The Artisan aphakia intraocular lens in the paediatric eye
Sminia, M.L.

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Chapter 9

GENERAL DISCUSSION
In this thesis the long-term outcome after the implantation of the Artisan aphakia intraocular lens, for different indications, in 37 eyes of 25 children is reported. How well did the Artisan aphakia IOL perform in terms of clinical outcome, IOL related problems and in terms of the outcome regarding the corneal endothelium? Furthermore, the axial eye length growth of 90 eyes of 45 children after unilateral cataract surgery is analyzed (Chapter 3).

In this chapter, the refractive outcome after IOL implantation in the growing paediatric eye (9.1), the clinical outcome of all series on the Artisan aphakia IOL (9.2) and the outcome in terms of the corneal endothelium (9.3) will be discussed. After evaluating the other types of IOL that can be considered in case of an absence of capsular support (9.4), the final conclusions will be presented (9.5).

9.1 The growing paediatric eye

No significant difference in axial eye length growth was found when comparing both eyes of 45 children operated for unilateral cataract (Chapter 3). However, in a subgroup of 25 children younger than 18 months at the time of the surgery (Group 1) significantly more myopic shift and changes in keratometry were found in the operated eye, when compared to the fellow non-operated eye. These differences were not found in the group of children that were older than 18 months at the time of the surgery (Group 2). When dealing with a paediatric eye, the refractive parameters, axial eye length, crystalline lens power and corneal curvature, are constantly changing. The axial eye length is known to increase the most in the first 18 months of life\(^1\). The major changes in keratometry occur during the first six months and the greatest changes in crystalline lens power during the first 18 months of life\(^2\).

In the Artisan IOL (both aphakia IOL and Iris Reconstruction IOL) series (Chapter 4, 5, 7, 8) the refractive outcome at the last follow-up was available in 32 out of 37 eyes. The range of refractive outcome was minus 12.5 to plus 3.5 spherical equivalent refractive error, with five of 32 eyes exceeding a myopia of minus 5, of which four exceeding minus 7. The age of the 32 children in the Artisan series of whom the final refractive error was recorded ranged from 4 to 11 years at the time of the Artisan IOL implantation. Regarding the fact that all children were older than 18 months at the time of the Artisan aphakia IOL implantation, the final myopia seems more than was to be expected. However, the series included children who underwent surgery for different indications, including eyes with corneal scars and encircling bands. In future, larger studies should include more detailed information and analysis of the final refractive error to make definite conclusions on the refractive outcome after Artisan aphakia IOL implantation. For now one can only speculate that if children become more myopic after Artisan IOL implantation, this might be a consequence of the location of the IOL in the anterior
119
chamber. It is reported that during eye growth the different components of the optic axis represent a different percentual share of the total axial eye length. The percentual share of the anterior chamber depth increases until about the age of 18 months, while the percentual share of the vitreous length increases until about the age of 13 years\(^3\). In that case, a fixed power IOL situated in the anterior chamber could cause myopisation up to an older age. More knowledge of the postoperative development of the cornea, position of the intraocular lens and the measurements of the different compartments of the eye (anterior chamber depth, length of the vitreous) is needed. This knowledge can contribute to a better prediction and a better understanding of final refractive errors in the growing eye.

9.2 CLINICAL OUTCOME

The visual outcome after cataract or crystalline lens surgery is variable in children and depends on many factors, such as the age at onset of the eye disease, the age at the time of the surgery, whether there is unilateral or bilateral eye disease, the cause of the eye abnormality, whether other eye abnormalities are present, and the degree of amblyopia. The children in our series underwent surgery for different indications, and therefore the expected visual outcome differed. The visual outcome in our series was comparable to the visual outcome as reported in the literature for the different indications: traumatic cataract\(^4-6\), congenital/juvenile cataract\(^7\) and lens dislocation in Marfan syndrome\(^8-11\). The outcome in traumatic cases can be favourable in case of small traumata, especially in the eyes of older children. In eyes with major anterior segment trauma, including central corneal scars and the resulting astigmatism, the expected visual outcome is worse. This was confirmed in our two studies on eyes with a perforating cornea trauma. The eyes that could be implanted with the Artisan aphakia IOL (Chapter 4) had a better visual outcome than the eyes that needed an Artisan Iris Reconstruction IOL (Chapter 5). The visual outcome in both series was comparable with reports on perforating anterior segment trauma in the literature\(^4-6\). The outcome in our bilateral cataract series (Chapter 7) was comparable to a large series on paediatric unilateral and bilateral cataract surgery with IOL implantation by Ledoux et al\(^7\). We report a visual acuity ranging from 20/50 to 20/25 in the four eyes of two patients with the Marfan syndrome (Chapter 8). This is comparable to reports on surgery for lens dislocation in Marfan syndrome found in the literature\(^8-11\). Accurate optical correction and amblyopia treatment are very important to come to the best visual outcome after surgery for any indication. Amblyopia has been reported to be the major cause of residual visual deficit after paediatric cataract surgery\(^7\). No intra-operative complications were reported in our series.

Two cases of short-term fibrinous uveitis (Chapter 4) were encountered. One case of
prolonged uveitis with increased intraocular pressure, which was surgically treated, occurred in one of the patients with extensive anterior segment trauma and an Artisan Iris Reconstruction IOL (Chapter 5). Paediatric eyes tend to react with more inflammatory responses than adult eyes after cataract surgery. In the majority of cases this can be treated with topical steroids, as in our patients. Posterior capsule opacification (PCO) accounted for a high number of second surgical procedures in our bilateral cataract series (Chapter 7). Posterior capsulotomy and anterior vitrectomy were not routinely performed in our series. These two procedures have become a preferred practice nowadays, which led to a decrease in the incidence of PCO. Currently, the Artisan aphakia IOL is almost solely implanted in case of capsular loss or dislocation (see later in this chapter), in which cases the posterior capsule is removed, which practically precludes PCO. Therefore, the incidence of PCO is not an important issue of concern in future use of the Artisan IOL.

In three eyes, one of the claws of the Artisan IOL dislocated. In two of these three eyes it involved an Artisan Iris Reconstruction IOL, which was implanted after trauma. In one eye the IOL dislocated spontaneously, in the other eye the IOL dislocated due to blunt trauma (Chapter 5). The third IOL that partially dislocated was an Artisan aphakia IOL implanted for juvenile cataract. In this latter patient the Artisan aphakia IOL partially dislocated twice after blunt trauma (Chapter 7). Boys are more frequently involved in eye trauma, with a ratio of approximately 3:1. Of the ten children with anterior segment trauma in our series, seven were boys and three were girls. Both patients with partial IOL dislocation, due to (recurrent) blunt trauma were boys. To prevent traumatic IOL dislocation, we advise our patients to wear protective glasses during contact sports and activities with an increased risk of eye trauma.

A retinal detachment was encountered in four eyes in our series. A retinal detachment occurred in two eyes after penetrating trauma, one eye implanted with an Iris Reconstruction IOL (Chapter 5), five years after implantation, and one eye implanted with an Artisan aphakia IOL (Chapter 4), 18 months after implantation. Traumatic eyes are more prone for retinal detachments, even more after penetrating eye trauma, as in our cases. Therefore, the retinal detachments can probably be attributed to the original eye trauma. A retinal detachment was also encountered in both eyes of a patient with Marfan syndrome (Chapter 8), one and nine years after Artisan aphakia IOL implantation. Retinal detachment is a well known complication in Marfan syndrome, with a reported incidence ranging from 5% to 26%. Retinal detachment is also a known complication after cataract surgery. Follow up of, and instructions to, patients and their parents about alarming signs and symptoms of a retinal detachment are important after lens extraction in patients after trauma and in patients with Marfan syndrome.

Prolonged uveitis with increased intraocular pressure, two of three partial lens dislocations and one of four retinal detachments occurred in the eyes that suffered from major anterior segment trauma that were implanted with an Artisan Iris Reconstruction
IOL (Chapter 5). Both cases with short term fibrinous uveitis and one of the four retinal detachments occurred in eyes with perforating corneal trauma, implanted with the Artisan aphakia IOL (Chapter 4). In summary, two of four retinal detachments, all fibrinous inflammatory responses, two of three IOL dislocations and the only case of elevated intraocular pressure were reported in eyes after trauma. One should take into account that any eye that suffered from penetrating trauma is at risk of serious late complications regardless of IOL implantation.

9.3 THE CORNEAL ENDOTHELIUM

We report endothelial cell densities within the expected range for eyes without cataract surgery in all series except, as was to be expected, in the traumatic series. A normal mean endothelial cell density (ECD) after long-term follow-up in the unilateral congenital and bilateral congenital and juvenile cataract series (Chapter 6, 7) and in the four eyes of two patients with Marfan syndrome (Chapter 8) was found. In the traumatic eyes (Chapter 4, 5, 6) a decrease in ECD and a strong negative correlation between the endothelial cell density and the length of the corneal scar was found.

We disclose two remarkable findings on the long-term outcome of the corneal endothelium. We found a large variability in endothelial cell densities in the bilateral congenital and juvenile cataract series (Chapter 7), and we found distinct changes in the endothelial morphology in the Marfan series (Chapter 8).

What explains the high variability in ECD in the bilateral cataract series? In one patient a low ECD was caused by a recurrent dislocation of the IOL. Details of the surgical and clinical history could not explain the higher nor lower than expected ECDs in the other patients. Children with secondary Artisan IOL implantation after congenital cataract extraction as well as children with primary Artisan IOL implantation after juvenile cataract extraction were included in this series. Endothelial cell densities which were higher than expected were found in the congenital cataract group, endothelial cell densities which were lower than expected were mainly found in the juvenile cataract group. Possibly the inclusion of eyes after both primary (juvenile cataracts) and secondary (congenital cataracts) IOL implantation has influenced the standard deviation of the ECD. Embryological studies have shown that the formation and development of the cornea is induced by the crystalline lens. Removal of the cataractous crystalline lens at a very early age, as in congenital cataract, might result in an altered development of the cornea, and may for example result in the greater central corneal thickness that has been reported after congenital cataract surgery. We found a trend, no significant correlation, toward an increasing ECD with an increasing CCT in our patients. Larger studies and serial pre- and postoperative endothelial cell counts and CCT measurements are necessary to monitor changes in ECD and differences between groups (Chapter 7).
An increase in the coefficient of variation of cell size (CV) and a decrease in the percentage of hexagonal cells (hexagonality) in the four eyes of two patients with Marfan syndrome were found (Chapter 8). These distinct morphological changes were not found in the other series reported in this thesis. However, changes in morphology are reported in non-operated eyes from patients with Marfan syndrome, with the most prominent changes in eyes with lens dislocation²², and were found in both eyes of one control patient with a dislocated lens out of the visual axis and RGP contact lens wear in the current study. This implies that morphological changes might also be present in the eyes of patients with Marfan syndrome after the implantation of other types of IOLs. Unfortunately no endothelial studies reporting the CV and hexagonality are available after the implantation of other types of IOLs in Marfan patients. The clinical consequences of the morphological changes that were found in the four eyes of Marfan patients are unclear, but might be limited, as we found a clear cornea and a normal central corneal thickness in these four eyes.

9.4 Other intraocular lenses in the absence of capsular support

The use of the Artisan aphakia IOL is currently indicated in the absence of capsular support. Other IOLs used in the absence of capsular support are sutured posterior chamber lenses (PCIOls), either sutured to the sclera or to the back surface of the iris, and angle supported anterior chamber lenses (ACIOls).

Good IOL centration and stable fixation of the IOL is important in case of absence of capsular support. The studies in this thesis show that the Artisan aphakia IOL is a stable IOL, with few dislocations. This was recently also reported by Zheng et al.²³. In a comparative study on eyes of adult patients with Marfan syndrome a decentration of scleral-fixated posterior chamber IOLs was found in 48.7% of eyes after one year of follow-up. No decentration of the Artisan aphakia IOL was found.

The most used IOLs in the absence of capsular support in children are sutured posterior chamber lenses, either sutured to the sclera or to the back surface of the iris. Recently Buckley et al.²⁴ and Asadi et al.²⁵ reviewed the literature on sceral sutured sulcus lenses in children. No case of lens dislocation was reported in all previous studies on sulcus sutured IOL in children, after a follow-up averaging three years at most. However, Buckley and Asadi report in their own studies on scleral sutured IOLs in children, a rate of late IOL dislocation of 9% and 24% respectively, after a mean follow-up of five years and six years and a half. The dislocation is a result of breakage of the 10.0 polyprolene suture. This dislocation typically occurs late, after a mean of four or more years after implantation.

Iris sutured posterior chamber lenses have been used in children.¹¹,²⁶,²⁷ No lens dislocations were encountered in 17 eyes of nine children after a mean of 16 months
of follow-up in a study by Dureau et al. Early dislocation of the iris sutured IOL was reported in five (29%) of the 17 eyes, after a mean of six months after implantation, by Yen et al. and in four (33%) of 12 eyes, after a mean of five months after implantation, by Kopel et al. 10.0 polypropylene sutures were used in these three studies. No breakage of the suture was encountered, yet an untied knot or slippage of the suture from the iris or IOL haptic are suggested as a cause of these early IOL dislocations. The longest mean follow up in these studies was 20 months. The concern of suture degradation in time remains.

Konradsen et al. report on sutured capsular tension ring and in-the-bag lens implantation, in 37 eyes of 22 children. The median follow-up was 27 months. Two eyes required secondary suturing for IOL dislocation, one and two years after the implantation. 10.0 polypropylene sutures were used.

The most frequent complications that were reported after the implantation of scleral sutured PCIOLs are intraocular hemorrhage, IOL tilt, iris capture and endophthalmitis. A high rate of posterior capsule opacification (31 out of 37 eyes, 84%) is encountered in eyes with sutured capsular tension ring and in-the-bag implantation.

The use of 9.0 polypropylene is suggested to overcome the problem of breakage of the 10.0 polypropylene suture. Yet the larger knot of this suture might erode through the scleral flap, exposing the patient to a higher risk of the (late) complication of endophthalmitis. Caution is justified when using any type of sutured IOL in the paediatric eye. The implantation of the Artisan aphakia IOL is technically less challenging and less invasive, and offers the advantage of sutureless fixation.

Angle supported IOLs can also be implanted without sutures. Morrison et al. report on eight eyes of five patients with lens dislocation due to Marfan syndrome, implanted with open-loop flexible anterior chamber IOLs. Pigment deposits on the IOL were seen in four out of eight eyes, of which one eye also had keratic precipitates. No corneal decompensation, IOL displacement or explantation was reported after a mean follow up of 12.7 months. Unfortunately, no information on the corneal endothelial cell density or morphology is provided. The modern open loop angle supported anterior chamber IOLs have been demonstrated to be comparably safe and effective when compared to other IOLs in the absence of capsular support in adults. Still, the incidence of corneal oedema and glaucoma was slightly higher with open- loop ACIOLs, when compared to scleral sutures PCIOLs in adults. Taking into account the small amount of studies on anterior chamber angle supported IOLs in children, the fact that complications have been reported when using angle supported IOLs in children, and the lack of long-term follow up of these lenses in children, it seems that this IOL should be approached with caution.
9.5 CONCLUSIONS

In this retrospective study on 37 eyes of 25 children, implanted with the Artisan aphakia IOL, good clinical results, few IOL related complications and a normal mean corneal endothelial cell density are reported. We believe the strength of our study is the long-term follow-up of 8.9 to 12.7 years for the different subgroups. Despite this long follow-up no late complications occurred.

The most important question that remains is whether the Artisan aphakia IOL is safe for the corneal endothelium in the longer term, and whether the high variability in ECD and the morphological changes found will result in problems with corneal clarity after many more years, or not. Our results show that the Artisan aphakia IOL is a well performing and efficacious IOL which seems comparable to, or even better than, other IOL options to correct aphakia in children that lack the necessary capsular support to implant a posterior chamber in-the-bag or sulcus IOL.

We cannot make definite conclusions about the safety of this IOL based on the current studies. However, the Artisan aphakia intraocular lens has shown to be safe in this group of paediatric patients that has been followed for more than ten years.