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ORIGINAL ARTICLE

Comparison of surgical outcomes of Carlevale sutureless scleral fixation and Artisan Aphakia intraocular lens

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Abstract

Purpose: To compare intra- and postoperative results of sutureless scleral fixated Carlevale intraocular lens (IOL) with iris fixated Artisan IOL.

Methods: Monocentre, retrospective analysis of refractive outcomes and intra- and postoperative complications of patients who received a Carlevale or Artisan IOL between January 2019 and March 2022.

Results: 178 eyes of 169 patients were included (101 Carlevale and 77 Artisan IOLs). The standard follow-up time was 1 month. Two statistically significant differences were found: in the deviation of the postoperative spherical equivalent of the refraction from the preoperative chosen IOL target ($p=0.019$; mean deviation was -0.46 in the Carlevale and 0.08 in the Artisan group), and the number of eyes with complications between the Carlevale and Artisan groups ($p=0.003$; 33 in the Carlevale and 42 in the Artisan group).

Conclusion: The current study is the largest so far comparing both refractive outcomes and complications after implantation of Carlevale and Artisan IOL. The Carlevale IOL does not carry a greater complication risk on the short-term follow-up. This provides additional evidence that the Carlevale IOL has to be added to the armamentarium of the ophthalmic surgeon.

KEY WORDS

Artisan, Carlevale, cataract surgery, complications, IOL, refractive outcome

1 | INTRODUCTION

When insufficient capsular support exists for intraocular lens (IOL) implantation in the capsular bag or the ciliary sulcus, other means of IOL fixation must be sought. The most widely used options are anterior or posterior iris fixation and scleral fixation (with or without sutures; Rossi et al., 2021).

Unfortunately, sutured scleral fixated IOLs have been characterized by a number of postoperative complications, such as suture erosions through the sclera or conjunctiva, breaking of sutures, IOL decentration or tilt, and infection secondary to suture exposure. In an attempt to prevent these complications, Gabor first described a sutureless technique to fixate an IOL to the sclera in the

ciliary sulcus, using a scleral tunnel. Although this technique already solved a lot of the pre-existing problems, IOL stability was still suboptimal. In addition to the instability, the use of an IOL with this technique is off-label, since the IOLs used are designed and approved for fixation in the bag or sulcus (Barca et al., 2020).

In 2014, a sutureless scleral fixated IOL was designed by Carlo Carlevale and fabricated by Soleko, Italy. Following the introduction of the Carlevale IOL several authors have reported good surgical outcomes of its implantation (Abed et al., 2021; Barca et al., 2020; D'Agostino et al., 2021; Fiore et al., 2021; Gabai et al., 2021; Januschowski et al., 2021; Rossi et al., 2021; Rouhette et al., 2021; Sidiropoulos et al., 2022; Vaiano et al., 2021; Veronese et al., 2020).

However, sufficient studies with adequate sample size providing insight into the safety profile of the Carlevale IOL and comparing it to established surgical options are lacking. At the time of writing, only 1 study reported the results of the Carlevale IOL in a study population of over 100 patients, 169 to be exact (Georgalas et al., 2021), and only three studies have compared the widely used iris claw IOL to the new sutureless scleral fixated Carlevale IOL: Seknazi et al. (2021) including 42 patients, Bodin et al. (2022) including 51 patients and Boccuzzi et al. (2021) including 18 patients.

In the current retrospective cohort study, the intra- and postoperative results of Carlevale IOL implantation are analysed, comparing patients who received an anterior or posterior iris fixated IOL (Artisan Aphakia model 205, Ophtec, Groningen, The Netherlands) and patients who received a sutureless scleral fixated IOL (FIL-SSF Carlevale, Soleko SPA, Pontecorvo, Italy; from now on referred to as Carlevale IOL) between January 2019 and March 2022.

2 | MATERIALS AND METHODS

2.1 | Study design

Monocentre, retrospective study design. The procedures were performed by 4 vitreoretinal surgeons (G.B, K.M., E.L. and C.P.) at Haga Hospital, The Hague.

2.2 | Study population

One hundred and seventy-eight consecutive eyes who had an iris claw or Carlevale IOL implanted in the period between January 2019 and March 2022 were included. No patients were excluded on the basis of pre-existing ocular conditions. A follow-up appointment took place 1 month after surgery. Some patients were then referred back to their own ophthalmologist, while others received new follow-up appointments at our VR department due to a complicated postoperative course or at the request of the patient. Two patients were excluded due to loss of follow-up (no follow-up appointment was registered; 1 received an iris claw IOL, the other a Carlevale IOL).

This study was approved by HagaHospital, The Hague in accordance with the Ethics Committee of Leiden, The Hague, and Delft (METC LDD) and was carried out in compliance with Dutch legislation and the Tenets of the Declaration of Helsinki.

The patients were divided into two groups. The first group included patients that had received a posterior or anterior chamber iris fixated IOL (Artisan Aphakia model 205, Ophtec, Groningen, The Netherlands) and the second group had received a sutureless scleral fixated Carlevale IOL (FIL-SSF Carlevale, Soleko SPA, Pontecorvo, Italy).

Pre- and postoperative subjective refraction, intraocular pressure, best corrected visual acuity (BCVA), dilated fundus examination, biometry (IOLMaster® 500, Zeiss, Germany), and optical coherence tomography scans (Xephilio OCT-S1, Canon Medical Systems, Japan) were obtained. Intra- and postoperative complications were reported.

2.3 | Intraocular lenses

The iris claw IOL is a non-foldable, polymethylmethacrylate (PPMA) IOL with an optic size of 5.4 mm and a total diameter of 8.5 mm (Figure 1). At the end of the 2 haptics is an interruption in the continuity of the haptic, designed for enclavation into the anterior or posterior mid-peripheral iris. The Carlevale IOL is a foldable (not preloaded), hydrophilic, acrylic IOL with an optic of 6.5 mm and a total diameter of 13.2 mm (Figure 1). At the end of the haptic, there is a T-shaped, 1 mm long and 2 mm wide plug designed for fixation in a sclerotomy opening of 23 or 25 gauge. (Seknazi et al., 2021).

2.4 | Surgical technique

All patients received a complete pars plana 25 gauge vitrectomy before IOL implantation with the Constellation® Vision System (Alcon). In case of IOL (sub)luxation, dropped nucleus or other retinal pathology, other vitreoretinal interventions were completed before the IOL was implanted. Optimal mydriasis was achieved

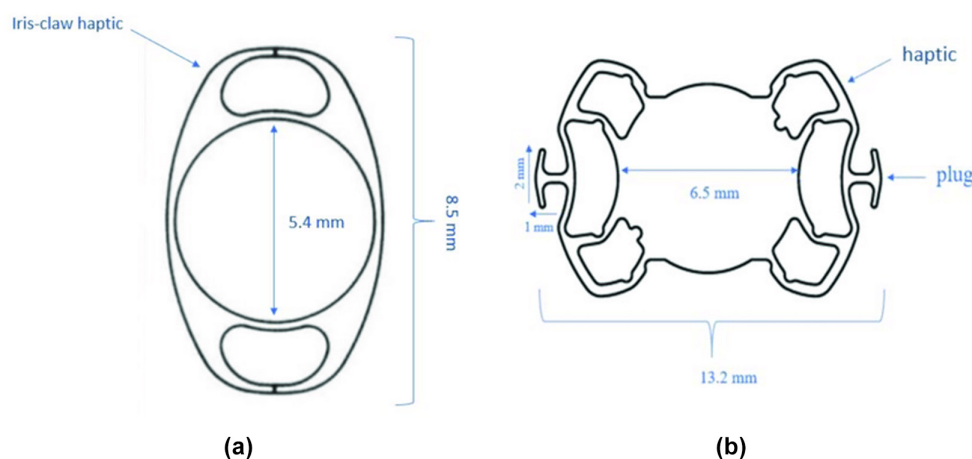


FIGURE 1 (Left) Iris claw IOL (Ophtec, Artisan Aphakia model 205, Groningen, The Netherlands); (Right) Sutureless scleral fixated Carlevale IOL (FIL-SSF Carlevale, Soleko SPA, Pontecorvo, Italy).

with the insertion of phenylephrine chlorhydrate 5.4mg+tropicamide 0.28mg insert opht (Mydriaser, Thea Pharmaceuticals Ltd., Clemont-Ferrand, France) in the conjunctival inferior fornix preoperatively.

3 | Iris claw artisan IOL

Two corneal sideports were placed at the 2 and 10 o'clock position. Carbachol 0.1mg/ml (Miostat®, Alcon, Switzerland) was injected intracamerally to achieve miosis. A scleral tunnel with a width of 8mm on average was created 1mm posterior from the limbus in a convex configuration in the superior quadrant. The incision extended into the anterior chamber. The iris claw IOL was inserted with an Artisan implantation forceps (Ophtec, The Netherlands). While the IOL was held in place anterior or posterior to the pupil, the haptics were enclaved on both the temporal and nasal side. Subsequently, the scleral tunnel was sutured with interrupted vicryl 8-0 sutures. The corneal side ports were closed through hydroseal. A small iridectomy was created.

4 | Sutureless scleral fixation carlevale IOL

A limited temporal and nasal conjunctival peritomy were performed. The cornea was marked at the 3 and 9 o'clock position, 180° apart. Subsequently, two scleral flaps were created with a width and length of 3.5mm and with corneal markings in the centre of the flaps. Two vertical sclerotomies were performed with a microvitrectomy 23 gauge knife or needle at 1.5mm from the limbus underneath the scleral flaps. A 2.2mm corneal incision slightly right to the 12 o'clock position and a corneal sideport on the opposite superior side were created. The IOL was inserted through the main corneal incision. Once the first plug of the IOL was visible in the anterior chamber, it was grabbed with an Ultra Peel 25 gauge microforceps (DORC, The Netherlands) through the dilated pupil and slowly pulled through the sclerotomy, while continuing the injection of the rest of the IOL through the main port. For the fixation of the second plug, an Ultra Peel 25 gauge microforceps was inserted through the corneal sideport and the second haptic was grabbed. The other hand passed a second Ultra Peel microforceps through the remaining sclerotomy and the second plug was pulled through the sclerotomy (handsake technique). The scleral flaps and conjunctiva were closed with vicryl 8-0.

4.1 | Statistical analysis

All statistical analyses were performed using IBM SPSS Statistics 25.0 (SPSS 25, IBM, New York, United States of America). For comparing baseline characteristics between the Carlevale and Artisan IOL groups independent samples t-test was used. A linear mixed model was used for testing the change in cylindrical refraction and BCVA between baseline and the one-month visit after vitrectomy, to correct for data that was not missing at

random (insufficient visual acuity and refraction measurement at baseline or postoperative, due to for example high intraocular pressure or inflammation or postoperative complications like corneal oedema). BCVA was collected in decimal visual acuity but transformed into logMAR visual acuity for statistical analysis. In all performed tests, a p -value of ≤ 0.05 was considered statistically significant.

5 | RESULTS

5.1 | Patient characteristics

In total, 178 eyes of 169 patients were included in the current study. Four patients had an Artisan or Carlevale IOL in both eyes and five patients had an Artisan implant that was later replaced by Carlevale implant.

The pre-operative BCVA and age were not significantly different between the Carlevale and Artisan group (Table 1). Seven patients in the Carlevale group and one patient in the Artisan group had a preoperative BCVA of light perception (LP). The indications for surgery are mentioned in Table 2.

5.2 | Visual and refractive outcome

The increase in postoperative astigmatism at 1 month after surgery in the Carlevale group was 0.47 ± 1.44 (mean $\pm$ SD; range -5.25 to 4.75) and in the Artisan group 0.52 ± 1.47 (mean $\pm$ SD; range -2.5 to 3). However, there was no significant difference between both groups ($p = 0.827$, linear mixed model).

The deviation of the postoperative spherical equivalent of the refraction from the preoperative chosen IOL target was calculated for 93 (out of 101) and 72 (out of 77) eyes in the Carlevale and Artisan groups, respectively. Not all patients were included for the analysis of this parameter since subjective refraction was not obtained in some patients at 1-month follow-up due to a severely limited visual acuity or lack of cooperation. The deviation was -0.46 ± 1.35 (mean $\pm$ SD; range -3.56 to 4.12) in the Carlevale group and 0.08 ± 1.60 (mean $\pm$ SD; range -3.21 to 8.77) in the Artisan group. The difference between both groups was statistically significant ($p = 0.019$, independent samples t-test). It is also worth mentioning that there was no significant difference in the deviation of the postoperative spherical equivalent of the refraction from the preoperative chosen IOL target between surgeons in both the Artisan and Carlevale group ($p = 0.714$ and $p = 0.284$ resp., one-way ANOVA).

The BCVA at 1 month after surgery had increased with 0.29 ± 0.75 (mean $\pm$ SD) logMAR in the Carlevale group ($n = 82$) and 0.42 ± 0.71 (mean $\pm$ SD) logMAR in the Artisan group ($n = 59$). This increase from baseline was statistically significant in both groups ($p = 0.001$ and $p < 0.001$ respectively, linear mixed model). There was no statistical difference in increase in BCVA between both groups ($p = 0.352$, linear mixed model). The missing values for postoperative measurements in BCVA represent postoperative visual acuity that was not quantifiable for

TABLE 1 Baseline patient characteristics.

	Carlevale	Artisan	<i>p</i> -Value
Eyes (<i>n</i>)	101	77	
Age (years)	69.1 ± 12.5	71.8 ± 11.8	0.591 ^a
Male gender	67/101 (66%)	47/77 (61%)	0.466 ^b
Best-corrected visual acuity in study eyes at baseline (logMAR)	0.71 ± 0.67 (<i>n</i> =85)	0.78 ± 0.67 (<i>n</i> =62)	0.532 ^a
Preoperative astigmatism	-1.16 ± 1.16 (<i>n</i> =79)	-1.16 ± 1.34 (<i>n</i> =53)	0.813 ^c
Intraocular pressure (mmHg) pre-op	18 ± 8.67 (<i>n</i> =95)	19 ± 8.36 (<i>n</i> =77)	0.673 ^a

Note: Data are either no. (%), or mean ± standard deviation.

^aIndependent sample t-test.

^bChi-squared test.

^cMann–Whitney U-test.

TABLE 2 Surgical indication for scleral or iris fixated IOL implantation.

	Carlevale	Artisan
Phakic lens dislocation after trauma	5	4
Spontaneous IOL dislocation	35	38
Aphakia after complicated cataract surgery	32	23
Primarily during complicated cataract surgery	9	8
Aphakia after trauma	7	2
IOL exchange due to photopsia	4	
IOL exchange due to problems with Artisan IOL	7	
Corneal decompensation due to Binckhorst IOL	1	
Iatrogenic IOL luxation		2
Shaving sulcus IOL	1	

statistical analysis (f.e. perception of light, hand movements, counting fingers). The number of missing values is greater for the parameter postoperative BCVA than postoperative subjective refraction, since even in the case of severely compromised visual acuity, subjective refraction was attempted and recorded if visual acuity could improve with refraction (for example from hand movements to counting fingers).

5.3 | Surgery

The mean duration of surgery was 57.4 min ± 24.4 (mean ± SD; range 19–131) in the Artisan group and 65.5 min ± 22.3 (mean ± SD; range 30–153) in the Carlevale group.

In the Artisan group, balanced salt solution was left in the intravitreal cavity in 95% of patients (73/77) and air was used as a tamponade in 5% (4/77). In the Carlevale group balanced salt solution was used in 74% (75/101), air in 24% (24/101) and SF6 gas in 2% (2/101). The indication for the use of gas was a co-existing retinal detachment.

5.4 | Intra-operative complications

In the Carlevale group three cases of intraocular haemorrhage were encountered (3%), out of which 2 occurred in the anterior chamber originating from the iris and 1

in the vitreal cavity due to bleeding from a sclerotomy. There was also one case of iridodialysis in this group (1%). The haptic of the Carlevale IOL slipped out of the sclerotomy due to a too large sclerotomy in one case (the sclerotomy was sutured and a new sclerotomy was created; 1%). In two cases the haptic broke at the long leg of the T plug (2%). This required subsequent removal of the IOL and reimplantation of a new IOL. In the Artisan Group 6, intra-operative intraocular haemorrhages were observed (7.8%), out of which 5 occurred in the anterior chamber due to iris trauma and 1 in the intravitreal cavity due to bleeding from a sclerotomy.

5.5 | Postoperative complications

The follow-up period was 160 ± 205 days (mean ± SD) and 254 ± 305 days (mean ± SD) in the Carlevale and Artisan group, respectively. In the Carlevale group, 42% (*n*=42) were referred back to their own ophthalmologist after the 1 month follow-up, while 58% (*n*=59) received additional follow-up appointment(s). In the Artisan group, this was 40% (*n*=31) and 60% (*n*=46) respectively. The complications mentioned here were observed at the 1 month postoperative appointment. After 1 month postoperative, the further follow-up was variable and data after 1 month were not available for a large number of patients. To reduce bias, complications that were registered after this period were not included in the statistical analysis. In the Carlevale group, postoperative complications occurred in 33 eyes (32.7%): postoperative cystoid macular oedema (CME) in 15/101 (14.9%), persistent corneal oedema at 1 month postoperatively in 14/101 (13.9%), bleeding (in anterior chamber or vitreous cavity) in 9/101 (8.9%), IOL tilt in 3/101 (3%), and extrusion of the haptic in 1/101 (1%). In the Artisan group postoperative complications were reported in 42 eyes (54.5%): CME in 20/77 (26%), bleeding in 16/77 (20.9%), persistent corneal oedema at 1 month in 8/77 (10.4%), (sub)luxation of the IOL in 5/77 (6.5%), postoperative hypotony (IOP < 5 mmHg) in 2/77 (2.6%), and IOL tilt in 1/77 (1.3%). The number or nature of complications did not differ among the different surgeons. Some patients had complications in multiple categories (e.g. CME and corneal oedema). This explains the discordance in numbers, i.e. the number of eyes with complications is lower than the accumulated complications in all the categories. There

was a statistical significant difference in the number of eyes with complications between the Carlevale and Artisan groups ($p=0.003$, Pearson Chi-Square test). In total, 17 patients required a second operation to treat the postoperative complication, 6/33 (18.2%) and 11/42 (26.2%) in the Carlevale and Artisan group, respectively. This difference was not statistically significant ($p=0.353$, Pearson Chi-Square test). The aforementioned complications are believed to be related to the specific intraocular IOL and IOL fixation technique used. However, the confounding effect of additional simultaneously performed surgical interventions on the development of a complication can, of course, not be completely excluded. A difference in complication rate between different surgeons could not be found in both the Artisan and the Carlevale group ($p=0.849$ and $p=0.244$ resp, chi-squared test).

6 | DISCUSSION

This is the largest study so far that compares the surgical outcomes of the Carlevale with the Artisan IOL. In this retrospective study, the Artisan IOL showed superior refractive outcomes, while the Carlevale IOL showed significantly less postoperative complications. This difference in refractive outcome has been hypothesized to be mainly due to the higher number of patients with persistent corneal oedema in the Carlevale group at 1-month follow-up, whereas the difference in postoperative complications has been thought to be mainly caused by the higher number of postoperative bleeding in the Artisan group. Therefore, the current study provides additional evidence that the Carlevale IOL has to be added to the armamentarium of the ophthalmic surgeon.

Our results are in line with already available studies. The Carlevale IOL was designed in 2014 and starting from 2020 several surgeons have reported their experience with this IOL in clinical studies. Bodin only evaluated the postoperative induced astigmatism and BCVA. He found less surgically induced astigmatism and overall better refractive outcomes in the Carlevale group compared to the Artisan group. Seknazi came to the same conclusion but also reported on postoperative complications such as IOL dislocation, CME, vitreous haemorrhage, hyphema, and a neurotrophic ulcer. IOL dislocation only occurred in the Artisan group. One postoperative haemorrhage occurred in both groups, but only required a second surgery in the Artisan group due to the extent of the haemorrhage. Boccuzzi compared not only the Artisan and Carlevale group but also the Yamane technique of IOL implantation, which is a flanged intrascleral transconjunctival IOL fixation with a double needle technique (Yamane et al., 2017). He also found no significant differences between the three groups when comparing complications. All studies found no difference in postoperative BCVA in all the groups.

In our study, no difference in postoperative astigmatism between both groups was found. There was, however, a significant difference in deviation of the postoperative spherical equivalent compared to the preoperative IOL target between both groups. This can be explained by the higher number of patients with persistent corneal

oedema at 1-month follow-up in the Carlevale group. Importantly, clinically the difference in refractive deviation from target had a tendency to decrease with longer follow-up. However, this tendency was not analysed statistically, since the follow-up period varied among patients. All patients received a 1-month follow-up. After this period some patients were sent back to their referring ophthalmologist, while some patients remained in follow-up for a longer period of time due to lack of a referring ophthalmologist or still ongoing treatment. Due to this discordance these results were not published in this paper.

Second, overall postoperative complications were more frequent in the Artisan group and this difference was statistically significant. Postoperative complications such as CME, corneal oedema, IOL dislocation, and tilt occurred in both groups but postoperative hyphema and/or vitreous bleeding occurred slightly more frequently in the Artisan group and this required reintervention more often than in the Carlevale group. Although the surgeons in this study had more experience with the Artisan IOL, postoperative complications were still more frequent in this group. It is possible that this IOL is more prone to postoperative complications due to the requirement of a large incision, the manipulation of the iris diaphragm and the less stable haptic fixation. The manipulation of the iris diaphragm was also mentioned by Seknazi as a possible cause for IOL dislocation, hyphema, and vitreous haemorrhage (Seknazi et al., 2021). The anterior placement of the Artisan IOL could also cause endothelial cell loss and corneal decompensation over a longer period of follow-up. However, endothelial cell count was not evaluated in our study.

Our findings show that the Carlevale IOL is a safe IOL when compared to the Artisan IOL. Even though none of the surgeons in this study had any prior experience with the implantation of this IOL, this did not translate into an increased intra- or postoperative complication risk. However, this study has several limitations. First of all, for the mixed model analysis of the preoperative BCVA there were several missing values due to the inability to quantify BCVA in logMAR (for example counting fingers, hand movement or light perception). This could have caused an underestimation of the effect during comparison of both groups. Second, the follow-up period of 1 month was short. Afterwards, some patients were sent back to their referring ophthalmologist, while some patients required a longer follow-up due to postoperative complications. Because of this variable follow-up period, the data analysis was performed with the outcomes at 1-month follow-up. This entails that postoperative measurements such as refraction and BCVA were sometimes absent or inaccurate due to a complicated postoperative course (for example persisting corneal oedema or CME at 1-month follow-up). Also, postoperative complications that presented after the patient was referred back to their ophthalmologist would not have been recorded in our analysis. Finally, the type of lens (Carlevale or Artisan) was not randomly assigned but rather depended on the preference of the surgeon at the time of surgery.

In conclusion, the Carlevale IOL does not carry a greater complication risk on the short-term follow-up,

even taking an initial learning curve into account. The surgical outcomes of the large series recorded in this study were the first Carlevale IOL implants performed by our team of surgeons. They had no previous experience with the implantation of this IOL. However, prospective studies with a longer follow-up period are mandatory to determine the long-term safety profile of this IOL.

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