OPHTHALMO CHIRURGIE

Scope of applications and experience record with a new generation of Add-On IOLs: The A4W lens

At the end of year 2011, some experts and numerous interested listeners met in Berlin to discuss latest developments in the area of Add-On IOLs introduced at a workshop there. Speakers of this event were Andreas Cordes, M.D., senior physician at Klinik für Augenheilkunde (Ophthalmic Clinic) in Merheim/Germany, as well as Gangolf Sauder, M.D., lecturer and medical director of Charlottenklinik für Augenheilkunde (Ophthalmic Clinic at Charlotte Hospital) in Stuttgart/Germany. Following an overview on the historical development, indications and performance characteristics of the latest generation of Add-On IOLs were presented and the experience record with the new A4W IOL from the 1stQ company were discussed with the workshop participants.



PD Dr. med. Gangolf Sauder



Dr. med. Andreas Cordes

History of Add-On IOLs

Actually, the implantation of two lenses is not really new, as Dr. Andreas Cordes explained in his introductory speech. The basic concept for implanting a second, additional IOL aimed primarily at the correction of refractive errors. First reports on the implantation of two posterior chamber lenses date back to the nineties of the past millennium. The surgical technique was described in the literature as implantation of a pick-a-back or piggy-back lens, which, at that time, was primarily used with patients of extreme hyperopia. Also, piggy-back lenses were implanted in particular with children suffering from cataract, as well as for the correction of post-operatively detected refractive errors.

Implantation of two posterior-chamber lenses into the capsular bag is very problematic

In the early phase of piggy-back IOL implantation, two posterior-chamber lenses were implanted into the capsular bag. The lenses used in these implantation procedures were, strictly speaking, not really designed to be jointly implanted into the capsular bag next to each other, as A. Cordes indicated. In particular, the direct physical contact of the two lenses with each other, the lens material used, plus the tight position leaving a very narrow interlenticular space, often caused post-operative problems, such as a hyperopic shift, following the implantation of this type of piggy-back lenses. Further complications experienced included, notably, pigment dispersion, caused by the sharp edge on the back of the lens, with the potential late effect of a pigment glaucoma, as well as deposit of amorphous material between the two PC lenses, described as interlenticular opacification, Elschnig pearls or red-rock syndrome. These problems occurred primarily as a consequence of cell migration from the active mitotic zone of the capsular bag into the space between the two lenses (Fig. 1).

Based on this experience from the early phase, a variety of possible solutions were investigated to solve the problems described. One of the proposed remedies suggested occluding the equatorial germination zone. Last – but not least – there was one prime aspect of key importance which triggered the research and development activity towards a new generation of Add-On IOLs: to distinctly separate the implantation site for the two lenses. This is being achieved by implanting one lens into the capsular bag, leading to an occlusion of the germination zone, while the second lens is being implanted into the ciliary sul-

cus in front. This, of course, required a special lens design for the Add-On IOL, suitable for sulcus fixation, as A. Cordes explained.

Indications for the implantation of an Add-On IOL

In the opinion of A. Cordes, one important indication for the implantation of an Add-On IOL of the more recent generation is the correction of a refractive error by implanting an additional Add-On IOL. This can be done with patients whose refractive status is static, which means to say: patients whose refractive situation does not change anymore. In this case, the implantation can be performed as a primary or secondary procedure.

Indications for a primary implantation in cases of static refraction

In this situation, the Add-On IOL is implanted in the first place. Potential patients would include those with a high degree of ametropia; however, it might as well be a premium IOL with additional functions such as astigmatic correction, multifocal capability or with blue filter. The primary implant is a basic IOL placed into the capsular bag, while the Add-On IOL is implanted into the sulcus. In contrast, high ametropia as indication for the implantation of an Add-On IOL has become virtually obsolete nowadays, because most IOLs can now be made available as specials in almost any diopter power.

Secondary implantation also beneficial for many patients with static refraction

Also for many patients who carry a posterior chamber IOL from a past cataract procedure, the secondary implantation of an Add-On IOL would be beneficial: It would allow accomplishing a spherical correction. However, a premium IOL might as well be implanted in a secondary procedure, to correct, for instance, an existing astigmatism or to integrate an additional multifocal function or a blue filter.

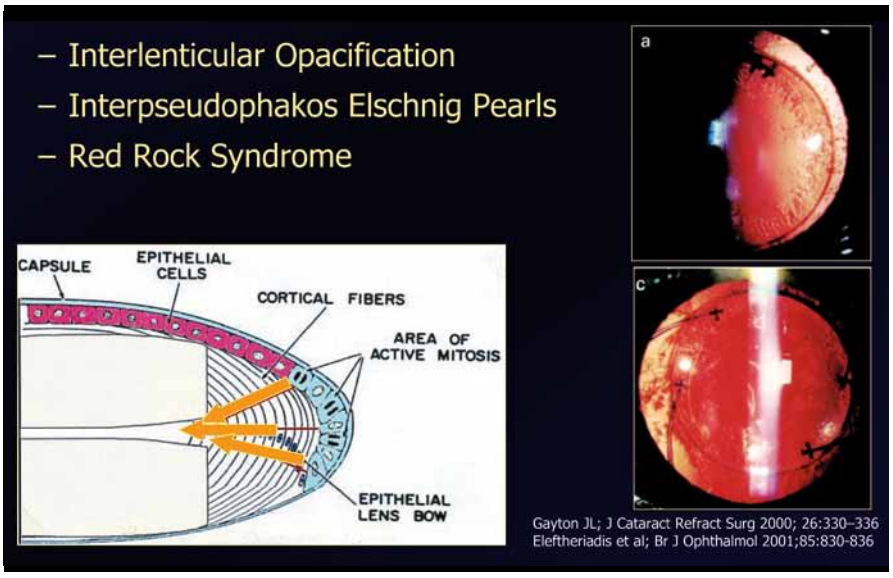


Figure 1: Opacification from migration of interlenticular material following implantation of piggy-back lenses.

Implantation of an Add-On IOL in cases of patients with dynamic refraction

The refractive situation with patients of dynamic refraction tends to change in the course of time. The implantation of an Add-On IOL offers an advantage for these patients, as the change in refraction may be remedied by a comparably simple exchange of the sulcus fixated Add-On IOL. With young cataract patients, the implantation of an Add-On IOL is particularly beneficial, as the growth in globe lengths causes a continuous change of refractive power. It would also be beneficial with patients who have undergone a vitrectomy procedure with silicone oil tamponade, which results in a hyperopic shift. Furthermore, there also exist indications for the implantation of an Add-On IOL with patients who underwent a circling procedure, following retinal detachment, for instance, and with patients suffering from post-operative astigmatism following a kerotoplastic procedure, as A. Cordes explained. These patients often receive a torical posterior chamber implant, which, however, may lead to problems in the long term. And these problems may be corrected much more easily at a later stage, especially with this group of patients, if an Add-On IOL was implanted earlier.

The Add-On IOL as premium implant with important additional features

Excellent optical results are achieved with the implantation of multifocal Add-On IOLs, which are better, to some extent, than those achieved with lenses implanted into the capsular bag: Depending on the lens style, the diffractive or refractive element advances closer to the aperture diaphragm, meaning the iris, which may

lead to an improved image quality in the pure optical representation. Another important aspect is the reversibility, which plays an essential role, especially when it comes to advising patients: Even after a longer period of time, the Add-On IOL can be explanted and/or replaced by another Add-On IOL, comparatively trouble-free. Post-operative surprises, like not achieving the expected calculated value, must also be mentioned in conjunction with the secondary implantation of an Add-On IOL. Anisometropia problems or a fine-tuning following a refractive lens exchange, would represent other areas of consideration. All such interventions with implantation of an Add-On IOL are less traumatic than a complete IOL exchange, as A. Cordes explained.

Cataract with children and patients with silicone oil tamponade: These are special indications for the Add-On implantation

In cases of cataract with children, there is a problem due to the fact that the globe length growth of the infantile eye has not been completed yet. If a child is operated at the age of six months or immediately after birth, 6 diopters must be added to the refractive power of the implanted lens, in order to account for the globe length growth. With the objective to achieve a good refraction right after the procedure, one lens may be implanted into the capsular bag and an Add-On IOL into the sulcus. This Add-On lens is removed in a second procedure at a later stage, once the globe length growth of the infantile eye is completed. For this procedure, the child should be approximately one year old, as A. Cordes pointed out, and the intervention should be made as quickly as possible once diagnosed. Moreover, there are also patients, who, after a silicone oil instillation, still enjoy good visual acuity but would need an IOL implant. In many of these cases an Add-On IOL would prove helpful. Hydrophilic IOLs are the ideal choice for this kind of indication, as they show only little silicone adherence, thus minimizing the risk of silicone adhering to the lens material. The Add-On IOL can be removed either after or together with the silicone oil.

Correction of astigmatism induced by keratoplasty with an Add-On IOL

A post-operative astigmatism is always a possible consequence of a keratoplastic procedure. Options to be considered in this case are a correction on the lens level or through implantation of a torical Add-On IOL. The intervention using an Add-On implant causes less surgical trauma, and the lens can be implanted quite easily. There is no surgical intervention with the transplant itself, and the implant procedure is reversible and repeatable, in case a keratoplastic re-operation should become necessary. An overview of indications for the implantation of an Add-On IOL is shown in table 1.

Presently, there are three different lenses on the market with a special add-on design, of which the A4W model from the 1stQ company is the most recent development (Fig. 2).

Table 1: Indications for the Implantation of an Add-On IOL

Primary Implantation	Secondary Implantation	Temporary Indication
Astigmatism	Anisometropia	Cataract with Children
Additional Multifocal Function	Additional Multifocal Function	Silicone Oil Tamponade
	Astigmatism	Circling Procedure (Cerclage)
		Keratoplasty

Table 2: High degree of Patient Satisfaction after Add-On IOL Implantation

Subjective Patient Satisfaction 6 months	MIOL	Add-On-MIOL
Subjective distant VA (1-10)*	7.63 / 8.5 / 0.5-9.9	8.33 / 8.40 / 7.5-9.2
Subjective close VA (1-10)*	7.30 / 8.50 / 2.6-9.7	8.11 / 8.40 / 5.0-9.8
Overall satisfaction (1-10)*	6.89 / 8.40 / 1.1-9.8	8.83 / 9.0 / 8.0-9.6
Glare (1-10)**	3.77 / 3.40 / 1-8.8	3.18 / 4.33 / 1-6.5
Halos (1-10)**	3.14 / 1.60 / 1-9.2	2.24 / 2.50 / 1.73

* 10 = total satisfaction
** 10 = very disturbing

In another contribution to the workshop presentations, Dr. Gangolf Sauder (Stuttgart) reported on his experience with Add-On IOLs and the new model A4W of 1stQ. G. Sauder has an experience record of over 10 years with the implantation of Add-On IOLs, and he is also involved in scientific research work on issues associated with this particular subject.

Differences of endocapsularly implanted MIOL as compared to Add-On MIOL lens systems

G. Sauder presented clinical data to the workshop participants, which resulted from a randomized, prospective study made in Stuttgart. This study comprised 2 patient groups of 23 patients each. The first patient group received a multifocal lens, implanted into the capsular bag, while the second group received a basis IOL (an aspherical monofocal lens), plus a multifocal lens, implanted, in each case, as Add-on IOL bilaterally into the ciliary sulcus. The data recorded in standardized questionnaires included uncorrected visual acuity at near and far, contrast sensitivity and patient satisfaction. The post-operative results of both groups were virtually identical in both areas, close and distant vision. There was no significant difference between the two groups.

Higher patient satisfaction in the Add-On patient group

The subjective patient satisfaction was better in the Add-On-patient group, even though there was no statistically significant difference. However, a statistically significant difference in favour of the Add-On IOL emerged from the category of general patient satisfaction. The results show that the patients, at least regarding the patient collective examined, do not have to be aware of potential refractive or surgical detriments, in particular with regard to glare, halos and contrast sensitivity.

Development of a new generation of Add-On IOLs with distinct technical improvements

There have been repeated reports on Add-On IOLs available so far, commenting on lens rotations experienced after implantation of torical lenses in the ciliary sulcus. Also, the standardized shooter insertion technique has not been possible with this type of lens so far. And there existed yet another problem: It was difficult to implement a truly standardized, predictable and biometrically verifiable distance between the two lenses, which in some cases caused variations in the refractive results. Furthermore, there were reports on adhesions between both lenses, which applied in particular when both lenses were made of silicone material.
Starting from this situation, a thinking process began, in order to find out which requirements were needed for a new and advanced Add-On IOL system, with the objective to ensure a truly stable implantation in the sulcus, as G. Sauder mentioned. Additional objectives were to allow a shooter implantation with the new lens via micro-incision technique and to achieve a stable distance from the basic IOL. Also, the new design was to offer a platform as premium lens (aspherical, with blue-filter function, multifocal, torical or spherical for the correction of anisometropias in the areas of hyperopia and myopia).

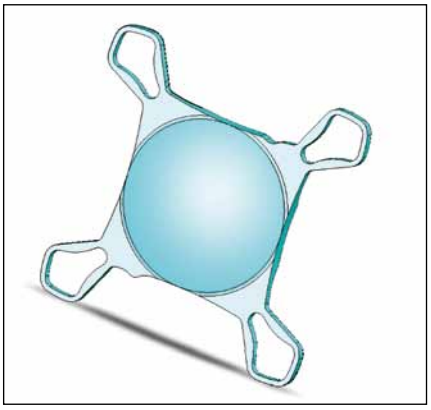


Figure 2: The A4W IOL model

Latest development in the spectrum of Add-On IOLs: The A4W lens

1stQ has a wide experience record of over 10 years in the area of Add-On lenses. The A4W model of 1stQ belongs to the latest generation of Add-On lenses, which incorporates all the considerations and requirements mentioned before. The A4W lens model has a 6 mm optic and an overall diameter of 13.5 mm. It is equipped with 4 soft haptics, which do not have the compressing effect in the ciliary sulcus, as one might expect from extended PMMA haptics. The haptic configuration has been designed in such a way that it provides much variability to adapt to anatomical conditions (Fig. 3). This Add-On IOL was developed with a basis design of a square shape. The reason to opt for this type of design was to avoid peripheral light scatter at the optic margin and to integrate a gap maintainer, which would prevent an adhesion with the basic IOL, located posteriorly, creating a stable and predictable distance from it. The material of the A4W model proves compatible with all other IOL materials. Figure 4 shows the haptics of the A4W in relaxed conditions (blue) and in compressed conditions (red). As the haptics of the A4W have been arranged symmetrically to rotation, any decentration or rotation of the lens are unlikely to occur.

Which aspects deserve special attention prior to, during or after implantation of the A4W Add-On IOL model?

First of all, it is essential to clearly identify both front and back of the A4W lens prior to implantation. Blunt forceps are used for manipulation, paying attention to the marks at the IOL at 1 and 7 o'clock serving for orientation of the A4W to avoid a placement of the lens on the back. Also, the exact positioning inside the shooter is important. The shooter is completely filled with Methocoel. The haptics are now exactly positioned in the shooter canal. Catching the haptics in this situation is to be avoided by all means. The actual implantation is performed through a 2.2 mm clear-cornea incision. Once the anterior chamber is erected by means of a viscoelastic solution, primarily in the area of the retroiridal space, the A4W lens is slowly pushed forward through the shooter. Right in the situation when both anterior haptics begin to open up, the surgeon should wait for a short moment until both haptics have unfolded. This helps to make sure the haptics do not bend toward the inside under the iris in the course of the advancing movement. Following a pupil constriction through Miochol, the lens should be rotated, which makes sure the haptics have securely unfolded in the sulcus. In case of a simultaneous implantation together with a basic IOL, great care should be taken to make sure that two of the A4W haptics do not accidentally get underneath the capsulorhexis, as G. Sauder mentioned. The special lens design with the 4 characteristic haptics of the A4W effectively prevents an iris capture, even in a mydriatic situation (Fig. 6). It is important to rinse the viscoelastic away, also from the interlenticular space, ensuring that this space is totally clean.

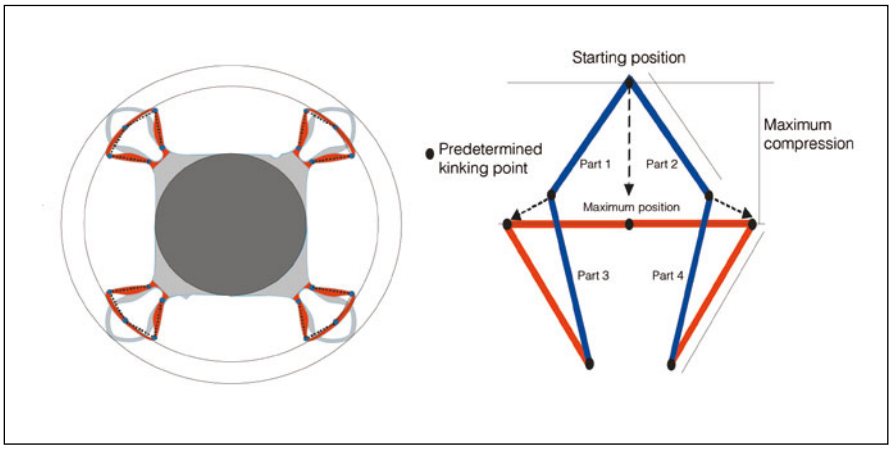


Figure 3: Design of the A4W IOL with special haptics

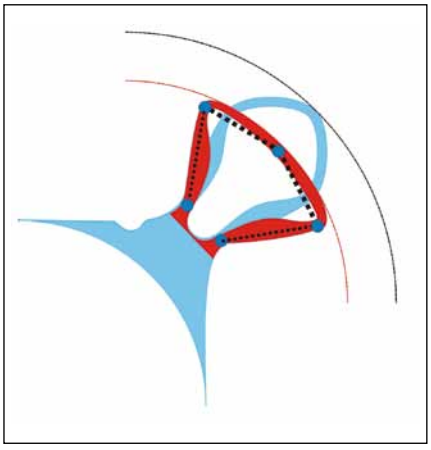


Figure 4: Haptic function of the A4W IOL

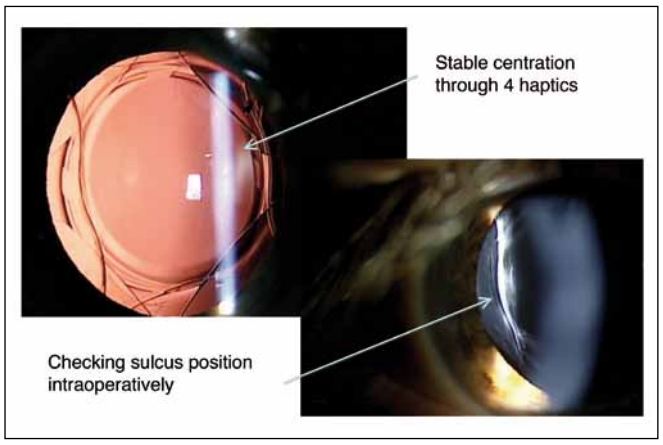


Figure 5a: Post-operative condition after the implantation of an A4W IOL

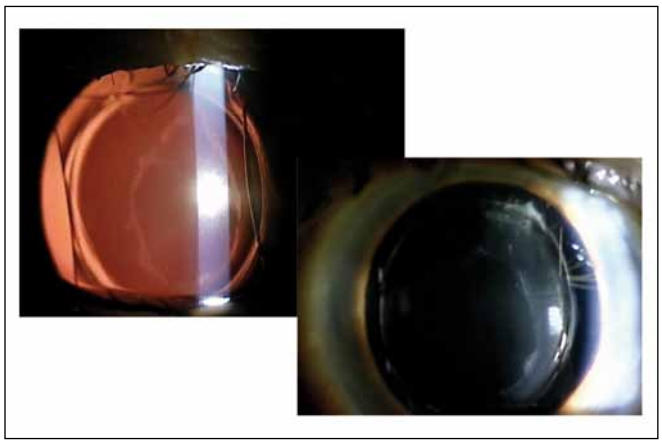


Figure 5b: Follow-up after 10 months

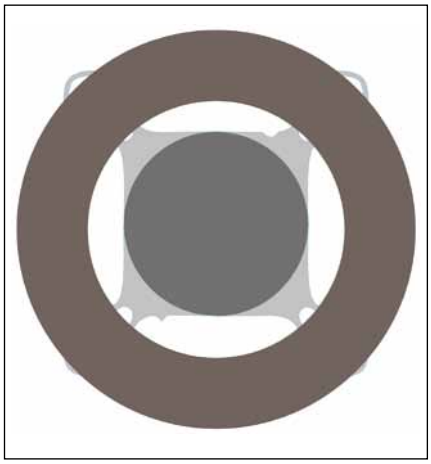


Figure 6: Prophylaxis of iris capture with the A4W IOL

No pigment dispersion and no changes in the chamber angle one year post-op

G. Sauder feels that the first results with the A4W lens are very promising: With the patients operated so far, the following situations were stated 12 months post-op: a stable refraction, a stable gap of 1 mm to the basic IOL, which means stable conditions without any deposits. Furthermore, no pigment dispersion was detected with the patients operated so far (Figures 5 a and b). For the future, the scientific interest at Stuttgart Charlotte Hospital will increasingly be focused on learning more about the ciliary sulcus and what it really looks like, as the sulcus, so far, has not been a place of prime interest in association with lens implantation. Comparatively few anatomical investigations have been conducted with regard to the sulcus so far. This applies in particular to the conditions and variability of this anatomical area. The main issue for the future, as G. Sauder pointed out in his final comments, will be defined as „individualization". This means: the lens functions must meet the patient's requirements as much as possible and the implantation should be performed as precisely and gently as possible under consideration of the individual anatomical conditions, so as to adapt to each patient's specific situation.

G. Sauder summarized the characteristics and benefits of the A4W IOL model from 1stQ as follows:

- From the perspective of surgical handling, the A4W Add-On IOL model from 1stQ is a distinct improvement and advancement.
- The lens allows an excellent centration due to the intelligent lens design of the A4W model.
- The A4W lens can be inserted through a minimum-size incision by means of a shooter. Its optimized design ensures a stable distance to the basic IOL.
- A small elevation on the back prevents the A4W lens from attaching to the basic IOL.
- The A4W Add-On model represents a platform for refractive surgery and is as such compatible with any basis IOL commercially available.
- The A4W lens can be implanted simultaneously as well as secondarily.
- Spherical corrections are possible in both the hyperopic and myopic ranges.
- Treatment of presbyopia with a diffractive array is another important area of possible application for the A4W IOL model.

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