IOL platform.10

A comparison with other implantable telescopic devices shows that SML has superior clinical outcomes for near vision and working distance. Each of other preexisting intraocular telescopes have different disadvantages, including restriction of peripheral visual field due to prismatic effect, induced astigmatism from a large limbal wound, the prerequisite of bilateral phakic status, and other potential complications as summarized in Table 3.3,5–8 Furthermore, most patients with advanced diabetic retinopathy usually have systemic coagulopathies caused by chronic kidney disease or antiplatelet medications. Thus, this group of patients may not be good candidates for large surgical wounds and complicated procedures where manipulation of supplementary IOL haptics may lead to increased risks of iris bleeding.5,6 The fact that the SML is specifically designed for ciliary sulcus implantation in pseudophakic eyes is one of the major advantages of this product because most intraocular telescopic devices require phakic status for simultaneously implanting one in-the-bag IOL and another sulcus-fixed lens (Table 3). For noncataractous phakic patients, we

| Table 3. Summary of Previous Studies on Currently Available Intraocular Magnifying Devices |
|----------------------------------|------|-------|------|-------|-------|
| Magnification | SML | ×2 | IMT | ×2.2–3.5 | LMI | ×2.5 | IOL-VIP | ×1.3 | IOL-AMD | ×1.25 |
| Prismatic effect | No | Yes | No | Monocular implantation | One in-the-bag, one sulcus | In-the-bag, with central mirror | One in-the-bag, one AC-IOL | With or without |
| Laterality | Monocular | Monocular implantation | Binocular implantation | |
| Lens position | Sulcus | One in-the-bag, one sulcus | In-the-bag, with central mirror | |
| Wound size (mm) | 2.2 UNVA | 12.0 CDVA | 6.5 CDVA, CNVA | 7.0 CDVA, near magnification | 3.0 CDVA, CNVA |
| Primary outcome | UNVA at 15 cm = 20/40 | CNVA at 20 cm = 20/63 | CNVA at 7.6 cm = 20/50 | CNVA at 40 cm = 20/100 |
| Mean postoperative near vision | N/A | Up to 40% | 5.8% | 7% | 18% |
| Mean ECD reduction | N/A | 6% risk of prolonged iritis | Fundus images blocked | Pupillary block, hyperopic shift‡ |
| Other complications | |

*A fellow eye is required for peripheral fusion.

†Articulate of IOLs.

‡In eyes with axial length <23.0 mm.

SML, Scharioth macular lens; IMT, the implantable miniaturized telescope (VisionCare Ophthalmic Technologies, Saratoga, CA); LMI, Lipshitz macular implant (Optolight Vision Technology, Herzliya, Israel); IOL-VIP, the intraocular lens for visually impaired people system (Soleko, Pontecorvo, Italy); IOL-AMD, injectable telescopic intraocular lens; AC-IOL, anterior chamber intraocular lens; BCVA, best-corrected visual acuity; ECD, endothelial corneal density.
suggest that they undergo cataract surgery with IOL placement first to most accurately perform the preoperative near simulation test. Although data on endothelial corneal density were not collected in this study, none of our patients experienced postoperative corneal edema during the entire follow-up period. Finally, in terms of surgery costs, the SML may be particularly beneficial in underdeveloped areas due to its improved affordability compared with other implantable telescopic devices.

It is important to recognize that the SML cannot be compared directly with most of the other devices mentioned because of the different correcting mechanisms involved (bifocal correction versus Galilean telescope) and different criteria for patient selection. For example, the SML works well with patients with moderate to severe visual impairment (best-corrected visual acuity 20/60–20/400), whereas the Implantable Miniature Telescope (VisionCare Ophthalmic Technologies, Saratoga, CA) was approved for patients with severe to profound (best-corrected visual acuity 20/160–20/800) visual impairment. The primary outcome of SML is the improvement of UNVA, whereas for the Implantable Miniature Telescope, it is improvement in CDVA.5

The limitations of this study include the small sample size due to highly strict inclusion criteria, lack of quality of life assessment, and inability to quantify the preoperative area of macular damage due to the generalized pathology. Owing to the relatively short follow-up in this study, long-term effects on the corneal endothelial function cannot be provided. Further studies are necessary to determine this. Fundus-related perimetry and autofluorescence may be used for preoperative assessment by using their ability to suggest the future PRL target.9

In summary, the SML supplementary IOL provides satisfactory outcomes for near vision and should be considered a practical option for individuals suffering from bilateral end-stage diabetic macular disease. A further controlled study, comparing patients with dry AMD, should be prospectively conducted to explore more clinical information on this device. Although no direct treatment is currently available for end-stage macular diseases, the SML IOL allows for significant restoration of near vision in these patients.

Key words: diabetic macular disease, intraocular telescope, piggyback intraocular lens, bifocal intraocular lens.

References
1. Nilsson UL, Frennesson C, Nilsson SE. Patients with AMD and a large absolute central scotoma can be trained successfully to use eccentric viewing, as demonstrated in a scanning laser ophthalmoscope. Vis Res 2003;43:1777–1787.