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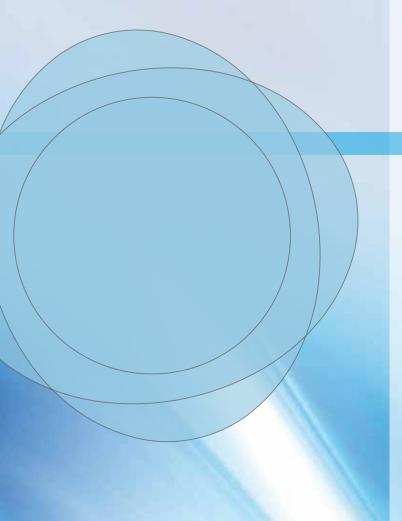
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BAG-IN-THE-LENS



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

BAG-IN-THE-LENS

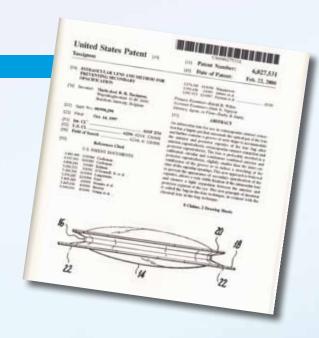
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BACKGROUND OF THE BIL

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.





Harold Ridley with his wife Elisabeth at the SOE 1999 in Stockholm

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."

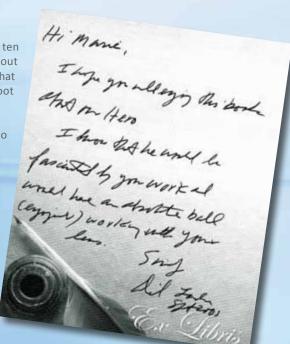
David Apple

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.



SURGICAL PROTOCOL / CATARACT PROCEDURE

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 ml adrenalin solution (see procedure medication) [2]
- ▶ injection of Healon GV for corneal protection [3]
- ▶ insertion of the caliper ring type 5 none 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 ml
- ► 1 syringe 1 ml
- ► NaCl bottle of 100 ml
- 2 aspiration needles (pink)
- zinacef 250 mg powder (sterile)

Procedure (in OR)

- ▶ take 2.5 ml NaCl in the 10 ml syringe
- ► inject these 2.5 ml NaCl into the bottle filled with zinacef 250 mg powder
- shake thoroughly until the zinacef powder is properly diluted
- using the 10 ml syringe, take 1 ml out of this solution
- ▶ fill the additional 9 ml of the syringe with NaCl

Procedure on surgical tray

- the instrumentist takes a 1 ml syringe mounted with a pink aspiration needle
- aspiration of 1 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 xylocaine solution Fittings

- ▶ 1 ml syringe
- ► 1 aspiration needle (pink)
- ► adrenaline ampoula 1 ml (1:1000)
- xylocard ampoula

Procedure

- ► take 0.9 ml xylocard in a 1 ml syringe
- ▶ add 0.1 ml of 1:1000 solution adrenaline

Procedure miostat solution Fittings

- syringe of 2 ml
- aspiration needle (pink)
- miostat ampoula (inside only is sterile!)
- ▶ BSS 15 ml

Procedure

- ► take 0.5 ml miostat in a 2 ml syringe
- ▶ add 1.5 ml BSS

Ocular Viscoleastic devices (OVD)

- ► Healon
- ► Healon GV

INSTRUMENTATION LIST

No.	Description	Comments	Ref. No.	Manufacturer
1	"Bag-in-the-lens" foldable IOL	28 % hydrophylic acrylic	89A-D-E-F	MORCHER®
2	Ring caliper (4.5 - 5 - 6)	To caliper the position of	Type 4L	MORCHER®
		the anterior capsulorhexis	Type 5	
3	Tassignon caliper ring positioner	To position the ring caliper in the eye	sh-7017	EyeTech
4	Ikeda angled 30° capsulorhexis 23g forceps	To perform anterior and posterior capsulorhexis	Fr 2268	EyeTech
5	Straight scissors in curved shaft	To adjust the capsulorhexis if needed	Fr 2295c	EyeTech
6	Naviject injector atraumatic/naviglide			
	- cartridge 2.5-IP injector set foldable	Up to +20.0 diopters	Lp 604420	Medicel
	- cartridge 2.8-IP injector set foldable	For all diopters	Lp 604410	
7	Rycroft/Helsinki hydrodissection needle 27G	To inject dispersive viscoelastic behind	1273E	Steriseal
		the posterior capsule		
8	41G needle	Idem than 7 but to be used in babies and children	E7370	Bausch & Lomb
	(same type from two different manufacturers)		1270.0.100	Dorc
9	Eye Cage alignment device	Based on limbal centration and corneal	ECT100	Technop
		Purkinje of the light of the microscope		

FREQUENTLY ASKED QUESTIONS

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.

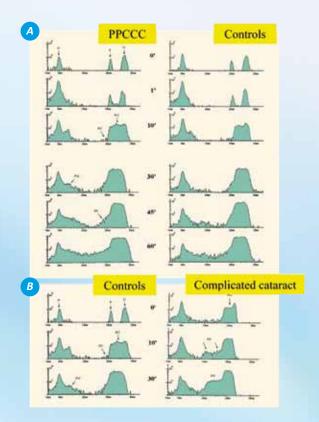
Literature:

V. De Groot, M. Hubert, J.A. Van Best, S. Engelen, S. Van Aelst, M.J. Tassignon (2003). Lack of fluorophotometric evidence of aqueous-vitreous barrier disruption after posterior capsulorhexis. J. Cataract Refract. Surg. 29, 2330-2338

A. Galand, F. van Cauwenberge, J. Moosavi (1996). Posterior capsulorhexis in adult eyes with intact and clear capsules. J. Cataract Refract. Surg. 22, 458-461

E. Stifter, R. Menapace, K. Kriechbaum, L. Vock, A. Luksch (2009). Effect of primary posterior continuous curvilinear capsulorhexis with and without posterior optic buttonholing on postoperative anterior chamber flare.

- A Shows identical fluorescein concentration in the anterior vitreous in the eyes with PPCCC than without PPCCC (Control) (0'-1'-10'-30'-45'-60').
- B Shows highly increased fluorescein concentrations in the anterior vitreous in the eys with complicated cataract cases compared to the controls.



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.

DVD Nr. 8

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 PPCCC.

DVD Nr. 8

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.

DVD Nr. 9



After having emptied the capsular bag of all lens material...



... NEVER re-fill the capsular bag with OVD !!



... on the contrary ONLY fill the anterior chamber with OVD on top of the anterior capsule and bring the capsule in a horizontal plane.



... after puncturing the posterior capsule inject the OVD through the hole until the blister is slightly larger than ...



... the ACCC. Perform then the PPCCC of the same size than the ACCC.

FREQUENTLY ASKED QUESTIONS

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.

▶ 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 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.

▶ 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.

▶ DVD Nr. 10/11

IS IT SAFE TO PERFORM A PPCCC IN A HIGH MYOPIC 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 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 vitreo-capsular interface.

DVD Nr. 1

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

There are two indications for CTR use:

- a. in case of weak zonules
- b. in case of axial length ≥ 26 mm

▶ 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 **routined** surgeon will perform a routine BIL case in 11 to 12 minutes. My fellows perform the surgery in 16 to 17 minutes.

LITERATURE BAG-IN-THE-LENS



All articles can be downloaded surfing on the UZA website www.uza.be/cataractBIL

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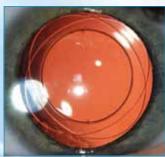
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TORIC BIL





- The toric BIL implantation is now also possible for astigmatism powers up to 8 Dpt.
- ► The first 52 eyes have been implanted with excellent clinical results (see literature bag-in-the-lens).
- ► The toric IOLs can be order 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 IMPLANTATION VIDEO LIBRARY

BIL SURGICAL TECHNIQUES

Nr	Indication	Particularities	Duration	DVD
1	High Myopia	CTR	2'26"	01
2	Uveitis Anterior	-	1'11"	02
3	Uveitis Anterior	-	1'06"	03
4	Uveitis Anterior	Stick-Caliper	3'43"	04
5	BILimplantOnly	Forceps Implantation	25"	05
6	PigmentAntVitr	ACCC + BIL insert	57"	06
7	BILimplantation	IOLrotation	51"	07
8	MetabolicCataract	Full Procedure	2'02"	08
9	89F IOL	LongerAnterHaptic	1'15"	09

BIL SPECIAL CASES

Nr	Indication	Particularities	Duration	DVD
1	WeekZonulFibers	ProleneLassoSclerFix	1'56"	10
2	TraumatLensLux	ProleneLassoSclerFix	3'44"	11

COMBINED BIL SURGERY

Nr	Indication	Particularities	Duration	DVD
1	BIL+PKP	OpenSkyBIL	2'20"	12
2	BIL+DSAEK	AnterChamber	2'18"	13
3	AntPhakicIOLexch	CTR	4'52"	14

BIL EXCHANGE

Nr	Indication	Particularities	Duration	DVD
1	RefractiveError	PostPKP	1'36"	15
2	RefractiveError	PostRK+Intacs	1′37″	16

CONGENITAL CATARACT

Nr	Indication	Particularities	Duration	DVD
1	Child Eye		4'13"	17
2	Child Eye	PostCapsPlaque	3'59"	18
3	YoungAdult	AntCapsPlaque	4'36"	19
4	Child Eye	VitrInterf/41Gneedle	3'	20
5	Marfan	DislocatedLens	5'55"	21
6	AnteriorPHPV	InterfaceDissection	6'02"	22

BIL IMPLANTATION VIDEO LIBRARY

IOL EXCHANGE

Nr	Indication	Particularities	Duration	DVD
1	Multifocal IOL	CapsularPeeling	2'45"	23
2	Acrysof	PosteriorCapsule	1′50″	24
3	Multifocal IOL	CapsularPeeling	3'41"	25
4	DecenSiliconeIOL	PCCCrupture	1'38"	26
5	DecenteredIOL	DamagedAcrysof	1'43"	27
6	OpaqueH60M	CapsularPeeling	2'31"	28
7	AcrysofYellow	ACCC>>PCCC	4'00"	29
8	TraumaticCataract	CTR	4'24"	30
9	Caps. Contr. Syndr.	Capsular Peeling	6′56″	31

TORICBIL

Nr	Indication	Particularities	Duration	DVD
1	SecundImplant	CleaningInterface	3'21	32
2	Cong.astigmat	PunkinjeCentration	1'24"	33
3	Cong.astigmat	PunkinjeCentration	2'59"	34
4	Trilogy	PunkinjeCentration	3'03"	35
5	Adult Cataract	Corneal astigmatism	3'32"	36

EDITED VIDEOS WITH SOUND

Nr	Indication	Particularities	Duration	DVD
1	3 cases	Implantation in ChildEye	7'52"	37
2	2 cases	Mysteries of the Anterior Hyaloïd	7′58″	38

HOW TO BECOME BIL USER

Those surgeons who are interested to implant the BIL can become certified after having performed the following training.

1. Wetlab and instructional course at the Annual ESCRS meeting on PPCCC, which is a prerequisite course to be allowed at the wetlab, with the following faculty:

Marie-José Tassignon, Howard Gimbel, Robert Stegmann, Tobias Neuhann, Ab hay 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

E-mail danny.mathysen@uza.be

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

BIL USERS AND INSTRUCTORS

ID number	Name	Contry	E-mail	Instructor for
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TECHNICAL INFORMATION

	Type 89A	Type 89D	Type 89F
	Indicated adult eyes or eyes of children.	Indicated for children or babies. procedures or in eyes with large pupils.	Indicated in combined cataract and vitrectomy
Design	Tassignon	Tassignon	Tassignon
Material	HYDROPHILIC COACRYL 28	HYDROPHILIC COACRYL 28	HYDROPHILIC COACRYL 28
Overall Length	7.5 mm	6.5 mm	8.5 mm
Haptic	0.15 mm	0.15 mm	0.15 mm
Optic	5.0 mm / BICONVEX	4.5 mm / BICONVEX	5.0 mm / BICONVEX
Standard power range	10 – 30 Dpt. (other diopters on request)	10 – 30 Dpt. (other diopters on request)	10 – 30 Dpt. (other diopters on request)
Estimated Anterior Chamber Depth AB*1	4.97 mm	4.97 mm	4.97 mm
Estimated Anterior Chamber Depth OB*2	5.08 mm	5.08 mm	5.08 mm
Estimated A-Constant AB*1	118.0	118.0	118.0
Estimated A-Constant OB*2	118.2	118.2	118.2



SECURITY ADVICE

- ▶ 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.

BIL IMPLANTATION VIDEO LIBRARY PART I

BIL IMPLANTATION VIDEO LIBRARY PART II