Precizon™ Toric

New concept in Toric optics

Clinical evidence supports: Transitional conic surface provides a greater tolerance for misalignment and improved outcomes.
Objective
Evaluation of a new toric IOL optic by means of intraoperative wavefront aberrometry (ORA system): the effect of IOL misalignment on cylinder reduction.
Study conducted by: Erik L. Mertens, MD, Medipolis Eye Center, Antwerp, Belgium

Introduction
Rotation of Toric IOLs have been well documented. It has been shown for every degree of rotation off intended axis 3% of effect is loss.

The traditional approach to addressing toric IOL misalignment has been through design modification of haptics to maximize stability.

The Precizon™ Toric (Ophtec BV, Groningen, the Netherlands) with transitional conic surface is the first toric IOL to address prevention of common rotation errors with both an enhanced haptic design for improved stability, and also improve optic designed to allow tolerance of misalignment errors.

Calculation for designing Transitional Conic Surface

<table>
<thead>
<tr>
<th>Residual error of the axis</th>
<th>0°</th>
<th>5°</th>
<th>10°</th>
<th>15°</th>
<th>20°</th>
<th>25°</th>
<th>30°</th>
<th>35°</th>
<th>40°</th>
<th>45°</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remaining Astigmatism</td>
<td>0%</td>
<td>25%</td>
<td>50%</td>
<td>75%</td>
<td>100%</td>
<td>125%</td>
<td>150%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Efficiency Loss</td>
<td>0%</td>
<td>25%</td>
<td>50%</td>
<td>75%</td>
<td>100%</td>
<td>125%</td>
<td>150%</td>
<td></td>
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<td></td>
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</tbody>
</table>

Power and asphericality calculated in 8 meridians. Every anterior axis compensates the aberation of the posterior axis.

The diopter power is calculated per meridian resulting in a constant power from the center of the lens to the edge.

The Precizon™ Toric (Transitional Conic Surface)
Clinical Study Goals
To intraoperatively compare the effect of misalignment of the Precizon™ and Lentis toric (Oculentis GmbH Berlin Germany) intraocular lenses (IOLs) on refraction by means of the ORA system and to compare postoperative outcomes.

Prospective, randomized, comparative study in which patients with cataract and pre-existing corneal astigmatism underwent routine cataract surgery with bilateral implantation of a toric IOL model.

Intraoperative wavefront aberrometry (ORA system) was used to assess the effect of IOL misalignment on cylinder reduction after which the lenses were rotated to the intended axis and surgery was completed.

Method and Materials
Emmetropia was targeted. Intraoperative refraction was measured at 10°, 5° and at 0° misalignment using the Optiwave Refractive Analysis (ORA) system wavefront aberrometer (WaveTec Vision Systems, Aliso Viejo, CA, USA). Uncorrected (UDVA) and corrected (CDVA) distance visual acuities, refraction and IOL misalignment were evaluated 1 month postoperatively. Postoperative IOL misalignment was assessed using a KR-1W Wavefront analyzer (Topcon, Tokyo, Japan).

Analysis
Toric IOL implantation in 10 eyes in each subgroup resulted in an average of 1.6° rotation with the Precizon IOL and an average of 2.2° with the Lentis Toric IOL.

For every degree of error in a toric IOL’s rotational misalignment, there is a 3.3 percent decrease in the correction of astigmatism. If a toric IOL is misaligned by 10 degrees, the astigmatism will be 33 percent under-corrected. If the toric IOL is misaligned by 30 degrees, there will be no astigmatism correction.

As indicated in previously published papers, we found the same under correction with misalignment with the Lentis Toric IOL by deliberately misaligning 10° and 5°.

Surprisingly we did not have the same results with the Precizon™ IOL. By misaligning Precizon™ 10° the under correction was on average 18% instead of the expected 33% as measured with the ORA and the average under correction with 5° misalignment was 9% instead of 15%.

<table>
<thead>
<tr>
<th>Degrees of misalignment</th>
<th>10° rotation</th>
<th>5° rotation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precizon™ under correction - loss of effect</td>
<td>18%</td>
<td>9%</td>
</tr>
<tr>
<td>Lentis Toric IOL under correction - loss of effect</td>
<td>33%</td>
<td>15%</td>
</tr>
</tbody>
</table>

EXAMPLE: Effective Loss of Cylinder Power

<table>
<thead>
<tr>
<th></th>
<th>Precizon™ @ 10°</th>
<th>Lentis IOL @ 10°</th>
<th>Precizon™ @ 5°</th>
<th>Lentis IOL @ 5°</th>
</tr>
</thead>
<tbody>
<tr>
<td>4D cy IOL</td>
<td>0.72D loss</td>
<td>1.32D loss</td>
<td>0.36D loss</td>
<td>0.6D loss</td>
</tr>
<tr>
<td>10D cy IOL</td>
<td>1.80D loss</td>
<td>3.30D loss</td>
<td>0.9D loss</td>
<td>1.5D loss</td>
</tr>
</tbody>
</table>

Conclusion
The new toric optic IOL Precizon™ gave similar results in terms of rotation one month postoperatively but performed significantly better in astigmatism correction and was less sensitive to misalignment in respect to the Lentis Toric IOL. Longer follow-up and a larger series is needed to support this findings.

Reference
This data submitted to ESCRS/2014

OPHTEC BV is the industry originator of refractive IOLs and today the market leader in phakic IOLs, and is one of industry pioneers in cataract IOLs, and innovator of trauma implantable devices. Ophtec has over 30 years of experience in meeting ophthalmologists’ needs with unique and proprietary, high quality products. OPHTEC brand is globally established and recognized.

For more information please contact: info@ophtec.com or visit OPHTEC web site at www.ophtec.com