

Ioltech Hydrophilic Acrylic, 10 Years of Follow-Up

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INTRODUCTION

Ioltech (now a company of Carl Zeiss Meditec) hydrophilic acrylic intraocular lenses were first marketed in 1996; the first models were the Stabibag, the Haptibag and the Tripode, and shortly thereafter, the Octobag. The first three models were the subject of a ten-year clinical study.

A first clinical study analyzed the performance of these intraocular lenses pre-operatively and post-operatively over the first six months and a second one evaluated their evolution ten years later.

The Carl Zeiss Meditec intraocular lenses currently in the acrylic range, are similar to the implants studied; only the size has changed as well as some of the refractive characteristics.

MATERIAL - METHOD

This is a ten-year study, from 1996 to 2006:

- A first study of 710 cases was the subject of a communication in 1998 at the ESCRS. It evaluated the intraocular lenses in the preoperative phase and over the first six months.
- A second, very recent study was the subject of a poster at the ESCRS in 2006. It analyzed the performance of the lenses in the 456 remaining cases of the first study at the end of 10 years.

Implants involved in the study were the Haptibag, the Stabibag and a very small number of the Tripode.

The Haptibag is a single piece lens inspired by the Kratz model with two loops inserted on an optical zone. Today it remains identical to its original design.

The Stabibag is a single piece lens with three perforated haptics, which provide high stability. This implant has evolved - as the optic has been expanded to create the XL Stabi; the edges were squared in order to limit capsular opacification and, more recently, the aspherical design (Zeiss Optic [ZO] model) was introduced.

The Tripode is no longer marketed because its design was close to the Stabibag one, but with fewer advantages.

The conditions of the two studies follow the same constants: a single surgeon for the surgical procedure and control provided exclusively by the operating surgeon.

For the first study, over 710 cases, there were:

- 350 women
- 190 men
- No exclusion criteria regarding the choice of cataracts
- 507 without particular field
- 193 with ophthalmological and/or general history

For the second study, the 456 remaining cases, there were:

- 216 women
- 109 men
- 233 right eye
- 223 left eye
- An average age of 80 ± 7 years

Haptibag

Methods

- Implantation started May 1996 and finished August 1997
- Number of patients enrolled: 109 M / 216 W Total: 325
- 456 surgeries with the same technique and follow up by the same surgeon
- Implantations of the lenses were performed under local anaesthesia
- Average Age: 80.7 Y
- 233 Right Eyes
- 223 Left Eyes
- Total of Stabibag: 314
- Total of Haptibag: 142
- Average time between visit: 11.08 M (± 4.49 M)
- Patients still enrolled at 10 Years: 218
- Patients with pathology which could affect visual function: 131
- AMD: 39
- OAG: 34

Stabibag

The 254 cases excluded between the two studies have not been reviewed for monitoring since 2002 due to death, moving away or serious general pathology.

The implantation technique was always the same:

- Topical or subconjunctival anesthesia performed by the surgeon
- 3.2 mm incision by a scalpel in clear cornea
- Rhexis by forceps, always of the same size: between 5.5 and 6 mm
- Phacoemulsification
- Continuous electrical irrigation/aspiration
- Implantation with the forceps
- No suture
- The viscoelastic used in 96 and 97 was Ophthalin, similar to the current Gelbag

The 2006 technique remains similar but differs in a few points: topical anesthesia is systematic; the corneal incision is reduced to 2.8 mm; rhexis by needle; the viscoelastic substance is either the Gelbag or Visthesia in more complicated cases; the lens is systematically introduced with an injector. It involves the RTU and more recently its evolution the Skyjet with its ready-to-use feature, since the lens is already loaded in a cartridge that is inserted directly into the injector.

The operator is therefore the same for all surgical procedures, the follow-up and posterior capsule opacification treatment by YAG laser.

Patients are systematically controlled over 48 hours, then three weeks later, then every 6 months, and, if no pathology should require it, every year.

Surgical recruitment of patients is non-restrictive (see "Methods"); no general or ocular pathology is excluded.

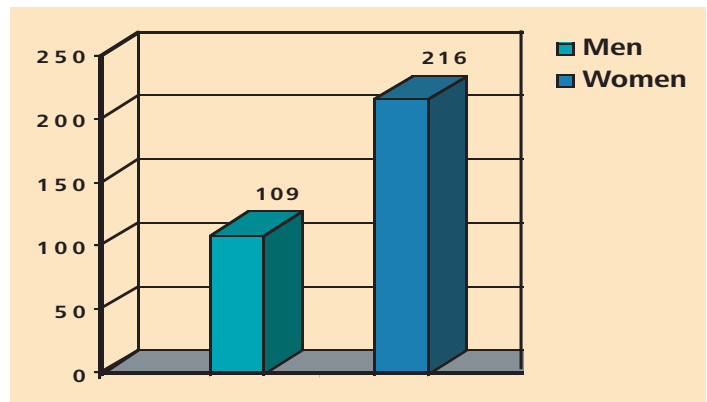
In 10 years, a number of ocular or general pathologies appeared, some modifying the visual function (OAG, AMD, venous occlusion) or their analysis (senile dementia).

At the outset, the intraocular lenses were distributed as follows:

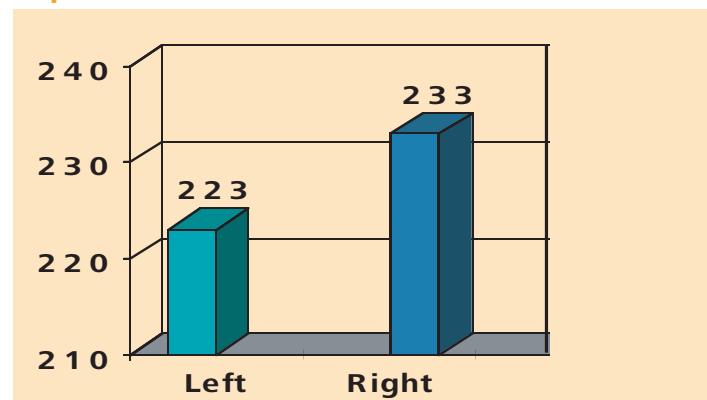
- Haptibag: 228
- Stabibag: 480
- Tripode: 2

In 2006:

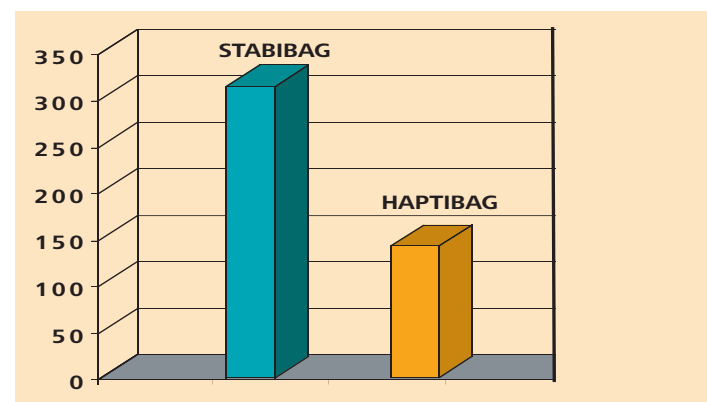
- Haptibag: 142
- Stabibag: 314
- Tripode: 0



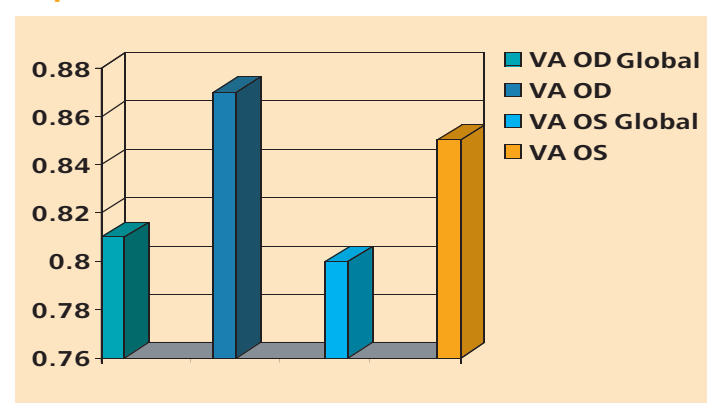
Population



Eyes



Implants



Visual Acuity

RESULTS - ANALYSIS

Early surgical follow-up: Day 0 to day 30

Optimal visual acuity at day 21: average obtained 0.88

Complications documented:

- In one case, a post operative capsular bag retraction following a strong, inflammatory reaction treated after three months by a large YAG laser treatment on the anterior and posterior capsule.
- 6 cases of ocular hypertension, 3 of which were transient and 3 others in the glaucomatous field; situation normalized after a medical antiglaucomatous treatment.
- 38 cases of cystoid macular oedema healed on day 90.

Long term surgical follow-up: from 30 days to 10 years

It emphasizes the following ratios at the visual functional level, excluding any ocular pathology:

RE: 0.87

LE: 0.85

These fall with the appearance of pathologies as glaucoma, vascular occlusion and especially AMD:

RE: 0.81

LE: 0.80

Apart from the pathology, the great stability of the visual function over 10 years is remarkable.

Results

- No discoloration
- No glistening
- No deposit on the surface
- No bag retraction
- No modification of the IOLs after YAG treatment and perfect stability
- No IOL explanted
- YAG Treatment: 382/456 representing 83.7% after 10 years
- Time before YAG treatment 4.87 Y (+/- 2.62 Y)
- VA OD without pathology: 0.87
- VA OD with pathology: 0.81
- VA OS without pathology: 0.85
- VA OS with pathology: 0.80

Additional pathologies are distributed as follows:

- Glaucoma 34
- AMD 39
- Venous occlusions 2

Treatment by YAG laser after 10 years:

Of the 456 remaining cases, 382 (83.7%) have been treated; the average treatment time is 4.87 years.

The performance of the lens after treatment is perfect. There is no modification of the structure or decentration.

The accidental impact points on the optics do not degrade the lens.

No lens has been removed in early post-operative phase nor in the following ten years.

Regular observation has not revealed any modification of the lens:

- No change in color, no yellowing
- No change on the surface of the lens, no fibrous surface
- No greying as it has been described in other acrylic models
- No deposits or glistening phenomena

A post-operative capsular bag retraction on a Stabibag following a strong, inflammatory reaction treated 3 months later by a YAG laser demonstrated the implant's remarkable softness. The loops rolled forward by the phymosis of the bag (atrophy) repositioned themselves without difficulty after a YAG on the anterior capsule by several slitting and posterior strokes.

Ten years later the implant had not moved. The softness of the material and its three supports avoided decentration.

CONCLUSIONS

The first study of 710 cases presented in 1998 showed the perfect performance of the lens during surgery and its remarkable tolerance in early follow-up with a particularly low rate of complications.

The second study after ten years analyzing the 456 remaining cases confirms this remarkable tolerance over the long term without alteration of the lens before and after capsulotomy and the preservation of its refractive quality corroborated by a stable visual function over time.