Artificial iris implantation

Lead Instructor: Kevin M. Miller, MD
Co-Instructors: Iqbal Ike K. Ahmed, MD
               Samuel Masket, MD
               Francis W. Price, Jr, MD
               Kenneth J. Rosenthal, MD

Course Description

This course will provide a comprehensive overview of the devices available from Morcher, Ophtec, and HumanOptics to reduce light and glare sensitivity in congenital and acquired aniridia. It will be taught by a group of ophthalmologists who are experienced in artificial iris clinical trials. Faculty will share their experiences using iris devices including indications, availability, preoperative planning, implantation tips, and outcomes. They will discuss how ocular comorbidities influence the decision-making process. They will also discuss how the amount of iris loss, partial versus complete, influences the decision-making process. Devices to be discussed include modified capsule tension rings, iris reconstruction lenses, and foldable silicone wafers.

Course Objectives

The course will consist of a series of 10-minute lectures covering the various topics. Lectures will be supplemented by surgical video and followed by panel discussion and opportunity for audience questions and comments. The course is intended to focus on the “how to” so that participants can take the information learned back to their practices and immediately begin applying it.

Course Outline

I. Indications and contraindications for artificial iris implantation
   A. Indications (all of the following are required)
      1. Congenital or acquired aniridia
      2. Cataract, pseudophakia, or aphakia
      3. Iris defect sufficiently large to cause photophobia, glare sensitivity, contrast loss, blurred vision, or multiplopia
   B. Contraindications (any one is sufficient)
      1. Asymptomatic patient
      2. Symptoms adequately treated by tinted glasses, tinted contact lenses, or contact lenses with an artificial pupil
      3. Phakic eye without cataract (unless the patient is willing to undergo simultaneous clear lens extraction)
      4. Iris defect small enough to close with sutures
II. Preoperative evaluation

A. Comprehensive eye examination with special emphasis on identification of ocular comorbidities
   1. Common ocular comorbidities in congenital aniridia (Figure 1) include:
      a. Limbal stem cell deficiency as evidenced by corneal epitheliopathy and pannus
      b. Secondary glaucoma
      c. Zonular laxity
      d. Foveal and optic nerve hypoplasia
      e. Nystagmus
   2. Common ocular comorbidities in acquired aniridia (Figure 2) include:
      a. Multiple previous surgeries
      b. Corneal scarring or failure
      c. Prior corneal transplantation
      d. Anterior and posterior synechiae
      e. Secondary glaucoma
      f. Traumatic ectopia lentis
      g. Zonular dehiscence
      h. Capsule rupture
      i. Retinal detachment

B. If the aniridia is congenital and sporadic, additional workup of systemic comorbidities should be performed looking for:
   1. Wilms tumor
   2. WAGR complex (Wilms tumor, aniridia, genitourinary malformations, mental retardation)

C. Assessment of the operative risk to the cornea
   1. Slit lamp biomicroscope examination
   2. Corneal thickness measurement
   3. Endothelial cell count and morphology analysis

D. Determination of the appropriate device(s) to implant based on the size of the iris defect and presence of zonule or capsule support. Devices currently available are manufactured by:
   1. Morcher GmbH (Stuttgart, Germany; www.morcher.com) (Figures 3-5)
   2. Ophtec BV (Groningen, The Netherlands; www.ophtec.com) (Figure 6)
   3. HumanOptics AG (Erlangen, Germany; www.humanoptics.com) (Figure 7)

E. Determination of the most appropriate device(s) to implant based on lens status
   1. Artificial iris device(s) only (Figures 8-10)
   2. Iris reconstruction lens (Figures 11, 12)

F. Determination of the best method of device fixation
   1. Capsular bag implantation
   2. Sulcus implantation
      a. Without suture fixation (Figure 13)
      b. With suture fixation to the sclera (Figure 14)
Artificial Iris Implantation  
ESCRS Instruction Course 21  
17th September 2011

Kevin M. Miller, MD  
Course Handout

c. With suture fixation to the iris

G. Following appropriate channels for device acquisition depending on local requirements. Most devices are CE marked in Europe. The US Food and Drug Administration has not approved a single artificial iris device. In the US it is necessary to refer patients to an ongoing clinical trial (www.ClinicalTrials.gov - search term, aniridia) or obtain:
   1. FDA compassionate use exemption
   2. Local institutional review board approval

H. Patient counseling regarding the cosmetic effects of artificial iris device implantation

III. Alternatives to Artificial Iris Implantation
   A. Tinted glasses or contact lenses
   B. Artificial pupil contact lenses
   C. Suture repair of small iris defects
   D. Corneal tattooing (seldom effective)

IV. Instrumentation, anesthesia and technique
   A. Instrumentation
      1. Instruments on a cataract or anterior segment surgery tray are usually sufficient.
      2. If the implant will be fixated to the sclera or iris, appropriate gauge polypropylene (Prolene) or polytetrafluoroethylene (Gore-Tex) sutures should be available.
      3. An irrigation-aspiration or phacoemulsification unit should be available to aspirate the ophthalmic viscosurgical device (OVD).
   B. Anesthesia
      1. Standard anterior segment anesthesia techniques are employed.
      2. Since manipulation of uveal tissue if often necessary, topical anesthesia is usually contraindicated.
   C. Technique
      1. Each aniridia device has unique implantation and fixation requirements. Manufacturer guidelines should be followed.

V. Complications of artificial iris implantation, their prevention and management
   A. Intraoperative
      1. Device damage or breakage
      2. Intraoperative discovery of pathology unidentified preoperatively (e.g., insufficient zonule support, peripheral posterior synechiae, loss of capsule integrity)
      3. Difficulty with device centration or alignment
   B. Postoperative
      1. Failure to cover the iris defect fully resulting in continued light and glare sensitivity
      2. Device decentration or misalignment (Figure 15)
3. Device migration
4. Intraocular lens decentration or dislocation
5. Iris tuck (Figure 15)
6. Prolonged anterior segment inflammation
7. Suture erosion through Tenon’s capsule and conjunctiva
8. Corneal endothelial touch and decompensation
9. Secondary glaucoma
10. Hyphema and/or vitreous hemorrhage
11. All other complications routinely associated with anterior segment surgery

C. Prevention of complications
1. Preoperative planning is essential, particularly with respect to sizing and fixation
2. Intraoperative avoidance of iris tuck
3. Proper burying of sutures to avoid conjunctival erosion

D. Management of complications
1. Repositioning of misaligned or malpositioned devices
2. Prolonged corticosteroid treatment of postoperative inflammation
3. Other care as dictated by the specific complication

References

Fig 1. Eye with congenital aniridia and cataract (courtesy of Kevin M. Miller, MD)

Fig 2. Eye with partial acquired aniridia and aphakia following rupture of a penetrating keratoplasty incision (courtesy of Kevin M. Miller, MD)

Fig 3. Morcher 96F partial aniridia ring (courtesy of Morcher GmbH)
Fig 4. Morcher 50F aniridia ring (courtesy of Morcher GmbH)

Fig 5. Morcher 67B aniridia implant (courtesy of Morcher GmbH)

Fig 6. Ophtec 311 iris reconstruction lenses (courtesy of Ophtec BV)
Fig 7. Dr. Schmidt Intraocularinsen Artificial iris (courtesy of HumanOptics GmbH)

Fig 8. Implantation of the first of 2 Morcher 50D aniridia rings (courtesy of Kevin M. Miller, MD)

Fig 9. Two Morcher 96F partial aniridia rings were implanted inside the capsular bag to treat this large postoperative iris defect. (courtesy of Kevin M. Miller, MD)
Fig 10. Before and after images of a patient implanted with a HumanOptics Artificial Iris. (courtesy of Kevin M. Miller, MD)

Fig 11. This completely aniridic eye underwent IOL removal and replacement with a Morcher 67B iris reconstruction lens. (courtesy of Kevin M. Miller, MD).

Fig 12. This eye underwent piggyback implantation of an Ophtec 311 to treat a hyperopic refractive error and postoperative iris defect. (courtesy of Kevin M. Miller, MD)
Artificial Iris Implantation
ESCRS Instruction Course 21
17th September 2011

Fig 13. Capsular bag fixation of 2 Morcher 50F aniridia rings (courtesy of Kevin M. Miller, MD)

Fig 14. This eye underwent repeat penetrating keratoplasty and secondary implantation with scleral suture fixation of an Ophtec 311 iris reconstruction lens. (courtesy of Kevin M. Miller, MD).

Fig 15. Superiorly decentered Ophtec 311 iris reconstruction lens secondary to iris tuck by the inferior haptic (courtesy of Kevin M. Miller, MD).