BAG-IN-THE-LENS

IOL and Technique
Modern intraocular lens implantation was introduced by Sir Harold Ridley in 1948.

“The cure of cataracts was established within perhaps one and one-half hours in Cavendish Square in 1948“.

Harold Ridley, 1952, BJO

From that very same moment, research in the field of cataract aimed at finding the solution for two major complications which were already described by H. Ridley:

“Two surgery-related problems triggered criticism for decades after Harold’s initial implant. The discussion of decentration and posterior capsule opacification (PCO) ... Harold himself noted these complications of extracapsular cataract extraction with IOL implantation in his earliest patients.”

David Apple, 2006
BACKGROUND OF THE BIL

The bag-in-the-lens was initially designed and patented as “intraocular lens and method for preventing secondary opacification”.

US Patent Number 6,027,531
EP Patent Number 0916320A2

The first surgical case using the BIL technique was in December 1999, a few months after having met H. Ridley in Stockholm at the SOE meeting where he was an invited guest and before he was knighted by the Queen Elisabeth II in 2000.

The postoperative follow-up of the bag-in-the-lens implantation has reached ten years now and no PCO, or in absence of capsular bag, we should rather speak about visual axis reproliferation (VAR), did occur. It is, as a consequence, very likely that PCO is under control (De Groot V. et al., 2005; Tassignon M.J. et al., 2006; De Groot V. et al., 2006; Leysen I. et al. 2006).

The centration stability of this new approach was also studied and turned out to be very stable over time (Verbruggen K. et al., 2007; Rozema J. et al., 2009).

PCO and centration are indeed two prerequisites before starting the implantation of more complex optics like toric and multifocal IOLs.

Implementation of toricity in the bag-in-the-lens is now finalized. The new challenge is to introduce a new approach for the alignment of diffractive IOL.

The clinical study on the bag-in-the-lens started in 2000 after approval by the ethical committee of the Antwerp University Hospital (1/47/136) and got the approval of the Belgian Social Security in 2004.

In 2006, David Apple wrote the following dedication in his book “Sir Harold Ridley and his Fight for Sight” edited by Slack and published in 2006.

“I know that he (H. Ridley) would be fascinated by your work and would have an absolute ball (enjoyed) working with your lens.”

David Apple
SURGICAL PROTOCOL

- temporal position of the surgeon
- opening of the limbus with a knife 2.8 mm (eventually 2.5 mm) [1]
- injection of 1.0 ml adrenalin solution (see procedure medication) [2]
- injection of Healon GV for corneal protection [3]
- insertion of the caliper ring type 5 NO tassignon [4] using the ring caliper inserter (sk-7017 EyeTech) [5]
- opening of the anterior capsule with the capsulorhexis forceps [6] (Ikeda 30° forceps) (Rr. 2268 EyeTech)
- removing the caliper ring
- injection of BSS between the lens and the capsule, hydrodissection [7]
- phaco-emulsion of the lens content [8]
- removing lens remnants with the IA mode [9]
- cleaning the capsule with BSS using the Helsinki needle (1273E Steriseal)
- injection of Healon GV on top of the anterior capsule [3] (never fill the capsular bag!)
- puncturing of the posterior capsule by using the tuberculin needle or 36G needle [10]
- injection of Healon through the puncture hole within the space of BERGER until the size of the blister is slightly larger than the anterior capsulorhexis [11]
- attention not to overfill the space of BERGER
- performing the capsulorhexis with the Ikeda forceps [6]
- insertion of the lens with the injector (Medicel Lp 604410)
- injection of miostat (see procedure medication) [12]
- removing of the Healon with the IA mode
- refilling the anterior chamber with BSS and hydration of the corneal wound [9]
- control of the water tightness of the wound
- injection of zinacef solution (see procedure medication) [13]

P.S. In paediatric cataract the procedure is slightly different:
- ring caliper 4.5 mm is used
- two sight ports of 1.0 mm are used for lens removal
- injection of Healon into the space of BERGER by means of a 41 G needle (Dorc 1270.0.100)
**PROCEDURES FOR MEDICATION**

Procedure *zinacef solution Fittings*
- 1 syringe 10.0 ml
- 1 syringe 1.0 ml
- NaCl bottle of 100.0 ml
- 2 aspiration needles (pink)
- *zinacef* 250.0 mg powder (sterile)

Procedure *(in OR)*
- take 2.5 ml NaCl in the 10.0 ml syringe
- inject these 2.5 ml NaCl into the bottle filled with *zinacef* 250.0 mg powder
- shake thoroughly until the *zinacef* powder is properly diluted
- using the 10.0 ml syringe, take 1.0 ml out of this solution
- fill the additional 9.0 ml of the syringe with NaCl

Procedure on surgical tray
- the instrumentist takes a 1.0 ml syringe mounted with a pink aspiration needle
- aspiration of 1.0 ml from the *zinacef* solution as explained
- use 0.1 ml in the anterior chamber, the remaining solution can be used to rinse the operated eye

**Procedure adrenaline/preservative-free xilocaine solution Fittings**
- 1.0 ml syringe
- 1 aspiration needle (pink)
- adrenaline ampoula 1.0 ml (1:1000)
- xilocaine ampoula

Procedure
- take 0.9 ml xilocaine in a 1.0 ml syringe
- add 0.1 ml of 1:1000 solution adrenaline

**Procedure miostat solution Fittings**
- syringe of 2.0 ml
- aspiration needle (pink)
- miostat ampoula (inside only is sterile!)
- BSS 15.0 ml

Procedure
- take 0.5 ml miostat in a 2.0 ml syringe
- add 1.5 ml BSS

**Ocular Viscoleastic devices (OVD)**
- Healon
- Healon GV

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**INSTRUMENTATION LIST**

<table>
<thead>
<tr>
<th>NO.</th>
<th>DESCRIPTION</th>
<th>COMMENTS</th>
<th>REF. NO.</th>
<th>MANUFACTURER</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&quot;Bag-in-the-lens&quot; foldable IOL</td>
<td>28 % hydrophylic acrylic</td>
<td>89A-D-E-F</td>
<td>MORCHER*</td>
</tr>
<tr>
<td>2</td>
<td>Ring caliper (4.5 - 5.0 - 6.0)</td>
<td>To caliper the position of the anterior capsulorhexis</td>
<td>Type 4L</td>
<td>MORCHER*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Type 5 NO</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Tassignon caliper ring positioner</td>
<td>To position the ring caliper in the eye</td>
<td>sh-7017</td>
<td>EyeTech</td>
</tr>
<tr>
<td>4</td>
<td>Ikeda angled 30° capsulorhexis 23.0g forceps</td>
<td>To perform anterior and posterior capsulorhexis</td>
<td>Fr 2268</td>
<td>EyeTech</td>
</tr>
<tr>
<td>5</td>
<td>Straight scissors in curved shaft</td>
<td>To adjust the capsulorhexis if needed</td>
<td>Fr 2295c</td>
<td>EyeTech</td>
</tr>
<tr>
<td>6</td>
<td>Navigject injector atraumatic/naviglide</td>
<td>To inject dispersive viscoelastic behind the posterior capsule</td>
<td>1273E</td>
<td>Steriseal</td>
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<tr>
<td></td>
<td>- cartridge 2.5-IP injector set foldable</td>
<td>Up to +20.0 diopters</td>
<td>Lp 604420</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- cartridge 2.8-IP injector set foldable</td>
<td>For all diopeters</td>
<td>Lp 604410</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Rycroft/Helsinki hydrodissection needle 27G</td>
<td>Idem than 7 but to be used in babies and children</td>
<td>E7370</td>
<td>Bausch &amp; Lomb</td>
</tr>
<tr>
<td></td>
<td>(same type from two different manufacturers)</td>
<td></td>
<td>1270.0.100</td>
<td>Dorc</td>
</tr>
<tr>
<td>8</td>
<td>41G needle</td>
<td>Based on limbal centration and corneal Purkinje of the light of the microscope</td>
<td>ECT100</td>
<td>Technop</td>
</tr>
</tbody>
</table>
IS IT SAFE TO PERFORM A PPCCC?

This question has been answered in the literature by many authors and research groups. However, we conducted a clinical study by measuring the fluorescein concentration in the anterior vitreous by means of fluorophotometry after cataract surgery, with and without PPCCC. The results of this study showed no increase in fluorescein in the anterior vitreous provided the anterior hyaloid remained intact.

Literature


HOW STABLE DOES THE CALIPER RING REMAIN ON TOP OF THE ANTERIOR CAPSULE?

In the bag-in-the-lens technique, the balance in pressure between anterior and posterior segment is crucial. The ring caliper is stabilised simply by pressurising the anterior chamber by means of OVD. The OVD which I prefer for this purpose is Healon GV (AMO, Abbott Medical Optics). I do not use Healon V, even not in children or babies.

The OVD in the anterior chamber has two functions:

- **protection** of the endothelium
- **counteracting** the positive vitreous pressure after having performed the corneal incision and before starting any manipulation in the anterior segment

Because in the BIL procedure, the balance of the eye is optimally respected throughout surgery, inflammation will also be very low.

The next question could be:

When is the anterior chamber properly filled with OVD? The answer is: As soon as you observe a reflux of OVD from the incision wound.

HOW CAN ONE EASILY DEFINE THE ANTERIOR FROM THE POSTERIOR HAPTIC?

If the posterior haptic is positioned vertically in the cartridge, this haptic will be horizontal once inserted and unfolded in the anterior segment of the eye.

The opposite will happen in case the posterior haptic is positioned horizontally.

In the future, preloaded cartridges will be available in order to avoid any confusion. To inject the BIL in the correct orientation will be particularly important when dealing with toric lenses since the toric component is located at one side of the Bag-In-The-Lens optic and preferentially oriented facing the cornea.
WHY IS IT NOT ADVISED TO FILL THE CAPSULAR BAG PRIOR TO PERFORM A PPCCC?

When performing a PPCCC, it is again very important to respect the pressure balance between anterior and posterior capsule. In case of overpressuring the anterior chamber, the posterior capsule will be pushed in close contact to the anterior hyaloid. This will increase the risk of puncturing the anterior hyaloid. In addition, the risk for capsule zipping while performing a PPCCC is much higher in the presence of a concave positioned posterior capsule compared to a horizontally positioned capsule.

In case of underpressure of the anterior chamber, the vitreous will move forward and the posterior capsule will be slightly convex. This situation is extremely dangerous for uncontrolled enlargement of the posterior capsule puncture performed for the injection of OVD in the space of BERGER.

What you have to remember, is:
- as soon as the capsular bag has been emptied from any lens material: refill the anterior chamber by injecting the OVD on top of the anterior capsule
- keep both anterior capsules close to each other
- puncture the posterior capsule in the middle of the area of the overlying anterior capsulorhexis
- use a microforceps to perform a well-controlled PCCC

\[\text{DVD Nr. 8}\]

HOW CAN THE BAG-IN-THE-LENS BE STABILISED ONCE INJECTED IN THE ANTERIOR CHAMBER?

Stabilisation of the lens once injected in the anterior chamber is again crucial and will allow a smooth and easy implantation.

By using the OVD needle (Healon regular or GV), the lens can be positioned so that the posterior haptic is acceptably horizontal, facing both capsulorhexis openings. It then can be pushed in close contact to the anterior capsule by injecting some more OVD on top of the anterior face of the lens optic.

By using the OVD needle, the lens is then displayed slightly to the right in order to position the posterior left haptic under the posterior capsule at the left side and by pushing very smoothly at the superior and inferior border of the optic, the capsules will automatically glide into the lens groove.

\[\text{DVD Nr. 2/3}\]
WHAT IS THE DEGREE OF TOLERANCE FOR THE SIZE OF THE ACCC AND PPCCC?

In adult eyes, the degree of tolerance is larger than in children or in babies. At least one of both rhexes should have the correct sizing which is between 4.5 to 5.0 mm. The bag-in-the-lens can still be implanted in case one capsulorhexis, whether it is the anterior or the posterior one, is too large, provided the other one has the proper sizing.

Improper sizing may occur in case of:
- inadvertent oversizing
- IOL exchange in which case the anterior capsulorhexis is oversized. It is then mandatory to carefully size the posterior capsulorhexis.
- IOL exchange in the presence of a large YAG laser capsulotomy. In this case the anterior capsulorhexis, measured by means of the caliper ring, should be of the proper sizing.

Too small anterior and posterior capsulorhexes should be avoided. This will make the implantation very difficult. The pressure needed to implant the lens will be too high causing an enormous stress on the zonular fibers.

C DVD Nr. 29

CAN THE LENS BE IMPLANTED IN CASE OF WEAK ZONULAR FIBERS?

Yes, the lens can be implanted in case of weak zonular fibers, taking the following points into account:
1. The use of a capsular tension ring, which should be positioned after the I/A of the cortex remnants.
2. A bimanual implantation technique is used: one hand retracts both capsules while the other hand keeps the lens in place.

While in the normal BIL implantation the capsule remains stable and the lens is manipulated to be properly positioned, in case of weak zonular fibers, the capsule is manipulated using a bimanual technique in order to glide the capsule into a stabilised BIL.

C DVD Nr. 10/11

IS IT SAFE TO PERFORM A PPCCC IN A HIGH MYOPIE EYE?

Our clinical experience allows to conclude that it is safe to perform a PPCCC in a high myopic eye. The rate of retinal detachment is the same in our series than in the literature. However, we always insert a capsular tension ring (CTR) in eyes presenting an axial length of 26.0 mm or more. The rationale behind this relies on the clinical evidence that these eyes often present an anterior vitreous schisis with a very large Berger’s space and as a consequence a very weak anterior vitreous support. We believe that by stabilising the capsule with a CTR, this will be beneficial for the stability of the anterior vitreous-capsular interface.

C DVD Nr. 1

WHICH ARE THE INDICATIONS FOR CTR IMPLANTATION USING THE BIL TECHNIQUE?

There are two indications for CTR use:
- in case of weak zonules
- in case of axial length ≥ 26.0 mm

C DVD Nr. 1/14

IS THE SURGICAL TIME INCREASED DUE TO THE SUPPLEMENTARY STEP OF PPCCC?

Once the learning curve is terminated, surgical time is increased of about half a minute compared to a procedure without PPCCC. A routine surgeon will perform a routine BIL case in 11 to 12 minutes. My fellows perform the surgery in 16 to 17 minutes.

HOW EASY CAN THE BIL BE REMOVED?

The BIL has the unique property to be easily removed at any postoperative time and exchanged by another BIL. The reason for exchange can be because of changes in the refractive power as it can be expected in pediatric cataract or to correct corneal astigmatism.

After having filled the anterior chamber with visco elastic material in order to control the pressure between anterior and posterior chambers, the posterior haptic can be pushed down with a blunt instrument. My preferred instrument is with the needle of the visco-elastic syringe. The capsular Soemering will then separate from the lens groove and the needle can be positioned behind the posterior haptic while viscoelastic material is injected in order to immediately push back the anterior vitreous face. The BIL can then be luxated anteriorly and freeded from its capsular support. It can then be approached like any other IOL (cut in pieces or cut off a triangular piece) in order to get it out from the anterior chamber and be replaced by the appropriate BIL.

POSTOPERATIVE WOBLLING OF THE LENS. DOES IT MATTER?

In some very few cases the patients may complaint of wobbling images immediately after implantation. This optical phenomenon is due to the fact that the patient’s capsular bag is quite big providing less stability of the BIL immediately after surgery.

However, the patient should be informed that most likely this symptom will disappear after five weeks postoperatively as soon as the capsular bag has been refilled by Lens Epithelial Cell reproliferation. This takes typically 5 weeks to two months to occur.
All articles can be downloaded surfing on the UZA website www.uza.be/cataractBIL


TORIC BIL

The toric BIL implantation is now also possible for astigmatism powers up to 8.0 D.

The first 52 eyes have been implanted with excellent clinical results (see literature bag-in-the-lens).

The toric IOLs can be ordered by using the dedicated order form that can be downloaded from the Morcher website www.morcher.com

Please look at the Video Library, section “Toric BIL”, to learn about the implantation technique.
### BIL SURGICAL TECHNIQUES

<table>
<thead>
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<th>Nr</th>
<th>Indication</th>
<th>Particularities</th>
<th>Duration</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>HIGH MYOPIA</td>
<td>Capsular Tension Ring</td>
<td>2'26&quot;</td>
</tr>
<tr>
<td>2</td>
<td>UVEITIS ANTERIOR</td>
<td>-</td>
<td>1'11&quot;</td>
</tr>
<tr>
<td>3</td>
<td>UVEITIS ANTERIOR</td>
<td>-</td>
<td>1'06&quot;</td>
</tr>
<tr>
<td>4</td>
<td>UVEITIS ANTERIOR</td>
<td>Stick-Caliper</td>
<td>3'43&quot;</td>
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<tr>
<td>5</td>
<td>BIL IMPLANT ONLY</td>
<td>Forceps Implantation</td>
<td>25.0&quot;</td>
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<tr>
<td>6</td>
<td>PIGMENT ANTERIOR VITREUM</td>
<td>ACCC + BIL insert</td>
<td>57.0&quot;</td>
</tr>
<tr>
<td>7</td>
<td>BIL IMPLANTATION</td>
<td>IOL rotation</td>
<td>51.0&quot;</td>
</tr>
<tr>
<td>8</td>
<td>METABOLIC CATARACT</td>
<td>Full Procedure</td>
<td>2'02&quot;</td>
</tr>
<tr>
<td>9</td>
<td>89F IOL</td>
<td>Longer Anterior Haptic</td>
<td>1'15&quot;</td>
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### BIL SPECIAL CASES

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<tr>
<td>10</td>
<td>WEAK ZONULAR FIBERS</td>
<td>Prolene Lasso Scleral Fixation</td>
<td>1'56&quot;</td>
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<tr>
<td>11</td>
<td>TRAUMATIC LENS LUXATION</td>
<td>Prolene Lasso Scleral Fixation</td>
<td>3'44&quot;</td>
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<tr>
<td>40</td>
<td>SECONDARY BIL IMPLANTATION</td>
<td>Capsule stretching an BIL centration by means of beans</td>
<td>18'33&quot;</td>
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### COMBINED BIL SURGERY

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<th>Duration</th>
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<tbody>
<tr>
<td>12</td>
<td>BIL + PKP</td>
<td>OpenSkyBIL</td>
<td>2'20&quot;</td>
</tr>
<tr>
<td>13</td>
<td>BIL + DSAEK</td>
<td>Anterior Chamber</td>
<td>2'18&quot;</td>
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<tr>
<td>14</td>
<td>ANTERIOR PHAKIC IOL EXCHANGE</td>
<td>Capsular Tension Ring</td>
<td>4'52&quot;</td>
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### BIL EXCHANGE

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<tr>
<td>15</td>
<td>REFRACTIVE ERROR</td>
<td>Post Penetrating Keratoplasty</td>
<td>1'36&quot;</td>
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<tr>
<td>16</td>
<td>REFRACTIVE ERROR</td>
<td>Post Radial Keratotomy + Intacs</td>
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### CONGENITAL CATARACT

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<tr>
<td>17</td>
<td>CHILD EYE</td>
<td>Posterior Capsule Plaque</td>
<td>4'13&quot;</td>
</tr>
<tr>
<td>18</td>
<td>CHILD EYE</td>
<td>Posterior Capsule Plaque</td>
<td>3'59&quot;</td>
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<tr>
<td>19</td>
<td>YOUNG ADULT</td>
<td>Anterior Capsule Plaque</td>
<td>4'36&quot;</td>
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<tr>
<td>20</td>
<td>CHILD EYE</td>
<td>Vitreous Interface / 41G Needle</td>
<td>3'00&quot;</td>
</tr>
<tr>
<td>21</td>
<td>MARFAN</td>
<td>Dislocated lens</td>
<td>5'55&quot;</td>
</tr>
<tr>
<td>22</td>
<td>ANTERIOR PHPV</td>
<td>Interface Dissection</td>
<td>6'02&quot;</td>
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### IOL EXCHANGE

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<td>MULTIFOCAL IOL</td>
<td>Capsular Peeling</td>
<td>2'45&quot;</td>
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<td>24</td>
<td>ACRYSOFT</td>
<td>Posterior Capsule</td>
<td>1'50&quot;</td>
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<td>25</td>
<td>MULTIFOCAL IOL</td>
<td>Capsular Peeling</td>
<td>3'41&quot;</td>
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<tr>
<td>26</td>
<td>DECENTRATED SILICONE IOL</td>
<td>Posterior Continuous Curvilinear</td>
<td>1'38&quot;</td>
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<tr>
<td></td>
<td></td>
<td>Capsular Peeling rupture</td>
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<tr>
<td>27</td>
<td>DECENTRATED IOL</td>
<td>Damaged IOL</td>
<td>1'43&quot;</td>
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<tr>
<td>28</td>
<td>OPAQUE H 60 M</td>
<td>Capsular Peeling</td>
<td>2'31&quot;</td>
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<tr>
<td>29</td>
<td>YELLOW IOL</td>
<td>ACCC / PCCC</td>
<td>4'00&quot;</td>
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<td>30</td>
<td>TRAUMATIC CATARACT</td>
<td>Capsular Tension Ring</td>
<td>4'24&quot;</td>
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<tr>
<td>31</td>
<td>CAPSULAR CONTRACTION SYNDROME</td>
<td>Capsular Peeling</td>
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### TORIC BIL

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<tr>
<td>32</td>
<td>SECUND IMPLANT</td>
<td>Cleaning Interface</td>
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<td>33</td>
<td>CONGENTIAL ASTIGMATISM</td>
<td>Pukinje Centration</td>
<td>1'24&quot;</td>
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<tr>
<td>34</td>
<td>CONGENTIAL ASTIGMATISM</td>
<td>Pukinje Centration</td>
<td>2'59&quot;</td>
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<td>35</td>
<td>TRILOGY</td>
<td>Pukinje Centration</td>
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<td>36</td>
<td>ADULT CATARACT</td>
<td>Corneal Astigmatism</td>
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### EDITED VIDEOS WITH SOUND

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<tr>
<td>37</td>
<td>3 CASES</td>
<td>Implantation in child eye</td>
<td>7'52&quot;</td>
</tr>
<tr>
<td>38</td>
<td>2 CASES</td>
<td>Mysteries of the Anterior Hyaloïd</td>
<td>7'58&quot;</td>
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</table>
HOW TO BECOME BIL USER

Those surgeons, who are interested in implanting the BIL, can become certified after having performed any of the following training:

1. Wetlab and Instructional Course at the Annual ESCRS meeting on PPCCC. This is a prerequisite requirement in order to partake at the wetlab with the following faculty:
   Marie-José Tassignon, Robert Stegmann, Tobias Neuhann, Abhay Vasavada, Rupert Menapace

2. Observership at the Antwerp University Hospital, Department of Ophthalmology
   Director: Prof. Dr. Marie-José Tassignon
   Faculty BIL users: Prof. Dr. Marie-José Tassignon, Prof. Dr. Veva De Groot, Dr. Jan Van Looveren, Dr. Stefan Kiekens
   Scientific coordinator: Danny Mathysen (danny.mathysen@uza.be)

3. Observership at any centers with certified instructors (see list instructors www.morcher.com)

A List of all current BIL-Instructors can be found on our website: www.morcher.com/infos/downloads.html

BEAN RINGS

In the absence of capsular bag or in case of weak zonular support the BIL can be stabilised and centered by means of beans positioned within the lens groove at the optical side and in the siliary sulcus at the peripheral side. The BIL will then be fixated in between both beans. In case of complete absence of capsular support, the BIL will be fixated at the sclera by means of two prolene 10/0 threads following the previously described “lassooing” technique.
Before beginning a procedure, be sure you fully understand the nature of the device and its proper implantation. Always view the DVD provided for a more complete understanding.

It is advisable to participate with an experienced surgeon before attempting to perform the procedure on your own.

It is recommended to insert a capsular tension ring (CTR) in all eyes with unstable capsule. Its insertion should be done once the crystalline material has been removed completely and before performing the PPCCC. Both the anterior and posterior capsule MUST be kept in close contact while injecting the CTR in order to allow proper insertion of both capsules in the lens groove during the lens positioning.

Due to the possibility of Iris capture it is recommended to keep the Iris in miosis for three days.