Author's response to reviews

Title: Rotational stability of the AcrySof SA60TT toric intraocular lenses.

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Version: 2 Date: 16 January 2008

Author's response to reviews: see over
Reviewer 1

Interesting topic. Toric IOLs (TIOL) become more and more popular for cataract surgeons. The well known AcrySof with a TIOL posterior surface promises good implantation results.

1) The used method to evaluate the TIOL rotation angle was the slit lamp beam method using a Haag Streit slit lamp. The smallest unit of the Haag Streit slit lamp angle is 15°. A measurement of TIOL rotation can only be performed with a precision of 7.5°. How do the authors receive results of -1° or +1° rotation angle?

Thank you for your comment. For the present study a specially designed eyepiece, replacing one of the 10x eyepiece, was inserted in the slit lamp. Looking through the eyepiece, a spirit level, a horizontal line, a black measurement line and a fixed circular scale with single degree steps could be seen. With the spirit level the eye piece could be adjusted to the horizontal. The black measurement line then could be rotated into the axis of the TIOL. The angle between the black measurement line and the horizontal line represented the angle of the TIOL. The angle’s amount could be read on the circular scale in one degree steps. In our clinic, the measurement with this special eye piece proved very good accuracy and reproducibility. We have changed the material and methods part to make the procedure of the angle measurement more understandable.

2) If the measurement method was only an angle measuring eyepiece at the slit lamp - How could the authors avoid the eyes cyclorotation or changes of the head position? Only this systematic failure can lead to a false measurement of ten and more degrees!

This is an important point you mentioned. Each time the angle of the TIOL was measured, the object (patient’s head) and the measuring instrument (eye piece and slit lamp) were aligned in a way that guaranteed similar measuring conditions and good reproducibility. We used a virtual line, built by the line between the pupils of both eyes, to provide the examiner with a (object) reference line. This reference line, and the horizontal line of the eye piece were matched. Once the patient's head and the slit lamp were correctly 'linked', the measurement of the axis of the TIOL was performed. Using this method, the postoperative angle of the toric lens could be determined similarly, providing the examiner with data that was comparable. Linking patient's head and the measuring instrument reduced the source of errors dramatically. It's a technique that can be used easily and fast, perfectly for a busy clinic. Because only the postoperative angles of the TIOL were compared in the study, the problem of cyclorotation, when changing position from upright to lying down, did not influence the results. Autorotation, as mentioned in your publications, can not be respected with the eyepiece method. Indeed, the use of simultaneous slide projection could improve the precision of the measurements. In accordance to your comments we have made the relevant changes in the method and the discussion part of the article.

3) Please, investigate photographs of the TIOL and use an overlay technique to evaluate the real rotation angle (e.g. iris structures, limbal vessels...).

We agree with your statement that there are better ways of measuring the angle of toric intraocular lenses. We will use the technique with photographs for future studies.

4) To achieve better statistical results, please present a larger number of implanted IOLs T3, T4, T5, otherwise the p-values should be larger than 0.05.

We agree that larger numbers of patients will increase the quality of the statistics. This article showed little scattering of the individual results. This suggests that even higher numbers of patients (more than 200) will unlikely change the key findings, which are that the used TIOL (with its design) remained fairly stable in the capsular bag, postoperatively.

5) The discussion is incomplete: Other groups showed smaller rotations of the MicroSil (please discuss your reference no.11). There are other designs in the market: Rayner centerflex, iris claw lenses... (Viestenz et al. Toric intraocular lenses and correction of astigmatism. Ophthalmologe 2007, 107: 620-627)

In accordance to your comment we modified the discussion and reference part with more information about other toric IOLs.

6) Was there a change of the astigmatic axis observed (comparing preop and postop axis as an indirect indicator of IOL rotation between week one and month 3 postop)?

Most of the postoperative cylinder values were 0 D or 0.25 D. It is very difficult to assess the axis of an astigmatism with such small amount of cylinder. Of course, eyes with higher cylinders showed deviations from the preoperative axis, but most axes remained within 10 degrees. Further comparisons between the change in the subjective cylinder axis and the position of the toric IOL were not performed in this study.
Reviewer 2
This is a nicely written report of a relatively small study of eyes receiving the AcrySof toric IOL. The study has been carefully performed and would be of interest to the readership. I would like to see several concerns addressed in the discussion.

First, the alignment measurements are stratified into increments as small as 2 degrees. While such precise measurements may be possible at the slit lamp when using a special reticle, such accuracy does not seem possible intraoperatively at the operating microscope. It would seem that increments of +/- 5 degrees of misalignment would be more practical and useful, since the "limiting" factor is the accuracy of intraoperative measurement and alignment. It may therefore be somewhat misleading to report data broken down into increments of single degrees.

Thank you for your comments. We completely agree. It is difficult to assess the right axis, although marked on the limbus, changed by the parallaxes, too. Because of this reason, we did not compare the preoperative with the postoperative axis of the lens in the present study. We did not ask the question "is the toric lens postoperatively really there, where we wanted to have it (where it was placed)". This article provides information about the postoperative position of the lens, the rotational stability in the capsular bag between 1 week and 3 months, assessed at the slit lamp only. Because the eyepiece for the slit lamp had a scale in one degree steps, this smallest unit was chosen to represent the accuracy of the measurement.

Second, and related is the assumption that any misalignment is due to rotation of the lens. The authors even go so far as to report whether the IOL "rotated" counterclockwise or clockwise. This degree of precision again seems to be based upon assumptions that may not be correct. Would such slight amounts of misalignment be just as likely to be due to imperfect surgical alignment? There are myriad issues, including parallax, that make is somewhat difficult to align toric IOLs perfectly intraoperatively, and the authors should at least acknowledge this as a possible explanation for any "misalignment". I suggest that all the tables be labeled as "misalignment" rather than "rotation". The latter term is making a diagnosis and assumption that I do not see sufficient proof of.

We agree that comparing the preoperative with the postoperative axis of the toric lens, the term 'misalignment' of the lens for all deviations would be the perfect choice. This study was looking only at the postoperative axis of the lens, analyzing the 'rotation' of the lens in the capsular bag. Because of the design of the lens, it is not symmetric in 2 axes. Gravity therefore can have an influence and rotate the lens in a certain direction. Further the contraction of the capsular bag does compress the haptics. We assumed, that this process could also induce a rotation in a certain direction. Out of these two main reasons we analyzed amount AND direction of the lens rotation in the present study.

While the tables may remain as formatted, I believe the discussion should caution against assuming that the IOLs are rotating, and that the study can detect rotation of as small an amount as a 2 degrees. The reader should not be led (by the counterclockwise/clockwise data) into trying to determine the likely direction of rotation from this study.

The precision of one degree steps, of course is on the optimistic side, and needs to be set in relation to the errors occurring from autorotation and head dislocation. In accordance to your comment we have made the relevant changes in the discussion.

Finally, the authors seem to be questioning why the net drop in refractive cylinder is not larger in the T5 group compared to the T4 group. Using the mean may not be the best measure when the sample size of each group is 20 eyes or less. It would be more interesting to know how many of the T5 group achieved a reduction of at least 1.75 D, compared to how of the T4 group achieved a reduction of at least 1.25 D. The problem with a small sample size is that just 2-3 eyes with aberrant results or inaccurate refractive data can significantly affect the mean. If we are to compare the T4 and T5 results, then showing us the breakdown of how many (and what % of) patients achieved the targeted reduction would be better than just presenting a mean.

Thanks for your comment. We were analyzing the data as mentioned by you, and completed the results part of the article.

Editor
We also notice that you are reporting a prospective clinical trial but have not cited a trial registration number.
This is a retrospective study. The word prospective in the abstract is an error and has been replaced. This error was overseen by my review of the manuscript and I very much apologize for that mistake. That is the reason why we didn't provide you with a registration number issued by a registry that meets the ICMJE criteria. The patients and methods part of the article is correct but misleading in the description of the study design. This part has been carefully rewritten to provide the reader with a comprehensible text. The mentioned clinical and surgical practice represents a standard approach for this type of procedure at our clinic.