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Title: The Effect of Lens Edge Design Versus Anterior Capsule Overlap on Posterior Capsule Opacification

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Abstract:

## \* Abstract (MUST be submitted as a separate file)

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ABSTRACT

#### **Purpose:**

To determine whether, lens edge design or Aanterior Capsule (AC) overlap on the Intraocular Llens (IOL), has greater effect on Pposterior Capsule  $\Theta_0$  pacification (PCO).

#### Design:

Retrospective cohort clinical study.

#### **Methods:**

Setting: Academic clinical practice.

<u>Patient or Study Population</u>: The patient population consisted of <u>259</u> uncomplicated surgical patients <u>(259 eves)</u> with no confounding comorbidity, and at least 1 year of follow-up after surgical placement of a second generation silicone or hydrophobic acrylic lens.

<u>Intervention or Observation Procedure(s)</u>: Digital retro-illuminated photographs were taken to ascertain PCO, Aanterior Ccapsular Oopacification (ACO), previous neodymium: YAG capsulotomy and degree of Aeanterior capsule overlap on the IOL optic.

Main Outcome Measure(s): PCO, ACO, YAG capsulotomy rate, and AC-anterior capsule overlap on the IOL optic.

#### **Results:**

One hundred forty-eight digital images (74 silicone and 74 acrylic) were measurable for both AC-<u>anterior capsule</u> overlap and PCO. Complete  $360^{\circ}_{-}$  degrees of AC-<u>anterior capsule</u> overlap on the IOL was associated with decreased PCO (P = <.001). A significant negative correlation was found between the <u>angle-degree</u> of AC-<u>anterior capsule</u> overlap and PCO (P = <.001). Evaluation of Posterior Capsule Opacification (EPCO), PCO, and YAG capsulotomy

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rates were similar between acrylic and silicone lenses. <u>Minimal anterior capsule overlap may also be associated</u> with PCO prevention.

#### **Conclusions:**

Implanting a lens with complete <u>AC anterior capsule</u> overlap on the IOL was found to significantly reduce PCO, which advantage appeared to be greater than PCO prevention by a truncated, sharp edge IOL design.

#### **Table of Contents Statement:**

When looking at quantitative measures of posterior capsular opacification (PCO), we found anterior capsular overlap of the intraocular lens (IOL) optic the single most important factor in preventing PCO. We also found a linear negative correlation with the amount of anterior capsular overlap and PCO. Minimal anterior capsule overlap of the IOL may also prevent PCO.

Corresponding author confirms that each co-author has seen and agrees with each change in this manuscript.

# \* Disclosure

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Ophthalmology and Visual Sciences, University of Utah.

The authors acknowledge that no conflicting commercial interest or relationship exists between themselves or any other proprietary entity mentioned in or pertaining to the subject matter, with exception to Randall Olson who has is a done past consultanting for Advanced Medical Optics.



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April 2, 2004

Thomas J. Liesang, M.D. Editor-in-Chief American Journal of Ophthalmology Mayo Clinic 4500 San Pablo Road Jacksonville, FL 32224-1865

# Re: AJO-03-2160 "Lens Edge Design Versus Amount of Anterior Capsule Overlap on the Intraocular Lens with Regard to Posterior Capsule Opacification"

Dear Tom,

Enclosed for your review is our resubmission of AJO-03-2160. The new document incorporates all of the changes you requested. I will address these issues one at a time:

- 1. A Table of Contents statement is now included as it's own file.
- 2. The Copyright Transfer Agreement form, Authorship Responsibility and Contributions to Authorship form, Sponsor Involvement/Financial Support form and an Author Disclosure Statement form for each co-author have been submitted to the AJO Editorial Office. (Please note these forms were sent previously but were never received by you so we are sending a copy of all of these forms instead of the original forms as it is difficult to get the signatures again from everyone involved. Please let me now if you need new original forms instead.)
- 3. We have added a statement on page 2 of the Abstract which states that each of the coauthors have seen and agree with each of the changes made to this manuscript.
- 4. Enclosed is a biographic sketch and digital photograph from the first author as per your request.
- 5. After re-editing for all of your suggestions, this has also been carefully reviewed and hopefully meets your concerns.
- 6. The title you suggested is now the new title.
- 7. The "e" has been added to silicone throughout the manuscript.

- 8. The number of eyes is now included in the Methods section of the Abstract.
- 9. PCO is now defined at the outset.
- 10. The 3<sup>rd</sup> sentence has been changed as per your suggestion (Page 2 of the Manuscript).
- 11. Lens epithelial cells is no longer capitalized.
- 12. The changes you suggested are included (Page 2 of Manuscript).
- 13. A reference to Dr. Hoffer (#13) has been included. Of the references available there really is no peer reviewed article, however, we picked the best one that was available.
- 14. We picked reference #13 in that the rest are either presentations or are from throwaway journals.
- 15. All of the issues as outlined are now addressed in the Methods section including specifically why we picked the patients the way we did (Page 3 of Manuscript).
- 16. Haag-Streit is no longer in all caps.
- 17. This has been redescribed and is now called "amount of anterior capsular overlap" instead of "angle". We have had several people review this, all of whom say it is now completely clear (Page 3 of Manuscript).
- 18. Capsulorrhexis is now spelled with two Rs throughout the document.
- 19. We have produced a table to include and describe the lens types (Table 1).
- 20. We have added the percents (Top of Page 5 of the Manuscript).
- 21. We have added the percents (Second paragraph on Page 5 of the Manuscript).
- 22. We have made the change as outlined (Second paragraph on Page 5 of the Manuscript).
- 23. The last sentence has been so changed (Second paragraph on Page 5 of the Manuscript).
- 24. The discussion has now been changed in regard to the original Hoffer opinion, however, we do not want to diminish the importance of Nishi who has done the bulk of all serious peer-reviewed scientific work on this subject (Third paragraph on Page 6 of the Manuscript).
- 25-27. These three questions overlap and we agree that we have a potential outlier group but not enough statistical power to prove a bimodal theory. For instance we do adjust PCO to take in account follow-up differences and PCO is still statistically similar (see query 25 and discussion at the end of paragraph 4). All of this is now included in the discussion in a substantial rewrite describing this alternate hypothesis.
- 28-29. We have completed a statistical analysis as requested and show no differences in regard to PCO (Second Paragraph on Page 6 of the Manuscript). All of these issues are now incorporated and explained in a cohesive manner. We feel the conclusions now flow from the data; however, the data in any extrapolation and re-evaluation does not have enough power to prove the new hypothesis.
- 30. This is already taken into consideration with other issues and is really a repeat of the concerns of the reviewer, which are now fully addressed.

- 31. Only one eye was scored and this was always the first surgery to avoid any bias concern. This is now mentioned in the Methods section (Second paragraph on Page 3 of the Manuscript).
- 32. I am surprised that the reviewer is not aware of the EPCO analysis system. This has become the gold standard. We have provided more information in the Methods section as well as a reference regarding how this is performed (Third and fourth paragraphs on Page 3 of the Manuscript).
- 33. Obviously, only the PCO in the exposed areas could be evaluated. We can't evaluate the PCO under the anterior capsule. We felt this was self-evident, however, we have further clarified this in the Methods section (Last paragraph on Pgae 3 of the Manuscript).
- 34. The number excluded in each category is now included (Results Section, second & third paragraphs on Page 5 of the Manuscript).
- 35-36. We have added the requested table (Table 1).
- 37. Already, there is barely enough power to address all the issues that we have, and once we further split into smaller groups I am very concerned the manufacturers will use subgroups to come to conclusions that are not really warranted. No one knows if PCO is a linear function, therefore, trying to extrapolate is a potentially unfair exercise and we are reluctant to extrapolate more than we have.
- 38. We have added references to the tables.
- 39. Key words are now spelled correctly.
- 40. We have now clarified this (see query 17).
- 41. The sentence mentioned is now redone (Last paragraph on Page of the Manuscript).
- 42. The abbreviations of concern are now spelled out.
- 43. Already addressed (see query 11).
- 44. Both silicone and the lens issues are now corrected (Page 2 of the Manuscript).
- 45. Indeed this is incorrect and this typo has now been corrected throughout the document.
- 46. This change is now made (Statistics section on Page 4 of the Manuscript).
- 47. This is now clarified. It never was intended to suggest that ACO is PCO, however, we have now made sure this is clarified (Page 4 of the Manuscript).
- 48. This is a result of a misunderstanding of how the table should be written (complete overlap is 360° of overlap). This change is now clear in the tables as it has always been in the text.
- 49. The correct term is "mean PCO" for both sections and is now so stated.
- 50. "Equally effective" is fine and that change has been made (Last paragraph on Page 6 of the Manuscript).
- 51. Indeed, there are 76 eyes and the missing eye in the table has now been correctly placed.

- 52. I agree the sentence is unclear and thus the first phrase has been removed (Bottom of Table 3).
- 53. The plus or minus is the standard deviation and is now so noted (Tables 2 & 3).
- 54. The apostrophe has been removed (Table 3).
- 55. The reviewer obviously missed the entire point. A sentence has been added to clarify this in that if he missed it others may miss it as well (Bottom of Page 8 of the Manuscript).
- 56. This is the cover letter requested.
- 57. All small changes from the metadata have now been corrected throughout the article.
- 58. We tried to assiduously follow the information for authors.
- 59. This is completed with this resubmission.

Hopefully we have met all of the concerns, and there are many. We do appreciate your willingness to reconsider this article, which does have important clinical information. We appreciate your patience and thank you for working with us.

Sincerely,

Randall J Olson, M.D. John A. Moran Presidential Professor and Chair of Ophthalmology Director, John A. Moran Eye Center

## \* Manuscript (incl. title, auth, corr.auth., demographics, references, legend)

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# The Effect of Lens Edge Design Versus Amount of Anterior Capsule

# Overlap on the Intraocular Lens With Regard to Posterior Capsule

Opacification

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#### INTRODUCTION[Entire document should be no more than 16 pages total]

<u>Posterior capsular opacification (PCO)</u> is the most frequent long-term complication following cataract surgery by phacoemulsification with IOL implantation<sup>14,23,24,44</sup>. Although PCO laser capsulotomy is effective, it is a significant cost burden and can be complicated by increased intraocular pressure, cystoid macular edema, and retinal detachment<sup>34,55,66</sup>. The cause of PCO following cataract extraction and IOL implantation is multifactorial and <u>is</u> postulated to depends on the IOL optic material, IOL design and surgical technique<sup>34,66,77,88</sup>.

In terms of surgical technique, it has been reported that there is less PCO in those lenses in which the capsulorhexiscapsulorrhexis rim is located on the IOL anterior surface for a complete 360°-degrees<sup>99,1049,1144,1242</sup>. Another key factor, discussed widely in the literature, is the design of the IOL edge that can lead to PCO prevention <sup>14,1343,14444443</sup>. Nishi et-al-has showned that regardless of lens material, the creation of a capsular bend in the posterior capsule (PC) produced a barrier to migrating Lens Eepithelial Ccells (LECs). Nishi and associates found this barrier could best be made by implanting a lens with a sharp, truncated edge-design<sup>15454514,16464645,17471216</sup>. Such a barrier effect has been postulated for many years<sup>1343</sup>.

Supporting Nishi's findings, several studies have found that a truncated hydrophobic acrylic lens\_is superior, in terms of PCO prevention, to second generation silicone lenses which have a more rounded edge design<sup>32,88,18181817</sup>. There are several other studies, however, which have shown similar rates of PCO between the two lenses<sup>1044,194948</sup>. Additionally, YAG capsulotomy rates and severity of PCO in silicone lenses have varied in the literature<sup>88</sup>. Many have postulated surgical technique is likely to be playing a role in this inconsistency and question whether it is more important than lens edge design in preventing PCO.

This present study attempts to reveal-determine which factor, <u>IOL material</u>, lens edge design or amount of <del>AC</del> <u>anterior capsule</u> overlap on the IOL, is more important in preventing PCO in both silicone and acrylic lenses.

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#### Methods:

<u>Setting</u>: Patients who had an acrylic lens implanted (<u>AcrysofAcrySof</u> MA\_60, MA-30, SA-30, Alcon, Fort Worth, TX, USA) between March of 1995 and January 2001 and or silicone lens (AMO SI-40NB, Santa Ana, CA, USA, Bausch and Lomb L1\_61-UV, Claremont, CA, USA) between January 1996 and February 2002 were enrolled. All lenses were implanted by Moran faculty members.

<u>Patient or Study Population</u>: By chart review, only surgically uncomplicated cases with no evidence of sight-limiting pathology or other diagnostic ocular problems were contacted and enrolled. All patients had capsular bag fixation and at least 20/25 uncorrected visual acuity in the early postoperative period. <u>While visual acuity is not importantan</u> outcome measure in this study, the accumulated database does correlate visual acuity with PCO so patients with retinal or other visually limiting pathology have been excluded. Only one eye (first surgery) from each patient was used. All patients enrolled signed an informed consent form approved by the Institutional Review Board (IRB). All IRB and HIP<u>A</u>PA regulations were followed.

Intervention or Observation Procedure(s): Patients had the appropriate pupil dilated and the position of the IOL was examined using the HaagAAG-StreitSTREIT 9000 slit-lamp. Following examination, digital capsular images were taken using retro-illumination with a high-resolution video slit lamp. PCO scores were calculated using the estimation of posterior capsular opacification (EPCO) analysis system. These images were also evaluated for the angle-amount of AC-anterior capsule overlap on the IOL optic. The image angleoverlap was measured for a full 360°-degrees if there was complete overlap of the AC-anterior capsule with the IOL. For those images whose AC anterior capsule did not fully cover the IOL, a protractor was used to determine the angle-amount in degrees (to the nearest whole degree) that the AC-anterior capsule did not-covered the IOL optic edge-to the nearest whole degree.

<u>Main Outcome Measure(s)</u>: Analysis was undertaken to compare both second generation silicone and hydrophobic acrylic lenses for <u>EPCO</u>, PCO <u>inside the capsulorrhexis or to the optic or iris margin</u>, <u>anterior capsular opacification</u> (ACO) <u>overlapping the IOL optic</u>, and central 3-<u>-</u>mm PCO. All variables were scored using the EPCO software. <u>This method has been previously described as to technique and reproducibility</u><sup>2020</sup>. <u>No PCOA clear posterior</u> <u>capsule would be an EPCO score of zero</u>. The highest score is a 4. The EPCO software enablesd the examiner to

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make both a planometric and densitometric assessment. The program also allowsed the digital images to be scored using comparison photographs of different densities and severities. The EPCO program then calculatesd the amount of PCO\_or ACO overlapping the IOL optic by multiplying the density of the opacification by the fraction of capsule area involved behind the IOL optic. An outline of PCO using the software was made using either the IOL edge, anterior capsulorhexiscapsulorrhexis edge or the iris; (depending on what was visible in each image) as the outside limit of evaluation. The images were further viewed to measure the degree amount of AC anterior capsule overlap on the IOL optic in degrees (complete overlap equals 360°) and determine if a YAG capsulotomy had been pereformed. The degree-amount of AC-anterior capsule overlapping the lens edge was determined and scored only when the eapsulorhexiscapsulorrhexis was visible for 360°-degrees.

<u>Statistics:</u> Data <u>were-was</u> entered into Microsoft Excel 2000 and imported into STATA/Intercooled version 8.1 for analysis. Patients were grouped by IOL type for comparison of the outcome measures of <u>EPCO-PCO</u>, central 3-<u>-</u>mm PCO, ACO, YAG capsulotomy rate and <u>AC-anterior capsule</u> overlap on the IOL optic. Because of non-normally distributed data, non-parametric tests were used to test for differences between patient groups, including the Mann-Whitney, Krus<u>k</u>al-Wallis and Chi squared tests.

We compared median mean\_values for ACO grading, EPCO, PCO and central 3\_mm PCO. The Mann-Whitney test was used to determine the differences between PCO in lenses with complete and incomplete AC-anterior capsule overlap in both IOLs. The chi-squaredchi-squared test was used to compare the differences in age and gender between of patients with the two IOL types, as well as compare proportions of patients with and without YAG capsulotomy in each lens group. PCO and ACO in eyes with complete versus incomplete AC-anterior capsule overlap over the IOLs was also compared using the chi squared test. The Kruskal Wallis test was used to determine the significance of the relationship between total PCO and the degree of AC-anterior capsule\_overlap in patients with incomplete AC-overlap. A difference in which the P-value was less than 0.05 was considered to be statistically significant.

**Results:** 

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Two hundred fifty-nine images from uncomplicated surgical patients were initially analyzed: 30 had an L1-61 IOL, 94 had an Allergan AMO SI-40 IOL, and 135 had an AcrySof IOL (40 were MA-30, 56 were MA-60, and 39 were SA-30 models: Table 1). The mean age of the 61 females and 63 males in the silicone group was 74 years and of the 69 females and 66 men in the acrylic group was 73 (gender and age statistically similar). Mean follow-up time of 35 months in the silicone group and 31 months in the acrylic group was statistically different.

A PCO score could be calculated in 209 images (81%), the remaining 50 were not calculated due to a previous YAG laser capsulotomy (N=36; 14%) or because the image was too dark to evaluate (N=14; 5%). Several measures of PCO-capsular opacification including the EPCO retro-illumination PCO analysis, YAG capsulotomy rate, central 3-mm PCO and ACO were measured. No significant differences in EPCO, PCO, YAG capsulotomy rate, and central 3-mm3-mm PCO measures were found between the acrylic and silicone groups. Significantly more ACO was found in the silicone group than in the acrylic group. Further analysis showed ACO was similar in the complete AC anterior capsule overlap silicone and acrylic groups, with more ACO in the incomplete overlap silicone group than in the anount of anterior capsule overlap and amount of ACO in the acrylic group but not in the silicone group.

AC-Anterior capsule overlap could be determined in 148 images (57%). In the other 111 images the iris blocked the IOL-edge due to inadequate dilation (N=61; 24%), the photograph was too dark to evaluate (N=14; 5%) or the patient had a YAG capsulotomy previously performed (N=36; 14%). Looking at In regard to PCO, there was a highly significant difference found between lenses with complete 360°-degree AC-anterior capsule\_overlap and those with less than 360°-degree of AC-anterior capsule\_overlap on the IOL in both acrylic and silicone lenses. When the complete overlap silicone and acrylic groups were analyzed, no significant differences in PCO were found. Results were similar in the incomplete overlap groups, with no significant difference between the two groups (Table 43). When AC-anterior capsule overlap may broken down into 30 degree30° increments, there was a significant inverse linear correlation between the amount of overlap and PCO, such that for every 30 degree30° increase in AC-anterior capsule overlap overlap, PCO decreased by .00135 EPCO units. The silicone group also had significantly more lenses with AC-anterior capsule overlap on the IOL (52 of 74 eves [70%]) than the acrylic group (52-of 74 patients and -20 of 74 eves (26%)patients respectively; Table 23). 16 eves with 90°-119° of overlap had low PCO values similar to those

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with complete overlap. These 16 eves, however, were not statistically different from the eves with 120°-270° of overlap in regard to PCO.

#### **Discussion:**

As expected, oOur study showed significantly less PCO in those IOLs with complete 360°-degrees of AC-anterior capsule\_overlap when compared to those with incomplete AC-overlap. A statistically significant inverse relationship between the degrees of overlap and PCO was also found to exist. These findings reveal the incidence and severity of PCO is strongly affected by, and <u>maybe</u> proportional to, the degree of AC-anterior capsule\_overlap that lies on the IOL. This is now a well documented principle There is supporting evidence of this in the literature<sup>04,1040,1144,1242</sup>. By placing the edge of the AC anterior capsule\_over the IOL optic for a full 360°-degrees our results suggest the lens is sequestered in the capsular bag, pushing the lens more-posteriorly due to the resistancepressure from the Acanterior capsule. This force may leads to greater contact between the IOL and the anterior surface of the Peposterior capsule. thereby, creating an effective barrier to migrating LECs<sup>33,1444443,21212149</sup>.

Another interpretation of our anterior capsule overlap data is that PCO prevention is bimodal. Sixteen patients with anterior capsule overlap of 90°-119° had a low PCO, as did all patients with more than 300° of overlap. This suggests that little or no overlap is equally effective as overlap on at least two sides of the IOL. Asymmetric forces could lift the side not covered and allow an avenue for LEC ingress. Our data does not have the power to definitively prove or refute this alternate hypothesis. If correct, then it is difficult to explain why 91°-119° of anterior capsule overlap would not produce this asymmetric force or why the best fit is a negative linear correlation. The sixteen patients with 90°-119° of anterior capsule overlap are not statistically different from the patients with 120°-299° of overlap, however, the power of this comparison is low. A much larger study, looking especially at PCO where there is no anterior capsule overlap, will be necessary to definitely answer this question.

There are several other-theories that exist concerning PCO prevention. Linnola<sup>2222</sup> (20) proposed a bioactive based bioactive based explanation, known as the sandwich theory. This theory suggests that the hydrophobic acrylic material is the most important factor in PCO prevention. Fibronectin and other proteins are theorized to give the acrylic lens a "sticky" property that allows a monolayer of LECs to form between the IOL and Peposterior capsule,

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preventing migration of additional cells behind the IOL. In contrast, first Hoffer<sup>1313</sup> then, Nishi et aland others have, proposed the discontinuous barrier theory. Nishi-Thev all argues a 360°-degree discontinuous bend in the Peposterior capsule, made by implanting an IOL with truncated sharp edges, is the key factor in preventing the migration of LECs<sup>15151514,16161615,17171716</sup>.

Present clinical evidence supports <u>Nishi's-the barrier</u> theory, making it difficult to explain why the rounded edge<sub>7</sub> second generation-silicone lens<u>es</u> and squared edge, acrylic lens<u>es</u> have statistically similar PCO scores in our study. One explanation may be that not all lenses analyzed in the acrylic and silicone groups are homogeneous and equally effective in preventing PCO. One study has shown a 5.5-<u>m</u>m optic <u>(SA-30 and MA-30)</u> is less effective in preventing PCO than a 6.0-<u>m</u>m optic <u>(all other IOLs studied)</u><sup>1242</sup>. The AcrySof SA-30 also does not have a truncated edge for a full 360<u>°</u>-degrees. Additionally, the silicone Bausch and Lomb L<u>1</u>161 lens edge is more round than the Allergan SI-40 lens. Given these findings the AcrySof MA-60 should result in the least amount of PCO and the Bausch and Lomb L<u>4</u>161 should result in the greatest amount of PCO. A <u>fair</u> comparison of these two lenses in our study could not be made, however, given that they were not comparable due to statistically different follow-up times. We did try an analysis assuming PCO progression is linearly/positively associated with time since surgery, and even with this time-associated PCO adjustment we did not find a statistical PCO difference between these two <u>IOLs</u>.

The significantly different follow-up times between the silicone and acrylic lenses are an issue in our comparison–It because it is generally accepted that a longer follow-up time is correlated with more PCO. The silicone group was found to have a significantly longer follow-up time but a similar PCO score as the acrylic group, so any bias is in favor of the acrylic group. The difference in follow-up time strengthens our observation that AC-anterior capsule overlap is more powerful than IOL edge design in preventing PCO, since those lenses with complete AC-anterior capsule overlap had significantly less PCO regardless of follow-up time differences.

Another factor that may explain the similar PCO scores between the silicone and acrylic lenses is the greater amount of ACO found in the silicone group. While the development of ACO, a fibrotic transformation of LECs on the capsulorhexiscapsulorrhexis free edge<sub>27</sub> can lead to capsulorhexiscapsulorrhexis constriction, IOL decentration and

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zonular weakness<sup>22222221</sup>, it has also been shown to be beneficial. Petternell recently showed with aggressive removal of LECs from the Acanterior capsule, that less ACO but more PCO developed (V. Petternell, MD, et al., "Effect of Capsule Polishing on PCO," presented at the XIXth Congress of the European Society of Cataract & Refractive Surgeons, Amsterdam, The Netherlands, September 2001). ACO creates a "shrink wrap" effect, resulting in a tighter wrapping of the capsular bag around the IOL. This wrapping may consequently gives a better seal between the IOL optic and Peposterior capsule, resulting in less PCO<sup>29,16464615</sup>.

Others have found similar benefits of ACO in regards to PCO prevention. Schauersberger and coauthors postulated silicone and acrylic lenses have different surface properties that play a role in the emergence and spreading of LECs. Although their study showed similar ACO rates between the acrylic and silicone lenses, they found the silicone lenses had extensive fibrosis of the eapsulorhexiscapsulorrhexis rim causing greater contraction of the capsule <sup>242/2423</sup>. A recent study <sup>25352523</sup> compared PCO in truncated silicone and acrylic IOLs and showed significantly less PCO in the silicone group at 18 months after surgery as further proof of this concept. Our present study shows significantly more ACO in the silicone than in the acrylic group, although when further analyzed there was only significantly more ACO in the incomplete AC anterior capsule overlap silicone group and not in the complete AC anterior capsule overlap group (Table 2). It is likely that the greater amount of ACO in the silicone group may have compensated for its less efficient rounded edge design when there was not complete AC overlap, resulting in similar PCO scores between the silicone and acrylic lenses<sup>1040</sup>.

Another interesting aspect of our study was a statistically greater number of silicone lenses with complete  $360^{\circ}_{\circ}$  degrees of AC anterior capsule overlap on the IOL than those in the acrylic group, (52/74 and 20/74 respectively). In a previous study<sup>1242</sup>, where we had similar <u>PCO</u> results when comparing a second generationrounded edge silicone and truncated edge acrylic lens, we had speculated this the greater anterior capsule overlap may explain the two groups similar PCO scores, here we had similar <u>a controlled for Accompared all lenses with or without anterior capsule</u> overlap in this our present study (Table 3), both the two groups remained statistically similar.

In a recently published study, Nishi et al. argued sharp optic edge design alone cannot provide a substantial barrier when a capsular bend is not formed. Nishi further stated the term "edge barrier effect" should be avoided since it is

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really the "capsule bending" effect of the edge that provides the barrier to migrating LECs<sup>20042024</sup>. Our findings show-suggest that complete or near complete AC-anterior capsule overlap on the IOL is significantly more important in creating a "capsule-bending" effect than implanting a lens with a sharp; truncated IOL edge design. Although implanting a lens with a truncated edge is important in preventing PCO it is even may be more eritical important to get complete or near complete AC overlap the anterior capsule for 360° on the IOL. Our findings reinforce thise concept that regardlessregardless of lens design or material, we need to overlap the IOL a complete 360 degrees, and if we are unable to overlap the anterior capsule for 360°; we should attempt to overlap the IOL as much as possible in order to reduce PCO. Whether PCO prevention related to anterior capsule overlap is bimodal with protection with anterior capsule overlap and also with minimal or no overlap can not be answered from this study. This issue deserves additional investigation and is an important unanswered question. Furthermore, studies looking at PCO should include AC-anterior capsule overlap information as important evidence of group randomization. Otherwise, PCO differences may be attributed to IOL design when in fact they are due to differences in anterior capsule overlap. Page 10 Smith, Lens Edge Design Versus Amount of Anterior Capsule Overlap

### ACKNOWLEDGMENTS

We acknowledge Clinton Thompson, BS, and Steven C. Alder, PhD (Department of Family and Preventative

Medicine, University of Utah) for their statistical consultation and assistance.

#### REFERENCES

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# Table 1

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## TABLES

## Table 1: IOLs studied

Material	Optic	Edge Shape	Number in
	Diameter		Study
Silicone	6.0	Round	94
Silicone	6.0	Round	30
Hydrophobic Acrylic	6.0	Truncated	56
Hydrophobic Acrylic	5.5	Truncated	40
Hydrophobic Acrylic	5.5	Truncated	39
	Silicone         Silicone         Hydrophobic Acrylic         Hydrophobic Acrylic	Silicone       6.0         Silicone       6.0         Hydrophobic Acrylic       6.0         Hydrophobic Acrylic       5.5	DiameterDiameterSilicone6.0Silicone6.0RoundHydrophobic Acrylic6.0Hydrophobic Acrylic5.5Truncated

\* Modified round edge (lenticular design)

<sup>†</sup> Not truncated where the two haptics insert

## Table 2

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## **TABLES**

Table 12: Measurement of capsulare opacification by EPCO analysis (+/- standard deviation) and

capsulotomy rate with silicone (LI-161, SI-40) and Acrylic (MA-60, MA-30, SA-30) IOLs with 1-3 years of

follow up.

Group	Mean ACO	ACO with	ACO with	EPCO-PCO	Central 3- <u>-</u>	YAG
		Complete	Incomplete		mm <mark>E</mark> PCO	
		overlap	Overlap			
Silicone	0.42 +/- 0.38	0.48 +/- 0.40	0.42 +/- 0.40	0.34 +/- 0.48	0.26 +/- 0.53	N=20 (17%)
<del>(n = 95)</del>	<u>N=95</u>	<u>N=52</u>	<u>N=22</u>	<u>N=95</u>	<u>N=95</u>	<u>N=115</u>
Acrylic	0.25 +/- 0.24	0.48 +/- 0.30	0.23 +/- 0.20	0.34 +/- 0.52	0.28 +/- 0.56	<u>₩</u> =16 (12%)
<del>(n = 114)</del>	<u>N-114</u>	<u>N=20</u>	<u>N=54</u>	<u>N=114</u>	<u>N=114</u>	<u>N=130</u>
P value	0.0003	0.59	0.03	0.94	0.96	0.26

# Table 3

Page 1

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# Table 32: Evaluation of PCO with varying degrees of anterior capsule overlap on the IOL's (N=148)

Degrees of AC overlap	Ν	Mean PCO <u>by EPCO Analysis</u>		
		<u>+/- Standard Deviation</u>		
All Patients				
0- <u>6089</u>	<u>θ1</u>	0.58 +/- 0.00		
<del>61-</del> 90 <u>-119</u>	16	0.20 +/- 0.25		
<del>91-</del> 120 <u>-149</u>	3	1.05 +/- 0.90		
<del>121</del> -150 <u>-179</u>	5	1.39 +/- 0.96		
<del>151-</del> 180 <u>-209</u>	9	0.68 +/- 0.49		
<del>181</del> -210 <u>-239</u>	3	0.37 +/- 0.31		
<del>211</del> -240 <u>-269</u>	13	0.42 +/- 0.50		
<del>241-</del> 270 <u>-299</u>	12	0.37 +/- 0.65		
<del>271-</del> 300 <u>-329</u>	10	0.18 +/- 0.21		
<del>301</del> -330 <u>-359</u>	4	0.23 +/- 0.11		
360/Complete Overlap*	72	0.20 +/- 0.37		
<360/Incomplete Overlap <sup>*</sup>	76	0.44 +/- 0.57		
Silicone				
360/Complete Overlap <sup>†</sup>	52 (70.2%)	0.18 +/- 0.29		
<360/Incomplete Overlap <sup>†</sup>	22	0.45 +/- 0.46		
Acrylic				
360/Complete Overlap <sup>‡</sup>	20 (27.0%)	0.23 +/- 0.53		
<360/Incomplete Overlap <sup>‡</sup>	54	0.44 +/- 0.61		

When all patients had AC overlap measured in 30 degree increments,  $t_{\rm T}$  here was a significant (P = < .001) negative.

linear correlation between degrees of overlap and PCO.

# \* Table of Contents Statement (Original Articles only)

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## TABLE OF CONTENTS STATEMENT

When looking at quantitative measures of posterior capsular opacification (PCO), we found anterior capsular overlap of the intraocular lens (IOL) optic the single most important factor in preventing PCO. We also found a linear negative correlation with the amount of anterior capsular overlap and PCO. Minimal anterior capsule overlap of the IOL may also prevent PCO.

Stacy R. Smith, MD, graduated from medical school at the University of Utah in 2003 and is doing her internship at the University of Utah starting July 2004. Following her internship, she will begin residency training at the University of Utah, John A. Moran Eye Center in the Ophthalmology department.

