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ORIGINAL ARTICLE

Incidence of posterior capsular opacification requiring Nd:YAG capsulotomy after cataract surgery and implantation of enVista® MX60 IOL

Incidence de l'opacification capsulaire postérieure nécessitant une capsulotomie au laser YAG après chirurgie de la cataracte et implantation avec enVista® MX60

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KEYWORDS
Cataract surgery;
Glistening;
Intraocular lens;
MX60;
Posterior capsule opacification

Summary
Purpose. — To evaluate incidence of posterior capsule opacification requiring Nd:YAG capsulotomy over 3 years in a large series of eyes implanted with the enVista® MX60 Intraocular Lens (IOL).
Methods. — A university-based, single-center, observational study of patients' medical records was conducted. Uneventful cataract surgery patients with in-the-bag implantations of the enVista® MX60 IOL with a minimum of 24 months follow-up were included in the study. Exclusion criteria were insufficient follow-up (< 24 months), intraoperative complications and combined surgery. The primary outcome measure was rate of YAG laser capsulotomy, while secondary outcome measures were time to YAG laser capsulotomy and rate of glistenings.

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Results. — A total of 245 eyes of 143 patients received the MX60 IOL and were followed in the same center. Of these, 226 eyes were included in the study. Mean age was 80.7 ± 8.3 years and M/F ratio was 42/101 (29.4/70.6%). The mean preoperative distance (logMAR) visual acuity was 0.67 ± 0.5, while postoperatively it was 0.31 ± 0.5 and 0.32 ± 0.5 at the last visit. The Mean ± SD follow-up time (min-max) was 35.2 ± 7.2, (24–48.4) months. The incidence of Nd:YAG capsulotomy over 3 years was 5/226 (2.2%). Average time between surgery and Nd:YAG capsulotomy was 32.17 months. Univariate analysis of age, gender, presence of comorbidity and baseline visual acuity found no predictive factors for capsulotomy. No glistenings were reported at any postoperative visit.
Conclusion. — The three-year cumulative incidence of PCO requiring Nd:YAG laser capsulotomy was 2.2% for the enVista® MX-60 IOL, with no glistenings observed during follow-up. This low rate confirms the excellent safety profile of this IOL.

MOTS CLÉS
Chirurgie de la cataracte ;
Microvacuole ;
Lentille intraoculaire ;
MX60 ;
Opacification de la capsule postérieure

Résumé
Objectif. — Évaluer l'incidence d'opacification de la capsule postérieure nécessitant une capsulotomie Nd:YAG sur 3 ans dans une série de yeux implantés avec une lentille intraoculaire (LIO) enVista MX60.
Méthodes. — Il s'agit d'une étude observationnelle monocentrique analysée rétrospectivement à partir des dossiers médicaux des patients. Les patients opérés de la cataracte ayant reçu un implant enVista® MX60 dans le sac avec un minimum de 24 mois de suivi ont été inclus dans l'étude. Les critères d'exclusion étaient un suivi insuffisant (< 24 mois), des complications périopératoires et une chirurgie combinée. Le critère de mesure principal était le taux de capsulotomie au laser YAG, tandis que les mesures secondaires étaient le délai de capsulotomie au laser YAG après l'implantation de la LIO et le taux de microvacuoles.
Résultats. — Un total de 245 yeux de 143 patients ont reçu les implants MX60 IOL et suivis dans le même centre. Parmi ceux-ci, 226 yeux ont été inclus dans l'étude. L'âge moyen était de 80,7 ± 8,3 ans et le rapport H/F de 42/101 (29,4/70,6 %). L'acuité visuelle préopératoire moyenne (logMAR) était de 0,67 ± 0,5, alors qu'en postopératoire elle était de 0,31 ± 0,5 et de 0,32 ± 0,5 lors de la dernière visite. Le temps de suivi moyen ± écart-type (min-max) était de 35,2 ± 7,2 (24–48,4) mois. L'incidence de la capsulotomie Nd:YAG sur 3 ans était de 5/226 (2,2 %). La durée moyenne entre la chirurgie et la capsulotomie Nd:YAG était de 32,17 mois. L'analyse univariée de l'âge, du sexe, de la présence d'une comorbidité et de l'acuité visuelle de référence n'a révélé aucun facteur prédictif de la capsulotomie. Aucun cas de microvacuole n'a été signalé lors d'une visite postopératoire pendant la période de suivi.
Conclusion. — L'incidence cumulée sur trois ans de la PCO nécessitant une capsulotomie au laser Nd:YAG de 2, 2 % pour la LIO enVista® MX-60 sans microvacuole observé pendant le suivi suggère un bon profil de sécurité de ce type d'implant de chambre postérieure.

Introduction

Posterior capsular opacification (PCO) remains one of the most common complications after cataract surgery [1] and is characterized by a gradual loss of posterior capsule transparency, linked to migration and proliferation of epithelial cells persisting in the capsular bag after surgery [2] This opacification of the capsule can lead to a secondary decrease in visual acuity when it obscures the visual axis, 3 but also reduced contrast sensitivity, and the emergence of visual symptoms such as halos [3]. Standard treatment of PCO is the neodymium-doped yttrium aluminum garnet (Nd:YAG) capsulotomy [4]. Although the Nd:YAG capsulotomy is a relatively safe and non-invasive intervention [5], it is associated with few complications, such as transient elevation of intraocular pressure, cystoid macular edema, secondary retinal detachment and intraocular lens damage[5]. Given the possible complication associated with its treatment, recent years have witnessed significant strides towards the prevention of post-capsular opacification [6].

Several factors can determine the performance of an IOL [7]. IOL shape and edge have been identified as an important determinant of post-implantation PCO, as outlined in a meta-analyse, which show that sharp edged IOLs were associated with reduced PCO scores, compared with round

edged IOLs [8,9]. In addition, several studies have demonstrated reduced posterior capsule opacification associated with the use of 360° sharp posterior optic edge IOLs [10–12] The lens biomaterial is also a key factor in the performance of IOLs [13]. As IOLs are being implanted at earlier ages and are expected to remain in-situ for life, long-term capsular and uveal compatibility of IOL materials as well as post-implantation transparency have become increasingly important [14].

The enVista® MX60 (Bausch&Lomb, Rochester, NY USA) obtained CE marking in 2010 and FDA authorization in May 2012. It is a hydrophobic, aspheric, monobloc, glistening-free ultraviolet absorbing chromophore lens. Its square edge and 360° barriers are intended to limit cellular migration, and therefore prevent posterior capsular opacification. The FDA study conducted in 100 patients demonstrated the effectiveness and safety of the lens in restoring visual acuity after cataract surgery [15]. A PCO evaluation, analyzed with the Evaluation of the Posterior Capsule Opacification (EPCO) software using retro-illuminated photo reported encouraging results, with a score near zero in the last 4–6-month visit [16,17] This EPCO software evaluation was conducted 24 months following implantation on a sub-group of 20 patients. The low score of 0.08 was encouraging, despite the small sample size. However, there was no published data of PCO rate requiring Nd:YAG capsulotomy in patients with enVista® MX60 IOL in the literature

In this retrospective study, the incidence of Nd:YAG capsulotomy over 3 years was evaluated in a series of eyes implanted with enVista® MX60.

Material and methods

We conducted an observational study. Eligible patients matching the inclusion criteria were identified by a retrospective review of patients' medical records. Informed consent was obtained from all participants. The study was conducted in accordance with the declaration of Helsinki, and all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during this research. Institutional Review Board approval was obtained.

Patients with cataract with an uneventful, in-the-bag implantation of the enVista® MX60 intraocular lens, with a minimum of 24-month follow-up were included. We prescreened and established an initial list of patients implanted with the enVista® MX60, ranked by date surgery since the first implantation (last quarter 2011–December 31, 2012), to ensure a follow-up of at least 24 months. All patients received standard phacoemulsification with IOL implantation in the bag in both eyes from the same surgeon. Patient medical records were reviewed to ensure their eligibility from December 2014 to March 2015: Implantation of the enVista® MX60 in the capsular bag, intact caspulorhexis, and the collection of patient's consent to the use of his/her medical data. If a patient was not eligible, s/he was replaced by the following patient on the chronological list. We collected demographic characteristics (age, sex,) comorbidities, significant complications and postoperative complications, which could impact the development of PCO. All included patients were followed postoperatively and had capsulotomy if needed during the follow-up in the same center. The decision of Nd:YAG capsulotomy to treat PCO was performed by the same surgeon, based on visual acuity, slit-lamp examination, and funduscopy. PCO has been assessed as a central opacification of the posterior capsule responsible of decreased visual acuity, and/or hindering the examination of the fundus and/or low quality of optical coherence tomography quality in patients with retinal diseases.

We also recorded dates of surgery, date of the last visit to the clinic and date of event capsulotomy. Visual acuity was measured in LogMAR before and after surgery, and before capsulotomy.

To establish the impact of Nd:YAG Laser Capsulotomy, Kaplan-Meier estimates of survival curves was used. The log-rank test, the Cox model were used to adjust the incidence rates, taking into consideration patient differences (age, sex, comorbidities) and the potential effect center. Statistical analysis was performed using SPSS for Windows (version 17.0/SPSS Inc, Chicago, IL). Statistical signification was set at $P < 0.05$.

Results

Characteristics of patients

A total of 245 eyes received the MX60 IOL implants, of these, 226 eyes from 143 patients were included in the study. Mean age of subjects ± SD (min-max) was 80.7 ± 8.3, (55–94 years) M/F ratio of 42/101 (29.4/70.6%) 19 eyes were excluded from the analysis: of these 18 (94.4%) had follow-up duration < 23.5 months and 1 (5.6%) had operative complication of posterior capsular rupture preventing in the bag implantation. A total of 18 patients received concomitant treatment with anti-VEGF injections for DMLA or diabetic macular edema.

Preoperative information

Mean ± SD (min-max) corrected distance visual acuity (Log MAR) prior to surgery was 0.67 ± 0.5 (0.10–3.00). Median IOL power was 22.3 D (2.0–30). Around 66 (29.2%) eyes had at least one comorbidity. The most common comorbidity was neovascular age-related macular degeneration (AMD), which was seen in 31 (13.7%) eyes. This was followed by diabetes in 18 (8%) and glaucoma in 13 (5.8%) eyes. Previous ocular surgery was found in 4 (1.8%) and other comorbidities (central vein occlusion, closed angle glaucoma) in 2 eyes (0.9%).

Postoperative information

Majority of eyes (221/226, 97.8%) had no postoperative complications. Persistent postoperative corneal edema found in 2 eyes (0.9%) of one patient which occurred at 1 month of follow-up in a patient with previous cornea guttata instead of careful surgery. Slight IOL decentration/tilt was present in 3 (1.3%) eyes. Mean postoperative distance VA ± SD (min-max) (Log MAR) was 0.31 ± 0.50 (0.00 to 3.00). Mean follow-up time was 35.2 months (23.5–48.4).

Mean corrected distance VA ± SD (Min-Max) after surgery was 0.25 ± 0.42 (0.00 to 2.00).

Information at last visit

The mean ± SD (Min-Max) duration between surgery and last visit was 9.5 ± 12 months (0.00–44), while the mean delay between cataract surgery and Yag was 32.17 months and the mean ± SD (Min-Max) corrected distance VA at last visit was 0.32 ± 0.50 (0.00–2.00). No glistening was recorded at any visit in the studied population (Fig. 1).

Incidence of capsulotomy

Around 5 eyes (2.2%) received YAG Capsulotomy due to posterior capsular opacification within an average time of 32.17 months. Incidence of YAG Capsulotomy at 12, 24 and 36 months were 0.93% (2/213 eyes), 0.93% (2/213 eyes) and 3.2% (7/213 eyes) respectively.

Predictive factors of Nd:YAG capsulotomy

In a Univariate analysis of factors predictive of Nd:YAG capsulotomy we found that gender ($P = 0.5378$, 95% CI = 0.221–18.06), presence of comorbidity ($P = 0.2107$, 95% CI = 0.449–37.564) and baseline visual acuity ($P = 0.2731$, 95% CI = 0.003–5.290) were not predictive factors of Nd:YAG capsulotomy.

Discussion

Reduction in the incidence of postoperative posterior capsular opacification and improvement in postoperative visual outcomes of patients receiving IOL implants are key factors in the design and production of IOLs. In this study of 226 eyes, we demonstrate a 2.2% three-year cumulative incidence of PCO requiring Nd:YAG laser capsulotomy in patients who have received the enVista® MX60 intraocular lens. This PCO rate is lower than previously reported (5.2% at 3 years and 11.9% at 5 years). On multivariate analyses, Sundelin et al. [18] found that the risk of requiring Nd:YAG laser capsulotomy was associated with younger age, follow-up time and the type of IOL (adjusted OR 9.4 [95% CI 2.5–35.7]). The group with hydrophilic 1-piece IOL (Akreos) exhibited a significantly increased risk of developing visually significant PCO with an incidence of 57.1% as compared to 8.6% in the group with hydrophobic 3-piece IOL (Tecnis) and 11.5% in the group with hydrophobic 1-piece IOL (Acrysof).

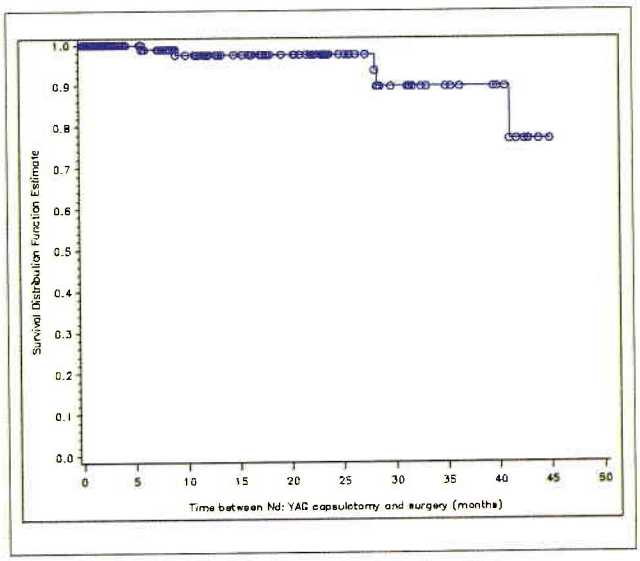

Figure 1. Time between Nd:YAG capsulotomy and surgery (months).

Few data about incidence of PCO requiring YAG capsulotomy in patients receiving enVista® MX60 intraocular lens was available in the literature. Packer el al reported low score of 0.032 using the EPCO (''Evaluation of posterior capsule opacification'') software in a prospective case series of patients who received enVista® MX60 at 6 months of follow-up. This is a morphological assessment of PCO where the density of opacification was graded on a scale of 0 to 4 (0 = none, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe) [16,17]. No glistening was observed in any visit for any subject in either these reports or our in our study. We suggest that the low incidence of PCO requiring YAG capsulotomy found in our study might be explained by the design and material characteristics of the lens. The enVista® MX60 is made from hydrophobic material and has a 360° posterior square-edged optic surface. Our study highlighted recent findings on the critical importance of a square posterior optic edge in prevention of PCO formation [18–21]. Furthermore, the MX60 IOL has step-vaulted haptics that translate the optic posteriorly for direct contact with the capsular bag, associated with its hydrophobic surfaces, leading to reduce PCO [22–24]

In addition, the age of our study population might be an important factor in the low incidence of PCO requiring Nd:YAG laser capsulotomy. The mean age of our study population is 80.7 years with more than 90% of patients were over 70 years of age at the time of surgery. About a third (29.2%) of our population had associated comorbidities at baseline. Importantly, the most common comorbidity was neovascular age related macular degeneration seen in 13.7% of patients, who concomitantly received anti-VEGF therapy. The impact of anti-VEGF therapy on the pathogenesis of PCO needs to be elucidated. However, we suggest that anti-VEGF therapy may play a role to manage PCO development since VEGF was found to regulated cell survival, growth and myofibroblast formation [25].

In this study, we found a mean interval between cataract surgery and Nd:YAG laser capsulotomy of 32.17 months (2.6 years), which is longer than previously reported in other studies, which have recorded mean periods of 15.8 to 24 months [26,27]

The main weakness of this study lies in the paucity of longitudinal cohort data, which makes it difficult to identify cofounding factors associated with our primary outcome. Another limit of our study is its retrospective nature. A longitudinal cohort with a comparator group with another IOL would help us to establish a greater degree of accuracy on the incidence of PCO requiring Nd:YAG capsulotomy following implantation of the enVista® MX60IOL.

Conclusion

Implantation of the enVista® MX60 is associated with low, three-year cumulative incidence rates of PCO requiring Nd:YAG laser capsulotomy.

Disclosure of interest

The authors declare that they have no competing interest.

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