

# Artificial Iris Implants for Post Ocular Damage Reconstruction: A Comprehensive Review

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## ABSTRACT

Traumatic aniridia, the partial or complete absence of the iris resulting from ocular injury, presents a complex challenge in ophthalmology. The iris plays a crucial role in regulating light entry into the eye, reducing glare, and enhancing image quality. Significant iris loss disrupts these functions, leading to debilitating symptoms such as photophobia (light sensitivity), glare, decreased visual acuity and cosmetic disfigurement. These symptoms can severely impair a patient's daily life and overall well-being. While various management options exist, including coloured contact lenses and corneal tattooing, they often fall short in addressing both the functional and cosmetic consequences of substantial iris loss. Artificial Iris (AI) implantation has emerged as a promising surgical technique to address these issues. This procedure involves the placement of a prosthetic device to replace the missing or damaged iris tissue. There are several different kinds of Prosthetic Iris Devices (PIDs), with varying levels of technical difficulties in implant and design. These include customised AI, endocapsular tension ring-based PID, and AI-Intraocular Lens (IOL) prosthesis. The aim of this review was to analyse various iris reconstruction techniques using artificial implantation following ocular damage. In addition to giving a thorough explanation about the ocular trauma and its related issues, this review article focuses regarding the AI implantation. The various implantation methods for anterior segment repair following ocular damage are highlighted in this article. The custom-made iris implant's adaptability allows for a wide range of uses, and the material's ability to fold minimises the requirement for large incisions within the eye, which is already traumatised.

**Keywords:** Implantations, Iris reconstruction, Ocular trauma, Prosthetic eye device, Pupillary function, Visual quality

## INTRODUCTION

Ocular trauma remains a significant public health concern due to its substantial social and psychological impact on individuals and communities. It is still the leading cause of monocular blindness globally, although the specific causes of eye injuries vary depending on factors such as geographic region, population demographics, socioeconomic conditions, and age groups [1]. The natural iris regulates pupil size and the quantity of light that reaches the retina. It has two primary layers: the posterior pigmented iris epithelium as well as the anterior fibrovascular stroma. An undamaged iris diaphragm is vital for reducing glare, photophobia, and optical aberrations caused by the lens and peripheral cornea. Iris defects can be either congenital or acquired. Penetrating ocular injuries, surgical complications (such as those resulting from phacoemulsification or iridectomy), and surgical excision of intraocular tumours are also common acquired causes. The severity of iris loss may vary from small segmental abnormalities to near total or full absence. Iris anomalies, irrespective of the underlying cause, can result in substantial functional disadvantages such as impaired visual performance and cosmetic issues [2].

One eye loss is equivalent to 24% of total body impairment. This rate rises to 85% in cases with bilateral blindness. The person's everyday life and professional abilities may be impacted by vision loss even if their eyesight recovers with proper patient care and therapy from the time of damage. Common ocular trauma cases seen in the Outpatient Department (OPD) include globe rupture, penetrating eye injuries, globe rupture with total loss of the iris and lens, severe blunt trauma resulting in iris damage and lens subluxation, and penetrating injuries from hammer-and-chisel accidents that involves metallic Intraocular Foreign Bodies (IOFBs). These different presentations highlight the growing need for comprehensive trauma prevention and care measures. Open globe injuries, in particularly, have a greater risk of causing blindness. Traumatic iris abnormalities

induced by abrupt or powerful strikes to the eye can result in severe ocular discomfort and vision impairment [3].

In more complicated situations, they may be linked to other conditions like glaucoma, traumatic cataract, lens opacity or luxation, a lens capsular rupture, corneal scarring and posterior segment issues [4]. The most prevalent symptoms in aniridic individuals are photophobia, increased glare from bright light, impaired contrast sensitivity and visual acuity. These patients could also have significant discomfort due to the unsightly look of their eyes, especially if they have significant iris loss. Ocular traumas, such as lens lesions and corneal injury, can also cause posttraumatic eyes to exhibit morphological and functional changes [5]. Until complete recuperation is accomplished, these eyes frequently require many surgeries. To lessen photophobia and enhance visual acuity in situations when there is not enough iris tissue for primary restoration, an iris prosthetic device might be implanted [6]. For those damaged eyes to heal anatomically and functionally as best they can, appropriate care is essential. The most effective technique is iris reconstruction in conjunction using IOL implantation [1].

In order to alleviate painful symptoms and produce an aesthetic impact, the first step is to reconstruct the damaged iris. The integrity of the iris and pupil is restored by repositioning the ruptured or dialysed iris with a 10-0 prolene suture. For the treatment of aphakic eyes without capsular support, many IOL implantation techniques have been proposed, including angle-supported Anterior Chamber IOL (ACIOL) and transscleral sutured Posterior Chamber IOL (PCIOL) [7-9]. Every surgical procedure has certain benefits and drawbacks. The use of iris-claw IOLs in clinics has increased throughout the past three decades [10,11]. Although this IOL was first created for aphakic patients, it was later shown to be a helpful tool for correcting phakic eyes with severe myopia and eye trauma. Iris-claw IOLs are intended for use in eyes with a normal pupil or a healthy iris since the claws need support from the opposing, mid-peripheral iris [12-15].

Multiple studies have thoroughly detailed the different surgical techniques for AI implantation in cases of partial or complete aniridia. The existing literature consistently highlights favourable outcomes, demonstrating improvements in functional vision, cosmetic appearance, and overall patient satisfaction [10,12,14]. Although complications are possible, the available research data indicates that the rate of complications will decrease in an indirect relation to the surgeon's increasing expertise and learning curve [16]. The aim of the review was to analyse various AI implantation techniques done post ocular damage and their functional outcomes.

### Critical Analysis of Various Artificial Iris (AI) Implantation Techniques

The repair of the iris following ocular damage has both practical and cosmetic issues. Iris loss or severe damage not only impairs the eye's ability to control light entrance, resulting in photophobia, glare, and diminished visual acuity, but it also has a significant aesthetic impact, frequently adding to psychological stress. AI implantation has emerged as a potential treatment for individuals seeking sight rehabilitation as well as cosmetic restoration [17]. Eyes with iris abnormalities are usually difficult to repair surgically [18]. The possible challenges of device implantation and the postoperative problems profile temper the promising functional and aesthetic results provided by tailored, flexible, AI. However, the burden of postoperative problems may be positively impacted by the endocapsular manner of device installation [16].

The eyes are frequently seriously pre-damaged if iris prosthesis is required. Iris damage typically results in eye injuries that impact other areas of the eye, particularly the cornea. Visual impairment may result from this. The probability of iris deficit, comprising iris sphincter tears and iridodialysis, ranged from 0.5 to 20.0% in retrospective investigations of patients with significant trauma or traumatic injuries. Iris prosthesis insertion in traumatic eyes should be done in a way that minimises further stress (e.g., tiny corneal incisions in eyes with weak scleral tissue, or sclerocorneal incisions in eyes with weakened ones) [5].

### Prosthetic Iris Devices (PID)

There have been several technological developments in the development of PIDs since the first iris-lens plane implant was deployed in 1991 [19]. The patient's preferences and the ocular anatomy should be taken into consideration while deciding whichever PID to utilise. For iris deficiencies bigger than three clock hours, there are several PIDs available. Three primary designs may be used to classify PID:

- Devices with iris-lens diaphragms.
- Devices based on endo-capsular Capsular Tension Rings (CTR) and
- Artificial iris that can be customisable [20].

There are many different versions of PIDs, with differences in materials, sizes, implantation sites, fixation techniques, and price. Considering each patient's particular anatomical characteristics, surgeons can choose the best course of action. Important factors in selecting the right device include the degree and severity of the iris defect, the condition of the IOLs, and whether or not the capsular bag is intact. It's also critical to keep in mind that individuals may have varying degrees of anxiety about the physical look and symmetry of their second eye following surgery. To make an educated choice and give the patient the best PID, surgeons should carefully consider these anatomical as well as cosmetic considerations [2].

**a. Iris-lens diaphragm based-devices:** In 1991, Sundmacher implanted an initial posterior chamber PID. These lenses have IOL-style haptics that act as an artificial iris, a stiff iris-lens diaphragm, and an opaque annulus around the periphery. Because they are composed of Polymethylmethacrylate

(PMMA), they have a huge diameter and an extremely stiff construction. They necessitate a huge 10.5 mm limbal incision because of their size and rigidity. Iris-lens diaphragm lenses can either be sutured to the sclera via fixation loops on the lenses' haptics or passively positioned in the sulcus, depending on whether there is sufficient capsular support [2,20].

From 10 to 2 o'clock, a conjunctival peritomy is made along the superior limbus if transscleral suture fixation is the plan. For transscleral fixation, scleral flaps are placed at 2 and 8 o'clock to make the 10 mm broad superior limbal incision. The iris-lens diaphragm device is inserted within the anterior chamber once the viscoelastic has been filled, and transscleral fixation is carried out using 9-0 prolene 1.5 mm posterior towards the limbus at the surface of the sulcus. The remains of the iris should be lifted away with viscoelastic, and care should be made to implant the device in the sulcus rather than at the anterior chamber angle or anterior to the iris [21,22].

The potential of iris-lens diaphragm devices to treat both aphakia and a significant iris defect with a straightforward implant is its primary benefit. According to literature, after implantation, patients report a considerable (75-100%) decrease in glare and an increase in visual acuity. They do, however, have a number of drawbacks. They all require a big corneal incision between 8 and 11 mm for implantation because of their size and stiff substance, which causes significant induced astigmatism. The device may decentrate, migrate, or tilt as a result of implantation in a location other than the sulcus, which has been noted in 20-30% of cases [2,21,23]. This was more frequently observed in situations requiring transscleral suture fixation. Because of their size, iris-lens diaphragm devices might be difficult to rotate and manoeuvre in the anterior chamber. As a result, they carry an increased risk of intraoperative iatrogenic injury to surrounding tissues, potentially leading to complications such as corneal decompensation, uveitis, glaucoma as well as hyphaema syndrome, and further iris trauma [2].

**b. Endocapsular Capsular Tension Ring (CTR) based-devices:** Devices based on endocapsular CTRs have a CTR backbone with different segmental iris plates. These devices may be put via a 3.5 mm wound since they are significantly smaller compared to rigid iris-diaphragm devices. They are often placed in the capsule, but they can also be placed in the sulcus; nevertheless, both locations necessitate a healthy capsulorrhexis and strong capsular support. The IOL must be implanted first if endocapsular CTR devices are being utilised in combination with cataract surgery [24]. This is because if the CTR device is introduced before the IOL, it has a higher chance of rupturing the capsule because to its sharp edges. Since the opaque iris lamellae prevent the red reflex, the capsule should thereafter be dyed. According to some experts, indocyanine green is more beneficial than trypan blue since it does not lessen capsular flexibility and fluoresces in the red spectrum when viewed under an operating microscope. A possible gap between the anterior capsule and the IOL should be opened with viscoelastic prior to the device is dialled in the capsular bag [25,26].

The primary benefits of endocapsular CTR devices have been the ability to be implanted with a little corneal incision, which lessens astigmatism following surgery. Furthermore, the possibility of insertion of this device into the capsular bag has been proved to reduce post operative inflammation and the occurrence of uveitis-glaucoma-hyphaema syndrome. The primary issue with these instruments is that it can be technically difficult to align two of them correctly, and there have been complaints that these sensors can break if they are overmanipulated. The more modern 50F varieties, on the other hand, require less intraocular manipulation because

of the smaller spaces between the fins, which makes alignment simpler and quicker [2]:

**c. Customisable artificial iris:** The adjustable artificial iris implant offers a considerably better aesthetic look than iris diaphragm devices as well as an iris ring since it only contains the iris diaphragm and no centre optic. Using a snapshot of the contralateral functional iris of the other eye, the customised artificial iris is made for each patient. The lack of previous cataract surgery is the absolute contraindication for this kind of implant. It has been shown that the implant itself causes cataract development. Furthermore, if the implant is not removed initially, further cataract removal will not be possible because to the set pupil aperture size and implant location. Therefore, in order to guarantee appropriate access for any future cataract-related operations, cataract surgery needs to be carried out prior to implantation [27].

### Surgical Techniques, Outcomes in Artificial Iris Implantation and its Repair

The "sandwich technique," published by Mayer C et al., includes connecting a three-piece IOL to the posterior of the prosthetic iris implant using IOL haptics. This is a more contemporary procedure that is being employed in aphakic patients. Penetration points are indicated 1 mm from the outer rim of the iris implant at angles of 0 and 180. After puncturing the proper penetration sites in the artificial iris with a bent 30-gauge cannula, the haptics are inserted into the cannula, ensuring that the optic remains posterior to the artificial iris and the haptic ends eventually lie on top of the anterior surface [15].

Bonnet C et al., conducted a 12-month research in which patients reported subjectively decreased glare during the day (53%), glare at night (49%), daily light sensitivity (60%), and nocturnal light sensitivity (42%). Despite not being designed to improve vision, 67% of eyes increased uncorrected visual acuity following surgery, whereas 28% remained unchanged at 12 months [28]. There were a few postoperative problems, including hypotony, high intraocular pressure, implant displacement, as well as postoperative iritis. The device was used when suture fixation was required, although it had a higher chance of dislocation and needed additional surgery to reposition, exactly as the iris-lens diaphragm devices [2].

Injured irises can be repaired using a variety of techniques. The Siepser slipknot, which repairs sphincter tears, and the mattress suture, which repairs iridodialysis, are perhaps the two most common and effective techniques for iris repair. Dr. Siepser developed the Siepser slipknot method in 1994 [29]. The remarkable benefit of this technique is that it allows the knot to be knotted extraocularly by sliding two opposing sutures in a way that causes the torn iris to be little disturbed. Injured iris and iris-fixed IOLs are now sutured using this approach. A 25-gauge needle and a 10-0 prolene suture were all that were needed for the modified running mattress suture approach utilised for iridodialysis repair. The needle point can attach to the sclera by grabbing as little of the iris root as feasible, which helps to restore a pupil's natural round shape. Knots can be shielded from degradation or exposure by scleral tunnel incisions. Additionally, with just one knot remaining, a flowing mattress suture can minimise surgery time [3].

### Implant Selection

The purpose of some implants is to cosmetically alter the colour of the iris in healthy eyes. The implantation was made into the anterior chamber of phakic eyes, leading to severe side effects such as uveitis and subsequent glaucoma [30-32]. Nonetheless, certain case reports describe successful posterior chamber implantation procedures for reconstructive reasons in aphakic and pseudophakic eyes [33]. Spitzer MS et al., used composite implant (iris + IOL) to treat coexisting aphakia brought on by trauma or prior surgery.

Composite implants can be made by either haptic tucking the IOL onto the implant or suturing it to the posterior surface of the AI implant [34]. Mayer C et al., used standard sclera-fixated IOLs to rectify aphakia; several methods have been documented for this purpose, most notably the sutured IOL and intrascleral haptic fixation methods (e.g., glued IOL, Yamane technique) [15]. Doroodgar F et al., reported the implantation of an artificial iris in an eye previously fitted with an anterior chamber iris-claw lens. To minimise the risk of decentration and thereby reduce potential irritation to the residual iris tissue and ciliary body, which could result in uveitis. The researchers opted to secure the artificial iris with two additional sutures when used in combination with a sclera-fixated IOL [35].

Without capsular support, implanting an IOL in an aphakic eye is a technically challenging procedure that varies according to the patient's age, iris and pupil conditions, and the surgeon's preferences [36]. The most common surgical approach is probably suspension of a scleral or sulcus-fixated PCIOL, especially since modified new techniques have been established. The benefits of this kind of operation include a natural posture, no decompensation of corneal endothelial cells, and no pressure that might cause the pupil or iris to burst. Sulcus-fixated PCIOLs, according to Dick HB and Augustin AJ, are still the recommended treatment for aphakia in eyes without capsular support that have suffered a large loss of iris tissue due to trauma or surgery [7]. Nevertheless, transscleral fixed IOL is a laborious procedure with potential short- or long-term side-effects, such as IOL tilting or decentring, suture erosion, and IOL dislocation may happen in certain cases [37].

### Operative Approaches in Traumatic Eye Injuries

When it comes to managing aphakic conditions, an ACIOL is a more convenient and accessible choice than a PCIOL. Although an ACIOL is straightforward to implant and relies on the AC's angle for support, endothelial cell loss and pupil distortion are possible complications. Long-term ACIOL installation could not be favoured in this patient population since ocular trauma frequently affects young person [7,38].

There are benefits to haptic fixation of a folding IOL on the rear of the artificial iris in terms of knotless and sutureless transscleral fixation. The scleral-fixated IOL-iris complex is still foldable, but it is not injector-inserted. However, when necessary, the artificial iris typically provides the option to simultaneously treat cataracts or aphakia in aniridia, which significantly enhances eyesight. Additionally, a prior laboratory evaluation shown that suturing an IOL to the AI may be carried out consistently and reliably without compromising optical quality. The following serious side effects are well documented to occur with the introduction of PIDs: corneal issues, retinal detachment, chronic inflammation, and secondary glaucoma [39]. A lower endothelial cell count before to surgery is frequently the consequence of preoperative conditions following severe ocular damage, however the amount of endothelial cell loss brought on by the implantation of an artificial iris itself is little more than that following routine cataract surgery. Another risk factor for individuals with traumatised eyes is increased endothelial cell loss, which also makes reconstructive operations challenging [Table/Fig-1] [5,16,40-46].

The literature supports the efficacy of several artificial iris devices in treating traumatic aniridia [43-45]. Studies have found considerable benefits in patient-reported outcomes, including as decreased photophobia and glare, increased contrast sensitivity, and overall satisfaction with the look of the rebuilt eye. These advantages are especially evident when implants are used in conjunction with IOL insertion in aphakic or pseudophakic eyes. Custom-designed, hand-painted iris prosthesis, in particular, have produced better aesthetic results because of their ability to match the patient's native iris [16,40,41].

Despite these benefits, artificial iris implantation does not come without hazards. Complications reported included implant

Author (Year)	Study design	Sample size (procedure used)	Follow-up time duration	Main findings
Srinivasan S et al., (2007) [40]	Retrospective case series	5 eyes (4 patients) (phacoemulsification procedure with IOL implant and insertion of IRIs)	16-42 months	All eyes had improved BCVA with 6/6 vision, and reduced glare/photophobia; no complications.
Sminia ML et al., (2008) [41]	Retrospective case series	5 eyes (5 children) (Artisan® iris reconstruction IOL implantation)	Mean 8.9 years	VA improved in 2, stable in 2, declined in 1; 42% ECD loss; IOL luxation, uveitis, RD noted.
Mayer CS et al., (2018) [16]	Retrospective cohort study	51 patients (artificial iris implantation)	4 years	Complication rate dropped over years; BCVA improved in 19 eyes; 25.5% had complications.
Wang H et al., (2020) [42]	Prospective interventional study	311 coloured iris reconstruction lenses in 38 patients. Group-1 (n=8) having no corneal pathology and Group-2 (n=30) having corneal pathology. (Combined artificial iris and IOL implantation)	1-9 years	At year 3, groups 1 and 2 improved their CDVA, UDVA, and subjective visual disturbance scores. Group-2 had higher rates of adverse events, surgical complications, and subsequent procedures. Endothelial cell loss was higher in Group-2 compared to Group-1.
Mayer C et al., (2020) [5]	Retrospective observational study	59 eyes (combined Artificial Iris (AI) and Intraocular Lens (IOL) implantation)	Not stated	VA improved (0.7→0.3 logMAR); contrast/glare improved; ECD ↓ (p=0.007); high patient satisfaction.
Mayer CS et al., (2021) [43]	Case series	3 patients (bilateral, binocular iris defect) (Artificial Iris (AI) implantation)	11–14 months	CDVA improved or stable; good cosmetic results; minor manageable ECD loss and contrast change.
Krishnan VM et al., (2021) [44]	Retrospective case series	6 eyes (custom-made Artificial Iris (AI) implantation)	1 month to 4 years	BCVA improved in 4/6 eyes; complications like RD and inflammation managed; no secondary glaucoma.
Khan HM et al., (2023) [45]	Retrospective case series	5 eyes (4 patients) (HumanOptics artificial iris implantation)	Up to 94 months	CDVA improved in 2 patients stable in 1, declined in 2; IOP ↑ in 3 eyes; good cosmesis.
Riedl JC et al., (2023) [46]	Retrospective cohort study	32 patients (ArtificialIris® (AI) implantation) total aniridia in a closed globe (Group-1, n=16) and after perforating globe injury (Group-2, n=16)	Not stated	Similar complications across trauma severity; prior surgeries ↑ in Group-2; timing not critical.

**[Table/Fig-1]:** Compilation of relevant studies and their findings [5,16,40-46].

AI: ArtificialIris; CDVA: Corrected distance visual acuity; IOP: Intra-ocular pressure; BCVA: Best- corrected visual acuity; IOL: Intraocular lens; EDC: Endothelial cell density; UDVA: Uncorrected distance visual acuity; IRI: Iridectomy/iridotomy; RD: Retinal detachment

decentration, chronic inflammation, increased intraocular pressure, uveitis, endothelial cell death, and, in rare cases, implant expulsion. Surgical difficulty rises in eyes with significant damage, inadequate capsular support, or pre-existing glaucoma. As a result, good patient selection, preoperative planning, and surgeon experience are important to attaining successful outcomes [16,25].

Furthermore, alterations in surgical method, includes sulcus fixation, scleral fixation, or capsular bag implantation, must be adapted to the anatomical and pathological characteristics of each eye. The lack of standardised surgical methods across centres makes it difficult to compare outcomes and generate uniform standards [17,47]. Future research should focus on improving implant materials and designs to increase biocompatibility and minimise complication rates. Long-term multicentre trials are also required to assess durability, safety, and visual results during lengthy follow-up periods. Furthermore, the development of less invasive implantation techniques and the use of sophisticated imaging for surgical planning may increase operative success and broaden indications.

## CONCLUSION(S)

Artificial iris implantation, especially when paired with an individualised IOL, represents a significant progress in the treatment of traumatic aniridia and aphakia. Beyond cosmetic restoration, it tackles functional difficulties such as refractive error, glare, as well as photophobia, resulting in a considerable improvement in quality of life. The ability to repair both iris and lens faults in a single surgery is a critical milestone in ocular reconstruction, with many techniques allowing for patient-specific customisation. When conducted correctly and with care, evidence suggests that complications are rare. However, best results need careful patient selection, surgical competence, and adequate postoperative care. Continued innovation in implant design, method improvement, and standardised criteria will improve both safety and long-term success. Overall, artificial iris implantation is an efficient and secure treatment choice for individuals who have experienced catastrophic iris loss.

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used to compile the available English-language articles on prosthetic iris reconstruction.

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