

Association between IOL design and incidence of PCO and Nd:YAG capsulotomy: A retrospective real world evidence study in the UK

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Background

- Posterior capsule opacification (PCO) is the most frequent complication following cataract surgery^{1,2}, with incidence figures ranging between <5-50%³
- PCO may develop in a few months to years following cataract surgery. Patients with PCO experience abnormal proliferation of lens epithelial cells on the posterior capsule, leading to visual obstruction and vision dimness^{4,5}
- Neodymium-doped yttrium aluminium garnet (Nd:YAG) laser capsulotomy is the only effective surgical treatment for PCO⁴, but could be associated with complications that include elevated intraocular pressure, retinal detachment, and endophthalmitis^{4,5,6}
- Previous studies have shown hydrophobic acrylic lenses to be associated with less frequent and less severe PCO^{7,8} and with longer time until the need for Nd:YAG capsulotomy⁹
- In this study, real-world incidence of both PCO and Nd:YAG in the 5 years post-cataract surgery were assessed in a large UK population, including their association with IOL design

Objectives

- To evaluate the long-term incidence of PCO and Nd:YAG capsulotomy in patients following cataract surgery at 5 years, comparing results for different single-piece acrylic intraocular lens (IOL) brands
- To estimate the adjusted odds ratios of PCO and Nd:YAG capsulotomy at 5 years post cataract surgery, based on IOL manufacturer/model and other covariates

Methods

Study Design

- This was a longitudinal retrospective cohort study including electronic medical record data collected from 7 UK ophthalmology clinics
- The study period was between 1st Jan 2010 and 31st Dec 2016
- The cohort included patients aged 65 years or older that underwent cataract surgery and were implanted with acrylic monofocal IOLs between 2010-2013
- For purposes of this analyses, only eyes undergoing cataract surgery up to the end of 2011 were included, to allow sufficient follow-up time post IOL implant
- The study population was restricted to patient eyes implanted with frequently used single-piece IOL models (i.e. implanted in at least 500 eyes during the study period) considering large sample size of the study

Statistical Analyses

- Bonferroni-adjusted series of pairwise comparisons were conducted, where the incidence of PCO and Nd:YAG capsulotomy at 5 years was evaluated in each IOL brand group, and compared using t-tests with the incidence observed in the AcrySof IOLs group
- To estimate the odds ratios for PCO and Nd:YAG capsulotomy at 5 years post cataract surgery:
 - An adjusted multivariate logistic regression analysis was performed by including different factors in the model: IOL brand/manufacturer (reference group: AcrySof), age, gender and other clinical and surgical characteristics
 - Stepwise method was used for variables selection (with a 5% level of significance)

Results

The inclusion criteria for the study population were:

- Cataract surgery with single-piece, non-toric, monofocal, acrylic lenses (with >500 occurrences)
- In-the-bag placement of IOL during surgery
- Age 65+ years at the time of cataract surgery
- Cataract surgery occurred between 1st January 2010 and 31st December 2011 → to allow at least 5 years of follow-up time
- Exclusion of eye with vitrectomy, previous pars plana vitrectomy, PPV, or eyes with >1 surgery

The resulting population included 20,763 eyes (from 16,595) implanted with different IOL brands (see Figure 1 and Table 1)

Figure 1: Study Population

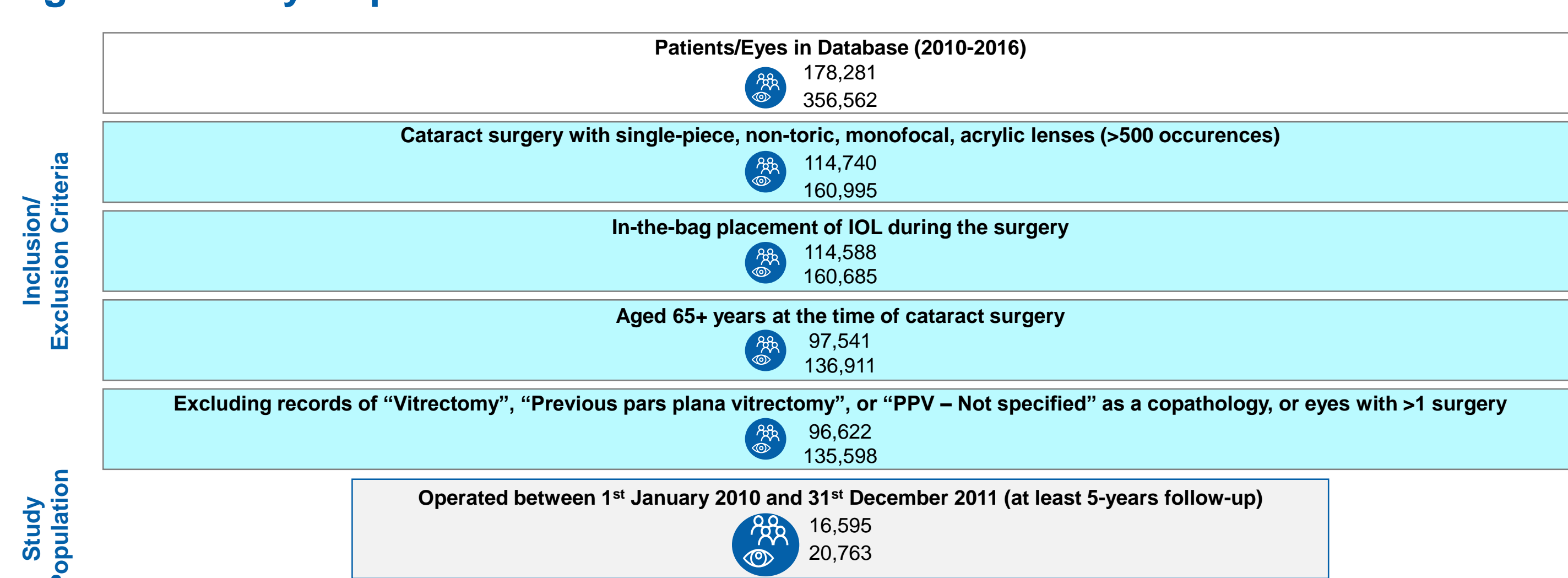


Table 1: IOL Brands Included in The Analysis

IOL Group	Optic Material	Composition	Eyes (N) (5-year Analysis)
Abbot Medical Optics (AMO) Tecnis	Hydrophobic acrylic	Co-polymer of ethylacrylate, ethyl methacrylate, 2,2,2-trifluoroethyl methacrylate cross linked with ethylene glycol dimethacrylate phenylethyl acrylate and phenylethyl methacrylate cross linked with 1.4 butanediol diacrylate	5,609
Alcon AcrySof	Hydrophobic acrylic	Co-polymer of phenylethyl acrylate and phenylethyl methacrylate cross linked with 1.4 butanediol diacrylate	5,342
Bausch & Lomb (B&L) Akreos	Hydrophilic acrylic	Acrylic polymer*	6,847
Lenstec Softec	Hydrophilic acrylic	Hydroxyethylmethacrylate (HEMA, 26% water content) and a polymerizable UV blocker	2,964

NOTE: AMO Tecnis group consists of ZCB00; Alcon AcrySof group consists of SA60AT and SH60WF IQ; B & L Akreos group consists of Adapt and MICS M60; Lenstec group consists of Softec 1 and Softec HD; Rayner Flex group had only 1 and was not included in analyses

*IOL polymer name could not be retrieved from technical specification/other online resources

Conclusions

- Choice of IOL implanted during cataract surgery can influence long-term outcomes, and this study demonstrates that single-piece AcrySof IOLs are associated with a significantly lower incidence of PCO and subsequently Nd:YAG capsulotomy, compared with other single-piece IOL brands at 5 years post cataract surgery
- These findings were confirmed even when adjusted for confounding effects (e.g. age, gender, baseline visual acuity, co-pathologies etc.)
- These results are consistent with those from other long-term, retrospective, real-world studies that compared hydrophobic and hydrophilic IOLs with regards to Nd:YAG and PCO outcomes following cataract surgery^{2,6}

References

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Results (contd.)

- 5-year cumulative incidence of both PCO and Nd:YAG was significantly lower (p<0.001) in the AcrySof IOLs group compared with all the other IOL brands in the Bonferroni-adjusted pairwise comparisons

Figure 2: Cumulative Incidence of PCO and Nd:YAG at 5 Years by IOL Brand

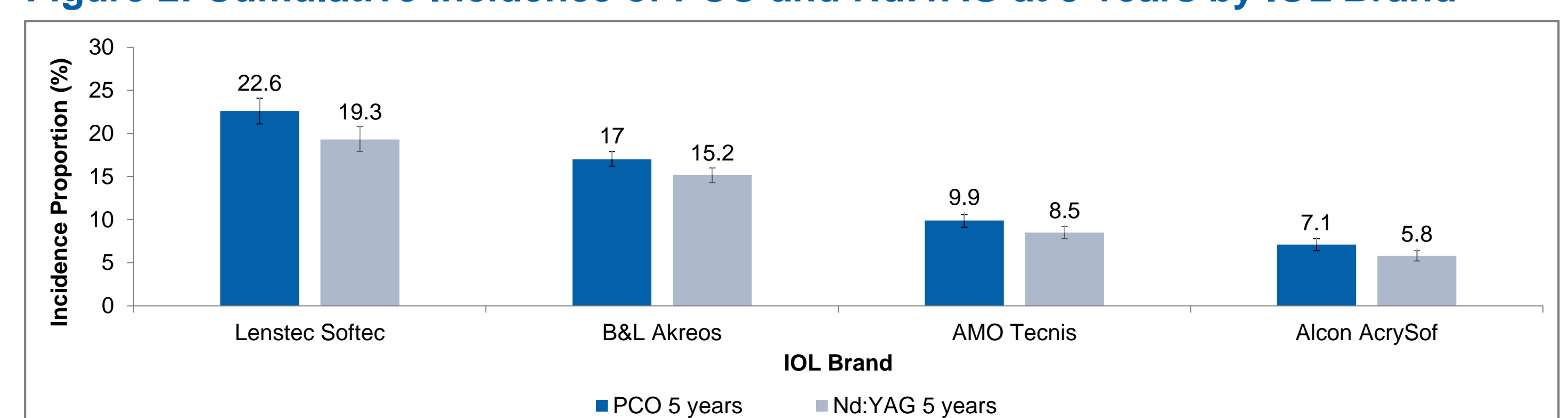


Figure 3: Adjusted Analysis of Nd:YAG at 5 Years Post-cataract Surgery

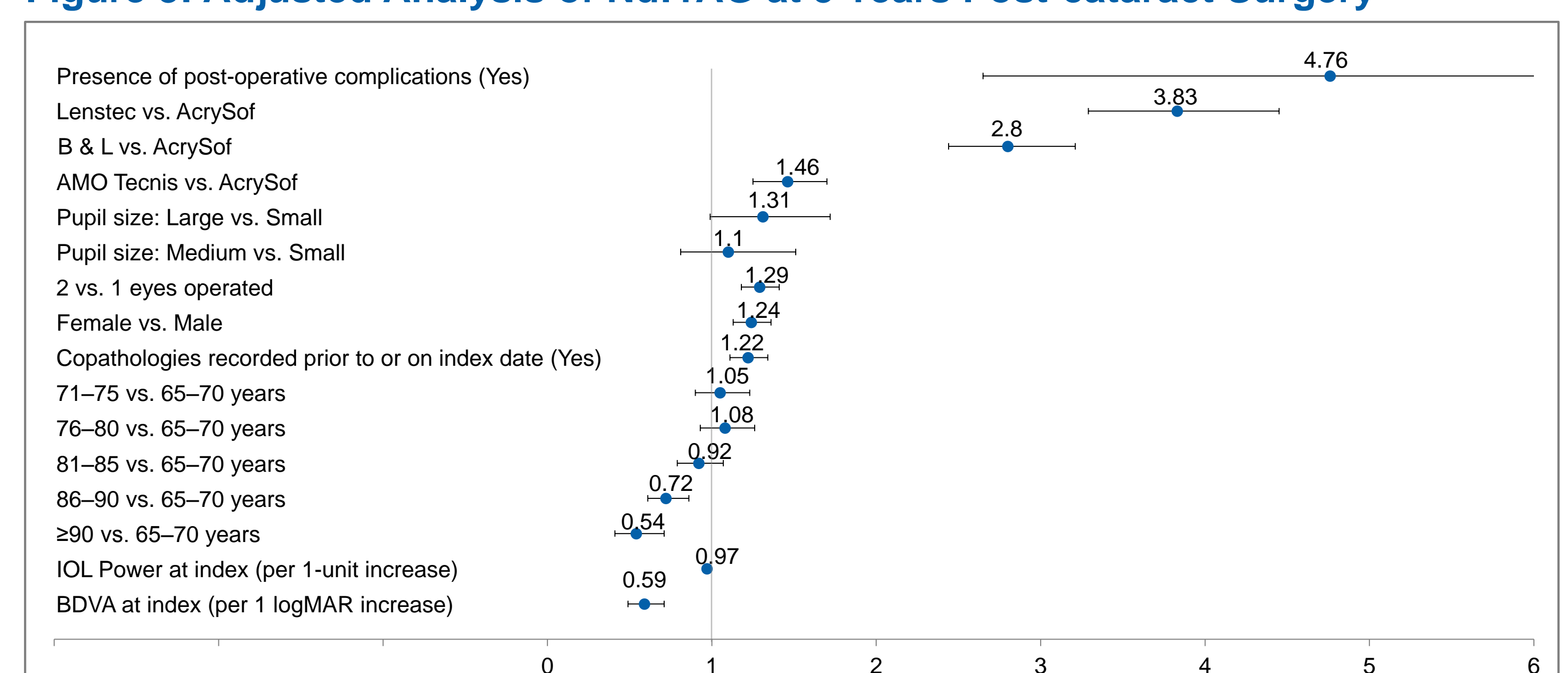
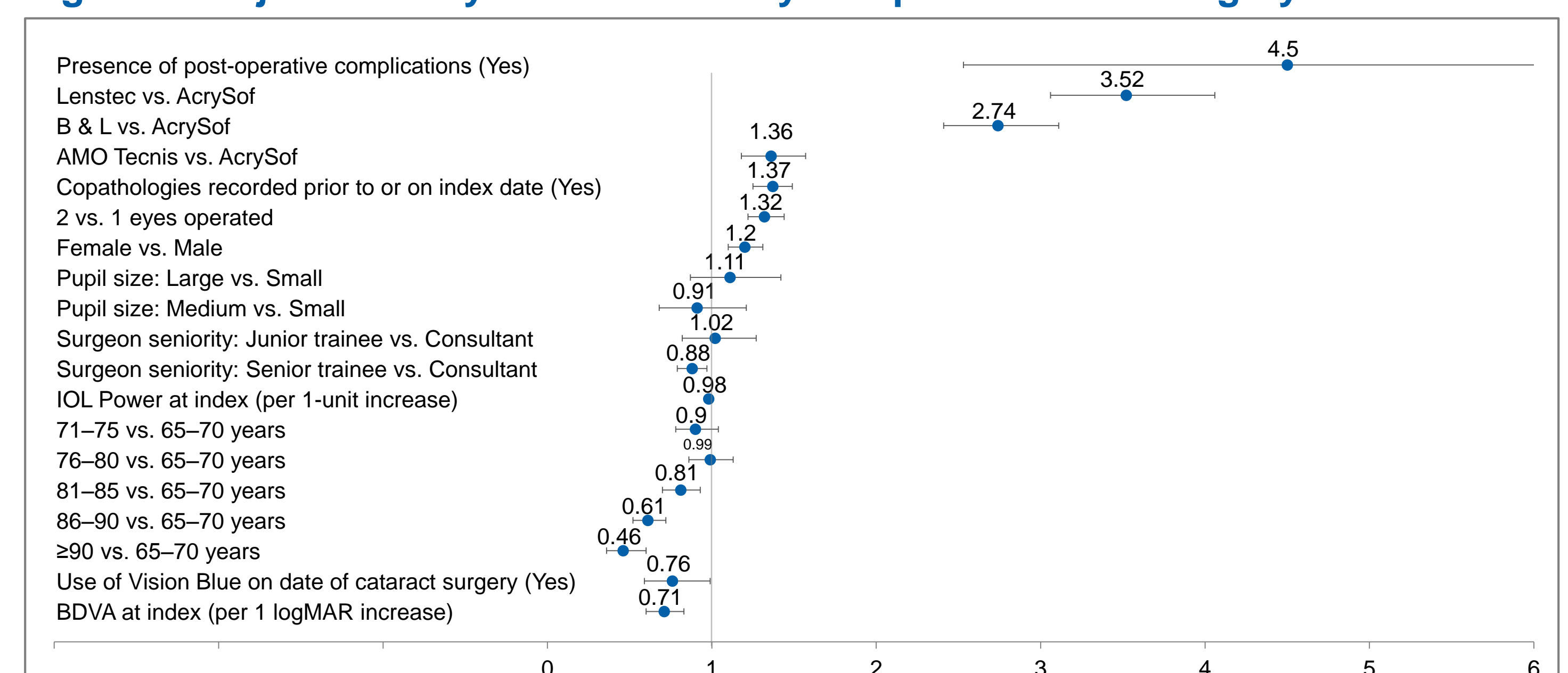


Figure 4: Adjusted analysis of PCO at 5 years post-cataract surgery



- The adjusted odds ratios confirmed the results seen in the pairwise comparison, with the Alcon AcrySof IOLs group less likely to undergo Nd:YAG (Figure 3) or PCO (Figure 4) at 5 years compared with AMO Tecnis, B & L Akreos, Lenstec and Softec IOLs
- AMO Tecnis were 1.46 (p<0.001) times more likely than Alcon AcrySof IOLs to experience Nd:YAG, and 1.36 (p<0.001) times more likely to experience PCO at 5 years
- B & L Akreos IOLs were 2.80 (p<0.001) times more likely than Alcon AcrySof IOLs to experience Nd:YAG, and 2.74 (p<0.001) times more likely to experience PCO at 5 years
- Lenstec Softec IOLs were 3.83 (p<0.001) times more likely than Alcon AcrySof IOLs to experience Nd:YAG, and 3.52 (p<0.001) times more likely to experience PCO
- Additional covariates that appear to increase the risk of Nd:YAG and PCO include younger age, female gender, cataract surgery on both eyes, occurrence of post-operative complications, and presence of co-pathologies on or prior to the index date

Strengths and Limitations

Strengths

- Longitudinal design and large sample size, which provided robust statistical power for comparative analyses
- The use of Medisoft EMR data, a validated and widely accepted source of research data
- Use of adjusted logistic regression to account for potential confounders

Limitations

- Absence of primary care data (e.g. missing co-pathologies) and secondary care data from other clinics (e.g. missing related procedures)
- Missing data, specifically with regards to death recording
- Absence of an indicator of patients de-registering from the clinic or moving to a different area, which meant follow-up was estimated as the time between cataract surgery, and data extraction or death (where recorded)