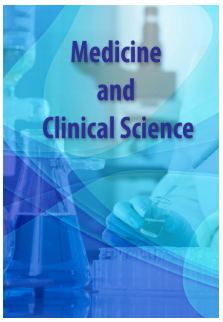
Medicine & Clinical Science

Research Article



Posterior capsule opacification (PCO) rate of a hydrophilic acrylic intraocular lens suitable for microincisional cataract surgery (MICS)

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Keywords

Secondary cataract; posterior capsule opacification; microincisional cataract surgery

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Abstract

Purpose: To determine the capsulotomy rate of MICS-IOL (IntraOcular Lens) L-313 compared to other IOLs.

Setting: Department of Ophthalmology of the Dietrich Bonhoeffer Klinikum (DBK) in Neubrandenburg, Germany, Teaching Hospital of the University Greifswald, Germany

Design: Monocentric, partly retrospective and partly prospective study

Method: Data from a total of 5.549 eyes implanted with MICS IOL LENTIS L-313 (OSD Medical GmbH, Berlin, Germany) during cataract surgery in our clinic between 9/2009 and 12/2013 were collected between 5/2013 and 10/2017. It is registered at www.clinicaltrials.gov (NCT03184428).

The performance of a laser capsulotomy was evaluated as a criterion for the presence of a clinically relevant PCO. The statistical evaluation was carried out using Kaplan-Meier statistics with the program STATISTICA, Version 13 (StatSoft, Hamburg, Germany).

Results: The average patient age was 73.75 years ± 9.06 (range 5 to 96) and 59.2% were female. The median follow-up period is 4.2 years. 4.224 data sets could be evaluated for patients over 54 years of age. The IOL L-313 PCO rate is 4.7% after 1 year, 8.2% after 2 years, 17.2% after 4 years and 22.4% after 6 years.

The L-313's PCO rate is low compared to other MICS lenses and two to three times higher compared to non-MICS lenses with a sharp optical edge. It is only half compared to that of (PMMA) lenses.

Conclusions: The L-313 IOL's PCO rate is approximately twice to three times higher than non-MICS IOLs with a sharp optical edge but low compared to the PCO rate of other MICS-IOLs.

Introduction

By improving the surgical technique [1-10] and introducing modern intraocular lenses, the posterior capsule opacification (PCO) rate after posterior chamber lens implantation has been reduced. However, it still remains the most common postoperative complication of cataract surgery [11-24].

PCO formation leads to reduced visual acuity and increased glare sensitivity and ultimately requires a Nd: YAG laser capsulotomy. The PCO rate varies considerably depending on the IOL -material and –design [25-28]. MICS-IOLs (microincision cataract surgery intraocular lens) appear to have a higher PCO rate than non-MICS lenses [29-81]. According to Menapace a lens is defined as a MICS lens if it can be implanted through a corneal incision ≤ 2 mm [82]. In this paper we use the term "non-MICS lens" to describe a IOL that is usually implanted through a wider incision.

The aim of this study is to determine the capsulotomy rate of the L-313 MICS-IOL (OSD Medical GmbH, Berlin) approved on the German market and to compare these results with the capsulotomy rates of other intraocular lenses (in particular with other MICS-IOLs) indicated in the literature.

Patients and Methods

Intraocular Lens

The LENTIS L-313 MICS lens (OSD Medical GmbH, Berlin, Germany) is a foldable, hydrophilic, one-piece acrylic posterior chamber lens with a hydrophobic acting surface, sharp optic and haptic edge, an optical diameter of 6.0 mm and a total diameter of 11.0 mm. The lens is implanted through a 1.8 mm diameter injector. We have been implanting this lens in our clinic since 2009 and, with over 7.000 implantations, have a sufficient amount of knowledge and experience to be able to make a representative statement about the postoperative PCO rate.

Patients and surgical technique

There was no co production of research within Patient and Public Involvement.

This study includes 5.549 eyes that were treated with the L-313 intraocular lens during cataract surgery at the Dietrich Bonhoeffer Hospital and Clinic in Neubrandenburg from September 2009 to December 2013.

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The patients were operated under retrobulbar anaesthesia, topical anaesthesia or intubation anaesthesia. Two corneal 1mm paracenteses were created. The capsulorhexis was performed manually (continuous curvilinear capsulorhexis) under viscoelastic protection (predominantly methyl cellulose, Zeiss, Jena, Germany) with a target diameter of approx. 5.0 mm. Then phacoemulsification and lens implantation were performed through a clear cornea incision. The incision was made on the steeper axis based on the pre-existing corneal astigmatism. The width of the incision was 1.8 mm (two such incisions) for biaxial phacoemulsification if corneal astigmatism was less than 0.5 dpt, 2.2 mm if corneal astigmatism was up to 1.5 dpt and up to 3.2 mm if corneal astigmatism was more than 1.5 dpt. The incision extension up to 3.2mm was performed at the end of the cataract operation as an anti-astigmatic incision. Seven different surgeons performed the surgeries and used the Divide & Conquer, Chip & Flip and Phakochop techniques. The cortical residues were always extracted bimanually. Each surgeon used either the polishing curette, diamond polisher, aspiration cannula or water jet polishing to polish the posterior capsule. The rear surface of the front capsule was not polished. Then, either under irrigation or after filling the capsular bag with viscoelastic, the L-313 lenses were implanted into the capsular bag (using an injector with a diameter of 1.8 mm). The corneal incisions and the paracenteses were then hydrated. Postoperatively, the patients received cortisone- and antibiotic-containing eye drops and ointments for about 4 weeks.

Data collection and statistical analysis

The data were planned to be collected from the database of the Dietrich Bonhoeffer Hospital and Clinic in Neubrandenburg by means of patient surveys, from the databases of the ophthalmologists providing follow-up treatment and eventually from an invitation of the patients to the Hospital. To save transportation costs patients that lived further than 50 km away from the hospital, were excluded.

The data was collected chronologically in four steps (the first retrospectively, the others prospectively):

First, all pre-, intra-, and postoperative data were retrospectively collected from patient files between May 2013 and March 2016, also with regard to whether a Nd:YAG-laser capsulotomy had already been performed. Neodymium-YAG capsulotomies already performed were recorded as uncensored cases with the Kaplan-Meier statistics and the patients without capsulotomy were censored with the last available follow-up date in our patient records.

Secondly, all patients with no current findings in their medical records were asked in filling out a standardised questionnaire whether and when a laser treatment of the PCO had been carried out in the meantime. The possible answers were “yes”, “no” and “I'm not sure”. This second study step was carried out prospectively after approval by the University of Greifswald’s Ethics Committee.

Thirdly, if the answer was uncertain or unusable, or if the patient did not respond, a telephone consultation was carried out with the patient.

In a fourth step, if the answer was still uncertain or unusable, or if the patient did not provide any feedback, the post-treatment ophthalmologists were asked to provide information on the posterior capsule opacification (by phone, written inquiry or by visiting the practice).

It was not necessary to invite patients to our hospital for assessment, as intended in the study protocol, because all necessary data could be collected in the first four steps.

Data collection included age, gender, lens density, duration of surgery, phaco machine used, phaco energy, phaco time, surgeon, IOL refractive power, incision size, and the combination of cataract surgery with other procedures.

No data on general diseases or other eye diseases was collected because the literature does not contain any significant correlations to these diseases [83,84]. For medical reasons, eyes in which a posterior capsule rupture had occurred intraoperatively were excluded.

If patients had undergone cataract surgery on both sides, both eyes were included in the database if there were no reasons for exclusion.

The statistical evaluation of the collected data was carried out with the program STATISTICA, version 13 (StatSoft, Hamburg, Germany) with the Kaplan-Meier analysis. For the correlation tests, the Spearman-Rank correlation test was used and a Bonferroni adjustment was made during test repetition.

Given that in the literature children and young adults have a higher and faster PCO development [85,86], the statistical evaluations for the group under 55 and the group from 55 or older were carried out separately.

To compare the PCO rates we collected with those of other MICS and conventional (non-MICS) intra-ocular lenses, publications were selected that used the Nd:YAG laser capsulotomy frequency as a criterion for the PCO formation [29-81]. Studies whose PCO criterion is based on other methods, such as the evaluation of retroillumination images, are not taken into account due to lack of comparability [87-123].

Some of the comparative publications have significantly shorter follow-up periods than our work. However, the follow-up period has a considerable influence on the PCO rate. We have taken the corresponding PCO rate from our Kaplan-Meier curve for the respective average follow-up time of each individual foreign publication.

Results

During the study period, a total of 5.549 eyes (women 59.2%, men 40.8%) received a LENTIS L-313 intraocular lens during cataract surgery. The average age of the patients was 73.75 ± 9.06 years (range 5 to 96 years).

A total of 952 eyes were excluded from the study (see exclusion criteria in the method section): 20 eyes (intraoperative posterior capsule rupture), 924 eyes (more than 50 km away), 8 eyes (lens exchange).

No follow-up findings were available for 209 eyes: 13 eyes (closure of post-treatment ophthalmologist’s practice), 64 eyes (lack of patient consent to the study), 131 eyes (not available in any general practitioner system), 1 eye (no follow-up). This leaves 4.388 eyes for evaluation.

The data on the 4.388 eyes were collected as follows: 155 eyes from our patient records, 1.356 eyes by mail from the patients, 1.397 eyes from phone calls with the patients, 1.480 eyes from the patient records of the licensed ophthalmologists.

Figure 1 shows the age distribution on the day of surgery. The average follow-up period is m=1.480 days (corresponding to 49.3 months or 4.1 years). The median is 1.527 days (corresponding to 50.9 months or 4.2 years). We classify the lens density on a scale from 0 (soft) to 4 (very hard). The average was 1.77 (n = 3.944). The duration of the operation was documented in minutes. It averaged 14.0 min (n = 4.068). Seven phaco machines (n = 3.906) were used for phacoemulsification: Millennium (Bausch & Lomb, Rochester, NY, USA): 2.322 eyes, Geuder Megatron (Geuder AG, Heidelberg, Germany): 1.091 eyes, EVA (DORC, Zuidland, the Netherlands): 93 eyes, Stellaris (Bausch & Lomb, Rochester, NY, USA): 13 eyes, OERTLI (Oertli Instrumente AG, Berneck, Switzerland): 301 eyes, Zeiss Visalis (Zeiss, Oberkochen, Germany): 53 eyes, Constellation (ALCON, Fort Worth, TX, USA): 33 eyes. The phaco energy was documented in % of the power. It averaged 31.9% (n = 3.864) and the effective phaco time was documented in seconds. It averaged 9.7 s (n = 4.088). Seven surgeons performed the cataract operations (n = 4.049): HH: 29 eyes, SE: 1.367 eyes, VE: 1.397 eyes, HA: 253 eyes, DRA: 565 eyes, WE 278 eyes, WEI: 69 eyes. The IOL refractive power was documented in diopters. It averaged 21.2 dpt (n= 4.224).

The incision size was divided into two groups. 3.649 of 4.224 eyes, were operated through a 1.8 or 2.2 mm incision and 575 eyes through a 3.2 mm incision. In 127 eyes cataract surgery was performed in combination with other procedures (e.g. vitrectomy or glaucoma surgery) and in 3.831 eyes a pure cataract surgery was performed.

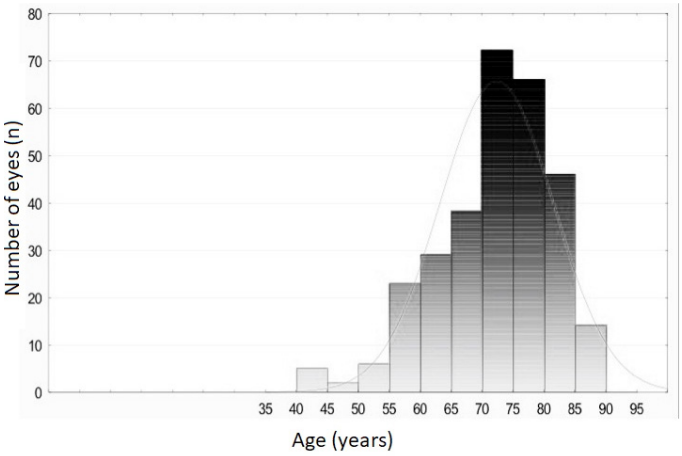

Figure 1: Age distribution of patients on the day of surgery (n = 4.388). The width of the age columns is five years and ranges, for example, from 45 to 49 years and so on.

Figure 2A shows the capsulotomy rate of IOL L-313 in patients younger than 55 (n = 164). Two time periods can be distinguished in this curve. In the first phase, the capsulotomy rate evolves almost linearly (7% per year) and relatively steeply over time. In the second phase (after approx. 4 years) a plateau appears to form (PCO development 2% per year).

Figure 2B shows the capsulotomy rate of IOL L-313 in ≥55 year-old patients (n = 4.224). The capsulotomy rate or PCO rate for these patients is 4.7% after 1 year, 8.2% after 2 years, 17.2% after 4 years and 22.4% after 6 years. In this curve, these two periods cannot be distinguished as clearly as in the younger patients. In the first 4 years, the PCO rate evolves at 3.5% per year. After the fourth year, this evolution is reduced to 2.6% per year.

The average capsulotomy rate was 10.4% and the average time (from day of surgery to day of capsulotomy) was 899.0 days (30.0 months). The median was a 9.6% capsulotomy rate after a median of 829 days (27.6 months).

To compare the PCO rates we collected with those of other MICS and non-MICS intraocular lenses, we have taken into consideration publications that also used the Nd:YAG laser capsulotomy frequency as a criterion for PCO formation [29-73, A-H]. The PCO rate correlates with patient and intraoperative data as follows (Spearman-Rank correlation):

Significant correlations (in eleven test repetitions a $p < 0.0045$ is required after Bonferroni adjustment for a statistically significant correlation with a probability of error of < 5 %): PCO rate to age ($r = -0.87$, $n = 4,388$, $p = 0.0001$), PCO rate to combined procedure ($r = 0.05$, $n = 4.224$, $p = 0.002$)

No significant correlations were found after Bonferroni adjustment of PCO rate to gender, lens density, operation duration, phaco machine, phaco energy, phaco time, surgeon, IOL refractive power and incision size.

Discussion

Posterior capsule opacification is the most common complication of cataract surgery in the postoperative process. A Nd:YAG laser capsulotomy is necessary when postoperative vision is impaired by the development of posterior capsule opacification. We have defined the laser treatment of a "clinically relevant" posterior capsule opacification as a measure for our analysis. Compared to evaluating retroillumination images, this parameter has the advantage that it takes into account the influence of the posterior capsule opacification on visual acuity. The posterior capsule opacification is only clinically relevant if it affects the visual acuity and we assume that in that case it was treated with Nd:YAG laser capsulotomy. The influence on visual acuity cannot be derived directly from pure area measurements of the posterior capsule opacification areas in retroillumination images.

In contrast to the evaluation of retroillumination images, the comparative evaluation using the Nd:YAG laser frequency requires a significantly longer follow-up time in order to achieve valid results. This prerequisite here is a maximum follow-up time of more than 6 years and a median follow-up time of 4.6 years.

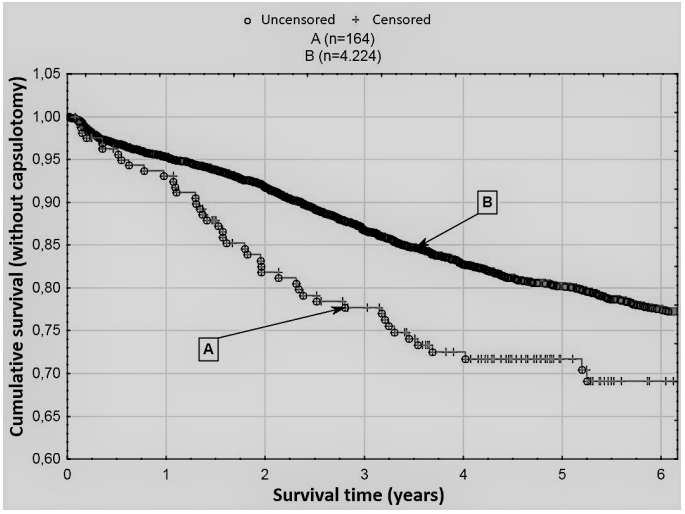

Figure 2: A: Kaplan-Meier curve of the PCO rate after L-313 implantation of patients younger than 55 (n = 164). The rate of PCO development from the first to the fourth postoperative year is 7% per year, followed by a plateau with an average PCO development of 2% per year.
B: Kaplan-Meier curve of PCO rate after L-313 implantation of patients older than 54 (n = 4.224). The average speed of PCO development from the first to the fourth postoperative year is 3.5% per year and then flattens out with an average PCO development of 2.6% per year.

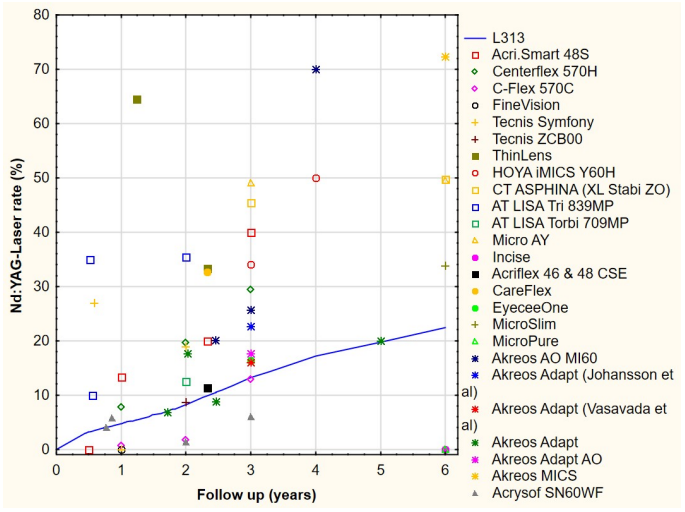

Figure 3: The L-313's capsulotomy rate is indicated by a blue line for up to 6 years in each case. The publications on the reference lenses are given as data points with the capsulotomy rate and follow-up time (see legend in the figure for coding). The majority of comparison lenses have a higher capsulotomy rate than the L-313.

To compare the posterior capsule opacification frequency of the LENTIS L-313 IOL (OSD Medical GmbH, Berlin, Germany) with other intraocular lenses, we have used publications that also used Nd:YAG capsulotomy as a criterion for posterior capsule opacification development [29-81].

Comparison with MICS lenses (Figure 3):

Three groups can be distinguished within the MICS lenses, depending on the PCO rate.

The lenses in the first group have a very low PCO rate of zero percent, e.g. the Acri.Smart 48S (Acri.Tec®, Hennigsdorf, Germany) after 6 months [29], FineVision (Physiol SA, Liege, Belgium) after 1 year58 and Incise (Bausch & Lomb, Rochester, NY, USA) and MicroPure (PhysIOL, Liege, Belgium) 6 years postoperatively [77]. After 850 days, the Acri.Smart 48S PCO rate is 20.0 % [64]. The data set in the work of Ruiz-Mesa et al [58] is quite small (n=40). We are not aware of the method used to determine the PCO rate in the work of Lesieur et al. [77] with regard to Incise and MicroPure.

In the second group are the MICS lenses with a low capsulotomy rate but comparable to that of L-313, C-Flex 570C (Rayner, London, UK) [48,71], AT LISA Torbi 709MP (Zeiss, Jena, Germany) [78], Akreos Adapt and Akreos Adapt AO (Bausch & Lomb, Rochester, NY, USA) [71,75], EyeceeOne (Bausch & Lomb, Rochester, NY, USA) [46], the Tecnis ZCB00 (AMO, Santa Ana, CA, USA) [78] and Acrysof SN60WF (ALCON, Fort Worth, TX, USA) [31,46,52,63]. This group also includes Acriflex 46 and 48 CSE (Acrimed GmbH, Berlin, Germany). According to the work of Spyridaki et al (Figure 3), the PCO rate of the AcriFlex 46&48 CSE is 11.4%. This puts the L-313 at 9.8%, similar to the Acriflex. The similarity of the PCO rates of these two IOLs (L-313 and AcriFlex) was to be expected because the AcriFlex 46 is the L-313's predecessor. The comparability of these two IOLs' PCO rates also confirms the validity of our comparison method, including the back calculation to the comparative publication's follow-up period. All these lenses have a sharp optic edge.

The third group consists of lenses with a higher capsulotomy rate than L-313. This group comprises Centerflex 570H (Rayner, London, UK) [30], ThinLens (Thinoptx Inc., Virginia, USA) [55,64], Hoya iMICS Y60H (HOYA, Tokyo, Japan) [60,61], CT ASPHINA, previously known as XL Stabi ZO, (Zeiss, Jena, Germany) [32,75,77], AT LISA Tri 839MP (Zeiss, Jena, Germany) [74], Micro AY IOL (PhysIOL, Liege, Belgium) [60,77], CareFlex (w2o Medizintechnik AG, Bruchsal, Germany) [64], Akreos AO MI-60 and Akreos MICS (Bausch & Lomb, Rochester, NY, USA) [71,80,81] and MicroSlim (PhysIOL, Liege, Belgium) [77] and Tecnis Symfony (AMO, Santa Ana, CA, USA) [58,74]. All these lenses except the Tecnis Symfony (AMO, Santa Ana, CA, USA) are made of hydrophilic acrylate. The ThinLens (Thinoptx Inc., Virginia, USA) and the Tecnis Symfony (AMO, Santa Ana, CA, USA) do not have a sharp optic edge, which we consider to be the most likely cause of the very high PCO rate.

Comparison with non-MICS lenses made of hydrophobic acrylate (Figure 4)

3 groups can be distinguished according to the PCO rate.

The lenses in the first group have a very low PCO rate. This group includes the Acrysof MA60BM, MA60AC, SA30AL, SN60WF (ALCON, Fort Worth, TX, USA) [22,40,46,49,52,53,57,71-73,79,80] and HOYA PY60AD (HOYA (Tokyo, Japan) [52]. All these lenses have a sharp optic edge.

The second group includes lenses with a capsulotomy rate comparable to that of L-313. This group includes the older model of the HOYA lenses with round optical edges, FY60AD (HOYA, Tokyo, Japan) [52], as well as Acrysof MA30, MA30BA, SA60AT, SN60D3 (ALCON, Fort Worth, TX, USA) [32,37,42,49,73,78], the Tecnis ZA9003 (AMO, Santa Ana, CA, USA) [78] and AR40e (AMO Inc., Santa ANA, CA, USA) with a sharp optic edge [32,43].

The third group consists of lenses with a higher capsulotomy rate than L-313. This group includes VA-60BB (HOYA, Tokyo, Japan) with an incomplete sharp optic edge [53], AR40 (AMO Inc., Santa ANA, CA, USA) with a round optic edge [43]. Almost all lenses in the first two groups have a sharp optic edge, while none in the third group do. One exception is the HOYA lens (the FY60AD is in the second group despite its round edge). However, in the work of Morgan-Warren [52] HOYA FY60AD (round optic edge) has twice the PCO rate of the HOYA PY60AD (sharp edge).

Comparison with non-MICS silicone lenses (Figure 5)

3 groups can also be distinguished.

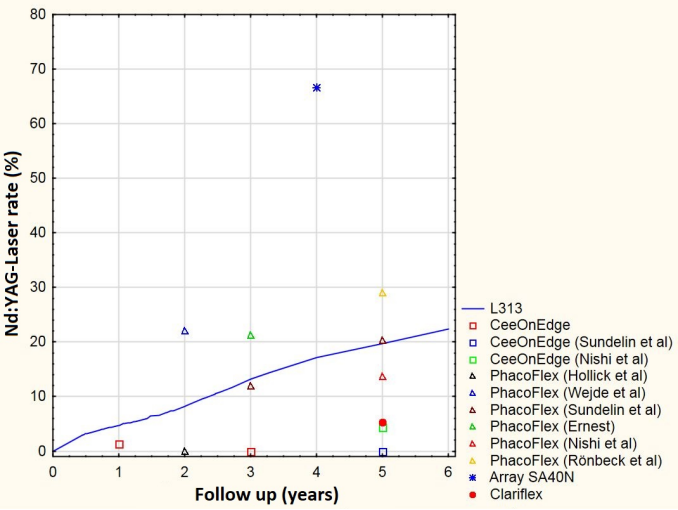

Figure 4: Comparison of L-313 IOL PCO rate with non-MICS hydrophobic acrylate lenses. The L-313's capsulotomy rate is indicated by a blue line up to 6 years. The publications on the reference lenses are given as data points with the capsulotomy rate and follow-up time (see legend in the figure for coding). The y-scaling deviates here, so that the results and fine differences of the different IOLs should be clearly visible. The majority of comparison lenses have a capsulotomy rate comparable to or lower than the L-313.

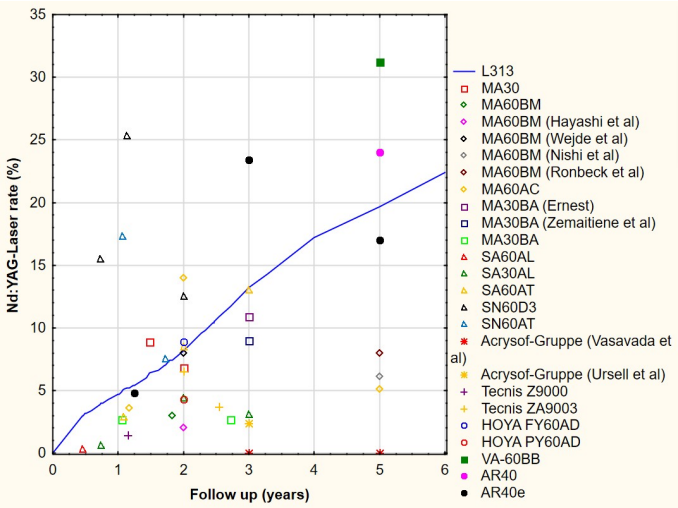

Figure 5: Comparison of the L-313 IOL PCO rate with non-MICS silicone lenses. The L-313's capsulotomy rate is indicated by a blue line up to 6 years. The publications on the reference lenses are given as data points with the capsulotomy rate and follow-up time (see legend in the figure for coding). The majority of comparison lenses have a capsulotomy rate comparable to or lower than the L-313.

The lenses in the first group have a very low PCO rate. This group includes CeeOnEdge (AMO, Santa Ana, CA, USA) [48,59,73] and Clariflex (AMO, Santa Ana, CA, USA) [53]. They are three-piece silicone lenses with a sharp optic edge.

The lenses in the second group have a capsulotomy rate comparable to L-313. This group includes PhacoFlex lenses (Allergan, Irvine, CA, USA), SI-30 and SI-40NB [41,53,57,68,64]. An exception is the work of Hollick et al [41] with low case numbers (n = 30). They are three-piece silicone lenses with a round optic edge.

The third group consists of lenses with a higher capsulotomy rate than L-313. This group includes Array SA40N, (AMO, Santa Ana, CA, USA), a three-piece silicone lens also without a sharp edge [38].

Again, it can be seen that all lenses in the first group have a sharp optic edge and those in the other two groups with the higher PCO rate have none.

Comparison with non-MICS lenses made of hydrophilic acrylate or PMMA (Figure 6)

2 groups can be distinguished.

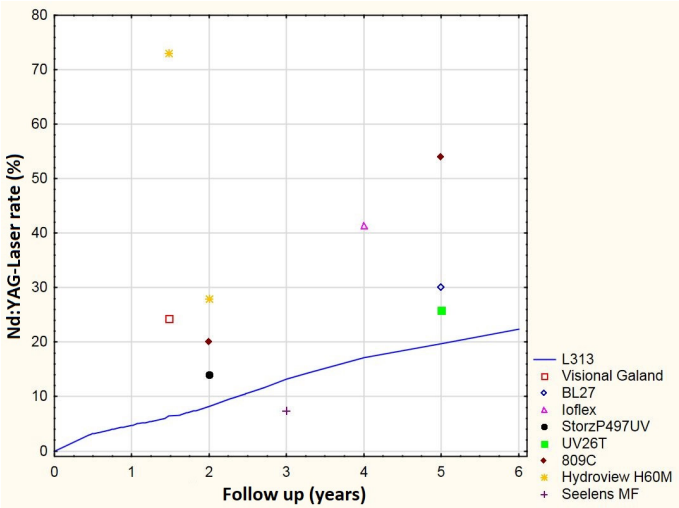

Figure 6: Comparison of L-313 IOL PCO rate with hydrophilic acrylate non-MICS lenses or PMMA lenses. The L-313's capsulotomy rate is indicated by a blue line up to 6 years. The publications on the reference lenses are given as data points with the capsulotomy rate and follow-up time (see legend in the figure for coding). The majority of the comparison lenses have a capsulotomy rate higher than the L-313.

The lenses in the first group have a lower PCO rate than the L-313. This group includes Seelens MF (Hanita Lenses, Israel), a one-piece hydrophilic acrylic lens with a sharp edge [76].

The second group consists of lenses with a significantly higher capsulotomy rate than the L-313. This group includes Hydroview H60M (Bausch & Lomb, Rochester, New Jersey, USA) [40,41,59], Visional Galand lens (Société médicale de précision, Genf, Switzerland) [42], BL27 (Bausch & Lomb, Rochester, NY, USA) [43], Ioflex lens (Mediphacos, Belo Horizonte, Brazil) [44], Storz P497UV (Storz, St. Louis, MO, USA) [41], die UV26T (Menicon, Nagoya, Japan) [53] and 809C (Pharmacia, Uppsala, Sweden) [57,64] .

Comparisons of PCO rates confirm the known fact that the IOL material (silicone < hydrophobic < hydrophilic and PMMA) and the IOL design (sharp optic edge < incomplete sharp edge < round edge) play an important role in PCO formation.

We were able to demonstrate a statistically significant correlation between age and PCO rate (p = 0.0001). This statistically significant correlation is also demonstrated by Eballé et al [85]. The PCO rate decreases slightly with age. Combined procedures have a significantly higher PCO rate (p = 0.002) than pure cataract operations. This statistically significant correlation is also demonstrated by Jun et al [124]. There was no significant correlation (p>0.05) between gender, duration of surgery, phaco machine, phaco energy, phaco time, IOL refractive power, incision size and surgeon. Menapace et al [125], Gonzalez et al [83], Westling et al [126], Hashemi et al [127], and Svancarova et al [128] were also unable to demonstrate statistically significant correlations to these OP data.

After Bonferroni adjustment, we were unable to demonstrate a significant correlation between lens density and PCO rate (p>0.0045).

In summary, the L-313 has a comparable or lower capsulotomy rate compared to other MICS-IOLs. Compared to non-MICS IOLs with a sharp edge, the L-313 PCO rate is comparable for some lenses and two to three times higher for others. The cataract surgeon is not guided solely by the criterion of risk of posterior capsule opacification when selecting an IOL. Other factors such as the required incision size , IOL power range, optic and haptic design, material, availability of injectors, intraoperative handling, asphericity, postoperative stability in the capsular bag and, of course, postoperative patient satisfaction are also of great importance. However, the knowledge of the PCO risk is also required for selection. We want to contribute to this with this work.

Clinical Trial Registry: NCT03184428

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