



Artificial iris implantation in various iris defects and lens conditions

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We describe 6 surgical techniques used to implant a silicone iris prosthesis: sector-shaped iris segments that require suturing, injector-assisted sulcus fixation, injector-assisted capsular bag fixation with an intraocular lens (IOL) and capsular tension ring, folded iris tissue implanted with a forceps and sutured to the sclera with a scleral-fixated IOL, “sandwich” or “backpack” implantation with an IOL, and open-sky implantation with a perforating keratoplasty. The results of the techniques performed in 51 patients are discussed. Sector-shaped iris segments required longer surgery because of the complexity of intracameral sutures and carried risks for knots to loosen and

sutures to cut through residual iris tissue. The combined implantation of an iris and IOL proved complex and lengthy but solved lens and iris abnormalities in 1 procedure and provided long-lasting stable conditions. The procedures that implanted a complete iris in pseudophakic eyes were shorter and required smaller incisions, a sutureless approach, and injector-assisted implantation.

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Iris defects can occur for numerous reasons whether congenital or acquired from loss of tissue following blunt or penetrating trauma. In many cases, patients with iris defects experience increased light sensitivity or photophobia, glare, and cosmetic impairment. In cases of iris defects deriving from trauma, the affected eyes often have additional alterations such as corneal and scleral scars, aphakia, traumatic cataract, and retinal damage.¹ The extent of the iris defect ranges from a persistent traumatic mydriasis and partial iris loss to complete aniridia. Congenital malformations of the iris are reported to be rare,² whereas acquired iris defects can often be associated with lens alterations such as traumatic cataract or aphakia.^{3,4}

Various conservative treatments are available for iris deficiencies, including colored contact lenses,⁵ sunglasses, corneal tattooing,⁶ and basic iris prostheses and intraocular lenses (IOLs) with opaque borders.^{7–11} The reconstruction of a pupil using iris sutures remains limited to circumscribed iris defects of approximately 2 clock hours. A relatively new option for treatment is the implantation of a custom-made artificial iris (Figure 1). The model shown received Conformité Européenne marking for use in the

European Economic Area in 2011 and is currently undergoing U.S. Food and Drug Administration approval in the United States. The highly versatile implant is made of silicone and can be implanted in various ways, using a variety of techniques, even independent of IOL implantation. We describe and evaluate surgical approaches and indications for implanting an artificial iris whether dependent on or independent of IOL implantation.

SURGICAL TECHNIQUES

Six techniques of artificial iris implantation (with or without IOL implantation depending on the size and type of iris defect and lens status) are presented and the advantages and shortcomings evaluated to better understand how to achieve optimum results for the patient.

Artificial Iris

The flexible silicone artificial iris (ArtificialIris, Humanoptics AG) (Figure 2) has an overall diameter of 12.8 mm and a fixed pupil aperture of 3.35 mm. The thickness decreases from the pupillary margin (0.40 mm) to the peripheral edge (0.25 mm). The surface of the prosthesis is handcrafted individually with silicone of different colors from

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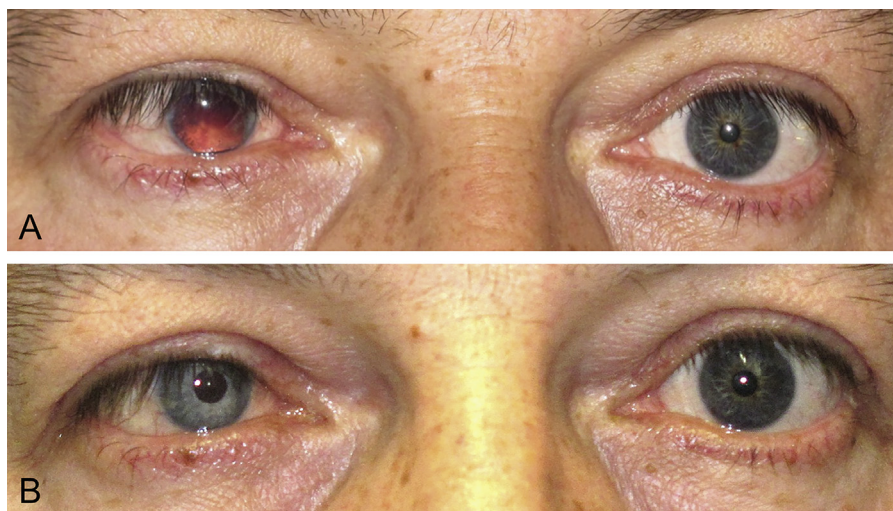


Figure 1. Preoperative (A) and 3-month postoperative (B) images after implantation of an artificial iris in the right eye of a 54-year-old patient with subtotal aniridia and aphakia after severe ocular trauma.

photographic documentation of the iris of the patient's healthy fellow eye. The back of the artificial iris consists of a smooth, opaque black silicone layer.

Basic Preparations All 6 iris implantation techniques require detailed patient information and careful planning of each iris reconstruction procedure. The following steps are recommended.

First, a high-quality true-color photographic image of the intact residual iris or the iris of the fellow eye should be acquired to enable production of each handmade artificial iris.

Second, the surgeon should choose the appropriate device depending on whether he or she plans to use sutures for iris fixation. The artificial iris can be produced with an embedded polymer fiber meshwork for transscleral use to prevent suture migration through the silicone. The artificial iris is designed for implantation in the ciliary sulcus. The patient's residual iris usually remains untreated. The new pupillary aperture could be covered or synechiae could complicate the implantation procedure. Because of the risk for cataract development, the artificial iris should be implanted in only aphakic or pseudophakic eyes.¹²

Third, the implantation procedure should be performed with a forceps or an injector system (Viscoject-Bio 2.2 Injector Set, Medcel AG) into the ciliary sulcus. The total

thickness of the IOL (0.5 to 1.0 mm), artificial iris (0.25 to 0.4 mm), and residual iris (about 0.5 mm) is less than the thickness of the natural human lens (3.5 to 5.0 mm) and therefore offers no contraindication to combined implantation. Depending on the implantation technique, the incision size should be kept to a minimum (minimum 2.8 mm, maximum 7.0 mm). Endothelial protection with extensive use of an ophthalmic viscosurgical device is important because the implant needs space to unfold.

All implants should be implanted in the ciliary sulcus or the capsular bag, not in the anterior chamber angle.

Because the required artificial iris diameter is determined in each case, the white-to-white (WTW) diameter is measured horizontally and vertically and then averaged. If necessary, the artificial iris can be trimmed with a trephine. Proper trephine size is important to ensure precise centering of the pupil postoperatively. In our 51 cases, the diameter of the implant was slightly smaller than that of the ciliary sulcus (approximately the same as the WTW distance of -0.5 mm).

Our customary approach creates 1 to several iridectomies in the implant (except in implants for the capsular bag implantation technique). Because of the soft and flexible texture of the prosthesis, a single-use trephine is recommended for concave iridectomies at the rim. Scissor-cut



Figure 2. Two views of the artificial iris. The color of the implant is custom made by the manufacturer based on the color of the fellow eye.

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