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**A Clinical Comparison of Single Piece and Three Piece Truncated Hydrophobic Acrylic
Intraocular Lenses**

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INTRODUCTION

Three Piece (3P) Truncated Hydrophobic Acrylic (AcrySof™, Alcon, Fort Worth, Texas)

Intraocular Lenses (IOL) have been widely accepted in the Ophthalmic community largely due to excellent biocompatibility¹ and the prevention of Posterior Capsular Opacification (PCO)^{2,3}.

The truncated edge of this IOL has been a major factor in this PCO prevention^{4,5}, however this edge can produce unwanted images (dysphotopsias)⁶, which may necessitate IOL exchange to resolve this problem⁷. Acrysof IOL's high refractive index and relatively flat anterior curvature also create a pupil reflection, which some find objectionable.

Single Piece (SP) AcrySof™ has a milled and smaller edge designed to decrease dysphotopsia and also has a steeper anterior curvature to diminish pupil reflection. SP became paired with the Monarch II™ (Alcon, Fort Worth, Texas) insertion device that has been easy to use and has decreased the incision size as well as facilitated insertion. The combination of SP plus this inserter has been very well received.

While the material is the same, there are properties that suggest these two lenses might not be clinically comparable. The haptics of the SP extend directly from the posterior surface leaving a potential gap in the 360° truncated edge, which may increase PCO. Also, the haptics are very flaccid and do not self-center the lens. This may create refractive instability as the capsule tightens with time and induces decentration. For all of these reasons, we completed this study to compare the clinical characteristics of 3P and SP after successful cataract surgery.

Methods:

Setting: Our first SP lenses were inserted in March of 2000. As the first lens available had a 5.5-mm optic, we only examined patients receiving SP from March 1, 2000 to January 31, 2001, and 3P from November 1, 1999 to March 31, 2001, who had 5.5-mm optics (AcrySof™ MA-30 & SA-30). Because the popularity of the SP at our institution rapidly eclipsed the 3P, in order to get comparable numbers, we had to extend the patient selection period for 3P. The majority of these patients had surgery prior to March 2000 when 3P was the most used IOL. Only Alcon Acrysof™ SP and 3P IOLs were studied.

Patient Study Population: By chart review, only surgically uncomplicated cases with capsular bag fixation without other diagnostic ocular problem (besides cataracts) were enrolled. All operated eyes were documented to be correctable in the immediate six weeks after surgery to at least 20/25, and the refraction that created this visual acuity was recorded. If more than one refraction was found, the one closest to but not over six weeks after surgery was recorded. About 60% of the patients who were eligible in both groups agreed to come in for a complete examination. After repeated attempts all patients within the enrollment period who would come in were included. No further attempts were made to examine those patients who could not come in.

Observation Procedures: After Institutional Review Board approval and signed informed consents from all patients, a complete examination was carried out in a masked fashion. Technicians were the only people to carry out the examinations, and they were without knowledge of which lens was in which eye.

After a careful manifest refraction, best-corrected and uncorrected LogMar visual acuity was determined. The pupils were then dilated. Retro-illumination photographs of the posterior capsule and then with less magnification to include the limbus, were taken with a digital slit lamp. The patients then completed an updated dysphotopsia outcomes questionnaire, previously described (Table 1)⁸.

Main Outcome Measures: Analysis was undertaken to compare both lenses for visual acuity with and without correction and for lens centration. Refractions were compared with the early postoperative refraction results to look at stability. Retro-illumination photographs of PCO and Anterior Capsular Opacification (ACO) were scored by the Estimation of Posterior Capsular Opacification (EPCO) software⁹. This program takes area and density of opacification into account for the score. The degree of anterior capsule overlapping the lens edge was determined when the capsulorhexis was visible for 360°. Digital photographs were also examined for presence of laser capsulotomy. All the results were placed in a spreadsheet, and analyzed.

Statistics:

Data was entered into Microsoft Excel 2000 and imported into Statistical Package for the Social Sciences (SPSS) version 11.0 and STATA/SE version 8.0 for analysis. Summary statistics were used to characterize patients participating in the study in terms of age, gender and mean follow-up time since surgery. Patients were grouped by IOL type for comparison of the outcome measures of uncorrected visual acuity, best-corrected visual acuity, refractive stability, ACO and PCO grading and anterior capsule overlap over the IOL. Due to non-normally distributed data,

nonparametric tests were used to test for differences between patient groups, including Mann-Whitney, Fisher's exact test, and χ^2 tests.

We compared median values for uncorrected VA, best-corrected VA, change in refraction (i.e. spherical equivalent) lens opacity, ACO grading, PCO, and degrees of anterior capsule overlap. Fisher's exact test was used to compare proportions of patients with and without YAG capsulotomy, eyes with complete versus incomplete anterior capsule overlap over the IOL, and patients with refractive shift within ± 0.5 D and ± 1.0 D. Spearman's correlation was used to determine the significance of the relationship between total PCO and the degree of AC overlap in patients with incomplete AC overlap. A χ^2 test was used to test for association between lens type and patients' assessments of unwanted images. Post hoc. χ^2 analyses were used to test for association between each response (no, minimal, annoying and debilitating unwanted images) and lens type, using a Bonferroni correction ($\alpha = 0.0125$).

Results:

Seventy-five patients were enrolled (36 3P and 39 SP). Age and gender were statistically similar, however as expected, the 3P follow-up time from surgery to examination was on average 37 days longer, which difference was statistically significant (Table 2).

Looking at refractive stability, the number of patients who had greater than 0.5 and 1.0 diopters of shift, and LogMar visual acuity with and without correction were all statistically similar.

Centration results were also similar (Table 3).

Looking at PCO, SP had significantly more PCO and significantly less ACO than 3P. While SP had more laser capsulotomies (six versus three), this was not significantly different. Anterior capsular overlap was statistically similar in the two groups. Combining all that had incomplete anterior capsular overlap, there was a significant inverse correlation between amount of overlap and PCO (Table 4).

The dysphotopsia questionnaire results were statistically similar other than SP had significantly less unwanted images off to the side of a light source and less central flashes of light from a peripheral light source than 3P (Table 5).

Discussion:

A significant attribute of the 3P lens has been its excellent PCO profile. This has been attributed to both a material effect^{10,11}, as well as its truncated edge. Nishi has shown that a truncated edge, when pushed into the posterior capsule, results in a barrier effect to lens epithelial cells and resultant PCO which effect is similar for hydrophobic acrylic, Polymethylmethacrylate (PMMA) and silicone IOLs^{4,5,12}.

Our study has shown SP has roughly twice the PCO of 3P after two years even though 3P had significantly longer follow-up, which would logically result in more 3P PCO. Mean PCO was clinically minimal in both groups. Correlating EPCO numbers with visual degradation is difficult because central opacification will have greater visual impact while peripheral PCO (because the area involved is greater) will have greater EPCO impact. In our experience EPCO values of 1.0 or greater generally measurably effect visual function. Capsulotomy rates,

although suggestive, were not significantly different, which is not surprising considering the small number of laser capsulotomies in either group. With SP haptics creating a break in the 360° discontinuous bend created by the IOL edge, these results were not unexpected.

The ACO differences however, were totally unexpected and clearly show an advantage for SP, which difference was highly significant. The large bulk of the SP haptics must prevent lens epithelial cell growth on the anterior capsule (the only obvious explanation that we see). We await other studies to confirm our finding. This however, does show that there can be an ACO and PCO disconnect. We reported a similar ACO and PCO disconnect in comparing a silicone IOL style with truncated hydrophobic acrylic IOLs in which they had similar PCO, while hydrophobic acrylic ACO was significantly less than that found with the silicone IOL¹³. This increased ACO with silicone (in comparison to truncated hydrophobic acrylic) has been documented by others¹⁴, while another clinical comparison of PCO in truncated hydrophobic acrylic and silicone was reported to be similar¹⁵.

Surgical technique is also important in PCO prevention. Large amounts of residual cortex can essentially blunt the truncated edge effect and lead to early and significant PCO. The size of the capsulorhexis opening is also very important. 360° overlap of the anterior capsule on the IOL uniformly holds and/or pushes the IOL back into the posterior capsule, thereby enhancing a discontinuous bend in the posterior capsule. Incomplete overlap is common as in our study and increases PCO¹³. One additional finding from our study is that with incomplete overlap the less the overlap the more the PCO. We should try to overlap the entire lens optic and, when we can not, overlap as much as we can. Too small a capsulorhexis can enhance capsular contracture and

complicate nuclear removal therefore; the perfect size is debatable. Because the capsular bag is not always concentric, the position of the anterior capsular opening may not (although it may appear well centered) line up with the IOL. We recommend a well-centered 5.0-mm capsulorhexis for a 6.0-mm optic and a 4.5-mm capsulorhexis for a 5.5-mm optic to try and guarantee a 360° overlap. The IOL can be rotated in the bag and often will move as much as 0.5-mm in its centration which movement will help better line up the anterior capsular opening for complete IOL overlap.

Visual acuity, centration and refractive stability were very much the same with both lenses. Even though the relatively flaccid loops of the SP lens will not self-center upon insertion, this particular IOL due to its tackiness will stay where placed. SP showed the same refractive stability as 3P.

Dysphotopsia has been a concern for patients with truncated hydrophobic acrylic IOLs^{6,7}. The high refractive index of SP and 3P is felt to increase dysphotopsia¹⁶. Clearly, however, the milled and smaller edge of SP resulted in less dysphotopsia than 3P, in the important issues of unwanted images off to the side of a light source and a peripheral light source creating a central flash of light. This difference was noted in two of the sixteen questions with the response to fourteen questions statistically similar. While we are concerned about type 1 errors, both questions are the only ones that relate specifically to truncated edge issues, so taken together we feel this finding is valid. Complaints and creation of dysphotopsia in a recent study were also shown to be less with a 3P truncated IOL with a milled edge compared with 3P IOL with a non-milled truncated edge¹⁷. This study showed resolution of all dysphotopsia by 3 months with both

IOL's while we had self-reported complaints in many patients at two years. This may be partially explained by differences in English and American patients and how questions were phrased. We have not had a zero dysphotopsia complaint rate for any IOL we have studied at any postoperative timeframe^{8,13,18}.

One form of dysphotopsia related to high refractive index IOLs is commonly noted as a temporal loss of contrast or vision¹⁹ and has been reported to be subjectively less with SP in comparison to 3P²⁰. We did not document any difference between these two lenses for this complaint. The one patient who declared this problem debilitating had an SP lens. A 6.0-mm optic should diminish this problem¹⁸. Manufacturers should continue to strive for novel treatments for dysphotopsia.

3P and SP with two-year follow-up were found to be very similar in regards to refractive stability and centration. There was no visual acuity difference between these two lenses. We documented that SP is significantly better in one aspect of dysphotopsia and will create significantly less ACO. On the other hand we found the SP PCO rate to be significantly greater than 3P.

Abbreviations:

SP (Single Piece), 3P (Three Piece), IOL (Intraocular Lens), PCO (Posterior Capsular Opacification), ACO (Anterior Capsular Opacification), EPCO (Evaluation of Posterior Capsular Opacification – a computer program), PMMA (Polymethylmethacrylate), SPSS(Statistical Package for the Social Sciences).

Human Subject Participation in Experimental Investigations:

This study was approved by the University of Utah's Institutional Review Board and meets all standards for studies of patients.

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