

Scharioth Macula Lens (SML)

Lente Macular Scharioth

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ABSTRACT

Objective: In this review we critically evaluated the publications on the intraocular implant of the Scharioth Macula Lens (SML) in patients with advanced stages of Age-Related Macular Degeneration (AMD). **Methods:** The literature search was done in Pubmed and Google Scholar database, with the term dry AMD, devices and Scharioth Macula Lens. We use prospective, retrospective articles or case reports published in English or Portuguese in the last five years under these terms. **Results:** A total of 19 articles were found, all in English. Of these, 5 were related to complications of cataract surgery and another to Exudative Macular Degeneration. Therefore, 13 references were used for this review. **Conclusion:** Scharioth Macula Lens was developed for pseudophakic eyes with AMD and has also been used in patients with other maculopathies. The initial results reported are encouraging.

Keywords: Macular degeneration; Lens, intraocular; Lens implantation, intraocular; Visual acuity

RESUMO

Objetivo: Revisar criticamente a literatura sobre o implante intraocular da Lente Macular Scharioth (SML) em pacientes com estágios avançados de Degeneração Macular Relacionada à Idade (DMRI). **Métodos:** A pesquisa bibliográfica foi feita nas bases de dados do Pubmed e Google Acadêmico, com os termos dry AMD, dispositivos e Scharioth Macula Lens. Utilizamos os artigos prospectivos, retrospectivos ou relatos de casos publicados em inglês ou português nos últimos cinco anos, com esses termos. **Resultados:** Foram encontrados um total de 19 artigos, todos em inglês. Sendo que destes, 5 relacionavam-se a complicações da cirurgia de catarata e outro à degeneração macular exsudativa e foram excluídos. Portanto, foram utilizadas 13 referências para esta revisão. **Conclusão:** A Scharioth Macula Lens foi desenvolvida como lente intraocular suplementar para olhos pseudofácicos com DMRI, mas vem sendo usada também em pacientes com outra maculopatias. Os resultados iniciais relatados são animadores.

Descritores: Degeneração macular; Lentes intraoculares; Implante de lente intraocular; Acuidade visual

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INTRODUCTION

Age-Related Macular Degeneration (AMD) is one of the leading causes of irreversible legal blindness in people over 65 years of age. It is estimated that the number of individuals with AMD is 196 million in 2020, and 288 million in 2040. This disease presents pathological alterations in the retinal pigment epithelium (RPE) and Bruch's membrane, including the appearance of ophthalmoscopically visible focal yellow accumulations between the retinal pigment epithelium and Bruch's membrane called drusen. According to the presence or absence of choroidal neovascularization, AMD can be clinically divided into two types: dry AMD, and neovascular or exudative AMD.⁽¹⁾

It is known that exudative AMD can currently be controlled with the use of drugs to block the actions of the vascular endothelial growth factor (VEGF) at different stages of the disease. Dry AMD is associated with the accumulation of free radicals of reactive species of oxygen and lipid peroxide, which evokes the local activation of chronic inflammation and leads to apoptosis of cells of the retinal pigment epithelium with secondary damage of the photoreceptors.⁽²⁾ The dry form accounts for about 80% of cases of AMD.

It is worth emphasizing that so far no treatment has proven to be effective in curing dry AMD, although there is a recommendation for the combined use of vitamins and antioxidants to reduce the rate of progression in the intermediate and advanced forms of the disease.⁽³⁾ Some clinical trials such as cell replacement and microenvironmental regulation of the retina represent new possibilities for approaches in the treatment of dry AMD. Near-sight decrease remains the major problem in all forms of AMD with considerable impairment in reading ability.⁽⁴⁾ For those who have vision loss due to macular degeneration there are resources for subnormal vision that do not always meet the needs of the patients. More recently, intraocular implants with telescope characteristics have become available.⁽⁵⁾

One of the devices in evidence today is the Scharioth Macular Lens (SML) developed in Germany by Professor Gábor B. Scharioth and then manufactured in Switzerland by laboratory Medcontur Ltd. It is a hydrophilic acrylic lens with bifocal design

for implant in the ciliary sulcus in pseudophakic patients (Figure 1). Its aim is to improve the near sight of patients with advanced stage of non-exudative AMD. Likewise, this lens may be indicated for patients with other types of macular disease other than AMD, such as myopic maculopathy, diabetic retinopathy, or hereditary retinal diseases.⁽⁶⁾

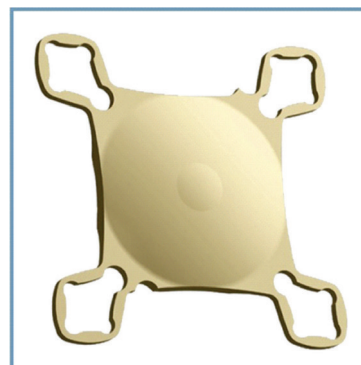


Figure 1: AddOn® Scharioth Macula

METHODS

The bibliographic search was done in the Pubmed and Google Academic databases with the terms dry AMD, devices, and Scariott Macula Lens. We used the prospective, retrospective papers or case reports published both English and Portuguese over the last five years with these terms.

RESULTS

A total of 19 articles were found, all in English. Of these, 5 were related to complications of cataract surgery, and another to Exudative Macular Degeneration. Therefore, 13 references were used for the present review.

Table 1 (adapted to Portuguese) can evaluate the initial results obtained by the professor Gábor B. Scharioth after implantation of SML in 8 patients, in which we verified that there was no worsening of the visual acuity to far sight nor of their visual field.⁽⁶⁾

Table 1
Visual acuity for far and near sight before and after surgery of the first 8 patients with implant of LIO macular Add-on

PATIENT	PRE AVCL	POST AVCL	PRE AVCL @40CM (+2,5 D)	POST AVCL @15CM (+6,0)	POST AVNP @15CM (LIO Macular Add-On)
1	0,4	0,4	0,32	0,5	1,0
2	0,12	0,12	0,064	0,1	0,2
3	0,4	0,4	0,4	0,64	1,0
4	0,05	0,05	0,064	0,064	0,064
5	0,16	0,16	0,1	0,2	0,4
6	0,2	0,2	0,1	0,2	0,5
7	0,1	0,1	0,1	0,2	0,26
8	0,5	0,5	0,26	0,5	0,64

Avcl = corrected visual acuity for far sight; AVCP = corrected visual acuity for near sight; IOL – intraocular lens; AVNP = uncorrected visual acuity for near sight.

DISCUSSION

Characteristics of the lens: this is a folding supplemental intraocular lens of hydrophilic acrylic with design for implant in a the ciliary sulcus of pseudophakic patients. In the part corresponding to the center 1.5 mm of the lens, the diopter power is 10 positive diopters (+ 10 D), with the remainder of the optic part being with neutral refractive power. It is a lens with four symmetrical haptics, and a total diameter of 13 mm (Figure 1). It must be inserted by the cartridge through an incision of at least 2,2 mm.⁽⁶⁾

The center portion of + 10 D allows magnification of the image 2 times at the recommended reading distance of 15 centimeters, according to mathematical calculations.

Visual results reported: Preliminary studies show that the magnification obtained corresponds to a change in acuity for near sight from Jaegger 13 (J13) preoperatively to J4 at the evaluation 6 months after surgery in 8 patients preliminarily evaluated.⁽⁷⁾ Scharioth reports improvement of 4.4 lines for near sight in eight patients when compared to the vision obtained by adding + 2.5 D for reading at 40 cm preoperatively.⁽⁷⁾

Preoperative evaluation / patient selection: in the initial studies, patients older than 55 years with dry macular degeneration without evidence of intra- or sub-retinal fluid were recruited by the optical coherence tomography, with corrected visual acuity from 0.05 to 0.4 (20/400 to 20/50) and pseudophakic.⁽⁸⁾

According to the manufacturer's recommendation, visual acuity for near sight with addition of + 6D should allow the reading of letters in line J6 or better in the distance of 15 cm (excluding patients with maculopathy in activity, iris atrophy or neovascularization, pupillary size less than 2.5 mm in photopic conditions, severe zonulopathies, anterior chamber depth less than 2.8 mm, narrow angle, and previous retinal surgeries). In addition to this data, there should be a substantial improvement in near sight compared to that obtained with the addition of + 2.5D at 40cm. The best vision eye was selected for surgery.⁽⁷⁾

Active maculopathy; neovascularization or iris atrophy; pupil with diameter less than 2.5 mm; anterior chamber depth greater than 2.8 mm; narrow cameralar sinus; previous retinal surgery; and severe ocular disease were considered exclusion criteria. All patients signed a consent form in accordance with the Declaration of Helsinki.⁽⁷⁾

Surgical technique: after adequate mydriasis and topical anesthesia, a corneal incision of 2.2 mm or greater is made, the anterior chamber is filled with viscoelastic, and then the lens is implanted in the ciliary sulcus in front of the existing one in the capsular bag. To inject the lens, the cartridge itself is used, and after verifying the correct positioning of the lens the viscoelastic is aspirated. At the end the incision is hydrated, ending the surgery.⁽⁶⁾ Steroid and antibiotic eye drops are used in the first week, keeping the topical corticosteroid up to one month after the procedure.

CONCLUSION

Currently there are several methods to help patients with loss of central sight, especially in relation to near sight activities as reading, looking at figures, etc. Image-magnifying devices, called subnormal sight features, may be difficult to handle especially for elderly patients who often do not adapt to their use. Individuals with visual loss caused by AMD fall within this group of patients.

Different intraocular implants have been developed to improve visual acuity in these cases by increasing the

magnification of the image in the retina and without the need to use magnifying glasses or other external devices. However, most devices cause visual field loss and binocularity, which can create difficulties related to mobility. Another feature of most IOLs for eyes with maculopathy is the fact that they require a corneal aperture larger than the one of the folding lenses routinely used, and are not adaptable to pseudophakic eyes.

Scharioth Macula Lens are foldable, and were developed as additional lens for pseudophakic eyes with AMD. It is an option to allow small incisions, use both in eyes with IOL in the capsular bag and in primary cataract, and that has been used also in patients with other maculopathies. The initial results reported are encouraging, the surgical procedure is easy to perform, and the rate of complications is very low.

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