Cataract Surgery With Implantation of a Mechanically and Reversibly Adjustable Intraocular Lens

*Acri.Tec AR-1 Posterior Chamber Intraocular Lens*

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If it were possible to adjust the refraction of a pseudophakic eye by means of an adjustable posterior chamber intraocular lens (PC/IOL), subjective comfort or visual function would be improved. This is especially true in children. Several approaches to create an adjustable intraocular lens (IOL) are currently under study.1-3 This field is still in an early stage of its evolution. The *Acri.Tec AR-1 PC/IOL (*Acri.Tec, Hennigsdorf, Germany) is a mechanically and reversibly adjustable PC/IOL, which has been implanted and adjusted in adult human eyes.3 So far the results after short-term follow-up of the initial cohort suggest that the use of this PC/IOL would be safe. Through continued observation of the eyes from this cohort we have tried to determine the long-term safety of this PC/IOL, behavior of the PC/IOL after Nd:YAG laser capsulotomy, and refractive stability of the eyes.

Changing the position of an implanted IOL along the optical axis will change the refraction of the eye. This principle can be used to create a mechanically and reversibly adjustable PC/IOL. After implantation, the outer part of the haptic of the PC/IOL becomes fixed in a determined plane behind the cornea. If the optic is connected to the outer part of the haptic in such a way that it can be moved along the optical axis, it will be possible to surgically change the refraction of the eye after implantation of the PC/IOL. The refraction of the pseudophakic eye is changed by moving the optic of the PC/IOL closer to the cornea to induce a myopic shift or moving it away from the cornea to induce a hyperopic shift.

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The prototype of the *Acri.Tec AR-1 PC/IOL used in these implantations is made of polymethylmethacrylate. It is a typically composed optical lens body and has a diameter of 5.5 mm. Connected to the optic is a haptic containing an adjustment element (Figures 1 and 2). This is formed by an interruption of the haptic consisting of a cylinder 1.0 mm high attached to the optic, which contains a piston attached to the outer part of the haptic. The cylinder and the piston can be moved relative to each other. This element allows the optical part of the PC/IOL to move along the optical axis. The range of refractive change per millimeter of displacement depends on the length of the eye. Short eyes experience large dioptric changes and long eyes experience small dioptric changes per millimeter of displacement of the optic along the optical axis. An eye of the average length of 23.5 mm will get a change of refraction of about 1.5 diopters (D)/mm displacement, allowing for an adjustment range of 2.0 to 2.5 D for the prototype PC/IOL. Adjustment of the lens is performed by an IOL optic manipulator (Figure 1).

The study was carried out on the initial patients with senile cataract who had received the *Acri.Tec AR-1 PC/IOL after consent was obtained from the ethics committee of Bayerischen Landesärztekammer.3 Patients were required to give informed consent before participating in the study.

During continual follow-up, eyes were monitored for appearance of the anterior and posterior segment of the eye. Refraction, best
visual acuity, and intraocular pressure were measured. Eyes also underwent Amsler grid testing. Thirty-five eyes of the first 35 patients (16 men and 19 women; median age, 76 years [range 61-90 years]) receiving this implant were included in the study; 2 eyes of 2 patients had undergone adjustment surgery 2 weeks after implantation of the PC/IOL. Thirty-three patients had a conventional PC/IOL implant in their second eye. Four patients died during the follow-up period. Thirty-four eyes had at least 6 months of follow-up, and of these, 31 eyes had more than 12 months of follow-up (median, 18 months [range 6-31 months]). Eyes that developed posterior capsule opacification underwent Nd:YAG laser capsulotomy.

**SURGICAL TECHNIQUE**

Following phacoemulsification, the *Acri.Tec AR-1 PC/IOL was implanted through a scleral tunnel under parabulbar anesthesia (in the same way as a conventional PC/IOL with loop haptics) by introducing the PC/IOL into the eye first with the leading loop, which was then placed into the bag. Once the trailing loop was in the eye, the loop was placed into the bag by rotating the PC/IOL.

Adjustment surgery is carried out through 2 corneal service paracenteses with 1-mm widths. An IOL optic manipulator with a T-shaped (Figure 1) or L-shaped spike is used to press down onto the piston, while a second manipulator is placed against the connection of the optic and the cylinder from the opposite side. The first instrument either pushes the piston from the anterior side while the second supports the cylinder from the posterior side or vice versa. This alters the position of the optic (Figure 2). Because the T-shaped or L-shaped spike will stop the movement when its horizontal piece hits the upper (or lower) end of the cylinder, the vertical part of the manipulator can push the piston only as far as it can enter the cylinder. The length of the vertical part is selected according to the desired adjustment distance.

**RESULTS**

None of the eyes with an adjustable IOL developed any signs of inflammation, corneal decompensation, iris atrophy, pupil distortion, or spontaneous capsular tear during surgery or the entire observation period (**Figures 3, 4, and 5**). Centration of the adjustable PC/IOL was maintained in all eyes. Comparison of eyes with the adjustable PC/IOL and eyes with the conventional PC/IOL in bilaterally pseudophakic patients showed no significant difference in central visual acuity, refractive stability, or intraocular pressure. Results of Amsler grid testing were normal in all eyes containing the adjustable PC/IOL.

Eighteen eyes developed posterior capsule opacification. There was
a higher incidence of posterior capsule opacification 1 year after implantation in the group of eyes with the adjustable PC/IOL than in the control group (Table). Treatment with Nd:YAG laser capsulotomy resulted in restoration of central visual acuity in all of the 18 eyes. Refraction remained stable and no adverse effects occurred in these eyes (Figure 4). The 2 eyes in which refraction had been adjusted by 1.0 and 1.25 D had a stable refraction for the entire observation period (18 and 15 months after adjustment surgery, respectively) and no complications of any kind (Figure 5B).

**COMMENT**

Implanting an adjustable PC/IOL will give patients a choice of specific refraction. Target refraction can be achieved by adjustment surgery. When relying only on preoperative biometry, there is no way to escape refractive surprises, as all conceivable methods of preoperative prediction of postoperative refraction are only approximate. Small deviations are usually tolerated by the patients. However, an unwelcome hyperopic refraction or an intolerable refraction constitutes a major reason for PC/IOL exchange. Such IOL explantations may become unnecessary if adjustable PC/IOLs are used. Adjustable IOLs could improve visual results if pseudophakic presbyopia is treated by creating monovision or by multifocal PC/IOLs. After implantation of a mechanically adjustable PC/IOL, a second proce-
dure is only required in case of refractive adjustment, and (in theory) the time of adjustment can be set any time after the PC/IOL has been implanted. In small pseudophakic children, a mechanically and reversibly adjustable PC/IOL may also offer the unique possibility of treating amblyopia and reducing the developing myopia. If necessary, after implantation one could adjust the pseudophakic refraction to create a low degree of myopia. Later, after myopia has increased with growth of the eye, one could conceivably do a second hyperopic adjustment to prevent higher degrees of myopia. This may become the most important application of this concept.

Our results confirm the long-term safety of the implanted *Acri.Tec AR-1 PC/IOL in adult eyes. In addition, the refraction remained stable in all eyes including those that had undergone Nd:YAG laser capsulotomy or adjustment surgery. This suggests that the concept of a mechanically adjustable PC/IOL is valid. The evolution of such PC/IOLs is certainly only at an initial stage and we expect many modifications to come tailored to the specific needs of the patient’s disease.

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Financial Disclosure: Dr Jahn shares a patent on the PC/IOL, which is licensed to *Acri.Tec.

References


Table. Clinical Characteristics of Eyes After Implantation of the *Acri.Tec-AR-1 PC/IOL

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Adjustable PC/IOL</th>
<th>Conventional PC/IOL</th>
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</thead>
<tbody>
<tr>
<td>Central Snellen visual acuity at last visit, median (range)</td>
<td>0.7 (0.2 to 1.0)</td>
<td>0.8 (0.3 to 1.0)</td>
</tr>
<tr>
<td>Change in spherical equivalent between 1 mo and last visit, median (range), diopters</td>
<td>0 (-0.5 to 0.5)</td>
<td>0.25 (-0.25 to +1.25)</td>
</tr>
<tr>
<td>Refractive astigmatism at last visit, median (range), diopters</td>
<td>-0.75 (0 to 1.75)</td>
<td>-0.5 (0.0 to 1.5)</td>
</tr>
<tr>
<td>Change in refractive astigmatism between 1 mo and last visit, median (range), diopters</td>
<td>0.0 (-0.75 to 1.0)</td>
<td>0.0 (-1.75 to +1.0)</td>
</tr>
<tr>
<td>Intraocular pressure, median (range), mm Hg</td>
<td>16 (11 to 22)</td>
<td>16 (12 to 22)</td>
</tr>
<tr>
<td>Eyes with normal Amsler grid results, No. (%)</td>
<td>32 (100)</td>
<td>32 (100)</td>
</tr>
<tr>
<td>Eyes with posterior capsular opacification after 12 mo, No. (%)</td>
<td>13 (42)</td>
<td>3 (10)</td>
</tr>
</tbody>
</table>

Abbreviation: PC/IOL, posterior chamber intraocular lens.

* Acri.Tec, Hennigsdorf, Germany.

N = 34.
N = 30.
N = 32.
N = 31.