Int Ophthalmol (2024) 44:371
https://doi.org/10.1007/s10792-024-03282-8

ORIGINAL PAPER

Clinical outcomes and complications of a new high-density polyethylene-based spherical integrated porous orbital implant

Antonio M. Garrido-Hermosilla · María Concepción Concepción Díaz-Ruiz · Javier Avilés-Prieto · Sandra Domínguez-Llamas · Isabel Romero-Barranca · José Antonio Aguiar-Caro · Francisco Espejo-Arjona · María Isabel Relimpio-López

Received: 11 April 2024 / Accepted: 17 August 2024

Abstract

Purpose To describe our experience over 6 years using a new high-density polyethylene-based spherical integrated porous orbital implants (Oculfit).

Methods This is an observational retrospective case series study analyzing all cases requiring Oculfit implants between February 2015 and September 2021. Clinical information regarding the population included, the characteristics of the implant, and the outcomes and complications during the follow-up were noted. The success of the implant was defined according to anatomical and functional parameters.

Results The study analyzed 90 cases of anophthalmic patients. The main causes for enucleation or evisceration were ocular decompensations (36.7%) and neoplasms (27.8% uveal melanoma and 7.8% retinoblastoma). Anatomical success was identified in 63 (70.0%) cases, functional success in 79 (87.8%) and complete success (anatomical + functional) in 61 (67.7%) cases. Factors associated with the functional success were age and exposure of the primary orbital implant. Complications appeared in 11 (12.2%) cases, which were completely resolved without sequelae in 4 (4.4%). Orbital explant was required in 5 (5.6%) cases.

Conclusion In our experience, Oculfit can be considered a useful alternative among the currently available options for orbital implants and has a good efficacy/safety profile.

Keywords Orbital implants · Oculfit · Enucleation · Evisceration

Introduction

In recent years, various types of porous orbital implants have been used in anophthalmic patients to improve prosthetic motility, thus achieving a better cosmetic effect and a more natural appearance [1]. Currently, high-density polyethylene spherical implants such as the MEDPOR (Porex Surgical, Inc., Fairburn, GA, USA) are commonly used in cases of evisceration or enucleation [2, 3]. These implants have been used successfully due to their significant biointegration [4].

However, the use of hydroxyapatite implants is accompanied by certain complications, including implant exposure, blepharoptosis, ocular discharge, implant infection or extrusion, conjunctival contracture or dehiscence, and ectropion [5].

A. M. Garrido-Hermosilla (✉) · M. C. Díaz-Ruiz · J. Avilés-Prieto · S. Domínguez-Llamas · I. Romero-Barranca · J. A. Aguiar-Caro · F. Espejo-Arjona · M. I. Relimpio-López
Department of Ophthalmology, Virgen Macarena University Hospital, Seville, Spain
e-mail: drgarridopublicaciones@gmail.com

A. M. Garrido-Hermosilla · F. Espejo-Arjona · M. I. Relimpio-López
Retics OftaRed, Institute of Health Carlos III, Madrid, Spain

Published online: 06 September 2024

Several innovations have been carried out in these implants with the aim of trying to reduce complications and improve tolerance, including changes to the implant surface to help minimize implant exposure or cone-shaped implants. Despite these initiatives, hydroxyapatite implant exposure rates are still high, up to 34%, and implant removal is necessary in up to 29% of patients [6–8].

Due to the abovementioned limitations, new materials and implant-shape designs are currently being investigated. More recently, the safety and biocompatibility of a new high-density polyethylene-based spherical integrated porous orbital implant (Fig. 1), OCULFIT (AJL Ophthalmic S.A., Vitoria, Spain), was tested in an experimental design with rabbits [9].

The results of this initial study indicated that the ophthalmic tolerance and biocompatibility of this new implant in rabbits were comparable to the clinically used MEDPOR. Therefore, Oculfit implants open a new opportunity to induce integration with the recipient's tissues. Unfortunately, to date, there are no published experiences about the use of Oculfit implants in a real-world setting, and studies are needed to determine the performance of Oculfit in clinical practice. Our group has been using Oculfit since 2015. The present report aims to describe our experience with Oculfit implants, and comment on their tolerability and complications. Our results will help to understand the effects of this orbital implant and contribute to pooling clinical experience that will help ophthalmologists weigh up the various options in clinical decision-making.

Subjects/materials and methods

This is an observational retrospective case series study in which we included all the cases requiring an orbital implant treated with Oculfit between February 2015 and September 2021. All cases with an Oculfit implant were included in the analysis, and there were no exclusion criteria. To evaluate the complications after implant placement, patients were followed up over time, until death or loss to follow-up. The date of the last available visit was noted, and clinical information was retrieved between both dates (intervention and last visit). Vital status was confirmed until February 17, 2022, which was taken as the current date.

For the present analysis, descriptive data were collected on the sample, including gender, age, symptoms, primary cause for evisceration or enucleation, conjunctival-tenon status, previous eye interventions including ophthalmic brachytherapy and time elapsed between the indication of evisceration or enucleation and the Oculfit implantation. The conjunctiva-tenon status was categorized as optimal and suboptimal. The optimal situation of the conjunctive-tenon were eyes that had not undergone surgical interventions or treatments that could affect the state of the conjunctiva-tenon, such as chemotherapy or chronic antiglaucoma, in the sense of increasing fibrosis and hindering post-surgical healing. Symptoms appearing in only one or two cases were grouped in the category of "other symptoms". The concept of ocular decompensation included situations such as corneal decompensation, secondary glaucoma, blind painful or non-painful eyes after trauma, blind painful eyes after end-stage glaucoma, disfigured eyes, etc., as well as other ocular decompensations.

The data recorded related to the implant were whether it was implanted with or without absorbable synthetic suture mesh, the diameter of the implant and whether a primary coating was used. In cases with an ophthalmic neoplasm, previous systemic chemotherapy, base size and height in mm, tumor type and local extension were collected. During the follow-up, all the complications that appeared were registered, as well as the surgical interventions required for their

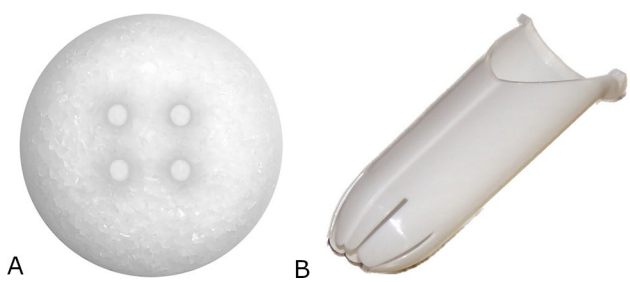

Fig. 1 Images of the Oculfit system. **A** Oculfit implant; **B** Oculfit injector

treatment, if necessary. The serial number of the orbital implant was also registered.

The final outcome of the Oculfit implantation was evaluated in anatomical and functional terms. The anatomical evaluation was carried out using the ophthalmologist's subjective evaluation, which included the aesthetic appearance with the external prosthesis (classified as good, fair, or bad), orbital volume with the external prosthesis as compared to the remaining eye (classified as symmetric or asymmetric), depression of the upper palpebral sulcus (classified as mild, moderate or severe), palpebral fissure compared to the remaining eye (classified as symmetric or asymmetric), lower palpebral laxity compared to the remaining eye (classified as symmetric or asymmetric), and fornixes (classified as wide or shortened). Anatomical success was defined as those cases presenting all of the following: aesthetic appearance with external prosthesis good or fair + orbital volume with external prosthesis similar to the remaining eye + slight or moderate depression of the upper palpebral sulcus + palpebral fissure similar to the remaining eye + lower palpebral laxity similar to the remaining eye + wide fornices.

Functional evaluation was also performed using the ophthalmologist's subjective evaluation, and included external prosthesis and orbital implant motility, both classified as none, limited or complete. Functional success was defined as those cases presenting complete external prosthesis motility and/or complete orbital implant motility.

Surgical technique

Enucleation was conducted in the standard manner: 360° peritomy, followed by intermuscular dissection, presuturing and sectioning of the rectus muscles (oblique muscles without presuturing), and sectioning of the optic nerve. The injector was used to insert the implant into the anophthalmic socket (Fig. 1). Then, the muscles were sutured with absorbable Vicryl 6-0 using the holes and tunnels on the anterior surface. Some cases required an absorbable Vicryl mesh to cover the implant and suture the muscles to it. Afterwards, the conjunctiva-tenon was closed in separate layers with Vicryl 6-0 and Vicryl 7-0. Evisceration was performed using the four-petal evisceration technique [10].

Ethics

This study followed the recommendations of the Declaration of Helsinki by the World Medical Association for studies with human beings. The treatments performed were selected to best meet each patient's needs. The present work retrospectively reflects routine clinical practice, the material had been previously approved for this use and did not have an ad hoc experimental design. As part of our routine clinical practice, the patients signed an informed consent form prior to each of the procedures described. The patients' personal data were kept strictly confidential and only the clinicians involved in treating the patient were given access to them. No personal data that allowed the patient to be identified were stored on the database.

The study was approved by our Institutional Review Board (Comité de Ética e Investigación Clínica, Hospital Universitario Virgen Macarena, approval acta CEI VM-VR_03/2021).

Statistical analysis

As this was a descriptive analysis, we included the univariate descriptive statistics of the patient's baseline characteristics and the characteristics of the clinical results, as well as intraoperative and follow-up complications. The qualitative variables are shown with the absolute and relative frequencies observed for the categories and refer to the total number of patients, unless otherwise specified. Continuous variables are described as mean and standard deviation (SD).

Comparisons between anatomical and functional success groups were made using the chi-squared test (or Fisher exact test) for categorical variables. Continuous variables were compared using unpaired Student's t-test, after assessing the normality of the variables with the Kolmogorov-Smirnoff test and homoscedasticity with the Levene test. Statistical significance was set at 0.05.

Significant and clinically relevant variables were entered into a backward binomial multivariate logistic regression analysis to identify factors associated with the success of the implant. We aimed to perform three regression analyses, one for variables associated with anatomical success, one for functional success and one for both anatomical and functional success as the

dependent variables. For each model, the relationship between the explanatory variables and the dependent variable was reflected as an odds ratio with 95% confidence intervals. The model fit was expressed as the coefficient of determination (R^2), as well as the percentage of classification. The goodness of fit was estimated using the Homer-Lemeshow test.

Results

During the study period, 90 cases were included. The description of these cases is summarized in Table 1. It was a predominantly male cohort for both pediatric (males 72.7%) and adult (males 62.0%) groups. The ages of the pediatric population ranged from 0 to 6 years. Cases in the adult population ranged from 23 to 90 years of age. Mean follow-up was 21.6 ± 16.1 months (median 20 months).

The other symptoms category included photophobia of the remaining eye, leukocoria, aesthetic alteration, periocular edema, bleeding, phosphenes, lesions of the iris, palpebral violaceous lesion, and secretions. Only one case presented with none of any of these symptoms. Previous ocular interventions included phacoemulsification, eye trauma, cataracts, vitrectomy, brachytherapy, glaucoma, and keratoplasty. The sample was composed of 32 confirmed eye neoplasms, 3 of them with metastases, two hepatic and one pulmonary, with an onset time of 21.5 (13.2) months. Scleral infiltration was identified in 16 cases (50.0% of neoplasms), which in 8 cases (25.0% of neoplasms) extended to the ciliary body. The extent of optic nerve resection was 8.8 (standard deviation 5.8) mm. All cases with exposure of an old primary orbital implant were due to a retinoblastoma. The majority of the implants were 20 mm (37; 41.1%), 21 mm (24; 26.7%) or 22 mm (13; 14.4%) in diameter. Mean diameter was 20.13 ± 1.53 mm (median 20 mm). The primary coatings used were abdominal dermal fat grafting (9; 10.0%), gluteal dermal fat grafting (2; 2.2%), and full globe donor sclera (1; 1.1%).

Anatomical and functional success

The results of the implant outcomes in the different variables recorded are summarized in Table 2.

Altogether, anatomical success was identified in 63 (70.0%) cases. The differences with those cases without this success are also summarized in Table 1. None of the explored variables were associated with this anatomical success. Functional success was achieved in 79 (87.8%). The associations with this functional success are summarized in Table 3. Cases with functional success were significantly older, with ocular decompensation and retinoblastomas as less frequent causes, and with some differences in the surgical technique or orbital implant. Complete success (anatomical + functional) was achieved in 61 (67.7%) cases. The description of cases with complete success (anatomical and functional) are summarized in Table 4. None of the variables explored were associated with this complete success.

Since none of the variables explored were associated with complete or anatomical success, a multivariate approach was not possible for these outcomes. The results of the multivariate analysis were therefore only produced for functional success, as shown in Table 5.

In this model, the classification percentage was 93.1%, with an R^2 of 0.41, and the Homer–Lemeshow test showed a p value of 0.384.

Complications

Eleven cases (12.2%) required some intervention due to pre-surgery conditions or complications after surgery (Table 6).

The first complications occurred 10.9 (SD: 13.4) months after implanting and consisted of 5 cases with exposure of the orbital implant, one conjunctival dehiscence (which ended up in exposure of the orbital implant), 2 cases of conjunctival granulomas and one aponeurotic ptosis with good upper lid levator function. There was ptosis in two cases, but this had existed prior to implanting and therefore was not related to the implant. In 5 (45.4%) cases, there was a complete recovery without sequelae.

Oculfit sphere explant was performed in four cases (4.4%). In one case of orbital implant exposure, an explant of the sphere was performed due to infection by *Aeromonas hydrophilia* and *Candida parapsilosis* and it was replaced with a bioceramic secondary implant of the same size along with abdominal dermal fat grafting. In the other three cases, the sphere was explanted, and an abdominal dermal fat grafting

Table 1 Descriptive data of sample according to anatomical success

Variable	Total sample (n = 89)	No anatomical success (n = 26)	Anatomical success (n = 63)	*P* value*
Descriptive data				
Gender (males)	56 (62.9)	15 (57.7)	41 (65.1)	0.512
Age (years)	53.4 (25.1)	51.0 (27.0)	53.7 (24.1)	0.646
Pediatric cases (n)	11 (12.2)	5 (19.2)	6 (9.5)	0.287
Intraocular pressure (n)				
Not available	15 (16.9)	7 (26.9)	8 (12.7)	0.336
Decreased (< 10 mmHg)	25 (28.1)	5 (19.2)	20 (31.7)	
Normal (10–21 mmHg)	30 (33.7)	8 (30.8)	22 (34.9)	
Increased (> 21 mmHg)	19 (21.3)	6 (23.1)	13 (20.6)	
Pre-implant symptoms (n)				
Pain	59 (66.3)	17 (65.4)	42 (66.7)	0.907
Loss of vision	18 (20.2)	3 (11.5)	15 (23.8)	0.190
Redness	10 (11.1)	3 (11.5)	6 (9.5)	0.717
Leukocoria	8 (9.0)	4 (15.4)	4 (6.3)	0.175
Other symptoms	8 (9.0)	3 (11.5)	5 (7.9)	0.589
Conjunctiva-tenon status (optimal)	44 (49.4)	11 (42.3)	33 (52.4)	0.387
Previous ocular interventions	64 (71.9)	19 (73.1)	45 (71.4)	0.875
Pre-intervention visual acuity	0.04 (0.1)	0.05 (0.15)	0.04 (0.1)	0.670
Main cause (n)				
Ocular decompensation	32 (36.0)	7 (26.9)	25 (39.7)	0.254
Neoplasm	32 (36.0)	10 (38.5)	22 (34.9)	0.752
Suspected uveal melanoma	25 (28.1)	6 (23.1)	19 (30.2)	0.499
Suspected retinoblastoma	7 (7.9)	4 (15.4)	3 (4.8)	0.090
Phthisis bulbi	16 (18.0)	6 (23.1)	10 (15.9)	0.544
Exposure of old primary orbital implant	3 (3.4)	2 (7.7)	1 (1.6)	0.203
Trauma	2 (2.2)	0 (0.0)	2 (3.2)	0.999
Endophthalmitis	2 (2.2)	0 (0.0)	2 (3.2)	0.999
Microphthalmia with orbital cyst	1 (1.1)	0 (0.0)	1 (1.6)	0.999
Neuropathy	1 (1.1)	1 (3.8)	0 (0.0)	0.292
Intervention data				
Operated eye (right)	36 (40.0)	11 (42.3)	25 (39.7)	0.819
Time elapsed from indication to intervention (months)	2.3 (3.7)	3.3 (4.5)	1.9 (3.3)	0.153
Type of intervention (n) Enucleation Evisceration	36 (40.4) 53 (59.6) 13 (50.0)	13 (50.0) 13 (50.0)	23 (36.5) 40 (63.5)	0.238
Type of material (n): Porous polyethylene implant (Oculfit) Porous polyethylene implant + absorbable synthetic suture mesh	54 (60.7) 35 (39.3)	14 (53.8) 12 (46.2)	40 (63.5) 23 (36.5)	0.397
Diameter of implants: 14–20 mm 21–22 mm	52 (58.4) 37 (41.6)	17 (65.4) 9 (34.6)	35 (55.6) 28 (44.4)	0.392
Primary coating	12 (13.3)	4 (15.4)	8 (12.7)	0.736

Results expressed as mean (standard deviation) or as absolute (relative) frequencies according to nature of variable. Percentages referred to total number of cases in each column

*Calculated by chi-squared of unpaired Student's *t* tests according to nature of variable

Table 2 Anatomical and functional results of prostheses

Variable	Results [N (%)]
Anatomical success	
Aesthetic appearance with external prosthesis †	50 (55.6)
Good	15 (16.7)
Fair	6 (6.7)
Bad	19 (21.1)
Not recorded in medical history	
Orbital volume with external prosthesis †	54 (60.0)
Symmetric	14 (15.6)
Asymmetric	22 (24.4)
Not recorded in medical history	
Depression of the upper palpebral sulcus †	48 (53.3)
Mild	12 (13.3)
Moderate	3 (3.3)
Severe	27 (30.0)
Not recorded in medical history	
Palpebral fissure †	52 (57.8)
Symmetric	13 (14.4)
Asymmetric	25 (27.8)
Not recorded in medical history	
Lower palpebral laxity †	80 (88.9)
Symmetric	9 (10.0)
Asymmetric	1 (1.1)
Not recorded in medical history	
Fornices †	87 (96.7)
Wide	2 (2.2)
Shortened	1 (1.1)
Not recorded in medical history	
Functional success	
External prosthesis motility †	10 (11.1)
Limited	68 (75.6)
Total	12 (13.3)
Not recorded in medical history	
Orbital implant motility †	8 (8.9)
Limited	79 (87.8)
Total	3 (3.3)
Not recorded in medical history	

†Evaluated subjectively by ophthalmologist performing follow-up visit

was performed. The three cases in which an Oculfit implant was indicated due to exposure of a previous implant went well, with no major complications, except for the appearance of two conjunctival granulomas in one case which were resolved by simple excision. By the end of the follow-up, 6 cases had died, 4 of them due to advanced neoplastic disease, one due to advanced chronic renal insufficiency and one due to a stroke.

Discussion

This paper reports our clinical experience in the use of porous ocular implants over 6 years. The results show that the use of Oculfit as an orbital implant achieves good results in most cases, with a low proportion of complications, which are usually resolved without sequelae. Interestingly, age and a previous orbital explant are factors associated with a poor functional outcome.

Since the first porous coralline hydroxyapatite orbital implant was introduced [11, 12], different materials have been used for orbital implants [12]. High-density polyethylene spherical implants are formed thanks to the polymerization of the ethylene molecules under high temperature and pressure. The inclusion of a net of interconnector porous enabled the direct suturing of the extraocular muscles without wrapping the implant. Moreover, the presence of pores allows fibrovascular ingrowth, which reduces the risk of orbital implant migration, extrusion, and exposure, and minimizes the rate of infection. Based on this design, the OCULFIT orbital implant was released offering a slightly different design to address the requirements that were gathered from different experts who have been using the MEDPOR implant.

Of note, currently, there is no consistent evidence suggesting a net benefit in porous vs non-porous implants. The advantages of porous implants mainly rely on their porous intrinsic nature: enhanced fibrovascular integration, theoretically reducing the risk of migration and extrusion, improved stability thanks to the ingrowth of tissue into the porous structure, or ease of muscle attachment. Additionally, the differences between porous and non-porous implants are evident in cases where the porous implant is pegged, in which better motility is achieved. The decision about the type of implant is currently based on the characteristics of the condition causing the ocular damage, the clinical history and age of the patients, and the experience and judgment of the surgeon [13]. The anterior smooth surface of Oculfit is intended to reduce the rate of exposure due to the friction of the roughened surface with the overlying tissues and a densely porous posterior surface that facilitates integration and minimizes the risk of long-term anterior migration/extrusion of the implant. This implant has been tested in rabbits, showing ophthalmic tolerance and biocompatibility [9]. Here, we present the first

Table 3 Descriptive data of sample and interventions according to functional success

Variable	Total sample (n = 87)	No functional success (n = 8)	Functional success (n = 79)	*P* value
Descriptive data				
Gender (males)	57 (65.5)	5 (62.5)	49 (62.0)	0.999
Age (years)	53.4 (25.1)	22.6 (28.8)	55.7 (22.7)	0.005*
Pediatric cases (n)	11 (12.6)	5 (62.5)	6 (7.6)	< 0.001*
Intraocular pressure (n)	15 (17.2)	7 (87.5)	8 (10.1)	< 0.001*
Not available	25 (28.7)	0 (0.0)	25 (31.6)	
Decreased (< 10 mmHg)	29 (33.3)	0 (0.0)	29 (36.7)	
Normal (10–21 mmHg)	18 (20.7)	1 (12.5)	17 (21.5)	
Increased (> 21 mmHg)				
Pre-implant symptoms (n):	59 (67.8)	17 (65.4)	42 (66.7)	0.907
Pain	18 (20.7)	3 (11.5)	15 (23.8)	0.190
Loss of vision	9 (10.3)	3 (11.5)	6 (9.5)	0.717
Redness	8 (9.2)	4 (15.4)	4 (6.3)	0.225
Leukocoria	8 (9.2)	3 (11.5)	5 (7.9)	0.687
Other symptoms				
Conjunctiva-tenon status (optimal)	43 (49.4)	4 (50.0)	39 (49.4)	0.999
Previous ocular interventions	62 (71.3)	4 (50.0)	58 (73.4)	0.219
Pre-intervention visual acuity	0.04 (0.1)	0.08 (0.2)	0.04 (0.15)	0.720
Main cause (n)				
Ocular decompensation	32 (36.8)	0 (0.0)	32 (40.5)	0.024
Neoplasms	30 (34.5)	5 (62.5)	25 (31.6)	0.118
Suspected uveal melanoma	23 (26.4)	1 (12.5)	22 (27.8)	0.675
Suspected retinoblastoma	7 (8.0)	4 (50.0)	3 (3.8)	< 0.001*
Phthisis bulbi	16 (18.4)	1 (12.5)	15 (19.0)	0.999
Exposure of old primary orbital implant	3 (3.4)	2 (25.0)	1 (1.3)	0.021*
Trauma	2 (2.3)	0 (0.0)	2 (2.5)	0.999
Endophthalmitis	2 (2.3)	0 (0.0)	2 (2.5)	0.999
Microphthalmia with orbital cyst	1 (1.1)	0 (0.0)	1 (1.3)	0.999
Neuropathy	1 (1.1)	0 (0.0)	1 (1.3)	0.999
Intervention data				
Operated eye (right)	34 (39.1)	5 (62.5)	29 (36.7)	0.253
Time elapsed from indication to intervention (months)	2.3 (3.7)	1.3 (2.2)	2.5 (3.9)	0.480
Type of intervention (n)	34 (39.1)	7 (87.5)	27 (34.2)	0.005*
Enucleation	53 (60.9)	1 (12.5)	52 (65.8)	
Evisceration				
Type of material (n)	54 (62.1)	1 (12.5)	53 (67.1)	0.004*
Porous polyethylene implant (Oculfit)	33 (37.9)	7 (87.5)	26 (32.9)	
Porous polyethylene implant + absorbable synthetic suture mesh				
Diameter of implants	51 (58.6)	8 (100.0)	43 (54.4)	0.019*
14–20 mm	36 (41.4)	0 (0.0)	36 (45.6)	
21–22 mm				
Primary coating	12 (13.3)	3 (37.5)	9 (11.4)	0.076

Results expressed as mean (standard deviation) or as absolute (relative) frequencies according to nature of variable. Percentages refer to total number of cases in each column. Statistics calculated by chi-squared of unpaired Student's t tests according to nature of variable

*Statistical significance

Table 4 Descriptive data of sample and interventions according to complete (anatomical + functional) success

Variable	Total sample (n = 87)	No complete success (n = 26)	Complete success (n = 61)	*P* value
Descriptive data				
Gender (males)	54 (62.1)	15 (57.7)	39 (63.9)	0.583
Age (years)	53.4 (25.1)	51.0 (27.0)	53.3 (24.4)	0.349
Pediatric cases (n)	11 (12.2)	5 (19.2)	6 (6.8)	0.227
Intraocular pressure (n)	15 (17.2)	7 (26.9)	8 (13.1)	0.340
Not available	25 (28.7)	5 (19.2)	20 (32.8)	
Decreased (< 10 mmHg)	29 (33.3)	8 (30.8)	21 (34.4)	
Normal (10–21 mmHg)	18 (20.7)	6 (23.1)	12 (19.7)	
Increased (> 21 mmHg)				
Pre-implant symptoms (n)	58 (66.7)	17 (65.4)	41 (67.2)	0.868
Pain	17 (19.5)	3 (11.5)	14 (23.0)	0.219
Loss of vision	9 (10.3)	3 (11.5)	6 (9.8)	0.811
Redness	8 (8.8)	4 (15.4)	4 (6.6)	0.192
Leukocoria	7 (7.7)	3 (11.5)	4 (6.6)	0.434
Other symptoms				
Conjunctiva-tenon status (optimal)	44 (50.6)	11 (42.3)	33 (54.1)	0.314
Previous ocular interventions	62 (71.3)	19 (73.1)	43 (70.5)	0.807
Pre-intervention visual acuity	0.04 (0.1)	0.05 (0.15)	0.04 (0.14)	0.350
Main cause (n)				
Ocular decompensation	32 (36.8)	7 (26.9)	25 (41.0)	0.213
Neoplasms	30 (34.5)	10 (38.5)	20 (32.8)	0.610
Suspected uveal melanoma	23 (26.4)	6 (23.1)	17 (27.9)	0.643
Suspected retinoblastoma	7 (7.8)	4 (15.4)	3 (4.9)	0.100
Phthisis bulbi	16 (17.8)	6 (23.1)	10 (16.4)	0.461
Exposure of old primary orbital implant	3 (3.3)	2 (7.7)	1 (1.6)	0.157
Trauma	2 (2.2)	0 (0.0)	2 (3.3)	0.350
Endophthalmitis	2 (2.2)	0 (0.0)	2 (3.3)	0.350
Microphthalmia with orbital cyst	1 (1.1)	0 (0.0)	1 (1.6)	0.511
Neuropathy	1 (1.1)	1 (3.8)	0 (0.0)	0.123
Intervention data				
Operated eye (right)	34 (49.1)	11 (42.3)	23 (37.7)	0.687
Time elapsed from indication to intervention (months)	2.3 (3.7)	3.3 (4.5)	1.2 (3.4)	0.168
Type of intervention (n)	34 (49.1)	13 (50.0)	21 (34.4)	0.173
Enucleation	53 (60.9)	13 (50.0)	40 (65.6)	
Evisceration				
Type of material (n):	54 (62.1)	14 (53.8)	40 (65.6)	0.302
Porous polyethylene implant (Oculfit)	33 (37.9)	12 (46.2)	21 (34.4)	
Porous polyethylene implant + absorbable synthetic suture mesh				
Diameter of implants	51 (58.6)	17 (65.4)	34 (55.7)	0.403
14–20 mm	36 (41.4)	9 (34.6)	27 (44.3)	
21–22 mm				
Primary coating	12 (13.3)	4 (15.4)	8 (13.1)	0.746

Results expressed as mean (standard deviation) or as absolute (relative) frequencies according to nature of variable. Percentages refer to total number of cases in each column. Statistics calculated by chi-squared of unpaired Student's t tests according to nature of variable

Table 5 Multivariate analysis of factors associated with functional success

Variables	Crude analysis		Adjusted analysis	
	OR	95%CI	OR	95%CI
Age (years)	1.050	1.018–1.083	1.056	1.019–1.095
Exposure of primary orbital implant	0.038	0.003–0.488	0.017	0.001–0.438

Results expressed as odds ratio (OR) with their 95% confidence intervals (95% CI)

Table 6 Complications during follow-up

Variable	Results*		
	Absolute count	% of total (n = 90)	% of those with complications (n = 11)
Number of interventions			
One	6	6.6	54.5
Two	3	3.3	27.3
Three	1	1.1	9.1
Four	0	0	0
Five	1	1.1	9.1
Description of complications			
Orbital implant exposure	6	6.7	54.5
Conjunctival granuloma	2	2.2	18.2
Exposure of sphere	5	5.6	45.4

*Results expressed in absolute (relative) frequencies. Percentages refer to total number of cases with (n = 90) and without complications (n = 11)

clinical experience in humans in a real-world clinical context.

In our experience, the esthetic and functional results have been optimal. Interestingly, none of the variables collected were associated with anatomical success. This suggests that the cases in which this anatomical success was not achieved may have been due to factors external to the ophthalmologic alteration itself or to the external prosthesis, such as its inadequate hygiene, the atypical nature of the anophthalmic socket or complicated ocular orbital surgery required in specific situations as a consequence of highly evolved and therefore complex ocular clinical pictures. However, we did find variables associated with functional success. In this multivariate analysis, it is important to keep in mind that only 8 cases had not achieved complete functional success. Therefore, we can say that functional success was clearly achieved in the majority of our cohort. Consequently, the relationships found in these 8 cases that are related to this absence of functional success should be validated by new cohorts with larger sample sizes.

Porous implants have a greater risk of exposure than non-porous implants, but, at the same time, less risk of migration and extrusion [12, 14]. Notably, the fact that functional success was not achieved in only 8 cases is relevant when interpreting the results of the associated multivariate study. It is, therefore, necessary to keep in mind that two of the variables associated with functional success (age and exposure to a previous primary implant) should be analyzed in the context that there are few cases with this lack of functional success. Therefore, these results should be interpreted with caution.

Age is a variable that may be relevant, as has been shown in studies of congenital anophthalmias in children [15]. In addition, several studies have separately analyzed populations with different age ranges. Our results showed that patients in the "functional success" group were significantly older than those in the "no functional success" group. This is probably because the implantation in children was related to the appearance of neoplasia as a cause of enucleation. Treatment of the tumor and the use of adjuvant chemotherapy would condition postoperative healing and put the implant at greater risk. Moreover, in pediatric age, adjuvant chemotherapy could condition postsurgical healing and, therefore, increase the incidence of complications such as exposures or extrusions of the orbital implant. Other factors might be at play to explain why functional success was associated with older patients, such as adherence to postoperative treatment and compliance with postoperative instructions, or even lower physical activity than younger patients, which could reduce the risk of trauma or displacement of the implant during the recovery period.

It should be noted that in previous studies, motility results were not reported with the desired frequency [16]. In general, ocular motility is good, but with some variability between studies for both adults [17, 18] and children [19–21]. Notably, implant motility was indirectly measured in some studies by detecting the amount of overlying conjunctival movement [18],

while others measured the implant and prosthesis movement using a custom-made slit-lamp device with real-time video and photographic documentation [17], and other authors assessed small and large angles of conversational eye movements with the prosthesis in place [19], with some studies not specifying the method used [20, 21]. Consequently, it would be necessary to have some objective way of evaluating this motility in daily clinical practice, in order to see the real impact on patients. Moreover, when comparing the results with those obtained with Medpor, a study evaluating 302 cases reported good orbital motility for all implants [22]. Our study showed that 87.8% of the sample presented total implant motility.

Additionally, it was also found that previous implant exposure is a risk factor for not achieving functional success. This should alert the surgeon to this at-risk population, in which a closer follow-up is probably needed. This correlation can be explained by different factors. Scar tissue formation, compromised tissue quality, or inflammatory response could reduce the availability of healthy tissue for a new implant, making it more challenging to achieve a stable and functional integration. Moreover, some patients who have experienced previous implant exposure might have underlying systemic or local factors that predispose them to complications. Additionally, these results are also similar to those obtained with Medpor implants, where the clinical effect of primary implant placement was better than that of secondary placement [22].

Another significant result was that all of the patients showing no functional success (n = 8) were implanted with a small diameter implant (14–20 mm). This finding could be explained by the fact that larger implants may better fill the orbital socket, providing more support and a closer fit to the surrounding tissues, leading to better stability and even pressure distribution.

Regarding the type of intervention, it was observed that patients who underwent enucleation were more prone to experience functional failure compared to those who underwent evisceration. Enucleation is a more extensive and invasive procedure compared to evisceration, leading to a more marked disruption of the orbital tissues, which leads to greater scar tissue formation and changes in orbital anatomy. This disruption can increase the risk of malposition, extrusion and other complications that contribute to functional failure.

Here, it should be noted that the main advantage of evisceration is the preservation of the sclera and the optic nerve, which provides a higher volume than enucleation. Additionally, the muscles remain over the scleral petals, providing better motility and functionality. However, it should be taken into account the difference in sample size between the "functional success" and "no functional success" groups. Therefore, these results should be interpreted with caution.

Complications with the use of orbital implants and external prostheses are common. When wearing a prosthetic shell, patients often complain of pain in the anophthalmic socket, discomfort or local irritation [16]. Infection is often one of the most feared complications. While not a common complication, it may develop months or years after implant placement, ranging in severity from cellulitis to the development of an abscess around the implant itself [23]. The number of cases with exposure of the orbital implant reported in the adults in our cohort is similar to or even lower than in other studies. Jung et al. reported a 9.3% exposure in 314 eyes from adults with an average age of 43 years using polyethylene implants [5], while Ma et al., reported 4.1% exposure in 104 cases, with an average age of 61 years, using porous polyethylene/bioglass implants, which is different from the implant explored in our study (a high-density porous polyethylene implant) [24]. Other authors have reported similar percentages of exposure to ours using hydroxyapatite implants [25, 26] or other types of implants [25, 27]]. The causes of this implant exposure are multifactorial and include poor fit of the external prosthesis, poor hygiene, or deterioration of the external prosthesis, amongst others. Accordingly, several non-implant-related factors may also influence the outcome.

The strengths of the present study include the study of the implant performance in a real clinical context, the sample size and the prolonged follow-up over time, during which all possible complications derived from prosthesis implantation were registered. However, it is important to keep in mind some limitations of our design in order to interpret the results correctly. Firstly, the retrospective design means that occasionally some data may be missing. However, our team collected the health care information very systematically to reduce the likelihood of finding missing,

extreme or inconsistent data. Second, the present work is not an experimental design. Our objective was to narrate our experience with a new type of orbital implant that has been scarcely mentioned in the literature. We, therefore, consider that our data provide the results of an experience with a novel implant that may help to position it among the various alternatives and may help the ophthalmologist with clinical decision-making. These data provide relevant information to design a comparative clinical trial with an adjusted sample size in the future. Another limitation is that the causes for enucleation or ocular evisceration surgery are not balanced, since this is an analysis that gathers clinical experience in a real-world context. As a consequence, cases of infection are underrepresented, as well as other possible causes of orbital implantation. Finally, the main outcome variables are based on subjective assessments of the ophthalmologist in charge of the case. Although more objective measures of these clinical outcomes are not available in our data, we consider that the fact that they were evaluated by the same team of professionals helps to keep variability in this assessment to a minimum.

In conclusion, this paper reports our clinical experience in the use of a high-density polyethylene-based spherical integrated porous orbital implant. The results show that the use of Oculfit as an orbital implant achieves good results in most cases, with a low proportion of complications, which are usually resolved without sequelae. Therefore, in our experience, Oculfit can be considered a valid alternative among the options currently available for orbital implants.

Author contributions AMGH performed most of the surgery, follow-up and data collection, and drafted the manuscript. MCDR, FEA and MIRL performed surgery, followed patients and contributed to the manuscript. JAP, SDL, IRB, JAAC helped in data collection and contributed to the manuscript.

Funding The authors did not receive support from any organization for the submitted work.

Data Availability No datasets were generated or analysed during the current study.

Declarations

Conflict of interest The authors have no relevant financial or non-financial interests to disclose.

References

1. Bigheti CP, Peitl O, de Ferreira GA, Schellini SA (2022) Amplitude of movements with conical or spherical implants in anophthalmic socket. Orbit 41(6):708–16
2. Goldberg RA, Dresner SC, Braslow RA, Kossovsky N, Legmann A (1994) Animal model of porous polyethylene orbital implants. Ophthal Plast Reconstr Surg 10(2):104–109
3. Lee S, Maronian N, Most SP, Whipple ME, McCulloch TM, Stanley RB et al (2005) Porous high-density polyethylene for orbital reconstruction. Arch Otolaryngol Head Neck Surg 131(5):446–450
4. Hornblass A, Biesman BS, Eviatar JA (1995) Current techniques of enucleation: a survey of 5,439 intraorbital implants and a review of the literature. Ophthal Plast Reconstr Surg 11(2):77–78
5. Jung S-K, Cho W-K, Paik J-S, Yang S-W (2012) Long-term surgical outcomes of porous polyethylene orbital implants: a review of 314 cases. Br J Ophthalmol 96(4):494–498
6. Shields CL, Uysal Y, Marr BP, Lally SE, Rodriques E, Kharod B et al (2007) Experience with the polymer-coated hydroxyapatite implant after enucleation in 126 patients. Ophthalmology 114(2):367–373
7. Yoon JS, Lew H, Kim SJ, Lee SY (2008) Exposure rate of hydroxyapatite orbital implants a 15-year experience of 802 cases. Ophthalmology 115(3):566-572.e2
8. Shoamanesh A, Pang NK, Oestreicher JH (2007) Complications of orbital implants: a review of 542 patients who have undergone orbital implantation and 275 subsequent PEG placements. Orbit 26(3):173–182
9. Fernandez-Bueno I, Di Lauro S, Alvarez I, Lopez JC, Garcia-Gutierrez MT, Fernandez I et al (2015) Safety and biocompatibility of a new high-density polyethylene-based spherical integrated porous orbital implant: an experimental study in rabbits. J Ophthalmol 2015:904096
10. Sales-Sanz M, Sanz-Lopez A (2007) Four-petal evisceration: a new technique. Ophthal Plast Reconstr Surg 23(5):389–392
11. Baino F, Potestio I (2016) Orbital implants: State-of-the-art review with emphasis on biomaterials and recent advances. Mater Sci Eng C Mater Biol Appl 69:1410–1428
12. Chen X-Y, Yang X, Fan X-L (2022) The evolution of orbital implants and current breakthroughs in material design, selection, characterization, and clinical use. Front Bioeng Biotechnol 9:800998
13. Heindl LM, Rokohl AC (2021) Orbital implants: material matters. Br J Ophthalmol 105(10):1337
14. Hauck MJ, Steele EA (2015) Dermis fat graft implantation after unilateral enucleation for retinoblastoma in pediatric patients. Ophthal Plast Reconstr Surg 31(2):136–138
15. De Ruiter BJ, Lesko RP, Knudsen MG, Kamel G, Shah J, Kotha VS et al (2022) An age-related algorithm for management of micro-orbitism from anophthalmia: a systematic review with supplemental case reports. Orbit 41(4):397–406

16. Wladis EJ, Aakalu VK, Sobel RK, Yen MT, Bilyk JR, Mawn LA (2018) Orbital implants in enucleation surgery: a report by the american academy of ophthalmology. Ophthalmology 125(2):311–317
17. Shome D, Honavar SG, Raizada K, Raizada D (2010) Implant and prosthesis movement after enucleation: a randomized controlled trial. Ophthalmology 117(8):1638–1644
18. Tari AS, Malihi M, Kasaee A, Tabatabaie SZ, Hamzedust K, Musavi MF et al (2009) Enucleation with hydroxyapatite implantation versus evisceration plus scleral quadrisection and alloplastic implantation. Ophthal Plast Reconstr Surg 25(2):130–133
19. Shah SU, Shields CL, Lally SE, Shields JA (2015) Hydroxyapatite orbital implant in children following enucleation: analysis of 531 sockets. Ophthal Plast Reconstr Surg 31(2):108–114
20. Choi YJ, Park C, Jin HC, Choung H-K, Lee MJ, Kim N et al (2013) Outcome of smooth surface tunnel porous polyethylene orbital implants (Medpor SST) in children with retinoblastoma. Br J Ophthalmol 97(12):1530–1533
21. Iordanidou V, De Potter P (2004) Porous polyethylene orbital implant in the pediatric population. Am J Ophthalmol 138(3):425–429
22. Chen Y, Cui H (2006) High density porous polyethylene material (Medpor) as an unwrapped orbital implant. J Zhejiang Univ Sci B 7(8):679–682
23. Pariseau B, Fox B, Dutton JJ (2018) Prophylactic antibiotics for enucleation and evisceration: a retrospective study and systematic literature review. Ophthal Plast Reconstr Surg 34(1):49–54
24. Ma X, Schou KR, Maloney-Schou M, Harwin FM, Ng JD (2011) The porous polyethylene/bioglass spherical orbital implant: a retrospective study of 170 cases. Ophthal Plast Reconstr Surg 27(1):21–27
25. Wells TS, Harris GJ (2011) Direct fixation of extraocular muscles to a silicone sphere: a cost-sensitive, low-risk enucleation procedure. Ophthal Plast Reconstr Surg 27(5):364–367
26. Liang T, Zhao G, Meng X, Zhang L (2006) Clinical analysis of hydroxyapatite orbital implantation after ocular trauma in 211 cases. Chinese J Traumatol Zhonghua chuang shang za zhi. 9(5):282–7
27. Jongman HP, Marinkovic M, Notting I, Koetsier L, Swart W, Schalij-Delfos NE et al (2016) Donor sclera-wrapped acrylic orbital implants following enucleation: experience in 179 patients in the Netherlands. Acta Ophthalmol 94(3):253–256