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Artificial iris: state of the art.

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ABSTRACT

Surgical correction of traumatic aniridia aims to improve quality of vision, compartmentalize anterior and posterior chamber, re-establish a satisfying cosmetic appearance. Various types of prosthetic iris devices (PIDs) are available, that differ in technical difficulty of implant and design: artificial iris-intraocular lens (AI-IOL) prosthesis, endocapsular capsular tension ring based PID, and customized AI. The choice depends to the pre-existing clinical condition after

severe ocular trauma and on patient's functional and cosmetic expectations. This systematic review of literature compared anatomical and functional outcomes of various types of PIDs. Of 185 articles found in literature, 70 fulfilled the eligibility criteria. 5 subgroups of PIDs were: Opthech, Artificial Iris from the Ophtec, Morcher, Humanoptics and 'other prosthesis'. Both glare and aesthetic outcome improved after surgery; in comparison to other PIDs, intraocular pressure (IOP) rise incidence was higher in the Morcher group (40%), whereas prosthesis dislocation incidence was higher in the Ophtech group (39%).

INTRODUCTION

Ocular injuries are frequently associated with iris structures damage. However, iris restoration is one of the most neglected aspects of ocular traumatology. According to Canavan and Archer, 37.3% of 212 eyes with severe blunt injuries had iris or pupillary abnormalities.[1] Viestenz and Küchle, in 417 cases of ocular contusion or globe rupture, found iris sphincter tears in 20%, iridodialysis in 10 % and traumatic aniridia 1%.[2] Okamoto et al observed iridodialysis in 41.3% of 374 eyes with open globe injury.[3] Iris damages include traumatic mydriasis, traumatic iris sphincter tear, iridodialysis, iris prolapse and traumatic iritis.[4,5,6,7] Traumatic aniridia is a complete or partial absence of iris tissue, as consequence of a dialysis of the iris root and extrusion of the iris through a scleral or corneal wound. It can be secondary to a penetrating trauma or, less commonly, to blunt trauma causing an acute rise in intraocular pressure (IOP) and a rupture in the point of least resistance of the eye.[8] A distinction must be drawn with pseudoaniridia, in which the iris is rolled up and pulled posteriorly by fibrin initially and scar tissue subsequently. The presence of major iris damage is both an indicator of ciliary body trauma, that increases the risk of phtisis, and of global

eyeball involvement. Once the globe is closed and once the eventual surgeries for retinal complications are managed, ocular reconstruction becomes important to improve the quality of vision, to compartmentalize anterior and posterior chamber (AC and PC) and to re-establish a satisfying cosmetic appearance.[9] Ocular reconstruction requires intraocular lens (IOL) for treating aphakia, iris prosthesis implantation for treating aniridia and, in case of corneal opacity, corneal transplantation.

The iris plays a critical role in pupil constriction, essential in reducing excessive light entry as well as increasing depth of focus during accommodation, with an optimal sight at pupil sizes about 3 to 5 mm.[10,11] Iris damages can determine glare, photophobia and reduced vision.[12] In addition, in combination with the lens, the iris assures the separation of anterior segment into AC and PC.[13,14] Therefore, aphakia and aniridia have to be corrected by the implant of various artificial IOL and/or artificial irises (AI), forming a new iris-lens-diaphragm.[15] Last but not least, morphological iris damages such as anisocoria, heterochromia and corectopia can lead to psychological discomfort and limit the patients communication skills: an observer unconsciously analyses a facial expression in less than 200 milliseconds, and an altered eye appearance is quickly noticed as annoying.[16]

There are various methods to correct iris deficiency, including iris surgery, eyelid surgery, cosmetic coloured contact lenses, corneal tattooing, intracorneal stromal implants and finally, intraocular implants.[12,13,17,18,19] Prosthetic iris devices (PID) provide a permanent and efficient solution to traumatic aniridia and can be categorized into 3 groups: AI-IOL prosthesis, endocapsular capsular tension ring (CTR) based PID, and customized AI.[20]

Firstly, AI-IOL prosthesis: the first who reported the use of an AC lens with an optic surrounded by a colored diaphragm was Choyce in 1959.[21] Later on, in 1970, John Pearce implanted a PC iris diaphragm.[12] Sundmacher et al, in 1994, reported the use of black diaphragm IOL in eye with congenital aniridia after cataract surgery.[22] The main advantage of

using iris-lens diaphragm is the possibility to correct both aniridia and aphakia simultaneously. At the moment, iris-lens diaphragms are produced by two main companies: Ophtec BV (Groningen, The Netherlands) and Morcher GmbH (Stuttgart, Germany). Both companies propose rigid and non-foldable prostheses, with a large diameter that requires a wide sclero-corneal incision (150° - 180°), with subsequent corneal suture and postoperative astigmatism.[23] Ophtec BV produces the *Artisan® iris reconstruction implant,* available only in black colour and *Artisan® iris reconstruction IOL*, available in four homogeneous colours, both made for iris enclavation.[24,25,24,26,27,28] Other models available in four colors are the *311 aniridia IOL II*, suitable for scleral, sulcus and intracapsular fixation and the *Circular supported Disc Lens***,** for intracapsular fixation.[28,29] Morcher GmbH produces single-piece iris-diaphragm black IOL models implantable into the ciliary sulcus with or without scleral fixation or in the capsular bag, that differ in overall diameter, in dimension of the implantation incision and in pupil aperture.[22,23,30,31,32,33,34,35,36] Other models include *Aniridia IOL of ocular vision lens style ANI5 (Intra Ocular Care Pvt. Ltd)* and an elastic diaphragm made of soft PMMA material described by Pozdeyeva et al.[37,38]

Endocapsular CTR based PID are segmented prosthesis insertable via smaller incisions, without the optical portion. Morcher produces a wide range of aniridia rings, only available in black colour and susceptible to fracture.[39,40] Various iris segments are available, intended for the implantation in the capsular bag or for placement in the ciliary sulcus and for different types of iris defects.[28,31,41,42] Ophtec produces the *Iris Prosthetic System (IPS)*, available in limited homogeneous colors and designed for the capsular bag.[43,44]

With the arrival of segmented prostheses that could be inserted via smaller incisions, the implant of PID became feasible in eyes with previous trauma or disease. However, neither the postoperative cosmesis nor the pupil diameter of such smooth uniform-coloured rigid AI was optimal. The *Customflex® Artificial Iris* (Dr. Schmidt Intraocularlinsen GmbH, Humanoptics

AG) is foldable and customizable, with good physiological design and realistic cosmetic appearance. It can be fixated by scleral suture or implanted into the capsular bag, without fiber ('fiber-free'), or with an embedded polymer fiber meshwork ('with-fiber'), facilitating the suturing of the device. The main limitation of this PID is the need to perform a combined surgery to manage aphakia in the absence of capsular support; it is not intended for placement in a phakic eye.[10,45] The implantation can be combined with IOL implantation.[46,47] Mayer et al describe six implantation techniques, with or without IOL implantation depending on the size and type of iris defect and lens status.[48] Various articles report a subjective improvement of glare, that Mayer et al attribute to a considerable reduction of the pupillary aperture that blocks scattered ultraviolet rays and minimizes the total amount of light reaching the back of the eye.[46,49,50,51,52] It provides excellent aesthetics results and represents a good functional iris diaphragm for compartmentalization.[46,49,50,51,52,53] Subsequent surgeries such as descemet membrane endothelial keratoplasty (DMEK) surgery or pars plana vitrectomy (PPV) are feasible also in the presence of this PID.[54,55] *Artificial Iris* from the Ophtec company (relabelled, originally Reper), manufactured by Reper Nizhny Novgorod, distributed by Ophtec, is a foldable, highly customizable IOL iris prosthesis, that combines the advantage of the simultaneous implantation of AI and IOL with the small incision required.[56,57,58,59] It includes models designed for sulcus or capsular bag fixation, presenting five and three haptics, with or without optical effect.[56,57] It is available in 120 different colours and iris patterns. The various designs and models of PIDs are resumed in Table 1.

Aside, *cosmetic artificial iris devices* aim to change the cosmetic appearance of the eye, predominantly in third world countries, where there is limited regulatory oversight of medical device. *NewColorIris* (Kahn Medical Devices, Corp) is foldable and positioned directly above the iris.[60] Complications described in literature as consequence of the implant for cosmetic use are glaucoma, corneal decompensation, uveitis, native iris damage, central

retinal vein occlusion and cataract.[61] *BrightOcular* (Stellar Devices LLC) is also foldable and designed to be placed in the sulcus in aphakic or pseudophakic eyes, in front of the IOL and behind any iris remnants.[62]

AIM OF THE STUDY

This review aims to collect the various types of PID with or without IOL described in literature and to analyse and compare anatomical and functional outcomes.

MATERIAL AND METHODS

The strategy of the study was based on the guidelines of preferred reporting items for systematic reviews and metaanalysis.[63] PubMed (the National Library of Medicine PubMed interface, www.pubmed.gov), Google Scholar, Web of Science, Scopus were the research engines to retrieve appropriate literature. Institutional review board approval was not required.

Search methods and articles selection

In the first research phase, the following keywords were searched: "management of traumatic aniridia", "traumatic aniridia surgical treatment", "prosthetic iris", "iris prosthesis" were. In the advanced research phase, articles containing keywords referring to the different types of artificial iris such as "Morcher", "Humanoptics", "Reper artificial iris" were added. Other articles listed in the bibliography of the collected articles and considered relevant to the current research were added. All the reports collected applying all keyword combinations in the electronic searching tool were examined by two reviewers (IG, TP). If insufficient information was obtained by the title or the abstract, the full text was examined, in order to evaluate whether the inclusion criteria were met. In doubtful cases, a discussion between the two reviewers and a third reviewer (RF) was required to solve the uncertainty. Articles

published in mother language rather than English were excluded. Articles were collected until February 2022. Articles presenting clinical cases of at least one patient, retrospective or prospective, of surgical implant of an iris prosthesis after acquired partial or total aniridia were reviewed. Articles with no complete data or in which the incidence of complication or the mean pre- and postoperative BVCA of the acquired cases was not deductible neither in the text nor in the tables and box plots were excluded.

Data collection and studies categorisation

The following data were collected: author's names, journal, publication's year, type of prosthesis, number of eyes, follow up (months), preoperative and postoperative best corrected visual acuity (BCVA) converted to logarithm of minimum angle of resolution (logMAR), complication rates. The aesthetic result and glare improvement evaluated as the improvement of these parameters, in more than 50% of patients in every single study.

Complication rates included: prosthesis dislocation, prosthesis rupture, insufficient aesthetic outcome requiring replacement, posterior capsular opacification, IOP rise, hypotony, ciliochoroidal detachment, vitreous haemorrhage, hyphema, residual iris retraction syndrome (RITS), persistent anterior uveitis, endophthalmitis, irregular astigmatism, silicon oil in the anterior chamber, cystoid macular oedema (CME), development of retrocorneal membrane, endothelial cells loss, corneal endothelial decompensation requiring DMEK, penetrating keratoplasty (PK) rejection, PK dystrophy, corneal suture rupture, panuveitis with neovascularisation and neovascular glaucoma (NVG), choroidal neovascularisation (CNV), retinal detachment (RD), severe complications requiring evisceration/enucleation.

Concerning the BCVA, visual acuity line scale adapted for low vision was used. The following conversion was calculated: finger count at 1 m equal to 1.8 logMAR, perception of hand movement equal to 2.3 logMAR, light perception equal to 2.8 logMAR, no light perception equal to 3 logMAR.

The articles were divided into subgroups according to the different types of artificial iris implants in Opthech, Artificial Iris from the Ophtec (originally known as Reper artificial iris), Morcher, Humanoptics and other prosthesis, that included artificial iris implants not belonging to the previous cited categories. For the articles reporting a series of patients in which one or more of them presented characteristics not meeting the inclusion criteria of the current study, a selection of the only eligible patients from the table of published data was made and summary statistics were calculated.

Statistical analysis

Pubblication bias was assessed using funnel plots and their symmetry visually evaluated. Heterogeneity among the studies was quantified using the I2 statistic value and it was considered statistically significant when P-value<0.1 of $\chi 2$ test or I2>50%. Prosthesis effects were pooled by means of a meta-analysis using the inverse variance method, log transformation of the outcome parameter, DerSimonian-Laird estimator for tau2 and Jackson method for confidence interval of tau2 and tau, Clopper-Pearson confidence interval for individual studies. Fixed-effect model to combine data was used when statistical heterogeneity was low. When P<0.1 or I2>50%, the random-effect model was used to provide a more conservative estimate of effect. Results were reported by forest plots. Potential clinical heterogeneity was assessed by meta-regression analysis with type of prosthesis as independent (group factor) variable and adjusting for length of follow up. Glare and aesthetic outcomes were reported in each individual study dicotomically (improved or not improved). Their association with type of prosthesis was assess by means of Fisher's exact test applied to the contingency table where the number of studies was weighted with study sample size. All analyses were conducted with RStudio 4.1.2 software.

RESULTS

The literature search returned a total of 185 articles after all keywords search combinations were applied. The flow chart, represented in figure 1, depicts the study selection process for the systematic review. Seventy articles fulfilled the eligibility criteria. The defined subgroups of PIDs were 5: Opthech (15 articles), Artificial Iris from the Ophtec (4 articles), Morcher (29 articles), Humanoptics (28 articles) and "other prosthesis" (3 articles). In the articles in which more than one type of iris prosthesis was used, the single cases were evaluated in the appropriate subgroup.

For BVCA, only studies who reported more than one case were evaluated (36 studies). No statistical difference of BVCA between the different prosthesis emerged. (Figure 2.) Regarding the complications of surgery, only complications with an incidence of more than five cases were evaluated. The following complications fulfilled these criteria: IOP rise, dislocation, uveitis, CME, PK rejection, RD, corneal endothelial decompensation, vitreous haemorrhage, hyphema, hypotony. IOP rise incidence was higher in the Morcher group (40%) in comparison to Humanoptics (21%), Artificial Iris (24%), Ophtech (29%) and "other prosthesis" (28%) (p value = 0.075). Prosthesis dislocation incidence was higher in the Ophtech group (39%), in comparison to Morcher (22%), Humanoptics (15%), Artificial Iris (24%) and "other prosthesis" (20%) (p value = 0.028). However, an asymmetry of the funnel plots of complications related with the type of prosthesis (IOP rise e prosthesis dislocation) was visually noticed. Both glare and aestetic outcome improved after PID implant. The group "other prosthesis", Morcher and Ophthec group reported a statistically significant higher incidence of glare improvement if compared to Humanoptics (respectively of 100%, 80% and 89% of cases versus 66% of Humanoptics). A better aesthetic outcome was statistically significant in Morcher in comparison to Humanoptics group (96% vs 87%, p = 0.035).

DISCUSSION

The ideal PID should both provide a permanent anatomical solution to traumatic aniridia and solve the functional issues related to it. In addition, the implantation should be easy and associated to a low complication rate. No difference in BVCA improvement among the different prosthesis emerged. BCVA improvement should not be a primary goal for the implantation of an AI: an eventual increase of the BCVA after surgery may result from cataract extraction, secondary IOL implantation or reconstruction of a new pupil with resulting enhanced depth of focus.[64] The glare reduction further improves the functional outcome. Humanoptics group lead to a lower improvement of glare when compared to other PIDs. This is a relevant finding, considering that glare is one of the most disabling symptom of iris damages, with consequent photophobia and reduced vision.[12] All groups of PID reached excellent aesthetic outcomes. Interestingly, even if the Humanoptics one is customizable and has a realistic cosmetic appearance, its aesthetic outcome was found to be worse than the Morcher group. This result could be related to the different expectation of the patient in relation to a homogeneous coloured PID and a customized one, considering that the Humanoptics AI is proposed to the patient with a precise cosmetic goal.

Every PID implant has the potential risk to reduce the patients BCVA in case of complications, and patients should be aware advised prior to surgery. The most vulnerable eyes are those with pre-existing, trauma-related complications. In literature also described cases of phthisis consequent to the implantation of various types of PIDs, in which its implantation triggered decompensation of posttraumatic eyes that had been stable over a long period.[44,65,66] The implant of PIDs can lead to recurrent bleeding into the AC, IOP rise, glaucoma, prosthesis deviation or dislocation, capsular fibrosis, sutures cutting through the residual iris tissue forming a secondary pupil, corneal decompensation, formation of posterior synechiae requiring synechiolysis, CME, RD.[49,53,64] Endothelial cell loss (ECL) can follow

this type of surgery, and is strongly influenced by concomitant surgical procedures such as anterior vitrectomy, capsulotomy, or peripheral synechiae lysisis; in addition, preoperative circumstances after severe ocular trauma are often responsible for an already reduced EC count before surgery.[49,53,66] The two most significant complications among groups were IOP rise, higher in the Morcher group, and prosthesis dislocation, higher in the Ophtech group. An asymmetry of the funnel plots of complications related with the type of prosthesis (IOP rise e prosthesis dislocation) was visually noticed. Therefore, the results should be handled with caution. In literature, secondary glaucoma has hypothesised to be related to the severity of the pre-existing trauma, to the management of the viscoelastic material, and to the IOL, if not properly fixated.[33] Although, this complication seem to be common also after implantation of other PIDs: in the case of Humanoptics, postoperative increase in IOP is probably due to pressure of the edges of prosthesis on the ciliary body and/or the entrapment of aqueous behind the implant compromising the angle. It must be highlighted that pre-existing glaucoma is a frequent ocular comorbidity in posttraumatic cases.[53,62,67] Multiple peripheral trephine punches at the perimeter of the implant could overcome this problem.[68] A raised IOP can be subsequent to angle closure secondary to RITS, a late complication described after implantation of Humanoptics. It consists in a progressive enlargement of the pupil and retraction of the residual iris subsequent to the entrapment of the residual iris in the fissure between the PID and the AC angle. The scleral fixation of the prosthesis with sutures or implantation in the capsular bag (including a CTR) seems to be a safer procedure that avoids this complication.[69] Regarding PID dislocation, it can happen up to several years after the implant; in the current review the higher rate was reported in the Ophtech group, mainly in cases of *Artisan® iris reconstruction IOL* implant, which has to be iris-enclaved.[27,60] Less prone to dislocation, even if more surgical challenging, are scleral-sutured PIDs, fixed by

durable threads such as 10.0 polypropylene sutures; the sutures are recommended to be covered with scleral flaps to prevent external suture erosion.

In conclusion, surgical correction of traumatic aniridia can be achieved with various types of PIDs that differ profoundly in technical difficulty of implant and design. The choice is strictly dependent to the preexisting clinical condition of the eye after severe ocular trauma and on the patient's functional and cosmetic expectations. AI-IOL prosthesis as *Artisan® iris reconstruction implant, Artisan® iris reconstruction IOL*, *311 aniridia IOL II* and *Circular supported Disc Lens* of Ophtec BV, and the single-piece iris-diaphragm black IOL models of Morcher GmbH are a good functional solution for the treatment of aniridia and aphakia simultaneously. On the other side, endocapsular CTR based PID of Morcher GmbH and *Iris Prosthetic System (IPS)* of Ophtec BV are recommended in cases of partial or total aniridia in presence of capsular support, as designed for an implantation in the capsular bag or in the ciliary sulcus. The progressive evolution of these prostheses has permitted also to satisfy cases of a higher patient's cosmetic expectation. The construction of customizable PIDs such as *Customflex® Artificial Iris* (Dr. Schmidt Intraocularlinsen GmbH, Humanoptics AG) or the proposal of morphological patterns of more realistic iris prostheses, such as the *Artificial Iris* from the Ophtec company, the use of non-rigid materials that allow them to be inserted in smaller corneal incisions, make these more recent prostheses preferable, without any doubt, to the previous rigid and monocolour prostheses. (Figure 3.) If the first is a solution that must be combined to the management of aphakia in case of absence of capsular support, the second one has the additional advantage of the simultaneous implantation of AI and IOL. Technically, the management of aphakia and aniridia with two different implantable devices (AI and IOL) is more challenging than the implantation of a device that combines the two characteristics. Six techniques of *Customflex® Artificial Iris* implantation (with or without IOL implantation depending on the size and type of iris defect and lens status) are described

by Mayer et al.[48] In cases of smaller but not directly suturable iris defects it is possible to implant a segmental AI ('Sector- or Segment-Shaped Artificial Iris Sutured Side-by-Side to the Residual Iris' technique). In pseudophakic eyes with a stable IOL in the bag and with larger iris defects or persistent mydriasis the suggested technique is the 'Injector-Assisted Sulcus-Fixated Complete Iris in Pseudophakic Eyes'. In cases of preexisting cataract and stable capsule, the suggested technique is the 'Injector-Assisted Implantation of a Complete Iris in the Capsular Bag in Combination with Planned Standard Cataract Surgery', with the addition of a CTR in the bag. For large iris defects that lack capsule support, a nonfoldable PMMA IOL and AI have to be fixated to the sclera with the 'Complete Iris Prosthesis Implantation Sutured to the Sclera in Combination with a Scleral-Fixated Intraocular Lens in Aniridia and Aphakia of Vitrectomized Eyes' technique. An alternative is the "Sandwich" or "Backpack" Iris Prosthesis Implantation in Combination with an Intraocular Lens in Aniridia and Aphakia' technique. Finally, the 'Open-Sky Implantation During a Perforating Keratoplasty' is feasible if combined to a perforating keratoplasty.[48] Regarding *Artificial Iris* from the Ophtec company, the transscleral fixation of the haptic rings is obtained with polypropylene 10.0 sutures covered by triangular scleral flaps.[56] The surgical technique for the implantation of these last PID models is difficult to standardize and to perform by inexperienced surgeons, as it requires surgical experience for the preparation of the flaps and for the management of scleral sutures in three fixation points. It requires the additional procedure of concomitant implantation of an IOL in aphakia conditions, or the PID-IOL anchorage before its implantation.

Finally, it has to be specified that not all the prostheses reported in the review are still available and even the most recent ones are currently difficult to find. Humanoptics have recently proposed non-customizable prostheses in three colours, less expensive than customizable ones.

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TABLE AND FIGURE LEGEND

Table 1. Summary table of the various designs and models of PIDs. PID, prosthetic iris device; AI-IOL, Artificial Iris – intraocular lens; CTR, endocapsular capsular tension ring

Company	Models	Category of PID	Implantation site	Size	Incision size	Central optics	Color
Morcher (Stuttgart,Germany) [20]	Aniridia implants	AI-IOL	Capsule bag/sulcus/scleral fixation	Overall diameter: 12.5-13.5 mm Optic diameter: 3.0-6.5 mm	> 10 mm	with or without	black
	Partial aniridia implants	AI-IOL	Capsule bag/sulcus	Overall diameter: 12.5-14 mm Optic diameter: 3.5-5.0 mm	> 7.0-8.0 mm	with or without	black
	Aniridia ring	CTR based PID	Capsule bag/sulcus: all implanted within the bag except type 96C	Overall diameter: 10.0-12.5 mm Inner diameter: 3.5-6 mm	> 2.0-4.5 mm	without	black
	Partial aniridia ring	CTR based PID	Capsule bag	Overall diameter: 10.0-11.0 mm Inner diameter: 4.0-6.5 mm	> 1.8-3.5 mm	without	black
Ophtec (Groningen, the Netherlands) [20]	311 Aniridia Lens II	AI-IOL	Capsule bag/sulcus/scleral fixation	Overall diameter: 13.75 mm Optic/inner diameter: 4.0 mm		with or without	black, brown, green, blue
	Circular supported Disc Lens [28]	AI-IOL	Capsule bag			with	black, brown, green, blue
	Iris Prosthetic System (IPS)	CTR based PID	capsule bag Single (IPS SE) or double (IPS DE) occluding elements and a central locking element	Overall diameter: 10.5-11 mm Inner diameter: 3.0-4.0 mm		without	black, brown, green, blue
	Artisan® Iris Reconstruction implant	AI-IOL	Iris-clawed	Overall diameter: 9.0 mm Inner diameter: 3.5 mm	Wide sclerocorneal incision 150°-180°	with	black
	Artisan® Iris Reconstruction IOL[70]	AI-IOL	Iris-clawed	Overall diameter: 10.0 mm Inner diameter: 4.0 mm	Wide sclerocorneal incision 150°-180°	with	black, brown, green, blue
	Artificial Iris (originally Reper), manufactured by Reper Nizhny Novgorod [57]	AI-IOL	Capsule bag/sulcus/scleral fixation	Overall diameter: 10.0-13.5 mm; optic/inner diameter: 3.5 mm	>3.5-4 mm foldable	with or without	120 different colors and iris patterns
De. Schmidt Intraocularlinsen GmbH (Humanoptics AG) [20]	Customflex® Artificial Iris	customized AI	Sulcus/scleral fixation; with or without polyester mesh for suture and sutureless fixation, respectively	Overall diameter: 12.8 mm inner diameter: 3.35 mm	>2.5-4.0 mm foldable	without	customizable

Figure 1. Flow chart shows detailed information on the articles screened, assessed for eligibility, and excluded or included for review. Seventy articles were divided on the basis of the type of prosthetic iris device (PID) into five subgroups.

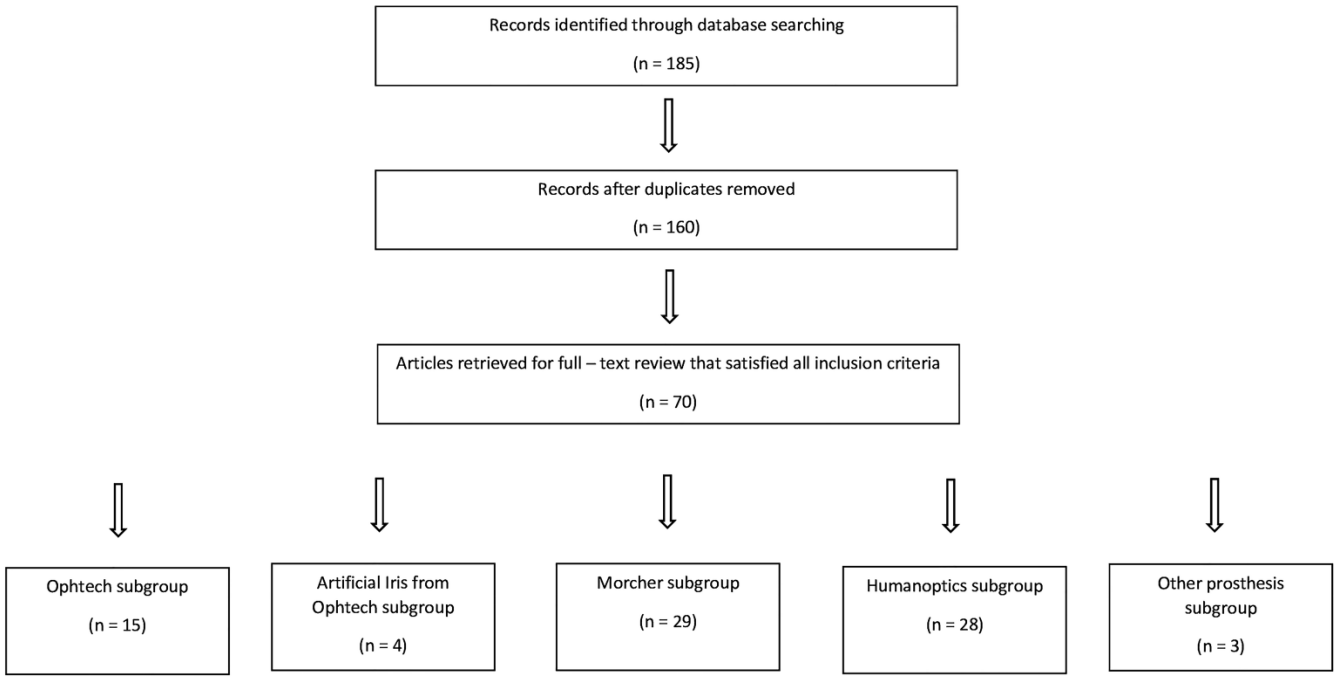

Figure 2. Forest plot of best corrected visual acuity (BVCA) outcomes in the different studies.

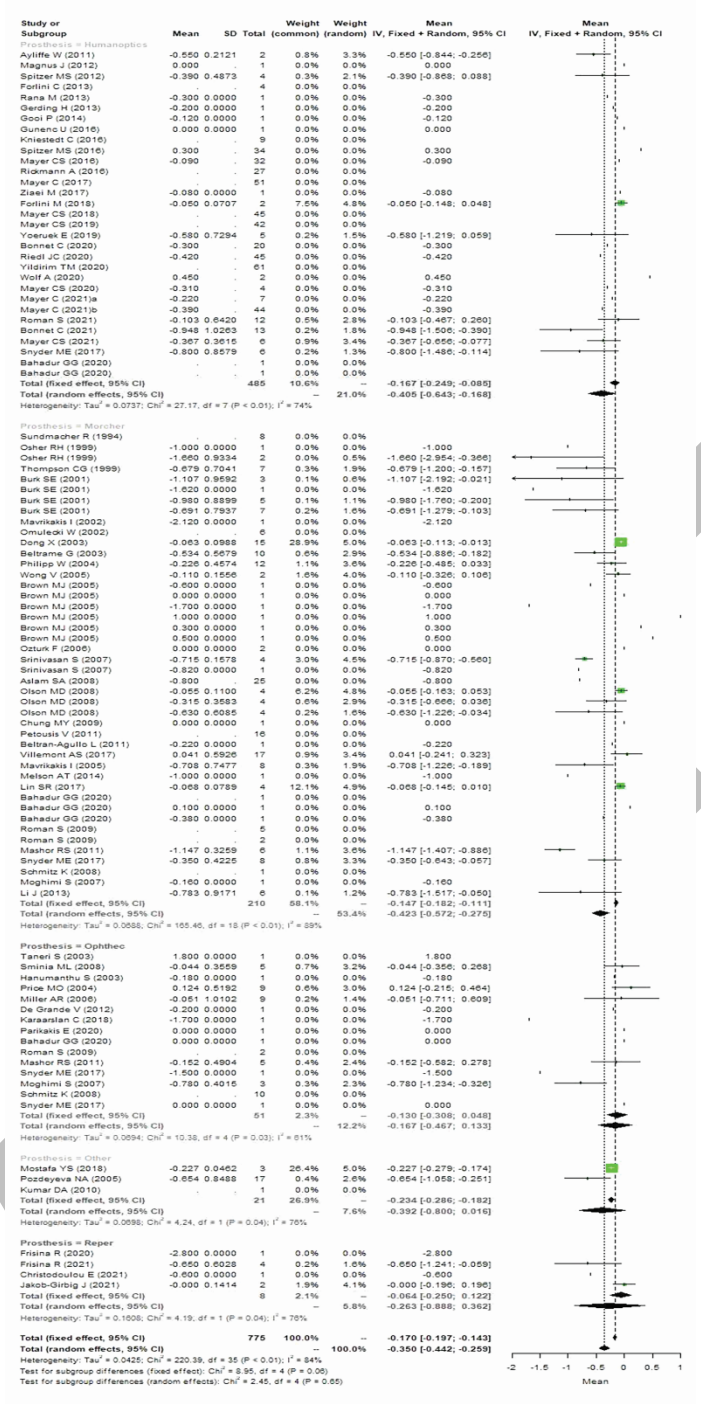

Figure 3.

a) 311 Aniridia Implant by Ophtec BV in the right eye.

b) Customflex® Artificial Iris by Dr. Schmidt Intraocularlinsen GmbH, Humanoptics AG in the left eye.

c) Artificial Iris (relabelled, originally Reper) manufactured by Reper Nizhny Novgorod, distributed by Ophtec in the left eye.