Innovative Implantation Technique

Bag-in-the-Lens Cataract Surgery

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ISBN 978-3-030-03085-8 ISBN 978-3-030-03086-5 (eBook)
https://doi.org/10.1007/978-3-030-03086-5

Library of Congress Control Number: 2018968144

This Springer imprint is published by the registered company Springer Nature Switzerland AG
The registered company address is: Gewerbestrasse 11, 6330 Cham, Switzerland

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Part I

Why Use the BIL?

1 The History of the Bag-in-the-Lens Implant

Marie-José Tassignon

1.1 Introduction

Back in 1999, I had the honor of meeting Sir Harold Ridley in Stockholm on the occasion of the European Society of Ophthalmology (SOE) meeting. He and his wife Elisabeth were guests of honor at the European Society meeting. I hoped to take advantage of this opportunity to discuss the concept of the bag-in-the-lens. Given that he was about 90 years of age, I realized that this was a "mission impossible" and felt satisfied with a picture in his company (Fig. 1.1). I wanted to explain some thoughts that I had on modifying, very slightly, his original design, which was round with a small edge surrounding the lens optic (Fig. 1.2). In the original drawings and publications [1–2], the Ridley lens was clearly intended to be positioned within the capsular bag and to fill this bag as much as possible. However, I still had the question of why such funny edges were placed at the periphery of the lens optic. My idea was to make that edge longer and to extend it out from both the anterior and posterior surfaces of the lens optic. This would create a groove between the flanges that could accommodate both the anterior and posterior capsules.

David Apple, professor of ophthalmology and pathology at Moran Eye Center, Salt Lake City, Utah, USA, dedicated a lot of his time to writing a bibliography of Harold Ridley [3]. He traveled to England many times to meet Sir Harold Ridley, not just as a colleague but as a personal friend. He was eager to hear the master describe his account of the discovery of the intraocular lens that would revolutionize cataract surgery worldwide in person.

In Chap. 11 of David Apple's book [3], Harold Ridley reported secondary cataract and lens "decentration" as "modern" cataract surgery's most common

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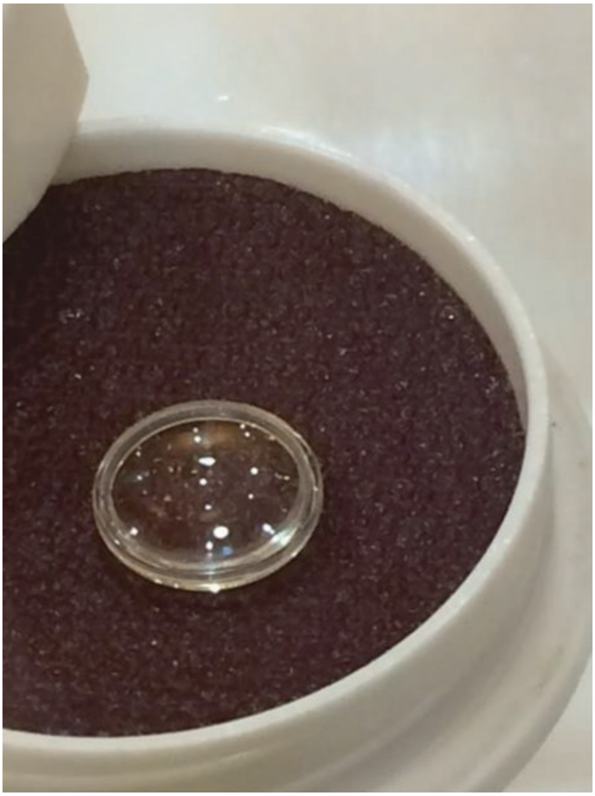
M.-J. Tassignon et al. (eds.), *Innovative Implantation Technique*,
https://doi.org/10.1007/978-3-030-03086-5_1

Fig. 1.1 With Harold Ridley and his wife Elisabeth at SOE in Stockholm 1999

Fig. 1.2 Harold Ridley's first IOL design, manufactured by Rayner[R], UK



postoperative surgical complications. The quest to solve these problems with the bag-in-the-lens began there.

Charles Kelman was a dear friend and mentor to me. He supported me on my quest to write the patent on the bag-in-the-lens and invited me, every year, to be a speaker at the "French Phaco courses," organized in New York. The aim of these French Phaco courses was to disseminate his message about the superiority of the phaco technique to the international community of French-speaking ophthalmologists in the USA. Charles Kelman spoke fluent French, since he spent many years in a French-speaking canton in Switzerland. He put me in contact with his attorney, who helped me in the administrative follow-up of the BIL patent which was issued in February 2000 [4]. It was remarkable to remember, from Charles Kelman's oral presentations, that although the phaco technique improved the surgical outcome dramatically, the most frequent complications remained. These included (Fig. 1.3):

1. Opacification of the lens capsular bag, which was ultimately referred to as posterior capsule opacification or PCO
2. Loss of accommodation (interest in restoring accommodation became reality starting from the mid-1990s on)

More than 40 years after the introduction of the first intraocular lens implantation and the advent of the phaco technique, PCO was still the most common complication after cataract surgery until Daniele Aron-Rosa [5] and Franz Fankhauser [6] came up with the disruptive Q-switched Nd-YAG laser, to mechanically open the opacified capsular bag. I knew Daniele Aron-Rosa as an excellent scientist with a warm personality. She was also very interested in art, and one of her hobbies was

Fig. 1.3 With Charles Kelman in New York, 1998

Fig. 1.4 (**a**) With Daniele Aron-Rosa in 2003 and (**b**) one of her paintings signed Genskof of that same period

painting. Her artist's name is Genskof, and I was fortunate to receive one of her paintings through a common friend, Dr. René Trau, in 2003 (Fig. 1.4). Franz Fankhauser's Q-switched Nd-YAG laser machine presented more treatment options than that of Aron-Rosa, and although I was not directly connected to him, he inspired me to use the laser to treat vitreal problems like premacular hemorrhages and floaters. The latter is now drawing a great deal of attention in ophthalmological practice, and while I will not elaborate on that topic here, I am of the opinion that floaters are very important in cataract surgery, particularly when using complex optics such as multifocal IOLs. The quality of the image, as perceived by the patient, will be influenced negatively by the presence of floaters.

Even though Nd-YAG laser capsulotomy was a real leap forward in modern cataract surgery, the effect of the foreign body reaction of the intraocular lens biomaterial on the capsular bag had not yet been solved. Our department showed that while performing a YAG laser could clear the visual axis, a significant amount of higher-order aberrations remained which indicated that Nd-YAG treatment did not provide as good an image, as there had been no PCO at all. We demonstrated that the incidence of ocular aberrations decreased but remained quite high compared to the immediate postoperative measurements [7]. Patient's quality of the image is, therefore, still suboptimal following Nd-YAG laser capsulotomy, even if the visual axis is optimally transparent to light. It became clear to me that while visual acuity can be excellent, patients may still suffer from a poor but sufficient "quality of vision." This new concept plays an important role when trying to understand why patients are unhappy after an uneventful cataract surgery and an implantation of an intraocular lens with complex optics.

1.2 BIL Concept

The BIL intraocular lens is "suspended" by the lens capsule, while the intraocular lens is inserted into the capsule bag (Fig. 1.5a) in the lens-in-the-bag method. At the core of the bag-in-the-lens principle is the sequestration of the lens epithelial cells of the inner plane of the anterior lens capsule and of the equatorial area of the crystalline lens into the sealed lens capsule (Fig. 1.5b, (a and b)). The area of contact of

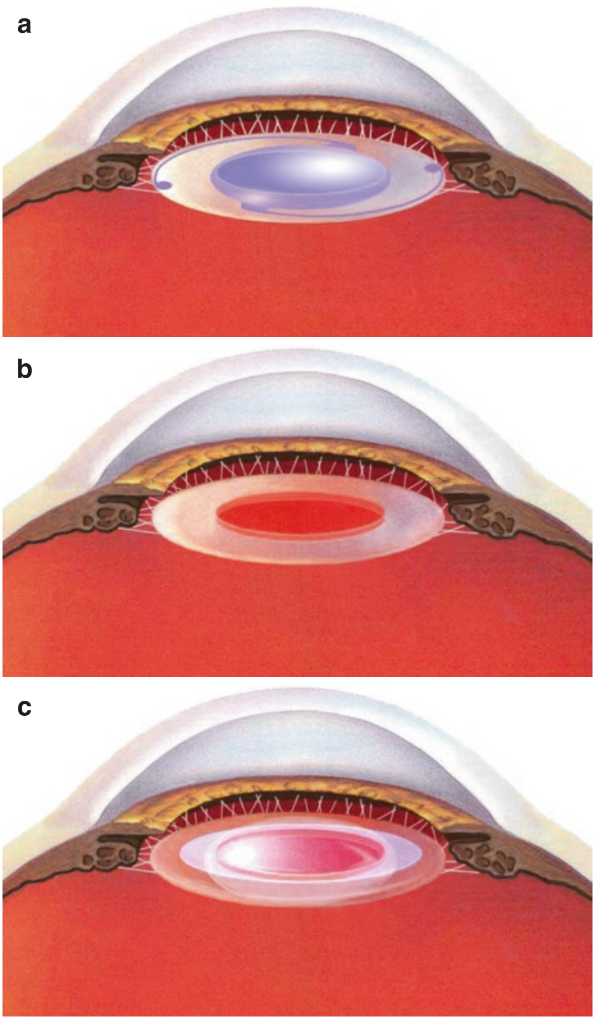


Fig. 1.5 Differences in concept in (**a**) the lens-in-the-bag in which the intraocular lens is inserted into the capsule bag and (**b**) the bag-in-the-lens implantation techniques where an anterior and posterior capsulorhexis is performed of similar size (a) in order to insert both together into the lens groove surrounding the lens optic (b). (Drawings made by R. Leysen)

the capsule bag (and accompanying lens epithelial cells) with the biomaterial of the intraocular lens is very large in the traditional lens-in-bag approach, while the contact of the biomaterial with the lens capsule is reduced to the lens groove with the bag-in-the-lens method. This major difference explains why the lens epithelial cells undergo very little metaplasia into myofibroblasts in the bag-in-the-lens implantation technique.

George Duncan from Norwich University (UK) and later on Michael Wormstone (Norwich, UK) spent a lot of their careers in exploring the mechanism behind

US006027531A

United States Patent [19]
Tassignon

[11] **Patent Number: 6,027,531**
[45] **Date of Patent: Feb. 22, 2000**

[54] **INTRAOCULAR LENS AND METHOD FOR PREVENTING SECONDARY OPACIFICATION**

[76] Inventor: **Marie-José B. R. Tassignon**, Wapenhaghestraat 10 IN 2600, Berchem-Antwerp, Belgium

[21] Appl. No.: **08/950,290**

[22] Filed: **Oct. 14, 1997**

[51] **Int. Cl.**[7] **A61F 2/16**
[52] **U.S. Cl.** **623/6**; 623/4; 128/898
[58] **Field of Search** 623/6, 4; 128/898

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Primary Examiner—David H. Willse
Assistant Examiner—Dinh X. Nguyen
Attorney, Agent, or Firm—Darby & Darby

[57] **ABSTRACT**

An intraocular lens for use in extracapsular cataract extraction has a haptic pat that surrounds the optical pat of the lens and further contains a groove of such shape to accommodate the anterior and posterior capsules of the lens bag after anterior capsulorhexis, extracapsular cataract extraction and posterior capsulorhexis. The lens is preferably inserted in a calibrated, circular and continuous combined anterior and posterior capsulorhexis, slightly smaller than the inner circumference of the groove as to induce a stretching of the rims of the capsular openings. This new approach is believed to prevent the appearance of secondary opacification of the capsules, allows a very stable fixation of the intraocular lens and ensures a tight separation between the anterior and posterior segment of the eye. This new principle of insertion is called the bag-in-the-lens technique, in contrast with the classical lens in-the-bag technique.

8 Claims, 2 Drawing Sheets

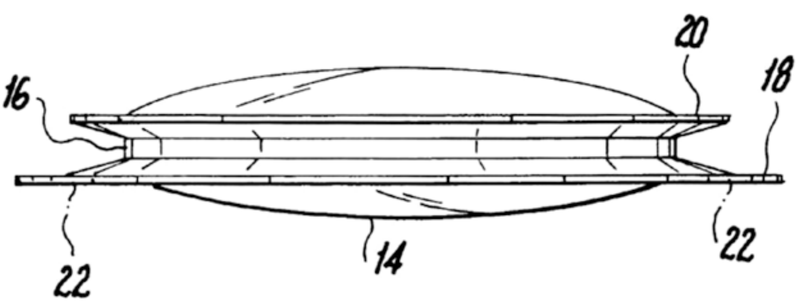

Fig. 1.6 Technical drawing made by Rudi Leysen for the US patent application of the bag-in-the lens

PCO [8]. Based on their studies, it became clear to me that the lens epithelial cells are very potent cells. The message was to keep them far away from cytokines or any other proteins that could trigger their transformation into myofibroblasts, causing fibrotic reaction and contraction of the capsular bag, while the lens epithelial cells keep the capsular bag flexible and transparent under normal physiological circumstances.

The idea of the bag-in-the-lens design came to me as I was listening to George Duncan's lecture in Amsterdam in 1997. I sketched out a drawing on a napkin, and I tried to explain the principle to Jan Worst and Albert Galant during a coffee break. Unfortunately, neither of them paid much attention to the concept. As I was traveling home by train, I sketched out the draft in greater detail, and the next day, I gave it to my very dear and close friend and co-worker Rudi Leysen (medical photographer at the department of the Antwerp University Hospital). He came up with the first technical drawing which I used for the US patent application (Fig. 1.6).

1.3 The Space of Berger

I knew about the different compartments of the vitreous body [9] based on the work of Jan Worst from Groningen, the Netherlands (Fig. 1.7), and more specifically of the presence of the space of Berger [10]. The space of Berger was first described by

Fig. 1.7 With Prof. Jan Worst at ESCRS meeting in Vienna in 1999

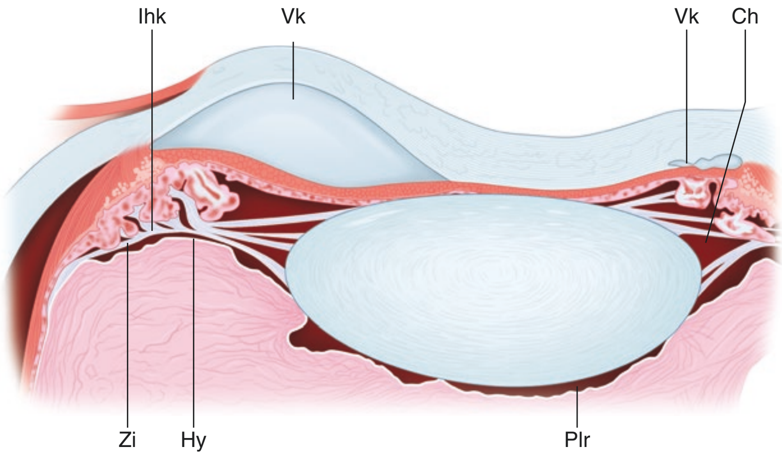

Fig. 1.8 Drawing by Emil Berger of the space defined between the posterior capsule and the anterior hyaloid, later on referred to as the space of Berger. (p 29–30 of Ref. [8])

the ophthalmologist Emil Berger from Graz, Austria. In his thesis, he made a drawing of this area located behind the crystalline lens and beautifully showed how the crystalline lens is completely immersed in water (Fig. 1.8). This space is extremely important to the bag-in-the-lens concept since it accommodates the posterior haptic flange of the lens. The total diameter of the posterior bag-in-the-lens flange haptic is, therefore, no larger than 7.5 mm since the space of Berger in adults is typically about 8–9 mm wide.

We will elaborate more on the importance of this space later in this book as well as on the new discoveries we have been able to make based on our clinical observations while performing a primary posterior continuous circular capsulorhexis routinely in adults and in children [11].

1.4 Conclusion

This book covers 26 years of research, which coincides with my 26-year chairmanship of the department of ophthalmology of the Antwerp University and of the Antwerp University Hospital in Belgium. Prior to this research, I was very active in discovering the effect of lasers on the retina and the vitreous, which was the topic of my PhD thesis defended in Leiden University in 1990. My best man at my PhD defense was Dr. Nikolaas Stempels, a young staff member at the University of Brussels at which I was senior staff at that time. I must thank him for his very supportive role and the many evenings we spent together in brainstorming about the most challenging ideas in the field of ophthalmology.

I have been lucky enough to have met some giants in ophthalmology. They have helped me in finding the answers I was looking for.