## 1. Guidelines for MIOL-Iris implantation

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### Preoperative Assessment

Serious condition of the injured eyes on presentation and pathological involvement of almost every eye structure (cornea, iris, lens, vitreous body, and retina) dictate delayed MIOL-IRIS implantation. Implantation surgery should be postponed to at least one year after the injury, except for some special cases when such an implantation is required by the condition of the injured eyes. The first and the main reason is presence of the post-traumatic swelling cataract. Its extraction could be carried out simultaneously with the intracapsular MIOL-IRIS implantation. The second indication arises when aniridia and aphakia are followed by severe retinal detachment requiring a prolonged silicone oil tamponade. To protect corneal endothelium from deleterious silicone oil contact iris-lens diaphragm should be artificially restored. The third reason for early MIOL-IRIS implantation could be the necessity of urgently performing penetrating keratoplasty in eyes with aniridia and aphakia, thereby providing an opportunity for a technically easier and safer implantation through an "open sky" approach.

In all other cases, there is a need for a phased surgery with MIOL-IRIS implantation no earlier than 1 year after the injury, because in the majority of cases there is a protracted blood-aqueous barrier breach. Additional surgical trauma could lead to excessive inflammatory reaction and worsen the treatment outcome.

Considering high prevalence of secondary glaucoma in patients with aniridia, great care should be exercised in preoperative evaluation of intraocular pressure (IOP) measurements and other signs of glaucoma. Secondary glaucoma should be aggressively treated by surgical procedures, although the magnitude and duration of hypotensive effect thereof remain low. Cyclodestruction and non-penetrating surgery with transciliary drainage appear to be most effective, as well as glaucoma drainage devices (Ahmed, etc.) and antimetabolites. After glaucoma surgery MIOL-IRIS implantation could be performed no earlier than 6-12 months provided that eye hydrodynamics has been stabilized. Adequate IOP control is the major success criterion for the main optical reconstructive surgical intervention with the use of MIOL-IRIS.

Patients with lattice degeneration of the peripheral retina should undergo the preliminary procedure of peripheral laser photocoagulation. The main prerequisite for the reconstruction surgery is complete attachment of the retina minimum within 1 year preceding the implantation. Rhegmatogenous retinal detachment, even local peripheral one without apparent danger of its expansion, must be surgically treated by means of episcleral buckling. Proliferative vitreoretinopathy would mandate a thorough subtotal vitrectomy with a 25 Ga probe.

The immediate preoperative preparation to MIOL-IRIS implantation surgery includes instillation of non-steroidal anti-inflammatory medications 3-4 times a day for 2-3 days before the surgical procedure. One day before and at the day of surgery 2.0 ml of a haemostatic drug Ethamsylate is given intramuscularly to prevent hemorrhagic complications. Instillations of antihypertensive medications are initiated before the operation, as well. Usually, timolol maleate beta-blocker 0.25-0.5% or betaxolol is given 2 times a day, whereas at the morning of the surgery a carbonic anhydrase inhibitor is instilled additionally. It is optimal to use the complex medications (Cosopt). If there is a risk of the increased IOP on the operating table, oral carbonic anhydrase inhibitor is administered in the morning of surgery. Any sedatives and hypnotics are necessarily used one day before and on the day of procedure.

Before surgery, all patients are informed on the rules of conduct during the surgical procedure, its possible outcomes and complications. Anesthesiologists who define the tactics during the interference examine patients. Traumatic history, extensive damage of the eye anatomy in these patients, the severity of previous surgical interventions, and psychoneurological status largely determine the increased vascular reactivity and the risk of developing vascular eye abnormalities. High qualitaty anesthesia is of great importance, especially for patients with labile psychic state, which is often typical for the younger men experiencing great internal stress during the procedure. One cannot underestimate the stress emotional reaction of the patients, which is associated with long waiting for surgery after the injury and worries about a favorable outcome not only functionally, but also in terms of cosmetic effects. Fear of a patient before the upcoming surgical intervention, internal emotional stress during the surgery procedure, and the anticipation of pain can lead to sympathoadrenal stimulation, prolonged and sustained spasm of blood vessels and the blood pressure increase. Rational means of anesthesia in such cases should be general anesthesia, which excludes the effect of patient's "participation", prevents the development of hyperalgesia, reduces the amplitude of hemodynamic changes; moreover, the vessels of the uveal tract become less sensitive to mechanical and physical stimuli during surgery. Furthermore, calcium channel blocker with a sustained effect - amlodipine 0.005 g – can be used before surgery as a measure to prevent intraoperative vasospasm. This is particularly important for vitrectomized eyes that are prone to precipitous hypotony at the time of MIOL-IRIS implantation through a relatively large incision and, as a consequence, to intense spasm of blood vessels supplying retina and optic nerve, or even to thromboembolism of ophthalmic vasculature. For such patients, the best type of anesthesia is laryngeal-mask general anesthesia. For the prevention of vascular complications during implantation, it is necessary to maintain continuous intraocular balanced salt solution irrigation with the bottle not higher than 70-90 cm from patient's eye level.

Anesthetic preparations on the day of operation includes premedication 30-40 minutes before the surgical intervention (intramuscular injection of Atropine, antihistamines, sedatives, opioid and non-opioid analgesics. Ten minutes before the surgery a retrobulbar block using 2.0 ml of 2% Lidocaine and lid akinesia per M.M. Krasnov's method are administered. During the surgical procedure, neuroleptanalgesia is produced by the simultaneous administration of a neuroleptic agent, e.g. acepromazine, and a narcotic analgesic. To lower blood pressure Pentamin or Clonidine could be used. Occasionally vasodilators are prescribed. During the surgery, continuous hemodynamic and cardiac monitoring is well justified. In cases of higher risk of hemorrhagic complications, Ethamsylate or aminocaproic acid are administered intravenously. At the end of surgery treatment in case of a risk of vasospasm during the surgery, it is recommended to execute the retrobulbar injection of 1% nicotinic acid or a mixture of 2% Papaverine with 0.5% Procaine, whereas 2.4% -10.0 ml of aminophylline with saline is administered intravenously.

After surgery anesthesiologists monitor a patient's condition for 30-60 minutes, and then for 2 to 3 hours a patient is advised to stay in bed.

**How to choose the MIOL-IRIS implantation method and its parameters**

Criteria for selection of method and extent of surgical procedure in case of aniridia are the following:

- Extent of iris tissue defect;
- Availability of undamaged capsular bag of the lens;
- Presence or absence of the aniridia fibrous membrane or the compacted fibrous anterior hyaloid;

- Extent and localization of cicatricial deformities of the anterior segment;
- Comorbidities of the posterior segment.

**Methods of MIOL-IRIS implantation may vary:**

- In case of cataractous lens, MIOL-IRIS implantation is performed by introducing MIOL-IRIS disk-type model F or MIOL-IRIS models A, C, after their ex tempore modeling by cutting support elements into the capsular bag;
- If there is lens capsule or fibrous aniridia membrane, the MIOL-IRIS implantation is performed by introducing the MIOL-IRIS models A, C into the ciliary sulcus directly on the lens capsule or the fibrous aniridia membrane without any additional suture fixation with the simultaneous excision of the central part of the membrane or discission of the lens capsule;
- In case of complete absence of or insufficient capsular support, the MIOL-IRIS implantation is performed by fixing MIOL-IRIS models A, C with non-absorbable sutures to the sclera at 1-3 points, depending on the extent of capsular remnants;
- In partial aniridia, the MIOL-IRIS implantation is performed by suture fixation of MIOL-IRIS to the sclera;
- In case of combination of iris pathology and severe corneal opacities, the MIOL-IRIS implantation is performed simultaneously with penetrating keratoplasty;
- In case of combination of iris pathology with changes in the vitreous body, the MIOL-IRIS implantation is performed simultaneously with vitrectomy;
- In case of combination of iris pathology with severe rhegmatogenous retinal detachment with fibrous degeneration due to previous unsuccessful surgeries with a long, 2-3 month, silicone oil tamponade, it is required to continue the tamponade and to create an artificial barrier between the anterior and posterior segments. The barrier is to lower known risks of corneal decompensation due to prolonged contact of the endothelium with silicone. The technique employed in these cases combines pars plana vitrectomy, epiretinal membrane removal, retinal reattachment under perfluorocarbon liquid followed by silicone oil exchange and MIOL-IRIS implantation.

For acceptable refractive outcomes optical power of MIOL-IRIS is calculated preoperatively using its A0 constants. These were calculated clinically using first implantations and are different depending on the fixation site: 119.8 – for intracapsular fixation and 119.4 – for ciliary sulcus fixation. A relatively small number of cases provided and their clinical heterogeneity prevent the calculation of A-constant as accurately as for any standard posterior chamber IOL. Complete or partial aniridia, large iris colobomata, traumatic mydriasis of over 8 mm in conjunction with traumatic aphakia, congenital cataracts, secondary cataracts, often with rough corneal scar or dystrophy and vitreoretinal pathology are main indications for MIOL-IRIS implantation. It is extremely difficult to predict postoperative refraction in these cases.

Color and textural pattern of implantable MIOL-IRIS is usually selected during primary patient consultation using dedicated fan-catalog of iris options, provided by the manufacturer. Then the desired color from the diagram, pattern and model with the catalog code symbol in line with the catalog numbering and refraction is ordered from the manufacturer Reper-NN Ltd.

When selecting the MIOL-IRIS color, first, the necessary basic color scheme is found on the edge of the fan-color calibrator, then, the iris pattern to suit individual parameters of the fellow eye iris pattern is selected from the palette provided.

Due to selection of MIOL-IRIS color and pattern with the fan-catalog in accordance with the fellow eye, it is possible to achieve good cosmetic effect of implantation. MIOL-IRIS model is determined depending on the area of iris defect and the presence of any supporting structures within the anterior chamber or lack thereof, as well as the need for the optical part.

Before MIOL-IRIS implantation, many patients need to undergo preliminary surgery procedures, such as vitrectomy, glaucoma treatment or surgery for detachment or degeneration of the retina. When patients are seen early after trauma, they should be informed on possible consequences and complications of early surgery and meticulously followed with appointments as frequent as their eye condition would dictate.

For the planned surgery in order to be safe from cancellation as a result of accidental damage to MIOL-IRIS, it is recommended to order two similar copies. The same practice exists in Europe. Conducting this type of surgery one should warn his/her patients about this potential problem. This is especially true for commercial clinics where unexpected problem may result in the increase in surgery costs.

**MIOL-IRIS implantation technology in cases of preserved capsular bag**

When the capsular bag is available for MIOL-IRIS fixation, surgeon should make a decision what tactics to choose after phacoemulsification phase: to implant MIOL-IRIS inside the capsular bag or onto it. Two aspects should be considered. First, extensive postoperative fibrosis of the bag in presence of a relatively large capsulorhexis may result in dislocation of the implant into the anterior chamber. We have seen this once in our practice in a patient with congenital aniridia, large-swinging nystagmus and cataract. The second aspect is related to heavy opacification of the anterior capsule, which by itself lightens the color of the “iris” part of MIOL-IRIS and obscures it. For intracapsular implantation in traumatic or congenital cataract cases with (almost) intact capsular bag, the MIOL-IRIS (models A, C) needs to be positioned. As an alternative, it is possible to use a special disk model F without haptic support elements of the overall diameter 9.0-10.0 mm. In addition, a standard posterior chamber IOL placed inside the capsular bag after phacoemulsification could be supplemented with the disk-shaped artificial iris 10.0 mm in diameter introduced either into the capsular bag over IOL lens or for “iris” models A, C on the anterior capsule in the ciliary sulcus area.

The surgical field is prepped in a conventional manner. Superficial anesthesia is established by instillation of 0.4% Oxybuprocaine, 0.5% Proxymetacaine, 1% Dicaine or 2% Lidocaine. At the discretion of the surgeon, on vitrectomized eye bridle suture on the superior rectus muscle could be placed. Intraocular access could be provided by sclerocorneal or corneal routes. With sclerocorneal approach conjunctival scissors are used to cut the conjunctiva along the limbus at 11-13 hour meridians. In case of heavy scarring in this area, the conjunctival peritomy is shifted in the temporal or nasal direction. Hemostasis is achieved by diathermy of episcleral vessels. For implants with optical power greater than 25-26 diopters forceps-assisted implantation is employed, while for thinner lenses an injector system is used. For planned forceps implantation a sclerocorneal tunnel with the dosed diamond blade is made with an incision in the sclera of 350 microns in depth and 5.5 mm in length in a frown configuration. Metal or diamond dissecting knife forms a channel in the layers of the peripheral cornea with a length of 2.5 mm. Two stab wounds are created. To improve control over anterior capsule, Trypan blue vital dye is applied under sterile air in the anterior chamber. Then the anterior chamber is filled with a cohesive viscoelastic to protect the corneal endothelium, to achieve stability of the anterior camera and to relieve tension from the lens capsule and zonular fibers. With the help of 30-Ga injection needle or capsule forceps, one makes the capsulorhexis of oval vertically elongated shape with a size of about 6.0 to 7.0-7.5 mm with the upper edge close to the periphery for ease of implantation of a relatively large MIOL-IRIS implant. At the same time surgeon tries to minimize tractions on zonular fibers to avoid iatrogenic dialysis. Then one carefully performs hydrodissection, which is necessary to ensure free rotation in the capsular bag, and hydrodelineation at which the inner compartment of the compact nucleus is dissected from epinucleus.

We prefer to perform phacoemulsification of the cataractous lens in aniridia with the “phaco chop” technique. First, a deep central groove is formed within the nucleus at ultrasonic powers of 30-50% in a pulse mode (15 pulses/sec) with vacuum of 150 mm Hg. Phacotip and chopper are used to break the nucleus into 2 halves and rotate them 90°. Then by aspiration the lower half of the nucleus is fixed. The phacochopper inserted through the paracentesis is set closer to the peripheral part opposite the ultrasound tip. Moving towards each other, they divide the fragment of the nucleus into 2 parts. This maneuver is repeated with the second half of the nucleus. Then resulting nuclear fragments are removed in pulse mode (10 pulses/sec) at vacuum of 250 mm Hg. Maximum ultrasound power is set at 50% for hard grade 3 nuclei, and at 20-30 % for softer grade 1-2 nuclei. Afterwards the ultrasonic tip is replaced by irrigation and aspiration tip and cortical masses are aspirated. At this stage of the surgery stability of the anterior chamber is best achieved by using bimanual technique with an automated irrigation and aspiration system of the phacoemulsifier consisting of two separated tubes, one for aspiration, and another one for irrigation.

For MIOL-IRIS implantation a standard set of Buratto forceps or the injector of Monarch type with cartridges A or B are used depending on the optic power of the lens. Cartridge C could be employed for no-optic artificial iris implantation. Capsular bag and anterior chamber are filled with the greater amount of ophthalmic viscosurgical device (OVD). For injector-assisted implantation an incision of no more than 2.7-3.2 mm depending on the cartridge is required, while for forceps implantation the incision is widened to 5.0-5.5 mm. For intracapsular fixation disk-shaped F model 10.0 mm in diameter is used as well as A or C models with truncated support elements. The implant is folded in half by the haptic pattern or in rough matte side in monochrome models outwards and implanted through the tunnel incision into the capsular bag to the end in the lower equatorial fornix.

The injection requires very delicate, careful implantation technique, because pushing through the cartridge may cause a too sharp jerky move of the MIOL-IRIS implant, which can lead to rupture of the bag. Therefore, a phased technique is possible: MIOL-IRIS is initially introduced into the anterior chamber, and then with the help of hooks and pushers - inside the capsular bag, which requires certain skills, considering large size of MIOL-IRIS.

The forceps technique at the beginning, during the movement through the channel, MIOL-IRIS is introduced into the plane of the channel section to the lower edge of MIOL-IRIS putting into the capsular bag, then it is rotated sagittally with the optical part to the cornea, the tweezers are loosened and the diaphragm opens in the front plane with its lower half in the capsular bag and with the top on the capsule. Simultaneously with the other hand via the paracentesis with Micro-ball the upper edge of capsulorhexis is removed upwards and the top edge of MIOL-IRIS is delicately put into the upper body of the equatorial capsular bag with pusher or “fork” first down at 6 hour direction, and then a little deeper and up, while releasing the edge of MIOL-IRIS. MIOL-IRIS takes its proper intracapsular position.

On completion of the case it is recommended to thoroughly remove OVD using the biaxial system of irrigation and aspiration. With monomanual irrigation and aspiration tip anterior chamber stability is inadequate due to mismatch between incision size and tip diameter. Therefore, in order to avoid dislocation of artificial iris from the capsular bag irrigation/aspiration tip is slightly pressed on the front surface of MIOL-IRIS in the optical zone. A spatula introduced through a side port incision could also be used for that purpose, especially when removing the tip from the anterior chamber. The anterior chamber is reformed by balanced salt solution. In some cases a small bubble of sterile air (about 0.2 mm3) is administered. The sclerocorneal incision is secured by a single 8-0 silk suture. The conjunctival wound is closed.

Similarly, MIOL-IRIS can be implanted after erbium laser phacoemulsification or manual small incision cataract surgery through a 2.6-3.2 mm clear corneal incision, depending on the cartridge used.

**MIOL-IRIS implantation on lens capsule or fibrous aniridia membrane**

Presence of lens capsule or fibrous aniridia membrane in the eye is an indication for MIOL-IRIS implantation in the ciliary sulcus without any additional suture fixation directly on capsule or membrane periphery after excision of its central part. Furthermore, this type of implantation is optimal for patients with congenital aniridia combined with nystagmus, since constant oscillatory eye movements and fibrosis of the capsular bag with time can dislodge MIOL-IRIS implanted into the bag into the anterior chamber.

When MIOL-IRIS is implanted by forceps, after similar treatment of the surgical site, standard anesthesia and side port incisions the operating surgeon forms corneal or sclerocorneal tunnel incision by the method described in Section 3. If there is a fibrous aniridia membrane gentle cautery is applied to newly formed blood vessels, usually present on the membrane, with the help of underwater diathermocaogulator. Then, the central part of the membrane with the diameter of about 7 mm is excised with Vannas scissors or strabismus scissors in the lower less accessible area. Bleeding vessels are re-coagulated. The main incision is extended to 5.5 mm. Through paracenteses the anterior chamber is filled with OVD. If the posterior capsule is intact, the anterior chamber is maximally expanded with OVD for safer MIOL-IRIS implantation. In case of peripheral remnants of the fibrous membrane present in the eye, a cohesive OVD (preferably containing hyaluronic acid) is carefully injected into the anterior chamber angle in a circular configuration to avoid OVD falling into the vitreous cavity, and the amount thereof should be minimal. Then elastic MIOL-IRIS implant is folded using a set of Buratto forceps with the iris pattern outwards and is delivered into the anterior chamber congruent to the incision plane before putting the lower support element into the ciliary sulcus backed by the capsule or membrane. Then MIOL-IRIS is rotated in the saggital plane with the optical part to the cornea with forceps hold gradually released. MIOL-IRIS spreads in the frontal plane so that its support elements lie in the ciliary sulcus and are circumferentially secured on the capsule or fibrous aniridia membrane remnants without additional suture fixation. Support elements that do not spread into the correct position at once are lead into the desired position using a Sinskey hook, an iris hook or a fork instrument. Then OVD is washed out in line with the procedure described in Section 3. An interrupted suture is placed at the main incision. The conjunctiva is sealed.

Support elements of the implant stretching from the saggital into the front plane, do not damage or tear the capsule, because MIOL-IRIS support elements do not have sharp terminations at the ends and are elastic, which provides for their delicate contact with the capsule without damaging the latter. In this sense, model C is absolutely safe. It is possible to use the combined MIOL-IRIS fixation in the eye: some support elements lie on the capsule, some are sutured. In addition, if the surgeon is not sure that the implantation will be standard, it is possible to conduct a preliminary thread through 1 or 2 support elements above and below, so in case of necessity one can immediately suture the implant to the sclera. In the same way one can proceed with cases of incomplete capsular support. In the segment of capsular defect, where a support element is to be placed according to preliminary layout, corneoscleral tunnel or scleral flap should be created, followed by suturing of the support element in this sector to the sclera.

MIOL-IRIS injector-assisted implantation either with optical part or without it onto the capsule is the “gold standard” of this type of surgical intervention. It requires no additional suture fixation. It is possible to place a standard MIOL-IRIS on the capsule or

its remnants or install an artificial iris over a posterior chamber IOL - a previously implanted one or the one implanted directly during the operation in the capsular bag. The MIOL-IRIS implantation with optical power of up to 24 diopters is possible through the injector with Monarch B cartridge, up to 20 diopters - through C cartridge.

Implantation of MIOL-IRIS with an optical power of over 24 diopters is possible through A cartridge. Before installing MIOL-IRIS into the cartridge one must not only introduce OVD into the cartridge, as is done in routine practice for IOL implantation, but also onto MIOL-IRIS itself, because of the risk of the lens blocking in the cartridge due to increased adhesion of materials. At the initial stage of pushing MIOL-IRIS in the cartridge with a difficult initial move of the implant, one can help the process a little with a thin spatula with the movements separating the lens from the walls of the cartridge. The implantation process should not be delayed; the diaphragm shall be immediately implanted until a new adhesion occurred.

Furthermore, in the majority of cases of primary or secondary MIOL-IRIS implantation onto the lens capsule posterior capsulotomy should be performed immediately after implantation at the end of the operation, since younger age and previous trauma predispose to posterior capsule opacification. Moreover, in congenital cataract patients primary capsulotomy shall be done because it is very risky to operate these patients for the second time for they suffer from a genetically determined keratopathy, prone to pannus development and opacification. Capsulotomy is performed with the vitreous cutter via a pre-set port in pars plana sclerotomy.

**MIOL-IRIS implantation in the absence of capsular support**

Complete or partial absence of the capsular support in the eye with aniridia and aphakia is an indication for MIOL-IRIS suture fixation to the sclera. For previously vitrectomized eyes it is important prior to implantation to pre-install an irrigation cannula of 25 Ga through the scleral port or corneal paracentesis to reduce the risk of sharp decrease of IOP at the time of MIOL-IRIS implantation. Lack of vitreous body and barrier function of the iris-lens diaphragm lead to rapid loss of liquid contents of the eye, to distortion of regular eye topography and make it difficult to perform surgical manipulations. The use of saline irrigation should be started before main incision is made and the eye is depressurized, because in response to short-term ocular hypertension the reflex constriction of blood vessels occurs, that makes them more resistant to subsequent IOP decline. On the other hand, excessive intraocular pressure may also predispose to sudden episodes of ocular hypotony. Thus, the height of irrigation bottle should not exceed 70-90 cm from the patient eye level. In this situation, it is most advantageous to employ a specialized surgical equipment for maintenance of constant intraocular pressure (of about 25 mm Hg), e.g. Constellation Vision System (Alcon Surgical).

**MIOL-IRIS implantation in complete absence of capsular support**

The surgical field is prepped as usual, and anesthesia is given. In avitreous eyes a bridle suture on the superior rectus muscle could be placed. Depending on the MIOL-IRIS model used, one shall mark up the position in the corneal and scleral area of 3 or 5 support elements by means of a 3- or 5-ray markers, so that to avoid scleral and limbal scars.

For ease of implantation, one of the support elements is often placed in the 6-o'clock meridian, whereas the other two at 10 and 2 o'clock for a 3-point fixation MIOL-IRIS model or 10:30 and 1:30 for a 5-point model.

Transscleral suture fixation of the support elements can be done differently. A traditional but a more technically demanding is suture fixation of the support elements in the pre-formed intrascleral pockets.

At the beginning, one forms the main incision for MIOL-IRIS implantation, for which the conjunctiva is separated with scissors along the superior limbus. Hemostasis

is achieved by diathermocautery. The sclerocorneal tunnel 1.5 mm from the limbus is created. In order to do it, one first makes a scleral incision with a diamond micrometer knife at a depth of 350 microns 5.5 mm in length with a frown or regular profile. Using a metal or diamond dissector one forms a 2.5 mm tunnel into the corneal periphery. Scleral incision is extended to both sides by 1-1.5 mm at one third to one half tunnel thickness without dissection to the cornea. These extensions are required to hide suture knots fixing two upper support elements, the tips of which in a 5-beam pattern of MIOL-IRIS are located 7.5 mm from each other. Two side port incisions are made 90 degrees to both sides of the main incision. In the meridian opposite to the main incision a conjunctival peritomy is performed, a limbal-based scleral flap with 2.0-2.5 mm sides at 1/3-1/2 scleral thickness is fashioned to hide a suture knot of the lower support element.

After preparing patient's eye for implantation attention is turned the implant. Three support elements are attached to a single- or dual-thread non-absorbable 9-0 polypropylene on a long slightly curved (1/4 circle) 0,2x4 mm needle. For fixing support elements to the sclera, 3 separate double-armed sutures or loop sutures are used. The first needle is passed through the main incision and brought out 1.0-1.5 mm from the limbus through the scleral pocket at the 6-o'clock meridian. The two needles attached to two other equidistant support elements are separately entered into the eye through the main incision and passed out in an ab interno fashion through the partial-thickness ends of the main incision. After that, the elastic MIOL-IRIS is folded in half with the pattern or matte side up with Buratto forceps, put in the frontal plane to the tunnel incision, the lower thread is stretched a bit, which prevents tangling of the filaments. Two other threads are tightened slightly and checked for correctness of their position. Then MIOL-IRIS is inserted through the scleral tunnel to the lower segment of the ciliary sulcus with the lower filament tightened again. Then MIOL-IRIS is rotated from the frontal to the sagittal place with forceps jaws gradually weakened, and the diaphragm takes the desired position with support elements put in line with the meridians of the needles coming out.

Having checked the correct location of threads in the eye, for which support elements are slightly put toward the center of the visible area with microhooks inserted through the paracenteses, the threads are pulled to the fixation locations and subsequently sutured to the sclera at 3 points. After this, the tunnel incision is made watertight by a single interrupted 8-0 virgin silk or polyglycolide suture so that two polypropylene knots are buried within the sclera. Scleral pocket is also closed by an interrupted suture. Then 8-0 silk sutures are used to close conjunctival incisions.

Less technically challenging is the method for scleral fixation using suture retrieval through a scleral tunnel as originally described by Hoffmann (здесь ссылка Hoffman RS, et al. JCRS 32(8):1259-63). This method can significantly reduce surgical trauma, minimize patient discomfort in the postoperative period and securely fix MIOL - IRIS. In short, after appropriate markup for 3 or 5 – depending on the model used – fixation points, often at 6, 10 and 14 hour meridians, scleral tunnels are formed in the centripetal direction. A 2.2 mm spear blade is entered at limbus and advanced for the length of its working at 1/3-1/2 scleral thickness.

Then the main corneoscleral or corneal tunnel 5.5 x 2.0-3.0 incision is fashioned for MIOL-IRIS implantation. After tying three separate non-absorbable 9-0 polypropylene sutures double armed with long 14 x 0,2 mm needles to 3 support elements, the needles are sequentially introduced into the anterior chamber through the main channel. They puncture the sclera and conjunctiva in an ab interno approach 1.0-1.5 mm behind the limbus in the area of pre-formed scleral tunnels. Two needles of the same suture go through each channel.

An *ab externo* approach could also be employed with injection needles introduced through scleral tunnels to serve as exit guides for suture needles.

Then suture needles are cut, and their threads are exteriorized at scleral tunnel openings with the use of a microhook with a ball at its end.

MIOL-IRIS is implanted through the main incision. Once the diaphragm takes its desired position with the disposition of support elements in line with the meridians of the needles coming out, one checks the correctness of suture location in the eye and pulls them into the points of fixing through the scleral tunnels. Each pair of threads is tied with 3-4 knots and buried within scleral tunnels. After that, the main incision through which MIOL-IRIS was introduced into the eye is sutured.

Both of these described methods for MIOL-IRIS fixation are carried out blindly with no direct visualization of the exact location, where needles pierce the sclera. On gonioscopy it is not infrequent to see that suture fixes a support element not in the ciliary sulcus but rather to the ciliary body, its processes, or iris root remnants. This may be due to post-traumatic distortion of the anterior segment anatomy, forward rotation of ciliary processes and their adhesion to angle structures, as well as to the wrong suture placement. In addition to pigment dispersion, glaucoma and chronic inflammation, incorrect MIOL-IRIS position – its tilt or decentration – may lead to a reduction of visual function in the post-operative period. Therefore, the ideal, but significantly laborious way of suture fixation of MIOL-IRIS support elements is with the use of an endoscope.

Endoscopically guided fixation could be carried out with the needle attached by a silicone cuff directly to the endoscopic probe. After localization of the desired area under visual control the needle is pointed to the projection of the ciliary sulcus.

These manipulations with the needle fixed to endoscope are feasible only for lower quadrants, but cannot be performed in upper quadrants, because sutures require preliminary fixing to the implant. For superior locations one needs to either use gonioscope intraoperatively, which is complicated by corneal folds during manipulations of the needle, or use an endoscope holding it in the other hand or with the help of an assistant. For the latter approach an additional limbal paracentesis in the lower quadrant is mandatory. When using endoscope, the method of MIOL-IRIS fixation to the sclera is of no importance and depends on the surgeon preference: forming corneal and scleral tunnels with a return profile or preliminary formation of intrascleral pockets.

**MIOL-IRIS surgical implantation technology with partial absence of the capsular support**

In case the capsular bag remnants in the eye present only in certain meridians, MIOL-IRIS shall be placed so that maximally use the remnants of the capsules for the seamless support of MIOL-IRIS in the ciliary sulcus in these meridians. The operation is conducted with the method similar to those one described in Section 5.1. A specific feature is that MIOL-IRIS is seamed to the sclera only in the meridian with no remnant capsule. MIOL-IRIS is located in the meridian with the preserved remains of the capsule on the surface thereof without additional suture fixation. In such cases, MIOL-IRIS can be fixed in 1-2 points. To do this, first one markups the support elements location, forms the cornea and scleral channels or cuts out scleral pockets at 1/3-1/2 of the thickness to the sulcus sclerae in the meridians, which are planned to be seamed with MIOL-IRIS, and performs the main channel incision with a length of 5.5 mm. The corresponding support element is attached a 9-0 polypropylene filament with a needle of 14 mm, which after passing through the front chamber is punctured out in the preliminary set meridian 1.5 mm from the sulcus sclerae in preformed scleral channels or pockets. If necessary, the other supporting element is sewn the same way. One can use the endoscope probe for direct visual inspection of the place of needle injection. Then, MIOL-IRIS is folded using a set of Buratto tweezers “capture-constrictus” and introduced into the front chamber, placing it in such a way that the support elements of MIOL-IRIS haptic part rested on the ciliary sulcus and based on remnants of the capsule in the respective meridians; in the places of suture fixation the filaments are strained, then fixed, the

channel incision is put a submersible junction seam, whereas the scleral pockets and the conjunctiva are sutured.

**MIOL-IRIS surgical implantation technology in case of the combined pathology of cornea, lens and rough corneal scars**

Rough scarring of the cornea in the optical area decreasing the vision acuity till OD, endothelial and epithelial dystrophy of the cornea, graft disease in combination with the aniridia or traumatic mydriasis, as well as with the cataract or aphakia serve as indications for the MIOL-IRIS implantation combined with simultaneous penetrating keratoplasty (PK) and, if necessary, with the cataract surgery. PK is possible to be conducted using the traditional method of cutting out the corneal discs with metal trephines of various structures, Barron vacuum trephines, as well as using the femtosecond laser (Fs-laser). The second method is applicable in the absence of major opacifications and scarring of the cornea in the area of cutting the corneal disc and has a number of undoubted pluses. Use of the Fs-laser makes it possible to program different profiles of corneal incisions, providing for their exact shape and size, and clearly correlate the diameter of trepanation - both of the donor and the recipient. This, in turn, contributes to the increase of biomechanical stability of the incision, the decrease of postoperative astigmatism value and achievement of better functional results. Fs-laser PK allows avoiding further injury of the endothelium, because the manipulations with the graft are more delicate, epithelialization of the graft is accelerated, it provides for a faster visual rehabilitation, the probability of infectious complications reduces, whereas the safety of surgery increases.

During the combined operation on the MIOL-IRIS implantation with traditional PK after the surgical site is treated and a local anesthetic is given two bridle seam on the upper and lower rectus are imposed, Flieringa ring is sewn (but in some cases it is difficult to cut scleral pockets for seam fixing of MIOL-IRIS). The locations of the support elements is marked with a marker. If there is no capsular support in the eye one plans the suture fixation of MIOL-IRIS, thus, after separation of conjunctiva 3 mm scleral pockets 2,0x2,0 are cut with their basis to the sulcus sclerae or in the opposite direction immediately from the sulcus sclerae at 1/3-1/2 of the sclera thickness. Three support elements of MIOL-IRIS are attached with 9-0 non-absorbable polypropylene filament. Then, the center of cornea is marked, a burr hole is cut using a trephine with the diameter of 7.0-8.0 mm, through which the needles are taken out ab interno in scleral pockets in 1.0-1.5 mm from the sulcus sclerae. Then, MIOL-IRIS is implanted through a burr hole, taking the support elements into the ciliary sulcus, where the filaments had been sewn in advance. Filaments are tightened and attached with seams to the sclera. The central orientation of the lens is checked. Scleral pockets are sutured. If there is a fibrous “aniridia” membrane or lens capsule in the eye MIOL-IRIS is implanted directly on them without any additional suture fixation, forming a hole in the center of the membrane or capsule with a diameter equal to the optical part of MIOL-IRIS. In case of the cataract lens in the eye, the extracapsular cataract extraction is performed through a burr hole with implantation of MIOL-IRIS model F with a diameter of 10.0 mm in the capsular bag or models A, C after cutting out the support elements on the surface of the capsular bag in the ciliary sulcus without any suture fixation. Then, a fresh donor graft with a diameter of 0.5 mm larger than the same of the recipient is cut out. In case of significant hyperopia at a brevis eye, it is better if the size of the donor graft exceeds the diameter of the recipient graft at 1.0 mm. The graft is pre-fixed with 4 sutures of 8-0, and then one makes a continuous circular or interstitial 10-0 nylon nodular suture. The preliminary seams are removed.

With the technique of fixing MIOL-IRIS in inverse corneal and scleral channels, channels are formed before cutting out of the corneal disc, and then the donor and recipient corneal discs are cut. Then MIOL-IRIS is implanted, the support elements are

fixed with preliminary 9-0 polypropylene filaments (one double node is made), after that the graft is sewn, the eye turgor is restored, the proper tension of nodes and MIOL-IRIS position is checked; the nodes fixing the support elements are finally tied and hidden in the intrascleral area.

Femtosecond penetrating keratoplasty is conducted with the femtosecond laser manufactured by IntraLase, which use infrared laser radiation at the neodymium glass with a wavelength of 1053 nm, impulse frequency of 60 kHz, impulse duration of 600-800 f/s, and the maximum power of the laser impulse of 12 mW. IntraLase laser creates resection planes by precision laser micro-incisions of tissues due to the impact of narrow femtosecond impulses.

The femtosecond laser forms the corneal disc by many consecutive micro-incisions performed with a high repetition rate, using the guidance system under computer control and IntraLase sterile disposable interface, containing a prefabricated aspiration ring, an applanation lens, a vacuum tube and a disposable syringe. The donor eye is imposed a vacuum system, consisting of a pre-sterilized aspiration rings connected with a vacuum tube with a disposable syringe, then an applanation lens connected to a laser system is put down; a corneal incision of a given profile is made under computer control. The incision begins from the front chamber, the laser beam moves upward and then along the circle. The laser beam successively goes through the rear epithelium, stroma and front epithelium.

In order to improve the biomechanical stability of the post-operation incision and reduce the post-operative astigmatism in case of femtosecond PK, it is recommended to form not straight but curved intrastromal cuts to increase the contact area of the donor and recipient corneal tissue, and to have a good approximation of its edges.

For instance, during the composite profile of the transplantation, first one makes the rear side corneal incision from the front chamber into the corneal stroma, then the lamellar blind-ended ring incision in parallel to the front surface of the cornea, followed by the front side incision - from the stroma to the front till the epithelial surface of the cornea. Such a procedure is conducted at the recipient’s eye by forming the corneal disk with the same parameters with the femtosecond laser. In the projection of a dense scar, one can see incomplete cutting of a corneal disc, which requires its further cutting with a diamond depressor. After forming corneal discs on the donor’s and recipient’s eyes, one separates the donor graft with a thin spatula, then transfers it to the recipient bed and fixes with 10-0 nylon nodes or submersible locking stitches.

**MIOL-IRIS surgical implantation technology in case of the iris pathology combined with changes in the vitreous body**

When the hemophthalmia or expressed destruction of the vitreous body is diagnosed in combination with the aniridia and aphakia or cataract, it is recommended to conduct two-stage surgery at intervals of 1-6 months. Simultaneous execution of microinvasive 23 or 25 G (preferably 25 + G) subtotal vitrectomy with the MIOL-IRIS implantation is possible only in case of destructions of the vitreous body and small hemophthalmus, when the retina is well visualized pre-operatively and one is sure in the absence of the need for extensive vitreoretinal surgery. After the treatment of the surgical site and local anesthesia, one makes the basic and additional incisions, produces 3 scleral punctures using trocars 25+G maximum 3 mm from the sulcus sclerae taking into account the possibility of a post-traumatic displacement of anatomical structures frontwise in the projection of the flat part of the ciliary body. It is optimal to use the ports with seals providing for maintenance of the stable IOP during the operation. One of the ports is installed with the irrigation cannula. The lens masses are removed, corneal and scleral channels for fixing MIOL-IRIS are formed, then the diaphragm is implanted and after that using the fiber and vitreous cutter tip of 25 Ga one performs the subtotal vitrectomy. In case there is a need to improve visualization of the vitreous body strands and the

rear hyaloid membrane, one implements staining thereof with Triamcinolone, in case of removal of the front limiting membrane of the retina one uses Membrane blue, in case of chorioretinal dystrophies and dumb breakages of the retina one conducts the endolasercoagulation.

In case of sufficient visualization during the combined surgery, it is possible to perform the vitrectomy via the first stage before phacoemulsification and MIOL-IRIS implantation, but a different tactics is preferable. Should there be a cataractous lens and the need to perform the simultaneous vitrectomy and the MIOL-IRIS implantation, at first, ports of 25 Ga are installed 3 mm from the sulcus sclerae, one of them is attached with the irrigation cannula, the other two are closed with special plugs (or one uses ports with seals, which is recommended), then one proceeds to the phacoemulsification (PE). The vitrectomy is performed to the maximum extent possible.

According to one of the above methods, MIOL-IRIS can be implanted after vitrectomy or immediately after the PE. The surgery ends with sealing of the scleral channel in case of insufficient sealing if needed - scleral punctures and conjunctival incisions.

**MIOL-IRIS surgical implantation technology in case of the iris pathology combined with the retinal detachment**

The basic condition for reconstruction surgery with the MIOL-IRIS implantation is the full adherence of retina. In case of severe concomitant of post-traumatic pathology in the form of aniridia, lens pathology and retinal detachment, a phased approach to the surgical interference is preferable. Only after the success of vitreoretinal surgery one should proceed to the MIOL-IRIS implantation phase, moreover, 6-12 months after the last successful vitreoretinal surgery at the earliest.

In the course of vitreoretinal surgery, in eyes with aniridia one can use all the techniques and achievements of the modern vitreoretinal surgery. Often after the traumatic iridodialysis in patients with a history of keratotomy, and, thus, the myopic and having peripheral chorioretinal dystrophy, all the problems are located at the extreme periphery of the retina. Therefore, in case of peripheral well visualized breaks of the retina or small separations from the dentate line, but without gross pathology of the vitreous body in the form of the fixed to the retina commissures, expressed destruction of the vitreous body or hemophthalmia, the use of episcleral circular indentations at the edge periphery as close to the periphery of the rectus muscle of the eye as possible is effective. At that, it is important not to “overuse” the straining force of the silicone sponge, because the high tension decreases the front diameter of the eyeball, which can then affect the right MIOL-IRIS location in the eye.

During the post-traumatic surgery in areas of rough sclerohorioretinal scars in case of penetrating injuries, sometimes it is necessary to resort to laxative retinotomy, occasionally – to the circular retinotomy. If there is a proliferative vitreoretinopathy (PVR) of B and C degrees from the front or rear contraction, with large tears and rigid retina one can conduct the vitreoretinal surgery with the use of short-term (less than 3 months) tamponade with substitutes of the vitreous body, including with silicone oils (HD - at the lower tears, 1000-5700 cc - at the upper ones). At that, it is recommended to add surgery with episcleral buckling in case of peripheral retinal tears or detachments of the retina. Decompensation of the cornea cannot develop during 1-3 months, but it requires a very careful monitoring and timely removal of silicone oil from the eye. During this time, one shall use antihypertensive installation medications and control IOP. It is optimal to use complex medications such as Cosopt combining a beta-blocker and a carbonic anhydrase inhibitor, or joint application thereof, in case of little effect it is possible to carefully (if there is no signs of active inflammation in the eye) transfer to treatment with prostaglandins (Xalatan, Travatan). Implantation of the iris and lens diaphragm in such cases is reasonable not earlier than 6-12 months after the removal of the silicone oil.

Only in the exceptional cases, when it was not possible to succeed as a result of vitreoretinal surgery and there is a need for the long-term use of tamponing materials for the vitreous body, the combined surgery procedure using the silicone oil 5700 cc and MIOL-IRIS implantation with peripheral coloboma at 6 hours direction as a media delimiter, which prevents contact of the silicone oil with the cornea, as well as the development of secondary glaucoma and the epithelial-endothelial corneal dystrophy.
Should it be necessary during the combined surgery after treatment of the surgical site and local anesthesia one shall make the episcleral filling of retinal tears with silicone sponge, and then perform the puncture of the sclera in the projection of the ciliary body plane, set the ports 25 or 23 Ga and attach the irrigation cannula. In case of a cataract lens, it should be removed, as described above, and then one puts a temporary sealing seam on the sclera and corneal channel. MIOL-IRIS shall not be implanted immediately, due to the opacity of the haptic in order not to impair the visualization of the peripheral retina. Then, the vitrectomy is conducted to the maximum extent possible, the epiretinal membrane is removed, the retina is straightened in a liquid perfluororganic compound, and the endolasercoagulation around the retinal tear is executed. Then MIOL-IRIS is implanted in accordance with one of the previously described techniques. The peculiarity of this implantation includes the necessity to suture the diaphragm in case of absence of the capsular support at least in 3 points for the following silicone oil tamponade not to misplace MIOL-IRIS from the frontal plane. The scleral channel shall be sealed securely. Then, the optical fiber and extrusion needle are introduced to remove perfluororganic compounds (PFOC), and PFOC are replaced with the silicone oil. The operation is finalized with sealing of the scleral and conjunctival incisions. Postoperatively, the patient is given the required position face up or down depending on the type of silicone, which is removed in 1-3 months. Should such a surgery be conducted as the initial treatment of subatrophy of an eyeball or in case of unsuccessful attempts to finish the removal of the oil tamponade, the oil removal is not planned. In case of such surgery proceduries, MIOL-IRIS has not only optical and cosmetic importance, but also serves as a media delimiter in a situation with a long-term tamponade of the vitreous chamber with silicone oil. Moreover, in case of the ciliary body detachment in the situation of the eyeball subatrophy, it shall be sutured throughout the detachment before the intravitreal stage of the surgery.