Scharioth Macula Lens: A new intraocular implant for low-vision patients with stabilized maculopathy- first experience

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Aims. To present the initial results of Scharioth Macula Lens (SML) implantation. The SML is a new add-on intraocular lens designed to increase uncorrected near visual acuity (UCVA) in patients with stabilized maculopathy.

Methods. Eight patients were included in the study. All met the indication criteria before SML implantation. An SML was implanted in the better seeing eye. Near and distance visual acuity were tested. Possible complications and patient complaints were recorded and patients were asked about their quality of vision after SML implantation. The examination was carried out on day 1, 1 week, 1, 3 and 6 months after surgery.

Results. Six-month-results are presented. Apart from one, all patients with the SML had good near visual acuity at a recommended reading distance of 15 cm. Preoperatively, the mean (min-max) near UCVA was J13 (J8-J16), mean distance BCVA was 0.27. Postoperatively, the best results were after 1 month – near UCVA was J2.5 (J1-J7), distance BCVA was 0.26. Three months after surgery, this decreased to J4.5 (J1-J8); distance VA remained 0.25. Six months postoperatively – near vision was J4 (J1-J8) and distance VA remained unchanged. Patients reported problems with reading speed and reading distance. Daily exercise improved their reading ability. One patient converted to wet AMD 3 months post-implantation.

Conclusion. The SML is a new hope for low-vision patients. It acts as a magnifier in the eye. It is a suitable method for increasing near visual acuity in patients with inactive maculopathy.

Key words: Scharioth Macula Lens, maculopathy, low-vision, near vision improvement

INTRODUCTION

Macular pathology causes a significant amount of vision loss and increases vision-specific disability, decreases quality of life, and may even increase mortality.

Macular degenerations and dystrophies often result in significant visual impairment which limits a patient’s daily activities requiring good central vision, such as self-care, reading, recognizing facial features, driving, watching television, and other social activities. Impaired vision is thus an important cause of depression and anxiety. In the developed world, age-related macular degeneration (AMD), diabetic or myopic maculopathy, and maculopathy after retinal vein occlusion are the most common macular degenerations. Near vision testing is a sensitive indicator of the presence of macular disease. To help visually handicapped patients, there are several external magnifying low visual aids available on the market, which are based on either optical or electronic magnification. Many older visually impaired adults have difficulty in getting used to a new device and refuse to use them. Some disadvantages of external aids can be surpassed using intraocular implants.

The Scharioth Macula Lens (SML; A45SML) acts as a magnifier in the eye. It is a new one-piece foldable intraocular lens (IOL) made from a copolymer of hydrophilic and hydrophobic acrylic. The lens is implanted into the ciliary sulcus in addition to a primary IOL in the patient’s pseudophakic eye. The lens is aspheric bifocal, with a 1.5 mm diameter central portion and an addition of +10 diopters (Fig. 1). The remaining optical zone is refractory neutral, or the diopters of this zone may be individually adapted. The lens is available in clear or yellow versions. It has the Conformité Européenne mark and is patent pending. Our initial clinical results from eyes implanted with the SML in patients with age-related macular degeneration are presented.

MATERIALS AND METHODS

This trial was conducted at the Department of Ophthalmology, University Hospital in Hradec Králové, Czech Republic, from January 2015. It was reviewed by the local ethics committee, all tenets of the Declaration of Helsinki were followed and all patients provided informed consent. Eight patients were included. All of the patients had met the indication criteria for implantation recommended by the inventor (prof. Scharioth, Recklinghausen, Germany) and manufacturer (Medicontur International, Geneva, Switzerland) before SML implantation: age eligible for the study over 55 years, best corrected distance visual acuity (BCVA) from 0.05 to 0.4, stabilized maculopathy and a pseudophakic eye. According to the recom-
sessions were hydrated. All of the patients were subjected to general anesthesia, an incision of 2.2 mm was made, the anterior chamber was filled with an ophthalmic viscosurgical device (OVD) and an add-on SML was placed in the capsular bag. After implantation, proper positioning of the haptics in the ciliary sulcus and IOL centration were achieved in the better seeing eye. Surgery was performed by the same surgeon (P.R.). After pupil dilatation and topical mydriatic drops, the anterior chamber remained clear. The Scharioth Macula Lens was monocularly implanted into the right eye four times and into the left eye four times. In patient No. 8 there was a problem with haptic damage during implantation, the tunnel was enlarged, the damaged SML was removed and replaced with a new SML and suture of incision was performed, all without any further complications or effect on postoperative recovery.

Apart from one, all of the patients with the SML acquired good near visual acuity at a recommended reading distance of 15 cm. Preoperatively, the mean (min-max) near UCVA was J13 (J8-J16), with +6.0 diopters J2 (J1-J5) and the mean distance BCVA was 0.27 (0.2-0.3). Postoperatively, the best results were after one month – near UCVA was J2.5 (J1-J7), and the distance BCVA was 0.26 (0.2-0.3). Three months after surgery, this decreased to J4.5 (J1-J8); distance VA remained at 0.25 (0.15-0.3). Six months postoperatively – near vision was J4 (J1-J8) and distance VA was unchanged at 0.24 (0.2-0.3). Reading results are shown in the Table 1.

Postoperative recovery of all of the patients was rapid. No complaints about diplopia or glare were recorded. The patients reported problems with reading speed and reading distance. Daily reading exercises improved their reading ability, and patients emphasized the need for good lighting conditions and having a rest when tired were the other crucial recommendations.

At the baseline and 1 day, 1 week, 1, 3 and 6 months after surgery, the examination included an assessment of uncorrected and best corrected visual acuity at distance (ETDRS charts), visual acuity at a near tested Jaeger reading chart, non-contact intraocular pressure (IOP) measurement, fundus photography, optical coherence tomography, and clinical examination, after pupil dilatation.

While reading, a chart was held at a comfortable reading distance and this was measured and noted. Possible complications were recorded and patients were asked about the quality of their vision after SML implantation. Reading performance was tested and training was provided and, if necessary, improvement of reading technique was recommended.

**RESULTS**

The average (minimal-maximal) age of participants of this study was 79 years (73-85 years). There were 3 men and 5 women. All of the patients underwent cataract surgery approximately 7.5 years (2-15 years) before SML implantation.

There was no difference between the mean preoperative and postoperative IOPs. Preoperatively, the mean IOP (minimum-maximum values) was 13 mmHg (11-16 mmHg), 1 day after surgery it was 13 mmHg (8-15 mmHg), one week postoperatively 14 mmHg (8-21 mmHg), and after one month it was 15 mmHg (9-23 mmHg).

Fig. 1. Correct centration of Scharioth Macula Lens in the eye, haptics fixed in a sulcus, central part of + 10 diopters on the visual axis, behind the SML there is an intraocular lens in the capsular bag.
Loss of field of vision, a short
magnifying low visual aids, amplifying the image to be
user, for example through magnification8. Several external
adapt visual information to render it more visible to the
as sound or touch (sensory substitution); and those that
information into alternative sensory information, such
according to their function: those that translate visual
suffered from AMD.

At the baseline, the mean central retinal thickness
(CRT) (minimum-maximum values) measured with opti-
cal coherence tomography (OCT) was 165 um (115-256
um). In all but two patients, there was dry AMD- geo-
graphic atrophy. In one patient (patient No. 1) there were
soft drusen, and in patient No. 8, there was a stabilized
wet form of AMD. One month after SML implantation,
the mean CRT was 182 um (166-211), three months post-
operatively 197 um (120-338), and after six months it was
176 um (110-212 um).

There were no reported adverse events during the
postoperative period except for one. Of the eight patients
with SML, one (patient No. 1) converted to wet AMD,
three months post-implantation, VA 0.1 and was unable to
read. The conversion was diagnosed early and the patient
underwent anti-VEGF therapy (ranibizumab) with stabil-
ing was better under very good light conditions. Distance
was also observed by the participants in our study, read-
magnified image will dominate when the patient focusses
on near objects. Miosis is accentuated with light and this
was also observed by the participants in our study, read-

**DISCUSSION**

Reading is one of the most frequently performed psy-
cho-physiological operations and requires cooperation
between the oculomotor system (miosis-convergence-ac-
commodation-eye tracking) and the visual system (optical
media of the eye, retina) and interpreting processes in the
brain. Age-related macular degeneration is the most
common cause of loss of reading vision among patients
older than 55 years7. All of the participants of this study
were younger than 55 years7.

Our experience with eight patients to date has been
very favorable. Apart from one, all of the patients in the
study with the SML, acquired good near visual acuity
at a recommended reading distance of 15 cm, without
compromising distance vision. The SML implantation is
feasible for standard cataract surgery and is tolerated by
patients. It does not disturb retinal examination including
OCT, which is important for diagnosing and monitoring
macular or optic nerve disc diseases14,15. Posterior cap-
sule opacification (PCO) is one of the most common
complications of cataract extraction with an intraocular
implantation. No development of a secondary cataract
or any other opacification between the two intraocular
lenses was found.

**Table 1.** Near visual acuity before and after SML implantation (measured with the Jaeger chart), uncorrected postoperatively.

| Patient No. | Age/sex | 1M postop | 1D postop | Preop uncorr. | Preop with +6.0 |
|-------------|---------|-----------|-----------|---------------|---------------|
| 1           | 76/M.   | J13       | J1        | J13           | J13           |
| 2           | 73/M.   | J5        | J2        | J2            | J2            |
| 3           | 85/F.   | J6        | J7        | J6            | J7            |
| 4           | 79/F.   | J13       | J13       | J14           | J14           |
| 5           | 78/F.   | J2        | J1        | J1            | J1            |
| 6           | 77/F.   | J14       | J13       | J8            | J8            |
| 7           | 85/M.   | J1        | J1        | J1            | J1            |
| 8           | 81/F.   | J1        | J1        | J1            | J1            |

D - day, W - week, M - month(s), M. - male, F. - female, J. - Jaeger, preop - preoperatively, postop - postoperatively

three months after surgery the mean IOP was 14 mm
Hg (11-19 mmHg) and remained unchanged six months
postoperatively. There were no problems with corneal de-
compensation after implantation.

The purpose of this study was to present the initial
experience with a new intraocular implant - the Scharioth
Macula Lens. The SML was first implanted in September
2013 by Gabor B. Scharioth. The implant is designed for
sulcus fixation in pseudophakic eyes to increase uncor-
corrected near visual acuity (UNVA) in patients with stabi-
ized maculopathy. It provides sufficient magnification of
2-3 times; the total magnification depends on the anatomy
of the eye and the final reading distance1. The effect of
SML is based on so-called Near Triad Reflex: miosis,
accommodation, convergence. Due to the effect of near
vision miosis, the central optical portion providing the
magnified image will dominate when the patient focusses
on near objects. Miosis is accentuated with light and this
was also observed by the participants in our study, read-
ning was better under very good light conditions. Distance
vision was not influenced by dilated pupils.

Low vision patients using visual aids are required to
use head or hand movements more often than natural eye
movements to scan the text, which results in vestibular-
ocular conflict and discomfort11,12. Images provided by
magnifying devices are different from images the patients
were used to seeing with healthy eyes. This, together with
the different reading techniques required to be used with
visual aids, is the reason why many older visually impaired
adults have difficulty getting used to a new device. Patient
motivation and daily reading exercises are of the utmost
importance for achieving the best results and satisfied
patients, also in the case of patients with SML in our
experience.
lens (IOL) implantation. Other opacifications of IOLs or on the interlenticular surface can also be observed in the case of piggy bag IOL implantations. No development of vision disturbing secondary cataract or any other opacification between the two intraocular lenses was found in any of the participants in this study.

The follow-up of the patients implanted with the SML is ongoing. They will be examined after one year and then every six months post implantation. Our department is also participating in an ongoing multicentric study, the initial results of which will be published soon.

The prospects of reading rehabilitation after SML implantation are promising; despite the very severe findings in the macula, the SML enables the patients involved in our study to read again and their quality of life has improved.

CONCLUSION

The Scharioth Macula Lens is a new hope for low-vision patients, it acts as a magnifier in the eye. It is a suitable method for increasing near visual acuity in patients with maculopathy. Based on our experience, careful preoperative examination, good indication and realistic patient expectations and cooperation are crucial for the optimal outcome. The prospects for reading rehabilitation after SML implantation are more than promising.

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