Multifocal Phakic Implant For Presbyopia Correction

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Correcting presbyopia is an essential challenge for refractive surgery. This particular type of surgery is not so much to do with restoring accommodation, but more a question of giving patients an opportunity of living without spectacles for distant and near vision. This opens the door to a number of compromises or alternatives to real accommodation surgery.

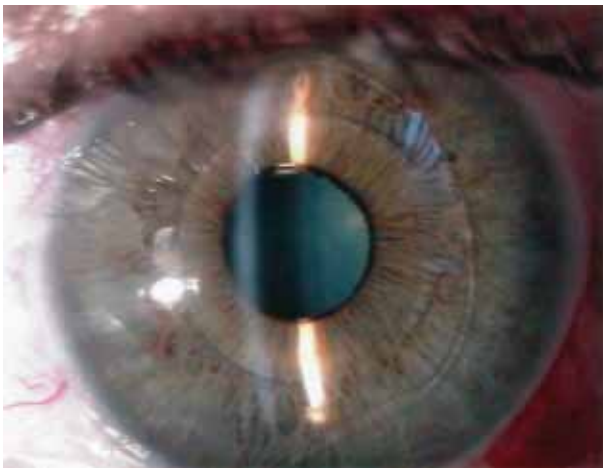
Presbyopia affects most people over the age of 45 and if we consider that in the United States 50% of the population is presbyopic (1), through extrapolation, this represents several billion individuals throughout the world.

Considering the degree of ammetropia (high / low myopia, high / low hyperopia, emmetropia) several options are available. Unilateral myopisation (monovision) of the dominant eye or multifocal correction of either the cornea or crystalline lens, either by adding a new lens or exchanging the crystalline lens if it is still transparent.

A choice is therefore available to both surgeons and patients as not one of all these techniques provides the perfect solution and in the years to come, it is quite probable that several different but complementary solutions will be available. We decided to work on three possible options: the cornea, the crystalline lens and the sclera and will give the results we obtained following implantation of a bifocal lens for correcting both slight ametropia and an average presbyopia of + 2.50 D

1) NEWLIFE. Bifocal phakic implant

The bifocal refractive phakic IOL is an anterior chamber angle-supported lens marketed under the trade name of NEWLIFE **(Ioltech,)*** . The optic is of soft 28% hydrophilic acrylic, the haptic is of poly (methyl methacrylate) (PMMA), and the footplates at the extremities are of hydrophilic acrylic. The 5.5mm diameter optic is divided into 3 zones: the center, which is for distance vision, the medium periphery which is for near vision; and the periphery which is for distance vision. The central zone diameter is 1.50 mm, and the near intermediate zone is 1.1 mm wide. (Fig. 1 et 2) The haptic is shaped like the number 2 and is available in overall diameters of 12.0 mm, 12.5 mm and 13.0 mm.



The IOL comes in powers between -5,00 D à +5,00 D for distant vision with a single addition of +2,50 D for near vision. This addition is a compromise, allowing a slight over correction for 50 year old subjects and a slight under correction for 60 year old subjects; these slight refractive inaccuracies will prove to be generally well accepted

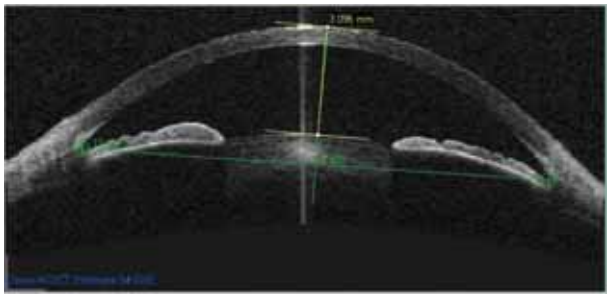
2) Anterior chamber dimension

a) Internal diameter.

For all angle-supported implants, it is essential to carry out a precise evaluation of the internal diameter of the anterior chamber. We began by using the white-to-white method, then we used a PMMA graduated sizer which was inserted into the anterior chamber during surgery. In fact, all these measurements are relatively approximate and for an implant to remain stable in the anterior chamber, it must not only be adapted to the eye's largest diameter in order to avoid rotation but also as near as possible in size to this diameter so that there is no pressure on the iris which in the long run gives rise to pupil ovalisation.

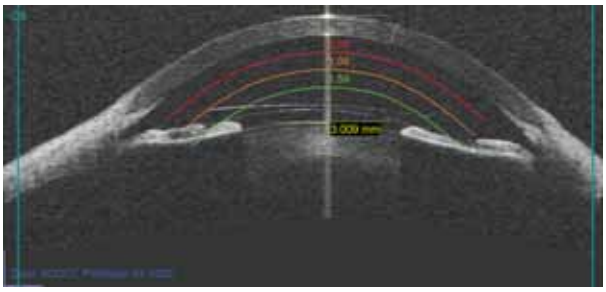
These problems can not be solved with the actual

ultrasound A and B Scan techniques. However, modern imaging techniques such as the ARTEMIS, ultra high frequency ultrasound equipment and the anterior segment OCT give more precise measurements of the anterior chamber's internal diameter. We were able to demonstrate in-vivo, and this was confirmed by Liliana WERNER on cadaver eyes, that in 75% of cases, the anterior chamber's internal vertical diameter was bigger than the horizontal one. In daily practice, we therefore systematically preoperatively measure the anterior segment helping us in the choice of implant. (Fig.3)



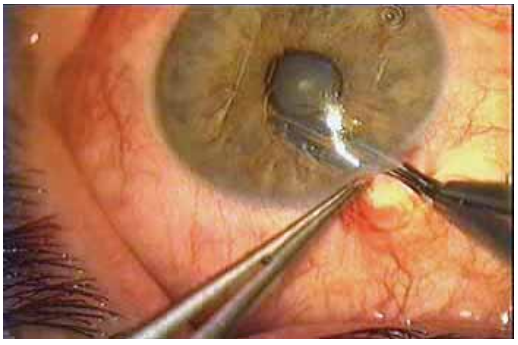
b) Anterior chamber depth.

Minimum anterior chamber depth must be equal to or above 3,1mm (measured from the corneal epithelium to the anterior surface of the crystalline lens). This is of course a safety notion but does not in fact take into account the implant's vault. (Fig.4)



3) Surgical Techniques

Topical, local regional or general anaesthesia was used based on the surgeon's or patient's choice. Surgery (Fig. 5) is relatively simple and consists in placing the lens, which is folded at the time of surgery, into the anterior segment of the eye in front of the iris.



A preoperative myosis is essential (preoperative installation of 2% Pilocarpine drops). A corneal or corneo-scleral incision is carried out with a 2.8mm calibrated knife. Viscous substance was injected into the anterior chamber, two paracenteses were made at 3 and 9 o'clock to allow subsequent manoeuvres in the anterior chamber .

The lens is folded into three with a special folder before being inserted. First the two leading footplates are introduced into the anterior chamber followed by the optic and trailing haptic. Once the lens is in the anterior chamber, pressure on the forceps is gently released and the optic unfolds. When the lens is open in the anterior chamber and depending on the largest axis, the implant will be rotated to fit this axis. It is essential that all the viscous substance is removed at the end of surgery to avoid postoperative hypertonia with URRETS ZAVALLA syndrome (fixed dilated pupil). The viscous substance is replaced with BSS. No sutures are required with the self-sealing incision. An iridectomy is not routinely suggested because the optic is soft and the optic / haptic junction can act as a gentle hinge. If mechanical blockage of the pupil in the anterior chamber occured, the iris was pushed forward and the optic, which is soft, would in turn be pushed forward letting the aqueous humour escape through the pupil. In the event of an inflammatory pupil blockage, mydriatic therapy would be proposed first and if that failed, an iridectomy with the YAG laser was done. At the end of surgery, *500 mg of DIAMOX®* is systematically administered intravenously and a tablet of 250 mg DIAMOX is also prescribed on the first night after surgery. A one-month antibiotic steroid eye-drop treatment is prescribed postoperatively.

a) Anatomical exclusion criteria

Only patients with normal anterior segments, normal endothelium cell counts, without ocular hypertonia or associated pathologies are considered. It is essential to have a clear crystalline lens and a normal macula.

b) Choice of Implant

To avoid rotation, the implant is placed along the axis of the anterior chamber's biggest diameter, which, in general is the vertical diameter. If for instance, the vertical diameter is the bigger diameter and the implant is placed on the horizontal diameter, this will lead to

instability and a risk of the implant rotating. If the implant is well placed on the largest axis, there is no longer any risk of rotation.

c) Power of the implant

Choice of the IOL optical power was based on distant refraction according to the HOLLADAY formula (2). The IOL comes in powers between - 5.00 D and + 5.00 D. A single addition is available with this model (+ 2.50D). All hyperopes between the age of 50 and 60 can be corrected in this way, knowing that the younger subjects will be slightly over corrected and the older subjects slightly under corrected. This under or over correction has no incidence on everyday life.

Any corneal astigmatism, (which alters the quality of the IOL), must be corrected beforehand either with laser or lasik in order to make the most of this multifocal implant.

4) Results

Our initial study concerned 55 eyes of 33 patients: 21 women, 12 men, 29 right eyes, 26 left eyes. Preoperative refraction was between -5.00 D. et +5.00 D.. There were 9 myopic eyes and 46 emmetropic or hyperopic eyes. The anterior chamber was over 3.1 mm in almost all of the cases and the endothelial cell density equal to or above 2000 C/mm2. Average age of patients was 54 ± 5.4 years (ranges between 45 et 70 years). The average follow-up was 42.6 weeks (ranges between 83 to 2 weeks).

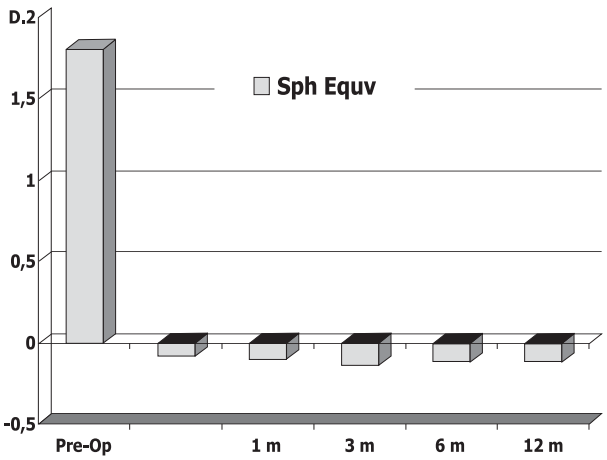
a) Refraction :

Mean preoperative refraction is + 1.8 D. ± 1.3 D. (ranges -2.75 D. to + 5.00 D.) Postoperative mean refraction is - 0.12 D. ± 0.51 D. (ranges -1.5 D. to 1.25 D.). There is therefore a very satisfactory precise refractive effect. Without going into detail, the first series of patients (BAIKOFF 3) for whom we used the VAN DER HEIJDE formula (4), showed a higher rate of myopisation than the patients subsequently operated on using the more precise HOLLADAY REFRACTIVE formula (2).

On the diagrams showing the evolution of the results after one-year follow-up, refraction remains stable. (Fig. 6)

b) Distant visual acuity :

Uncorrected preoperative visual acuity was 0.41 ± 0.29 (decimal scale), and postoperative uncorrected visual



acuity (UCVA) was 0.78 ± 0.20 (decimal scale). This uncorrected visual acuity (UCVA) result is equivalent to the other refractive surgery techniques where the mean result is around 0.8 (5-7). Preoperative best corrected visual acuity is 0.98 ± 0.02 and postoperatively best corrected visual acuity drops to 0.92 ± 0.09. This loss of visual acuity is the result of a drop in contrast sensitivity due to the multifocal lens. It is a well known fact that multifocal lenses reduce image lighting, decreasing contrast sensitivity and BCVA. This has been observed in pseudophakic IOLS. (8)

c) Near visual acuity.

Before surgery, near BCVA is PARINAUD 2.03? ± 0.1. Post operative UCVA is PARINAUD 2.3 ± 0.6 (ranges 2 to 3)

d) Efficacy and safety ratio :

The optical and refractive target was obtained, as distant UCVA was satisfactory with an 94% safety ratio (Postoperative BCVA / preoperative BCVA) and an 80% efficacy ratio. (Postoperative UCVA / Preoperative BCVA). These results were slightly below those that we normally observe with refractive implants where the two factors are respectively between 120% and 140% and around 100%. (9-12) Finally, UCVA was satisfactory in most cases as 84% of eyes operated on obtained 0.6 or better for distant vision and PARINAUD 3 or better for near vision both without correction. These figures correspond to a normally demanding population leading normal everyday lives.

5) Anatomical Results - Incidents and Complications

a) Loss of visual acuity :

One patient showed a 3-line loss of BCVA three months

after surgery of both eyes. Residual myopia existed but despite the correction of this myopia, the patient's visual acuity did not improve. The posterior pole was explored (angiography, OCT, Visual field, colour vision) and was normal. Three or four months after surgery visual acuity returned to 1.0. This patient had PRK at a later date to correct her residual myopia with an excellent optical result.

A second patient found her visual acuity reduced to 0.5 and it was impossible to improve after surgery whereas preoperatively she had 0.8. In fact, this 70 year old patient presented a moderate cataract.

The addition of a multifocal lens in front of a slightly opalescent crystalline lens leads to a very severe drop in visual acuity for two reasons: decrease in light transmission due to the incipient cataract, and a decrease in the lighting of the focused image. Infact, crystalline lens opalescence can reduce retinal illumination by 30% and the added effect of a multifocal lens is therefore particularly harmful. The implant was removed at the same time as cataract surgery was performed by phakoemulsification using the same 3.2mm incision. A monofocal implant was inserted into the bag with excellent visual results and a postoperative corrected visual acuity of 1.0.

b) Loss of contrast sensitivity :

Loss of contrast sensitivity was not studied objectively, and patients may be sensitive to it after surgery of the first eye as they can compare with the other non operated eye. A slight greyish sensation is perceived. Once the second eye has been operated on, there is no element of comparison and the discomfort is better accepted. In mesopic vision, that is to say reading at night in dim light conditions, some patients occasionally wear additional glasses.

c) Reduction of retinal illumination:

We have seen that the problem with multifocal lenses was a reduction of retinal illumination. One patient suffered from this problem because of an pre-existing crystalline lens pathology.(cf. supra).

The problems we are faced with concern anatomical predispositions such as senile myosis. A study should be carried out to define the acceptable minimum pupil diameter for this type of implant.

Therefore, multifocal lenses must be contraindicated for patients with slight macular pathologies such as Drüsens or epithelium pigment disorders because they are particularly sensitive to reductions in retinal illumination.

d) Halos :

One of the problems of multifocal lenses is the possibility of parasite optical side effects. We have mentioned before that multifocal lenses reduce contrast sensitivity, however, they also produce halos that are particularly disturbing in night vision. 18% of eyes and 24% of patients complained of halos, but these had no incidence on night driving except in two patients out of 33 (6%).

This high percentage of complaints concerning halos disappears in time because the brain adapts to this inconvenience. In the end, very few patients complained of this discomfort and in time none of them requested change or removal of the implant for this particular reason. Thanks to the Visante™ OCT pupil ovalisations have almost disappeared as the size of the implant is now correctly adapted to the largest axis which is generally the vertical one.

e) Pupil Ovalization

10% of slight pupil ovalizations showed up under the slit lamp's intensive light. There were fewer under normal lighting. Generally, pupil ovalizations are the result of over sizing the implant.

f) Cataract

No implant-induced cataracts have been observed in this study to date.

g) Ocular Hypertonia

No ocular hypertonia induced by the implant has been observed in this series to date.

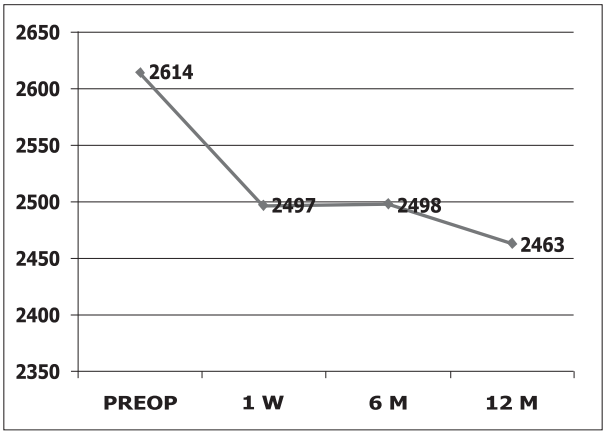
h) Endothelium

After a year, mean endothelial cell loss is below 5%. The results meet the FDA's guidelines. (Fig 7)

i) Explantations :

4 explantations were carried out on patients who were disappointed with the results. One patient had excellent near and distant vision, 1.0 (decimal scale) and PARINAUD 2 but was not satisfied with the intermediate vision. He therefore requested that the implant be removed.

Two explantations were suggested because of



insufficient visual results. (cf. supra patient with cataract). One was due to unsolvable postoperative diplopia. In both cases, they recuperated their initial visual status.

Optical defects are inevitable with multifocal lenses, therefore patient selection must be very strict. Patients too demanding and who think that they will recuperate the vision they had at the age of 20 must be excluded and before surgery, it is essential to provide precise information concerning the risks and drawbacks of this procedure.

6) Summary

Since this preliminary study, we have continued to use this technique and to continue rigorous patient selection. The results are confirmed and more than 80% of the patients have an distant UCVA over 0.6D and PARINAUD 3 or better for near vision also uncorrected . This means all the patients lead normal lives without glasses in diurnal conditions; only a few (less than 10%) need them in mesopic conditions, for instance to read at home in the evenings. In this series, everyday acts are done without glasses. Halos are generally well tolerated and the loss of contrast sensitivity is unavoidable. This technique can therefore be proposed but very strict inclusion criteria must be taken into account with regards to anatomy and psychology. This procedure can only be offered to patients with an anterior chamber depth equal to or above 3.0 mm, with an open angle, with a healthy endothelium and without anterior segment or retinal disorders (Fig 8). Any astigmatism must be corrected either before or after implantation. Patients that are too demanding must be excluded as well as patients who, for professional reasons, have to drive at night. The interest of phakic implants is their reversibility, in our series we had no persistent pupillary ovalisation after explantation. In certain cases, a mono correction is possible on an emmetropic subject by placing an implant in the dominated eye only. If the result is satisfactory, surgery can be limited to just one eye, and surgery of the other eye proposed only if the patient wishes it. Experience has shown us that patients who had post operative slightly hypermetropic refraction were more satisfied than patients slightly myopic. This had already been proved with multifocal pseudophakic implants (STEINERT 13). However, to obtain a satisfied patient, it is important to explain that the correction of presbyopia with this multifocal implant for phakic eyes is a compromise between an excellent preoperative vision with glasses and a good postoperative vision without glasses.

Newlife Multifocal phakic implant for the correction of presbyopia

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NB: An important part of this article (text & illustrations) has already been published in the Journal of Cataract & Refractive Surgery 2004;30:1454-1460 courtesy of Elsevier, Philadelphia USA.

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