MICHELE FORTUNATO

FROM PSEUDO-ACCOMODATIVE IOLS TO FEMTOSECOND LASER:

my whole life dedicated to the development of cataract surgery in children

With the collaboration of Angela Turtoro, Salvatore Crugliano, Antonio Di Zazzo (Federica Fortunato prize winners) and the friendly contribution of Claudio Carbonara, Antonio Cuttitta, Gianfranco Cuttitta, Raffaella Morreale e Vincenzo Savoca Corona
Dedicated to my little star FEDERICA
# TABLE OF CONTENTS

## 26 YEARS OF USE OF PSEUDO-ACCOMMODATIVE IOLS IN PEDIATRIC PATIENTS. PERSONAL EXPERIENCE

- Disadvantages ................................................................................................................... 13
- Advantages ......................................................................................................................... 14
- Conclusion .......................................................................................................................... 15

## IOLS USED .......................................................................................................................... 17

## DEVELOPMENT OF SURGERY TECHNIQUES ................................................................ 22

- Congenital cataract extraction without IOL implantation .................................................. 28
- Cataract and tunica vasculosa lentis (TVL) and/or persistent hyaloid artery and persistent hyperplastic primary vitreous (PHPV) ........................................................................................................................................... 29
- Treatment of Ectopia Lentis .............................................................................................. 34
- Aniridia cataract .................................................................................................................. 35
- Secondary implant with support .......................................................................................... 37
- Secondary implant with partial or without any support ....................................................... 38
- Secondary implantation with iris enclavation .................................................................... 40
- Secondary implantation with scleral fixation ..................................................................... 43
- Capsulotomy with 23/25-g vitreous cutter ........................................................................... 49

## Femtosecond laser–assisted cataract surgery (FLACS) in pediatric patients

## BIOMETRY IN CHILDREN ................................................................................................. 62

- Introduction .......................................................................................................................... 62
- Keratometry .......................................................................................................................... 64
- Biometric screening ............................................................................................................. 65
Biometric formulas.................................................................67
Possible causes of error..............................................................68
I waited 26 years before writing this booklet. Thus, I had the opportunity to study, understand and prove the potentialities of pseudo-accommodative IOLs in restoring lost accommodation due to lens exportation.

During all these years, I had the opportunity of using most of the bifocal and/or multifocal IOLs produced and implanted mainly in adults and children from 4 weeks to 14 years old.

It is well known that lens exportation produces immediate loss of accommodation. This event results being less serious in adults, already lacking to varying degrees of accommodative activity, but it
becomes very damaging in children, where the accommodative activity is essential for visual development.

For this reason, I favorably welcomed the introduction of the first 3M P-IOLs and I asked Prof. Vadalà, who was my chief physician at the Bambino Gesù hospital of Rome, to allow me to start implanting them in adult patients. After having implanted a substantial number of IOLs in adult patients and verified their effectiveness, I started implanting pseudo-accommodative IOLs also in children.

I implanted the first pseudo-accommodative IOL on March 17, 1989, in a 5 years old child suffering from traumatic cataract. The patient, now a woman with two children, despite an insufficient and sporadic rehabilitation therapy, still has an 8/10 visual acuity and a near vision of 1j. Although there were some negative aspects (such as a rigid IOL needing a larger corneal cut, the pseudo-accommodative system to be improved, etc.), after the first sixteen 3M cases, I carried on my experience and started implanting second-generation pseudo-accommodative IOLs (Array, ReZoom), whose flexibility allowed them to be introduced through a much smaller cut.

Second-generation IOLs certainly had improved features, but reduced the near addition to +3.50, insufficient in childhood. Among all the P-IOLs available at that time, Pharmacia’s was undoubtedly the most commonly used, because, despite its rigidity, it maintained a +4 near addition and a very effective pseudo-accommodative diffractive system.
I also used ReZoom refractive lenses, but they were too much linked to pupillary functionality and therefore useless in case of postoperative synechiae.

At a later stage, I adopted other very good diffractive flexible lenses, but their pseudo-accommodative activity was not always satisfying, as they lacked near addition, which is important in children (+3/+2.50). IOLTECH produced a IOL with a singular, clover-shaped design, with a +4 addition, a better pseudo-accommodative activity, but a limited range of powers; while Rayner’s IOLs had a +3 addition and an insufficient pseudo-accommodative activity. I started to use the new AcriTec Twin P-IOLs, which provided good pseudo-accommodation.

These IOLs were designed to be implanted twinned, distance/near the one and near/distance the other, but I preferred to use two distance/near similar lenses, in order to avoid visual discomfort for my little patients.

In the following period, also thanks to the suggestions given by my research group, which included foreign and Italian colleagues (P. Leuemberger and F. Simona, Prof. Vadalà and me, C. Lovosolo and the school of Prof. L. Mastropasqua), AcriTec lenses were modified and Acri Lisa lenses were developed. These lenses had a +4 addition and, most important, a very high range of powers with more than 34 diopters. In addition, there even was the possibility of requiring IOLs with higher powers, up to 42 diopters.
Alcon Restor’s third-generation, pseudo-accommodative lenses appeared on the market some time later. They were anodized, flexible and with macular pigment protection systems.

At first, these lenses had a +4 addition. Later, they were produced with a +3.50 addition, which was then lowered to +3, and therefore they were not adequate for the use in pediatric patients.

Technis created a flexible, anodized IOL, which was developed from the bifocal rigid IOL of Pharmacia, with a +4 addition and a fairly wide range of powers, very effective in pediatric patients.

In these years, the prolonged use of P-IOLs allowed me to significantly refine my surgical strategy, thus improving the
technique I still currently employ: 2 corneal accesses (9-12 for OD, 12-3 for OS); capsulorhexis or capsulotomy, if it is impossible to perform rexhis; mechanical aspiration of lens masses with Buratto cannulas; widening of the 12 o'clock corneal incision and diffractive P-IOL implant, with a +4 addition, in the bag.

I avoid performing posterior capsulorhexis and/or anterior vitrectomy, to optimize IOL stability in the bag.

Following the appearance of the secondary cataract, I perform posterior pars plana capsulotomy with 23-G, or better, 25-G vitreous cutter.

I no longer perform YAG laser posterior capsulotomy in order to avoid the IOL be chipped or damaged and let it remain as intact as possible.

I no longer perform surgical capsulotomy or anterior vitrectomy, except in cases where implantation is not provided for, or where there is already a posterior aperture of the capsule, in order to avoid IOL instability or shifting due to the vitreous push or to the presence of vitreous fibrils in the anterior chamber.

In 26 years, I have personally performed more than 1200 P-IOL implants, such as primary or secondary implants, in the sulcus or in the bag, including scleral fixation, of all the previously described IOLs.

**Disadvantages**

**IOL decentration**, occurring sometimes in sulcus implants. It is singular to find children who have very good vision, despite the lens
displacement, due to their ability to take advantage of diffractive rings.

**Difficulties in performing correct autorefractometry.** It is sufficient, though, to have good retinoscopy experience to avoid this inconvenient.

**Contrast sensitivity loss** is almost zero when using new generation IOLs. I can affirm, without any doubt, that in children this problem is not as strong as it is reported in adults, since children learn to see with the implanted IOLs, and therefore they maximize the potentialities of the lenses and overcome any deficiencies.

I never incurred a failure in accommodation functioning; on the contrary, I encountered insufficient activity when using IOLs with addition lower than +4. Even in the first 3M IOL implantations, where there was an insufficient accommodative activity, after some years I noted, with surprise, that children had obtained a good, though late, pseudo-accommodative activity.

In some cases, patients reported the presence of glare, above all in adults with first and second generation implants.

**Advantages**

**Immediate pseudo-accommodative activity recovery** in all implanted cases.

**Better functional recovery** with respect to monofocal IOL implantations.

I had to substitute very few IOLs: 9 for severe refractive errors, 7 for serious damage of IOL, after YAG laser capsulotomy, which had caused the loss of accommodative activity.
Conclusion

For P-IOL implants we need to follow the same rules used for monofocal IOLs, which imply performing gradual under-correction depending on the age of the young patient at the moment of the implantation.

The success in using P-IOLs led me to define the characteristics of the ideal P-IOL:

- it should be flexible;
- it should be diffractive, instead of refractive, i.e. independent from pupillary activity, often altered by sinechiae;
- it should have a +4 near addition;
- it should have a wide range of dioptric powers, at least up to +35-40 diopters.
Our Experience in the Implantation of First Generation Multifocal Iols in Children

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RESULTS

Since all patients had been specifically selected, good uncorrected vision for distance was obtained in 6 eyes, with acuity ranging from 6/10 (2 eyes) to 10/10 (4 eyes). In the remaining 10 cases a cylindrical correction ranging from -0.75 to +1 was necessary.

1st character for near was obtained in 12 cases (uncorrected in 6 eyes and using the correction for distance in 6 eyes), but in 4 eyes this required an add of +3.50 sph (2 eyes with primary and 2 eyes with secondary implantation), in absence of changes such as decentration, pupillary block, pigment on the IOL, or other.

All patients, however, were able to comfortably read III-IVth character without glasses. All patients underwent visual field testing (no changes were observed) and contrast sensitivity evaluation with Dall.
IOLS USED

Pharmacia IOL

**Bifocal diffractive biconvex**
- Constant: 117.7
- Diameter of optic: 6 mm. Length: 12 mm
- Material: PMMA, modified with heparin
- Powers: 15-26 (½ D steps)
- Addition for near: +4.00 D
- Implantation: bag/sulcus

IOL Allergan Array

**Multifocal refractive biconvex**
- Foldable, silicone optic 6 mm. Length 13 mm.
- Constant: 118
- Powers: 6-30 D (½ D steps)
- Addition for near: +3.50 D
- Implantation: in the bag
Bifocal, biconvex, acrylic, hydrophylic, foldable. Constant 118. Powers from 17 to 24 D, >1/2 D. Length 10.5 mm. Optic 6 mm. Implantation: bag. Addition: +4.00 D.

Acri Tec Twin and Acri Lisa

Bifocal, biconvex, acrylic, foldable with 25% water content, hydrophobic. Constant 118.

Powers from 16 to 28 D, >1/2 D, da 29 a 40 D, >1 D. Length 11 mm. Optic 6 mm. Implantation: bag. Addition: +4.0 D.
Acri Twin 527/523

- Bifocal foldable, 3 piece, biconvex,
- acrylic, square edged optic
- length 13mm, optic 6.5 mm
- Powers 0-40D, >0.5D from 16-28D, >1D from 0-15D and from 29-40D
- Constant 118 Addition: +4.00 D
- Implantation: sulcus/bag

AMO Re Zoom

Multifocal, flexible, acrylic hydrophobic, biconvex.
length 13 mm,
PMMA haptics
optic 6 mm. Powers from 6 to 30 D, 0.5 steps
Constant 118.4
Implantation: bag/sulcus
Addition: +3.50 D
Rayner

Multifocal, acrilic hydrophilic, single piece
Length 12.5 mm
Plate 6.25 mm
Constant 118.0
Powers 18 D-23 D
Addition +3D
Implantation: bag

Alcon Re Store

Multifocal apodized, biconvex, acrylic hydrophobic foldable, length 13 mm, optic 6 mm, powers from 6D to 30D, > ½ D
Constant 118.4, implantation : bag
Addition +4.00 D, +3.00 D
AMO Tecnis

Multifocal, flexible silicone, 3 piece, optic 6 mm, length 12 mm
Prolated spherical anterior surface, diffractive posterior surface
Powers 5-40 D, >0.5 D
Constant 119
Implantation: bag
Addition +4.00 D

Soleko

- Primary implantation in the bag, in the sulcus
- Range 10-40 D
- For secondary implantation:
  - in the sulcus
  - scleral fixation
- Refractive multifocal with +4 addition for near
DEVELOPMENT OF SURGERY TECHNIQUES

Sir Ridley was the first who had the idea of implanting a IOL made of inert material, plexiglas, in an aphakic patient: in 1949, he realized that RAF pilots could tolerate in the eyeball plexiglas fragments deriving from exploded plane windows, without having inflammatory reactions.

In 1955, Prof. B. Strampelli was the first to implant IOLs in adult patients in Italy; afterwards, in 1965, Prof. C. Maggi, Prof. Strampelli's student, performed the first implantation of an anterior scleral fixation IOL that he realized himself, in a child at the Bambino Gesù Hospital of Rome. He then improved the surgical technique with the posterior scleral fixation IOL implantation.

Therefore, I can affirm, without any doubt, that pediatric implantology is the feather in the cap of Italian ophthalmology.
Modern congenital cataract surgery was mainly perfected by a group of Israeli researchers (Ben Ezra, Blumenthal, Dahan) who used the technique described below. They inserted an anterior chamber maintainer (which often took the name from the same researches) in the inferior temporal sector of the eye to be operated. Then they made two corneal incisions at about 3-9 or 2-10 o'clock through which, after injecting a viscoelastic substance and blocking the infusion, they performed an anterior capsulotomy with a cystotome, by making small and close incisions on the capsule, or performing a capsulorhexis, which is more difficult due to the great capsule elasticity in childhood. They performed manual
exportation of lens masses with Simcoe needle-cannula or with mechanical cannulas.

They made an aperture in the posterior capsule with a cystotome or a cutter, completed with vitreous scissors or a vitreous cutter, and performed an anterior vitrectomy with the same instrument. They opened the cornea at 12 o'clock, widening the cut with corneal scissors and performed the IOL implantation in sulcus through a cut larger than 6.5 mm. They performed basal iridectomy to avoid secondary hypertonia caused by pupillary block. The more or less continuous infusion allowed the cleansing of the anterior chamber and the removal of organic residues. They closed the corneal entrances with nylon suture stritches 10.0, which had to be removed in 30/60 days.

Later, when flexible or foldable IOLs arrived, surgeons adopted the same technique, halving the corneal cut and performing a 3.2 mm tunnel. Where possible, they tried to perform the IOL implantation in the bag, in order to give more stability to the implant. However, they performed posterior capsulotomy and anterior vitrectomy.

Some researchers suggested pushing the IOL plate behind the posterior capsule, which is a quite difficult procedure.

During the years, I decided to avoid the use of the anterior chamber maintainer, keeping it only for congenital cataract extractions without implantation and with posterior capsulotomy and anterior vitrectomy, and for secondary implantations, performing all the procedures with the viscoelastic substance, which was carefully removed at the end of the operation.
Even more recently I performed the following procedure: 2 sole corneal incisions, at 9-12 o'clock for OD, and 12-3 o’clock for OS, capsulorhexis, sometimes with dye, mechanical extraction of lens masses, widening of entrance at twelve o'clock, foldable IOL implantation in the bag, without performing either posterior capsulotomy or anterior vitrectomy.

For tunnel suture, I prefer using 10.0 vicryl reabsorbable suture, which does not need to be removed in 30-60 days. The other corneal incision can be closed with hydrosuture or with a 10.0 vicryl suture.

*Capsulorhexis*
Mechanical extraction of lens masses

Pseudo-accommodative IOL implantation
*Congenital cataract extraction without IOL implantation*

The surgeon inserts the anterior chamber maintainer in the inferior temporal sector of the eye to be operated. He performs two minimal corneal incisions (at 3-9 o'clock or 2-10 o'clock), through which it is possible to perform anterior capsulotomy by means of a cystotome, making small, close cuts on the anterior capsule, or performing capsulorhexis by means of K-Way or Caporossi forceps.

The surgeon proceeds with the mechanical suction of lens masses and, through a 23-G or 25-G vitreous cutter, he performs the following procedure: posterior capsulotomy (leaving a good posterior capsular support for secondary implantation), anterior vitrectomy, basal iridectomy, essential to avoid secondary hypertension caused by pupillary block.

It is possible to close the cuts by means of hydrosuture of the corneal accesses or 10.0 vicryl suture.

I prefer to carry out all these surgical procedures with a 23/25-G vitreous cutter with manual suction, in order to balance the suction at best. Lastly, I inject an intracameral antibiotic and an air bubble, which provides a diagnostic aid during the days after the operation, besides a good maintenance of the AC.

In fact, if the bubble remains at least during the following 2-3 days, it means that the corneal incisions are strongly sealed.
Cataract and tunica vasculosa lentis (TVL) and/or persistent hyaloid artery and persistent hyperplastic primary vitreous (PHPV)

The surgeon inserts the chamber maintainer in the inferior temporal sector of the eye to be operated and performs a corneal incision through which it is possible to introduce cystotome and forceps. He then carries out a capsulotomy or capsulorhexis and, by means of Buratto cannulas, extracts the lens material (which most of times is transparent). He applies diathermy on the vessels in the posterior capsule that appears thick and fibrotic. He opens the posterior capsule with a cutter and partially exports it with vitreous scissors and a vitreous cutter, leaving a space for the IOL secondary implantation. The surgeon should use a great attention in avoiding traction on the ciliary body, which might create later damages (retinal detachment, hypotonia).

My suggestion is to always perform a basal iridectomy, in order to avoid hypertonia caused by secondary pupillary block. Corneal incisions must be sutured with 10.0 vicryl.

In case of persistent hyaloid artery or persistent hyperplastic primary vitreous, the surgeon adopts the same technique used for TVL, and, once applied diathermy on the hyaloid artery, he exports it, or exports the primary vitreous, with a vitreous cutter, by inserting a trocar in the pars plana.
Treatment of Tunica vasculosa lentis
Pseudo-accommodative IOL implantation in PHPV

Treatment of PHPV via pars plana
Treatment of Ectopia Lentis

In case of ectopia lentis, it is possible to use mini-invasive surgery techniques.

It is possible to perform an anterior full lens extraction, or lensectomy, by inserting an anterior chamber maintainer in the inferior temporal sector of the eye to be operated, and proceeding with the full lens extraction by means of a 23-G vitreous cutter with manual suction, through a minimal corneal incision. Lastly, the surgeon closes both corneal incisions with a 10.0 vicryl suture.

In my opinion, this technique can be dangerous because BSS infusion and suction/fragmentation procedures can provoke the luxation of the subluxated lens in the vitreous chamber. It is better and safer to perform pars plana lensectomy, with posterior infusion, by inserting two trocars at a 3-3.5 mm distance from the corneal limbus, so as to insert the infusion cannula and the 23/25-G vitreous cutter (it is best to use the 23-G one because it assures a better suction/fragmentation). The posterior infusion allows to push the subluxated lens towards the posterior chamber, therefore performing a safer procedure.

The vitreous cutter is supported by manual suction, which is more easily adjustable even for simple lens masses suction. The full lens extraction is completed in the point of contact with the scleral indentation.

Once the trocars are exported, I administer two subconjunctival steroid injections above the scleral incisions, so as to allow an optimal suture.
Aniridia cataract

Lens opacity treatment in case of aniridia also allows to create an artificial iris, using "cosmetic" monofocal artificial lenses of different colors.

The first rigid monofocal artificial lenses were, in our experience, toxic and badly tolerated in these particular eyes.

Nowadays, there are flexible cosmetic artificial lenses of different colors as well as colored implants of different sizes in case of partial aniridia.

I suggest the following technique, more useful in terms of better functional recovery and a good treatment for photophobia in these visually impaired children.

I perform a corneal incision and inject a viscoelastic substance in the anterior chamber.

I mark a 5 mm corneal area to perform a capsulorhexis of equal size, and open a second corneal entrance. I carry out a mechanical suction of lens masses, widen the corneal incision at 12 o'clock and implant the bifocal diffractive artificial lens in the bag.
After a few weeks, the capsular fibrosis creates an artificial iris and the patient presents pseudo-accommodative activity given by the bifocal lens.

From an aesthetic point of view, the cosmetic IOL implant is undoubtedly better-looking, but the bifocal diffractive artificial lens is certainly more functional and grants a much higher visual recovery compared to a monofocal IOL implant.

**PSEUDO-ACCOMMODATIVE IOL IMPLANT IN ANIRIDIA**
Secondary implant with support

This procedure must be performed as follows. The surgeon inserts an AC maintainer in the inferior temporal sector of the eye to be operated and performs a short corneal incision at 12 o'clock or above the basal iridectomy. He injects a viscoelastic substance below the iris and there he enters a spatula, he frees the posterior sinechiae, restoring the sulcus.

In case of no basal iridectomy, it is preferable to perform it at the beginning of the operation, in order to carry out the above procedures.

The surgeon creates a 2.7-3.2 tunnel that will then be used for the implantation. The iris is pinched with a forceps and is pulled a few millimeters towards the outside, where it is cut by means of Vannas scissors, thus performing the basal iridectomy.

During the steps of freeing the sinechiae, it is necessary to avoid any procedure that could make the iris vessels bleed. In case of bleeding, it is advisable to increase the direct infusion or insert viscoelastic substance and cauterize the bleeding vessels by applying diathermy. It is also necessary to avoid any traumatic procedures that might cause the rupture or loss of the rear support of the posterior capsule. After restoring the sulcus, the surgeon widens the incision at 12 o'clock up to 3.2 mm; he inserts the IOL, laying it on the iris, and with the help of a hook, he gently places it in the sulcus. This procedure is safer than trying to insert the IOL directly into the sulcus, with the risk of losing it in the vitreous through the posterior capsulotomy. If the surgeon needs to insert the IOL directly in the sulcus, he can use a slipway, which helps
placing the IOL in the sulcus. This procedure, though, may result more complicated than that performed with the hook.

After the IOL implantation procedure, the surgeon injects acetylcholine, in order to verify that the IOL remains in position and that the pupil is properly stretched. In case they are not, the surgeon can slowly rotate the IOL to correctly position it in the center of the pupillary foramen, and massage the iris with a spatula or pull it toward the pupillary area with a forceps so as to lay it out properly.

All these procedures are made to avoid space reduction, camerular angle-closure or anterior sinechiae formation due to the IOL loops pushing on the iris.

The incisions are closed with 10.0 vicryl sutures or with hydrosuture. It is then necessary to inject antibiotic and an air bubble in the anterior chamber

**Secondary implant with partial or without any support**

In case of insufficient sulcus support after the cataract extraction, it is possible to adopt different secondary implantation strategies.

The anterior chamber maintainer is inserted for the direct infusion; the surgeon performs the corneal incision and frees the posterior sinechiae, restoring the sulcus, as described above.

In case of insufficient sulcus, the surgeon can use a flexible pseudo-accommodative IOL, which I specially commissioned to an Italian company: it can be used for sulcus, bag and scleral fixation implants, due to the presence of a hole on the loop.
A piece of prolene thread, by means of a straight needle, is tied through the hole. On the side where the insufficient sulcus support has been identified, the surgeon performs a triangular scleral window with the base oriented towards the cornea.

He implants a refractive IOL with a loop in the sulcus. At this point, he inserts in the sclera, below the scleral window, a 27-G needle, with a bend of about 60°, oriented towards the posterior chamber center, and makes the straight needle pass through the 27-G needle.

As soon as the surgeon is sure that the straight needle has been inserted in 27-G needle, he removes the latter extracting it from the sclera and takes hold of the straight needle with the prolene thread, which has just come out from sclera.

Once the IOL is centered, the surgeon passes a curved needle with prolene thread in the scleral area next to the prolene thread tied to the IOL and performs several knots around the latter, taking care of the fact that the scleral window must cover it. Afterwards, he closes the scleral window with 7.0 vicryl suture and the corneal incisions with 10.0 vicryl suture.

If the functional recovery of the aphakic patient is insufficient for the difficult use of bifocal glasses or contact lenses and additional near glasses, which are compulsory for secondary implantation, in case of full absence of posterior support, for example after a lensectomy, it is possible to practice two different secondary implantations:

- monofocal IOL implantation with iris enclavation, for children up to 6/7 years old;
flexible pseudo-accommodative IOL implantation with scleral fixation, from 6/7 years old children onwards.

Secondary implantation with iris enclavation

The secondary implantation can be performed with anterior or posterior iris enclavation. In both cases it is necessary to perform three corneal incisions at 10, 12 and 2 o'clock and inject a viscoelastic substance in the anterior chamber. The surgeon must then insert a monofocal IOL with gills (crab-like) and anchor them to a portion of the enclavated iris by means of a special spatula introduced through a corneal incision, first from one and then from the other side. If an anterior implantation is necessary, it is advisable to inject acetylcholine in the anterior chamber or prepare the patient with miotics.

If it is necessary to perform a posterior iris enclavation implantation – recommended to avoid chronic corneal endothelium injuries – it is suggestible not to use miotics. The surgeon must hook the loops to the iris and, while firmly holding 2/3 of the IOL behind the iris by means of an Eckart forceps with the remaining IOL laid on the iris, he inserts the iris between the loop gills with the help of a spatula.

The surgeon passes the Eckart forceps, which is keeping the IOL plate firmly in position, to the other hand and performs the same procedure for the other IOL loop, after having passed also the second loop under the iris.

It is then necessary to wash the anterior chamber and remove the viscoelastic substance as well as any iris pigment remains. The
surgeon extracts the anterior chamber maintainer and closes the corneal incisions with 10.0 vicryl sutures.
The following figure is taken from the book "OCT in età pediatrica" (OCT in pediatric patients)
Secondary implantation with scleral fixation

I prefer to perform scleral fixation implantations on patients who are at least 6 years old, when their eyeball size is already quite consolidated, so as to avoid tension and traction of the prolene thread on the sclera due to the growing eyeball. In order to reduce surgery times, I prepare the pseudo-accommodative IOL on a serving table by tying two prolene threads anchored to the straight needle through the two holes at the loops’ extremities. The surgeon inserts the anterior chamber maintainer in the inferior temporal sector of the eye to be operated. He frees 2/3 of the conjunctiva from 7 to 4 o'clock for the OD and from 4 to 7 o'clock for the OS and
creates two triangular scleral windows at 3 and 9 o'clock with the base oriented towards the cornea.

He inserts a 27-G needle with a 120° curve in the sclera, under the scleral window, bringing it to the center of the posterior chamber. He passes the prolene straight needle, which is anchored to the pseudo-accommodative IOL loop, from the posterior chamber into the 27-G needle. After ensuring that the straight needle is sufficiently inserted in the 27-G needle lumen, he removes the 27-G needle by extracting it from the sclera and, as soon as the straight needle appears, he extracts it keeping the thread suspended. The same procedure is performed on the opposite side.

The prolene thread crossing can be also performed with a straight needle introduced from the sclera at 3 or 9 o'clock and pulled out on the opposite side at 9 or 3 o'clock, after having been introduced directly in the 27-G needle positioned on the opposite side of the prolene needle. The prolene thread is then cut in two parts and tied to the IOL loops through the loop hole.

This strategy is very efficient, but requires more time and, therefore, the eyeball needs to stay open for a longer period.
The surgeon realizes a corneal tunnel at 12 o'clock and inserts the IOL, positioning it with a hook.

Once the IOL is positioned in the posterior chamber in the pupillary foramen center, the surgeon, holding the prolene threads on opposite directions, passes a curved needle, anchored to the prolene thread, in the sclera, next to the exit of the other prolene thread, which has already been anchored to the straight needle. He ties the ends of all the threads with several knots, taking care of the fact that the scleral window must cover them. The same procedure is repeated on the opposite side, properly centering the IOL, closing the corneal tunnel with 10.0 vicryl suture and irrigating BSS in order to tense the threads and give consistency to the eyeball.

The scleral windows and the conjunctive are closed with 10.0 vicryl suture. The anterior chamber maintainer is removed, hydrolyzing
the corneal entrance of the chamber maintainer or closing it with a 10.0 vicryl suture, as for the corneal tunnel.

I report here a different surgical strategy adopted by some surgeons (Zeppa and others) who perform scleral fixation without suture, using a three-pieces monofocal IOL with prolene loops. The prolene loops are pulled out from the posterior chamber with a vitreous forceps inserted under the scleral window; they are then anchored and stabilized to the sclera only by means of organic glue.

This glue is also used to close the two scleral windows, without using vicryl suture.

In pediatric patients, I prefer to adopt the first system because it is more stable; in fact, in all six cases of sutureless operation I performed, I incurred IOL dislocation and in one case a loop broke due to a trauma.
> 6 years: multifocal IOL implant with scleral fixation

*SF pseudo-accommodative IOL, 30 days after surgery*
Capsulotomy with 23/25-g vitreous cutter

It is better to extract secondary opacity of the posterior capsule via pars plana with a 23 or 25-G vitreous cutter. This is due to the fact that YAG laser capsulotomy often provokes IOL chipping or opacification.

Chipping hinders the pseudo-accommodative effect of the diffractive IOL.

Posterior capsulotomy with vitreous cutter is performed inserting two transconjunctival trocars, at 3/3.5 mm from the corneal limbus: one for infusion and the other one to house the 23/25-G vitreous cutter. They can either be positioned both on the temporal side of the eye to be operated, or on the opposite side, but in the latter case, procedures are often obstructed by the patient’s nose. The manual suction vitreous cutter, introduced by means of the trocar, will allow the perfect extraction of the posterior capsule, accurately freeing the diffractive IOL rings and making them efficient again.

Once the trocars have been extracted, the surgeon injects subconjunctival steroid above the scleral incisions, so as to allow them to be closed at best and also to exercise an antiinflammatory action.

Those who have experience with mini-invasive vitreoretinal surgery, know how to perform transconjunctival scleral incisions that allow for a perfect closure.
At first, the surgeon enters the trocar in the sclera, almost parallel to it; then, with a strong action, he enters the sclera perpendicularly. This will allow the correct closure of the scleral path when the trocar is extracted. Another sensible action consists in extracting the infusion trocar first.

Extracting the trocar used to introduce the vitreous cutter first, could in fact result in the infusion push re-opening the first sclerotomy.

Irremediably damaged IOL after YAG LASER capsulotomy
Posterior capsulotomy via pars plana with 23-G vitreous cutter
Femtosecond laser–assisted cataract surgery (FLACS) in pediatric patients

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Femtosecond laser technology (femtolaser) was introduced in 2001 for ophthalmic surgery as a new technique for creating lamellar flaps in laser in situ keratomileusis (LASIK). In the last few years, this technology has been implemented as a tool for cataract surgery and has been recently introduced also for pediatric patients. While femtosecond laser-assisted cataract surgery seems to have the potential to improve safety, accuracy, and clinical outcomes, this technology, compared to traditional surgery, brings along a host of technical, clinical and financial challenges (given the high cost of the required equipment).

Current femtosecond laser technology systems use neodymium: glass 1053 nm (near-infrared) wavelength light, which allows the light to be focused at a 3 µm spot size, accurate within 5µm in the anterior segment. A great advantage of this technology is given by the ultrashort light pulses, of seconds, that allow eliminating the collateral damage of surrounding tissues and the heat generation

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often associated with other technologies such as excimer and neodymium: YAG lasers.

As it happens with other laser technologies used in ophthalmology, femtosecond laser energy is absorbed by the tissue, causing the formation of gas plasma (free electrons and ionized molecules) which tends to rapidly expand, creating cavitation bubbles with consequent tissue separation (photodisruption). Current femtosecond laser platforms are not integrated with usual surgery equipment used for cataract operations, therefore, femtosecond laser-assisted cataract extraction is a procedure which requires two steps: in the first step, patients are positioned under the laser-cut equipment for the relevant procedure, and in the second step, they are transferred under the traditional cataract surgery equipment in order to perform phacoemulsification or, for pediatric patients, phaco-aspiration.

The first step consists of three phases: docking (creation of a stable interface between the equipment and the patient's ocular surface), imaging (image acquisition) and laser treatment.

**Docking**

The currently available femtosecond laser tools have different approaches for docking. The interface systems can be divided into:

- contact (applanating) and
- and noncontact (nonapplanating).

Contact systems tend to have a smaller diameter and may fit a smaller orbit better.
Noncontact devices, in addition to a less increase in intraocular pressure (IOP), offer a wider field of operation view and a lower risk of corneal folds that can cause areas of incomplete capsulotomies beneath them (Schultz et al.; Talamo et al.).

Proper docking requires the head to be secured and a perfect alignment of the patient's body. This can be an issue when operating patients with bone malformations. In addition, the patient must be able to remain still for the several minutes required for the following imaging and laser treatment steps.

The size of the femtosecond laser platform impedes the use of masks or other devices for artificial ventilation, only allowing deep sedation rather than a general anesthesia for pediatric patients. Thus, for obvious reasons, in many cases of pediatric cataract surgery it is impossible to use femtosecond laser technology.

*Positioning of the patient under sedation on the femtosecond laser platform*
Finally, the orbit must be able to accommodate the suction ring for docking, a condition that is more unlikely in children, especially in patients with microphthalmia syndrome.

**Imaging**

Femtosecond laser platforms use either spectral-domain OCT or 3-D CSI to image the treatment plan and map the reference points for the treatment.

*Anterior segment reconstruction and identification of reference points for treatment in imaging step*
Summary of points of reference and lines for treatment (up) and femtosecond laser treatment completion (down)

The cornea must be centered within the applanated area in order to adequately perform the corneal incisions (tunnels, secondary incisions and possible arcuate incisions) and the capsulorhexis, so as to avoid the decentration of the corneal cuts or of the capsulorhexis.

Corneal and anterior capsule transparency critically affect imaging. Any scarring, edema, or corneal folds, even caused by docking, may diminish the quality of the image, resulting in an incomplete or
wrong laser application. This can be an issue for all pediatric patients who, due to anterior segment dysgenesis, have corneal and anterior segment transparency alterations (e.g. corneal leukoma, capsular fibrosis) resulting in the impossibility to proceed and the necessity to perform a traditional surgical treatment.

During the acquisition phase, the patient must remain still for a few minutes, while the image is being captured. The surgeon evaluates the images to make sure that the anterior segment structures are correctly identified by the imaging system and to ensure proper alignment.

The capsulorhexesis then centered within the pupillary border. The capsulorhexesis diameter is pre-set at 5 mm, but it can be modified according to pupillary dilation (which needs to be monitored during the whole femtosecond laser treatment step) and IOL selection.

The surgeon chooses a lens fragmentation pattern (commonly used patterns include 4, 6, or 8 segments with or without the use of lens softening).

The imaging platform automatically defines a safety distance from the posterior capsule (generally 500 to 800 µm) that is displayed on the OCT guidance for approval by the surgeon, who can adjust this distance according to the strumental imaging data.

**Laser Treatment**

The laser treatment can last from 30 seconds to 3 minutes, depending on the laser platform and the degree of lens softening.

The following operations are then performed: anterior capsulorhexesis, requiring from 1.5 to 18 seconds; lens fragmentation
(from 30 to 60 seconds depending on the lens softening); and finally corneal cuts, which can be painful and cause issues when the collaboration of the patient is needed, especially in case of children.

IOP (intraocular pressure) increases during the laser treatment and can induce a mild circumferential subconjunctival hemorrhage,
which typically resolves in a couple of days. IOP increase issues must be taken into account, and this treatment should be avoided in patients for which an intraocular pressure increase could lead to severe consequences (e.g. patients suffering from congenital glaucoma, retinal rhegmatogenous or vascular anomalies). If suction is lost during the procedure, the suction ring can be reapplied to complete it, although, in some cases, gas bubbles formation can prevent the imaging analysis, resulting in the impossibility to continue with the femtosecond laser treatment, especially if this happens when performing capsulorhexis.

Once the laser treatment has been completed, docking is slowly released and the patient is transferred on the table for the second step of this surgery, which, as previously mentioned, uses traditional surgery equipment.
In case of pediatric patients, the surgeon can then proceed with the phaco-aspiration, taking into account that the ocular structures have changed because of the laser treatment. In fact, once the surgical incisions are opened (if obtained by means of the laser) or performed, and the viscoelastic substance is injected in the anterior chamber, the surgeon must pay great attention when performing the capsulorhexis, which can be incomplete or have radial incisions. This risk is reduced by recent software and hardware improvements. When performing hydrodissection, in order to avoid posterior capsule rupture, the surgeon must dislodge any gas bubbles that have formed between the posterior capsule and the lens, by gently compressing and tilting the latter, at the same time performing hydrodissection so as to push the bubbles in the anterior chamber (Roberts et al.). Moreover, in some cases, it may be difficult to see the edge of the cortex because it matches with the capsulorhexis one, making its extraction a little more challenging with respect to traditional surgery. Finally, being the femtosecond laser treatment a highly computer-dependent procedure, the surgeon must be at any time ready to revert to traditional surgery in case of "computer system failure".

Contrarily to what other authors describe (Trifanenkova), we also suggest avoiding the performance of posterior capsulotomy with femtosecond laser, in order to have an always intact and stable capsular bag during the aspiration phase of lens masses and also to prevent the presence of unwanted vitreous or vitreous fibrils that could make the foldable IOL instable in the bag. In our opinion, also
in traditional ophtalmosurgery, posterior capsulotomy must be performed in a second moment via pars plana, by means of a 23/25 gauge vitrectomy, during a later narcosis, when the IOL (especially a pseudo-accommodative one) is already stable in the bag.

**Outcome after 5 days from surgery**

In conclusion, femtosecond laser assisted surgery, even for pediatric patients, represents a new, interesting prospective because it allows to simplify and standardize the critical steps of traditional cataract surgery, reducing the total duration of the operation compared to this last one (FIGURE 7). However, currently, its difficult execution in general anesthesia and the above-described issues, mostly related to docking and imaging for pediatric patients, only allow a limited use of FLACS with respect to what was expected.
BIOMETRY IN CHILDREN

Claudio Carbonara, Vincenzo Savoca Corona

Introduction

Lens opacity can manifest at birth or appear during the first months of a child's life, due to congenital metabolic alterations. This opacity, in the first years of life, interferes with normal visual development.

Dealing with congenital cataract in pediatric patients is particularly complex: identifying the power of the IOL to be implanted is the greatest challenge, given that the small eyes of these patients are in their full dynamical development phase, and that in time they will change their biometric and refractive parameters. It is necessary therefore to be able to identify and predict, with the greatest precision, the power that will make the child, in its adult age, get closer to emmetropia or just to a slight myopia.

Congenital cataract is often one aspect of a complex malformation syndrome involving the cardiovascular system. It is, therefore, of primary importance to conduct all the investigations necessary to obtain the most complete clinical picture.

It is of the utmost importance that the general anesthesia, necessary for the surgical operation, is performed by a medical team familiar with pediatric anesthesia. The striated muscles of the eye, when collecting biometric and surgery data, must be absolutely relaxed, since any muscle tension could provoke an alteration in the biometric parameters and an increase in the ocular pressure.
Improvements in pediatric cataract surgery, achieved in the last twenty years, allow for very early cataract extraction and intraocular lens (IOL) implantation, even during the first year of a child's life. Cataract extraction and its substitution with a IOL represent the most appropriate treatment to avoid irreversible amblyopia. The desired refractive outcome after the artificial lens implantation, as well as the surgery, is crucial to minimize anisometropia and ensure an acceptable refraction for the long term.

In infants and children, serious mistakes can easily be made, caused by the rapid change of the corneal curvature and the biometric parameters in the first months of life.

Corneal curvature at birth is 52 D, at one month of life it reaches 46 D, at six weeks 44 D and, finally, at 36 months it is 43 D. Lens passes from 34 D at birth to 28 D in the first six months of life, stabilizing at about 20 D in the adult age. Axial length at birth measures 17 mm, after three years it is 22 mm and in thirteen years old children it measures 24 mm. The anterior segment at birth is 80% complete, at six weeks differentiation has occurred while emmetropization arises at 6-8 years.

Biometric data collection in pediatric patients is a difficult issue for eye doctors, above all if children are uncooperative and require the doctor to perform the necessary tests for the choice of the IOL power in the preliminary phases of the lens extraction operation, while the patient is under general anesthesia. This involves the need to use several specific instruments that allow biometric data collection while the patient is in supine position.
During the biometric screening it is strictly necessary that the doctor makes sure that he does not deform the eyeball with the eye speculum, since this would distort the biometric measurements. Very light pediatric eye speculums are available (Janach, with 5 mm or 8 mm blades) which are suitable for this kind of patients and do not modify the shape of the eye structure.

**Keratometry**

With cooperative children, the surgeon can try to perform manual or automatic keratometry in clinic, before the operation.

With non-cooperative children, the doctor must measure the corneal curvature during the general anesthesia with a portable keratometer (many of different brands are available: Nikon, Alcon, Nidek, Kowa, etc.) just before the surgery, while the patient is in supine position.

The examiner must try to carefully align the portable keratometer with the patient visual axis.

In children younger than one years old, keratometry assessment is not necessary since, during the first six months of life, the corneal curvature changes quickly from 52 D to 43 D; therefore, for the lens dioptic power assessment, a 44 D average value is used. If it is impossible to measure the corneal curvature, the doctor can use, as a last resort, approximate reference scales.
Biometric screening

Biometric screening must be performed with an immersion or contact A-scan ultrasonic test. In my opinion, it is better to avoid the contact technique because it is less precise, more dependent on the operator’s ability and more invasive, since it exposes the patient to the risk of corneal micro-abrasions.

Contact biometric screening must be performed only if the immersion system is not available or if the child’s eye is too small to place the Prager shell, essential for immersion A-scan. This technique requires a training period for the examiner, who has to learn the precise movements necessary to perform this screening. Contact biometric screening is the less precise biometric technique, since the excessive compression of the probe placed on cornea – which is more fragile in pediatric patients – might produce a deformation of the anterior chamber, generating an error in the axial length measurement (from 0.3 mm to 1 mm) and a consequent error in the selection of the power of the IOL to be implanted.

The anterior-posterior axis measurement carried out by means of the immersion technique is performed while the patient is in supine position, by placing on the eyeball a transparent plastic cylinder, specially designed for this kind of operation, filled with saline. The

<table>
<thead>
<tr>
<th>Age (months)</th>
<th>K (D)</th>
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<tbody>
<tr>
<td>0-3</td>
<td>47.9</td>
</tr>
<tr>
<td>3-6</td>
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<td>6-12</td>
<td>45.1</td>
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<tr>
<td>12-18</td>
<td>44.9</td>
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<tr>
<td>18-30</td>
<td>43.6</td>
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<tr>
<td>30-42</td>
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cylinder should adhere to the conjunctiva, one millimeter away from the limbus, or slightly more.

Different kinds of cylinders are available on the market, with different diameters, some of which are already inserted on the probe. These cylinders, also known as Ossoinig shells, when leaning against the perilimbal conjunctival surface, do not modify the corneal curvature nor the axial length.

The biometric screening is performed by immersing the probe in the cylinder. Using this method, the probe does not touch the corneal surface and the display screen highlights 4 peaks representing the anterior-posterior corneal surface, the lens anterior and posterior surfaces and the vitreoretinal interface surface. To be more precise, we should say that there are 5 peaks, since the corneal one is bifid because it indicates both the anterior and the posterior corneal surface.

To ensure the display of the anterior-posterior eye axis, it is necessary that all 5 peaks occur at a maximum and with a steep increase. A saw-toothed or a staircase behavior – especially on the retinal peak – as well as an echo with a not maximum rate, would in fact indicate a non-perfect alignment of the ultrasonic beam with the examined structures.

Anterior-posterior eye axis measurement is therefore obtained by automatically or manually placing the pointers on the peaks and measuring the distances between the highlighted ones, from the corneal peak to the retinal one.
**Biometric formulas**

Another big challenge is predicting refraction change in pediatric patients, i.e. children whose eyes are in the dynamic growth phase, typical of the infant age, and whose refraction will stabilize only in the adult age. Children eyes undergo a great change during time, both in terms of axial length and corneal curvature, especially in the first six months of life.

This growth generates a substantial refraction change in pseudophakic pediatric patients once they reach the adult age. Most of surgeons aim at hypocorrecting infants, selecting a IOL that leaves the child hypermetropic, with the objective of reaching emmetropia in the adult age.

Existing biometric formulas were not meant for short eyes, narrow anterior chambers and sharp corneal curvatures, such as those of pediatric patients, therefore they lack in reliability.

Biometric formulas used to calculate IOL power are SRK/T, Hoffer-Q, Holladay-I and Holladay II. The Hoffer Q formula was proven to be the most reliable because of its high-performance in pediatric patients’ short eyes. The Holladay II formula requires more information that, usually, are difficult to collect in a child.

It is recommended to aim at an initial post-surgery hypermetropia, which can vary according to the child's age, in order to obtain, after some years, emmetropia or a slight myopia. At the moment of selecting the power of the IOL to be implanted in a pediatric patient, it can be helpful to follow some guidelines proposed by Dahan and Tassinari.
TASSINARI

GUIDELINES IN RELATION TO AGE:

- under 2 years old, 20% less than the biometric data
- between 2 and 4 years old, 10% less than the biometric data
- between 5 and 8 years old, 5% less than the biometric data
- over 8 years old, 100% of the biometric data

DAHAN

PEDIATRIC PATIENTS UNDER 2 YEARS OLD:

- biometric data and 20% undercorrection
- 2-8 years old children -> biometric data and 10% undercorrection

OR ONLY REFERRING TO THE AXIAL LENGTH:

- 17 mm ➔ 28 D
- 18 mm ➔ 27 D
- 19 mm ➔ 26 D
- 20 mm ➔ 24 D
- 21 mm ➔ 22 D

Possible causes of error

*Instrumental error*. Instruments are calibrated for adult eyes and not for smaller eyes, as those of a pediatric patient.

Ultrasounds have a 1550 m/s average velocity, calculated as the average of the different velocities the ultrasonic beam has when passing through the different density tissues of the eye. In children,
eye components’ proportions are different, especially for what concerns the lens, which, in proportion, occupies more space in relation to an adult one.

It is be better, in pediatric cases, to follow the system suggested by Jack Holladay, which allows, independently from the eye size, to obtain reliable outcomes. My suggestion is to set all ultrasound velocities at 1532 m/sec and then add 0.32 mm to the biometric measure of the axial length obtained in this way.

This allows to avoid the error caused by the eye size, which, in very small eyes, occurs due to the increase of ultrasounds velocity (caused by a low presence of liquids) when passing through the vitreous of a very hypermetropic eye (1561 m/sec), and, on the contrary, to the reduction in ultrasound velocity (1549 m/sec) when passing through a vitreous with a great liquid component, typical of a very myopic eye.

*Measurement error.* During the biometric data collection, errors can be made, that alter the refractive outcome of the post-surgery target.

The lack of fixation in patients under general anesthesia generates a corneal decentration when measuring the corneal curvature. The soft consistency of a child's eye, during contact biometric scanning, can give rise to blunders due to the handpiece pressure on the cornea, which can generate errors on the axial length of up to 1 mm.

*Biometric formulas.* The target power of IOL to be implanted is obtained by a series of calculations based on biometric data and the A-constant of the IOL. Both the A-constant and the biometric
formulas have been developed on adults eyes, so they are less precise on pediatric patients’ small eyes.
Doctor Michele Fortunato was born in Aliano (Matera) on the 17th of October 1955. He attended primary and lower secondary school in Sant'Arcangelo (Potenza), high school (liceo classico) at Convitto Nazionale Vittorio Emanuele II in Rome. He graduated in Medicine and Surgery at University La Sapienza of Rome with top marks, choosing then specialization in Ophthalmology and attending a post-graduate course at the Ophthalmology Clinic of Geneva.

He has been working as an ophthalmologist since 1990 at the Ophthalmology department of Pediatric Hospital Bambino Gesù of Rome.

He wrote more than 130 scientific, 3 monographs about pediatric ophthalmology, some patents like patent about corneal freezing in refractive surgery and patent about rheology of aqueous humor (canalography). Moreover he discovered the subcutaneous circulation system with indocyan angiography.

He is cofounder of two professional associations: Association Internationale pour l'Enfance et la Réhabilitation Visuelle (AIERV) and Associazione Italiana di Oculisti Pediatri e Pediatri (AIOPP).

His principal professional interest is visual rehabilitation.